Subcutaneous Golimumab (GLM) Plus DMARDs for Rheumatoid Arthritis, Followed by Intravenous/Subcutaneous GLM Strategy (P06129 AM2) (GO-MORE)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00975130

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History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

Part 1 of this trial will assess the safety and effectiveness of subcutaneous (SC) golimumab administered by autoinjector once monthly, when combined with different disease-modifying antirheumatic drug (DMARD) regimens used in daily rheumatology practice. Subsequently, Part 2 will study if a strategy of intravenous (IV) golimumab to induce remission followed by SC golimumab to retain remission is superior to continuing a SC regimen.

Condition	Intervention	Phase
Arthritis, Rheumatoid	Biological: SC golimumab Biological: IV golimumab	Phase 3

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open-Label Study Assessing the Addition of Subcutaneous Golimumab (GLM) to Conventional Disease-Modifying Antirheumatic Drug (DMARD) Therapy in Biologic-Naïve Subjects With Rheumatoid Arthritis (Part 1), Followed by a Randomized Study Assessing the Value of Combined Intravenous and Subcutaneous GLM Administration Aimed at Inducing and Maintaining Remission (Part 2)

Resource links provided by NLM:

Genetics Home Reference related topics: rheumatoid arthritis

MedlinePlus related topics: Arthritis Rheumatoid Arthritis

Drug Information available for: Golimumab

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants Achieving a Good or Moderate European League Against Rheumatism (EULAR) Response at Month 6 [Time Frame: Month 6] [Designated as safety issue: No]

  EULAR response was assessed at the end of Month 6 by the Disease Activity Score using the 28 tender and swollen joint count calculated with erythrocyte sedimentation rate values (DAS28-ESR). A good response was defined as a decrease >1.2 units and a final DAS28-ESR < 3.2 units, while a moderate response was defined as a decrease > 1.2 units and final DAS28-ESR >= 3.2 units, OR a decrease of 0.6 to 1.2 units AND final DAS28-ESR <= 5.1 units

- Number of Participants Experiencing Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) Remission at the Start of Month 11 and End of Month 12 [Time Frame: Start of Month 11, End of Month 12] [Designated as safety issue: No]

  The number of participants experiencing DAS28-ESR remission was evaluated at the start of study Month 11 and the end of study Month 12. The DAS28-ESR is expressed on a unit on a scale with the minimum score=0 (best) to maximum score=10 (worst). Remission was defined as DAS28-ESR <2.6.

Secondary Outcome Measures:

- Mean Change From Baseline in the Number of Swollen Joints by Concomitant Methotrexate (MTX) Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the mean number of swollen joints was calculated at study Month 2, Month 4, and Month 6 by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week). A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Disease Modifying Antirheumatic Drug (DMARD) Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by participant baseline background DMARD treatment regimen at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in the Number of Swollen Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints by participant baseline concomitant corticosteroid treatment was calculated at study Month 2, Month 4, and Month 6 . A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the mean number of swollen joints by the number of baseline participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the mean number of swollen joints was calculated by the participant duration of disease at study Month 2, Month 4, and Month 6. The participant duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints by participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6 by the participant's level of baseline disease activity, as measured by DAS28-ESR. A total of 28 joints were evaluated. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in the Number of Swollen Joints by Baseline Rheumatoid Factor (RF) Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The change from baseline in the mean number of swollen joints was calculated by the participant baseline level of RF at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Baseline Anti-Cyclic Citrullinated Antibody (Anti-CCP) Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in the mean number of swollen joints was calculated by the participant baseline level of anti-CCP at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in the mean number of swollen joints was calculated by the baseline participant smoking status at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in the Number of Swollen Joints by Eligibility for Anti-Tumor Necrosis Factor (Anti-TNF) Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in the mean number of swollen joints was calculated by the baseline participant eligibility for anti-TNF treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Swollen Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by the participant baseline expectation of treatment outcome at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by the physician experience level at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis.

- Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by the physician experience level with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in the Number of Swollen Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by the baseline number of patients the physician treats with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The number of patients treated with biologics is defined as the number of patients treated by the physician in the last month with biologics for rheumatoid arthritis.

- Mean Change From Baseline in the Number of Swollen Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of swollen joints was calculated by the physician's expectation of treatment outcome at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The physician's expectation of treatment outcomes was assessed at the start of Month 4 at which time physicians were asked to rate their expectations of treatment outcome in each participant as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in the Number of Tender Joints by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by participant concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The mean change from baseline in the number of tender joints was calculated by participant background DMARD treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in the Number of Tender Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by participant baseline concomitant steroid treatment at study Month 2, Month 4, and Month 6. A total 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the number of participant DMARD failures at baseline at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the participant duration of disease at study Month 2, Month 4, and Month 6. Duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the participant baseline level of disease activity, as measured by DAS28, at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in the Number of Tender Joints by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in the mean number of tender joints was calculated by the participant baseline level of RF at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the participant baseline level of anti-CCP at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the baseline participant smoking status at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in the Number of Tender Joints by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the baseline participant eligibility for anti-TNF treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.

- Mean Change From Baseline in the Number of Tender Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the participant baseline expectation of treatment outcome at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the physician experience level at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience

managing rheumatoid arthritis.

- Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the physician experience level with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in the Number of Tender Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints was calculated by the baseline number of patients the physician treats with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The number of patients treated with biologics is defined as the number of patients treated by the physician in the last month with biologics for rheumatoid arthritis.

- Mean Change From Baseline in the Number of Tender Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the number of tender joints. was calculated by the physician's expectation of treatment outcome at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The physician's expectation of treatment outcomes was assessed at the start of Month 4 at which time physicians were asked to rate their expectations of treatment outcome in each participant as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant global assessment of disease activity was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a visual analogue scale (VAS; 0mm [best] -100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant baseline level of disease activity was

calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- mm [Best]Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant global assessment of disease activity by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in Participant Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The mean change from baseline in the participant global assessment of disease activity by the physician's expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in the Erythrocyte Sedimentation Rate (ESR) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in participant serum ESR was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by concomitant DMARD background treatment was calculated at study Month 2, Month 4, and Month 6. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in serum ESR by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the participant serum ESR by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis.

- Mean Change From Baseline in ESR by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in ESR by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in ESR by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in ESR by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The mean change from baseline in participant serum ESR by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in ESR by Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in ESR by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in ESR by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in ESR by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum ESR by the physician's expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in C-Reactive Protein (CRP) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The change from baseline in participant serum CRP was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by concomitant DMARD background treatment was calculated at study Month 2, Month 4, and Month 6. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in serum CRP by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The mean change from baseline in the participant serum CRP by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis.

- Mean Change From Baseline in CRP by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. DAS28-ESR scores of > 3.2 to <=5.1 indicate moderate disease activity and DAS28-ESR scores of > 5.1 indicate high disease activity.

- Mean Change From Baseline in CRP by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in CRP by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in CRP by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6.

- Mean Change From Baseline in CRP by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in CRP by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in CRP by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in CRP by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in participant serum CRP by the physician's expectation of treatment outcome was evaluated at study Month 2,

Month 4, and Month 6. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in physician global assessment of disease activity was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease by concomitant DMARD background treatment was evaluated at Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by participant baseline smoking status was calculated at

study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] -100mm [worst]) with increasing scores indicating increased level of disease. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the physician global assessment of disease activity by the baseline physician expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in DAS28-ESR Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst).

Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX+sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.

- Mean Change From Baseline in DAS28-ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
  [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR <3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6
  [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed on a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed on a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR >5.1 = high disease activity, DAS28-ESR <3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
  [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR with increasing scores indicating increased level of disease burden. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. Increasing scores indicate increased burden of disease. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. Increasing scores indicate increased burden of disease. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease

activity, and DAS28-ESR <2.6 = remission. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in DAS28-ESR Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in DAS28-ESR Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-ESR score by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in DAS28-ESR Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in DAS28-ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Mean Change From Baseline in DAS28-CRP Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a

score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts & swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP >5.1 =high disease activity, DAS28-CRP <3.2=low disease activity, and DAS28-CRP <2.6=remission. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 =leflunomide.

- Mean Change From Baseline in DAS28-CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP with increasing scores indicating increased burden of disease. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-CRP > 5.1 = high disease activity, DAS28-CRP < 3.2 to < =5.1 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-

CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in DAS28-CRP Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.

- Mean Change From Baseline in DAS28-CRP Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the DAS28-CRP score by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in DAS28-CRP Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in DAS28-CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity,

or remission.

- Mean Change From Baseline in the Simplified Disease Activity Index (SDAI) Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10cm [worst]) and level of C-reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.

- Mean Change From Baseline in SDAI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0 cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease with increasing scores indicating increased burden of disease. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum

score=86 (worst).

- Mean Change From Baseline in SDAI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

- Mean Change From Baseline in SDAI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the SDAI by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in SDAI by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in SDAI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in SDAI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in SDAI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
  [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] - 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Number of Participants Who Achieved DAS28-ESR EULAR Response [Time Frame: Month 2, Month 4, Month 6]
  [Designated as safety issue: No]

  EULAR response was assessed at the end of Month 2, Month 4, and Month 6 by the Disease Activity Score using the 28 tender and swollen joint count calculated with erythrocyte sedimentation rate values (DAS28-ESR). A good response would was defined as a decrease >1.2 units and a final DAS28-ESR < 3.2 units, while a moderate response was defined as a decrease > 1.2 units and final DAS28-ESR >= 3.2 units, OR a decrease of 0.6 to 1.2.

- Number of Participants Who Achieved DAS28-CRP EULAR Response [Time Frame: Month 2, Month 4, Month 6]
  [Designated as safety issue: No]

  DAS28-CRP EULAR response is defined as a good or moderate response that results in a DAS28-CRP >=0.6.

- Number of Participants Achieving Low Disease Activity and Remission at Month 2, Month 4, and Month 6 [Time Frame: Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The number of participants achieving low disease activity or remission was calculated by the DAS28-ESR, DAS28-CRP, and SDAI at study Month 2, Month 4, and Month 6. Low disease activity by DAS28-ESR was defined as >= 2.6 to 3.2, and remission was defined as a DAS28-ESR <2.6. Low disease activity by DAS28-CRP was defined as DAS28-CRP >=2.6 to 3.2, and remission was defined as DAS28-CRP >2.6. Low disease activity by SDAI was defined as SDAI >5.0 to <=20, and remission was defined as SDAI <=5.0.

- Mean Change From Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline the disability index of the HAQ was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst)with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
  [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.

- Mean Change From Baseline in HAQ-DI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6.

The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in HAQ-DI by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in HAQ-DI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).

- Mean Change From Baseline in HAQ-DI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the HAQ-DI by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in HAQ-DI by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in HAQ-DI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with

a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in HAQ-DI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a scores ranging from 0 (best) to 3 (best) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in HAQ-DI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Number of Participants Who Achieved Minimal or Absence of Functional Impairment [Time Frame: Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The number of participants that achieved minimal or absence of functional impairment as assessed by the HAQ at study Month 2, Month 4, and Month 6 was calculated. Minimal or absence of functional impairment was defined as a HAQ score of <=0.5. The HAQ evaluates participants on a scale of 0 to 3, with 0=with no difficulty, 1=with some difficulty, 2=with much difficulty, and 3=unable to do.

- Mean Change From Baseline in the EuroQOL (EQ-5D) Quality-of-Life Questionnaire by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  Concomitant MTX dose was defined as low < 10mg/wk, medium >= 10 to < 15 mg/week, and and high >=15 mg/week. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. DMARD Combination 1=MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2=MTX + leflunomide; Combination 3=MTX +sulfasalazine; Combination 4=MTX + hydrochloroquine, chloroquine, chloroquine phosphate+sulfasalazine; Combination 5=leflunomide.

- Mean Change From Baseline in EQ-5D by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal

score.

- Mean Change From Baseline in EQ-5D by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.

- Mean Change From Baseline in EQ-5D by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.

- Mean Change From Baseline in EQ-5D by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The mean change from baseline in the EQ-5D by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.

- Mean Change From Baseline in EQ-5D by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

The mean change from baseline in the EQ-5D by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).

- Mean Change From Baseline in EQ-5D by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

- Mean Change From Baseline in EQ-5D by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.

- Mean Change From Baseline in EQ-5D by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.

- Mean Change From Baseline in EQ-5D by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant indicates their health state by ticking the box against the most appropriate statement. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

- Number of Participants With a Participant Acceptable Symptom State (PASS) at Month 4, Month 6, and Month 8 [Time Frame: Month 2, Month 4, Month 6] [Designated as safety issue: No]

  The number of participants achieving PASS was evaluated at study Month 2, Month 4, and Month 6 was calculated. PASS is participant self-evaluation tool that uses a VAS 0mm (best) - 100mm (worst), with a score <=31 representing an acceptable PASS.

- Mean Area Under the DAS28-ESR Curve From Study Month 6 to Month 12 [Time Frame: End of Month 6, End of Month 12] [Designated as safety issue: No]

  The DAS28-ESR is a continuous disease measure which is a composite of 4 variables: the 28 tender joint count, the 28 swollen joint count, ESR, and participant assessment of disease activity measure on a visual analogue scale. The DAS28-ESR has numeric thresholds that define high disease activity (> 5.1), low disease activity (< 3.2) and remission (< 2.6). Minimum score=0 (best) to maximum score=10 (worst). The DAS28-ESR area under the curve can be calculated from the DAS28-ESR score versus time curve to provide an assessment of changes in disease activity over time. The area under the DAS28-ESR score versus time curve was computed using the trapezoidal rule and using raw DAS28-ESR score values at Part-2 Baseline, end of Month 12, and at least 2 intermediate time points. The DAS28-ESR area under the curve was then averaged over the total duration (months) and expressed as units on a scale.

- Percentage of Participants Achieving Remission [Time Frame: Start of Month 8, Start of Month 9, Start of Month 10, Start of Month 11, End of

Month 12] [Designated as safety issue: No]

Remission was defined as achievement of a DAS28-ESR < 2.6.

Enrollment:	3366
Study Start Date:	September 2009
Study Completion Date:	February 2012
Primary Completion Date:	August 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: SC-GLM50 In Part 1 of the study, participants received subcutaneous golimumab treatment at a dose of 50 mg once monthly for 6 months in combination with background DMARD treatment.	Biological: SC golimumab Subcutaneous golimumab at a dose of 50 mg administered once monthly. Other Name: SCH 900259, subcutaneous
Experimental: IV GLM 2 mg/kg + GLM50-SC After 6 months of treatment in study Part 1, participants with good or moderate response but not in remission will receive intravenous (IV) golimumab at a dose of 2 mg/kg once monthly for a period of 6 months or until remission is achieved. Participants will receive IV GLM at a dose of 2 mg/kg at the start of Month 7, and then at the start of Month 8 and Month 10 if the subject has not achieved remission at any of these IV administration visits. If remission is achieved, participants were switched to subcutaneous golimumab at a dose of 50 mg once monthly until study end, in combination with background DMARD treatment.	Biological: SC golimumab Subcutaneous golimumab at a dose of 50 mg administered once monthly. Other Name: SCH 900259, subcutaneous Biological: IV golimumab Intravenous golimumab administered up to 3 times (month 7, 8, 10) during a period of 6 months at a dose of 2 mg/kg of body weight. Other Name: SCH 900259, intravenous
Experimental: GLM50-SC After 6 months of treatment in study Part 1, participants with good or moderate response but not in remission will receive subcutaneous golimumab at a dose of 50 mg once monthly for a period of 6 months, in combination with background DMARD treatment.	Biological: SC golimumab Subcutaneous golimumab at a dose of 50 mg administered once monthly. Other Name: SCH 900259, subcutaneous

Detailed Description:

Participants who had a good or moderate European League Against Rheumatism (EULAR) response but not achieve remission at the end of Part 1 were invited to participate in Part 2 and were randomized to either intravenous golimumab (IV GLM) + subcutaneous golimumab (SC GLM) or SC GLM alone.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

For Part 1:

- Age >=18 years, either sex, any race.
- Diagnosis of RA according to the 1987 revised American College of Rheumatology (ACR) criteria.
- Active disease despite DMARD treatment
- Subject must be taking at least one of the allowed DMARDs, and must be able to continue with it during the trial.
- Eligibility for anti tumor necrosis factor (TNF) use according to the following criteria:
  - Participant must have failed conventional treatment according to the investigator's opinion OR local guidelines.
  - Local guidelines regarding safety screening of anti TNF candidates (ie, tuberculosis [TB] screening and other safety screening such as vaccination, if applicable) must be met. Chest X-ray and either a PPD skin test or QuantiFERON®-TB Gold test are also required.
  - Anamnesis and physical examination must make the participant eligible for anti TNF use and trial participation according to the investigator's judgment.

For Part 2:

- Participant must have completed Part 1 of this trial.
- Participant must have:
  - good or moderate response to SC golimumab at the end of Month 6 compared to Baseline, AND.
  - no DAS28 ESR remission.
- Both the investigator and the subject must agree to switch the participant's treatment to IV administration as may be required in Part 2 of this trial.
- The investigator must judge that no safety events (eg, serious adverse events [SAEs], serious infections, marked injection-site reactions or intolerance to drug) have occurred that could reoccur or aggravate with increased drug exposure.

Exclusion Criteria:

- History of biologic drug use for RA.
- Evidence of active TB. or latent TB that is untreated.
- Moderate to severe heart failure
- Certain inflammatory rheumatic disease other than RA or certain systemic inflammatory condition
- Allergy to latex

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Combe B, Dasgupta B, Louw I, Pal S, Wollenhaupt J, Zerbini CA, Beaulieu AD, Schulze-Koops H, Durez P, Yao R, Vastesaeger N, Weng HH; GO-MORE Investigators. Efficacy and safety of golimumab as add-on therapy to disease-modifying antirheumatic drugs: results of the GO-MORE study. Ann Rheum Dis. 2014 Aug;73(8):1477-86. doi: 10.1136/annrheumdis-2013-203229. Epub 2013 Jun 5.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Schulze-Koops H, Giacomelli R, Samborski W, Rednic S, Herold M, Yao R, Govoni M, Vastesaeger N, Weng HH. Factors influencing the patient evaluation of injection experience with the SmartJect autoinjector in rheumatoid arthritis. Clin Exp Rheumatol. 2015 Mar-Apr;33(2):201-8. Epub 2015 Jan 29.

Dasgupta B, Combe B, Louw I, Wollenhaupt J, Zerbini CA, Beaulieu A, Schulze-Koops H, Durez P, Wolff V, Yao R, Weng HH, Govoni M,

Vastesaeger N. Patient and physician expectations of add-on treatment with golimumab for rheumatoid arthritis: relationships between expectations and clinical and quality of life outcomes. Arthritis Care Res (Hoboken). 2014 Dec;66(12):1799-807. doi: 10.1002/acr.22371.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00975130 History of Changes
Other Study ID Numbers:	P06129 2009-011137-26 CTRI/2009/091/000883
Study First Received:	August 20, 2009
Results First Received:	July 18, 2012
Last Updated:	October 8, 2015
Health Authority:	Canada: Health Canada

Additional relevant MeSH terms:

Arthritis	Immune System Diseases
Arthritis, Rheumatoid	Joint Diseases
Autoimmune Diseases	Musculoskeletal Diseases
Connective Tissue Diseases	Rheumatic Diseases

ClinicalTrials.gov processed this record on April 20, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Subcutaneous Golimumab (GLM) Plus DMARDs for Rheumatoid Arthritis, Followed by Intravenous/Subcutaneous GLM Strategy (P06129 AM2) (GO-MORE)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00975130

First received: August 20, 2009
Last updated: October 8, 2015
Last verified: October 2015
History of Changes

Results First Received: July 18, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Arthritis, Rheumatoid
Interventions:	Biological: SC golimumab Biological: IV golimumab

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Golimumab 50 mg Subcutaneous (GLM50-SC)	Participants received GLM50-SC once monthly for a period of 6 months in Study Part 1.
Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	Participants achieving good or moderate response but not in remission at the conclusion of Study Part 1 received IV-GLM at a dose of 2 mg/kg at the start of Month 7, start of Month 8, and start of Month 10 if remission was not achieved at any of these IV administration visits. If remission was achieved, participants were switched subcutaneous golimumab at a dose of 50 mg once monthly.
SC-GLM50	Participants achieving good or moderate response but not in remission at the end of Study Part 1, received subcutaneous golimumab at a dose of 50 mg once monthly for a period of 6 months in Part 2 of the study.

Participant Flow for 2 periods

Period 1: Study Part 1

	Golimumab 50 mg Subcutaneous (GLM50-SC)	Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	SC-GLM50
STARTED	3366	0	0
COMPLETED	3086	0	0
NOT COMPLETED	280	0	0
Adverse Event	150	0	0
Lost to Follow-up	19	0	0
Withdrawal by Subject	61	0	0
Protocol Violation	13	0	0
Did Not Meet Protocol Eligibility	9	0	0
Administrative	4	0	0
Withdrew Consent	24	0	0

Period 2: Study Part 2

	Golimumab 50 mg Subcutaneous (GLM50-SC)	Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	SC-GLM50
STARTED	0	250 [1]	255 [1]
COMPLETED	0	212	238
NOT COMPLETED	0	38	17
Adverse Event	0	14	7
Lost to Follow-up	0	0	1
Withdrawal by Subject	0	13	5
Withdrew Consent	0	6	2
Did Not Meet Protocol Eligibility	0	4	1
Administrative	0	1	0
Protocol Violation	0	0	1

[1] Good/moderate responders without remission at the end of Part 1 were invited to enroll in Part 2.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
GLM50-SC	Participants received 50 mg of golimumab subcutaneously once monthly for a period of 6 months. 3280 enrolled participants were included in the Efficacy-Evaluable population; baseline characteristics are presented for this population.

Baseline Measures

	GLM50-SC
Number of Participants [units: participants]	**3280**
Age [units: Years] Median (Full Range)	**53 (18 to 88)**
Gender [units: participants]	
Female	**2716**
Male	**564**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Achieving a Good or Moderate European League Against Rheumatism (EULAR) Response at Month 6 [Time Frame: Month 6]

Measure Type	Primary
Measure Title	Number of Participants Achieving a Good or Moderate European League Against Rheumatism (EULAR) Response at Month 6
Measure Description	EULAR response was assessed at the end of Month 6 by the Disease Activity Score using the 28 tender and swollen joint count calculated with erythrocyte sedimentation rate values (DAS28-ESR). A good response was defined as a decrease >1.2 units and a final DAS28-ESR < 3.2 units, while a moderate response was defined as a decrease > 1.2 units and final DAS28-ESR >= 3.2 units, OR a decrease of 0.6 to 1.2 units AND final DAS28-ESR <= 5.1 units
Time Frame	Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Efficacy Evaluable population in Part 1 of the study excluded participants without a DAS28-ESR at baseline and at least 1 post-line value DAS28-ESR or those that had very poor data quality due to incomplete documentation.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants Achieving a Good or Moderate European League Against Rheumatism (EULAR) Response at Month 6 [units: Participants]	**2692**

No statistical analysis provided for Number of Participants Achieving a Good or Moderate European League Against Rheumatism (EULAR) Response at Month 6

2. Primary: Number of Participants Experiencing Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) Remission at the Start of Month 11 and End of Month 12 [Time Frame: Start of Month 11, End of Month 12]

Measure Type	Primary
Measure Title	Number of Participants Experiencing Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) Remission at the Start of Month 11 and End of Month 12
Measure Description	The number of participants experiencing DAS28-ESR remission was evaluated at the start of study Month 11 and the end of study Month 12. The DAS28-ESR is expressed on a unit on a scale with the minimum score=0 (best) to maximum score=10 (worst). Remission was defined as DAS28-ESR <2.6.
Time Frame	Start of Month 11, End of Month 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR.

Reporting Groups

	Description
IV-GLM2/SC-GLM50	Intravenous golimumab 2 mg/kg followed by subcutaneous golimumab 50 mg once monthly.
SC-GLM50	Subcutaneous golimumab 50 mg administered once monthly for for 6 months (study Months 6-12).

Measured Values

	IV-GLM2/SC-GLM50	SC-GLM50
Number of Participants Analyzed [units: participants]	**242**	**248**

Number of Participants Experiencing Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) Remission at the Start of Month 11 and End of Month 12 [units: Participants]		
Start of Month 11	**58**	**64**
End of Month 12	**59**	**67**

No statistical analysis provided for Number of Participants Experiencing Disease Activity Score 28-Erythrocyte Sedimentation Rate (DAS28-ESR) Remission at the Start of Month 11 and End of Month 12

3. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Concomitant Methotrexate (MTX) Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Concomitant Methotrexate (MTX) Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the mean number of swollen joints was calculated at study Month 2, Month 4, and Month 6 by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week). A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Concomitant Methotrexate (MTX) Dose at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n =142)	**-4.7 (4.46)**
Low MTX Dose - Month 4 (n=142)	**-6.3 (5.37)**
Low MTX Dose - Month 6 (n=142)	**-7.7 (5.59)**

Medium MTX Dose - Month 2 (n=526)	**-4.6 (4.45)**
Medium MTX Dose - Month 4 (n=526)	**-6.2 (4.98)**
Medium MTX Dose - Month 6 (n=526)	**-7.1 (5.37)**
High MTX Dose - Month 2 (n=1995)	**-4.5 (4.67)**
High MTX Dose - Month 4 (n=1995)	**-6.2 (5.07)**
High MTX Dose - Month 6 (n=1995)	**-6.9 (5.30)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Concomitant Methotrexate (MTX) Dose at Month 2, Month 4, and Month 6

4. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Disease Modifying Antirheumatic Drug (DMARD) Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Disease Modifying Antirheumatic Drug (DMARD) Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by participant baseline background DMARD treatment regimen at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Disease Modifying Antirheumatic Drug (DMARD) Background	

Treatment at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1681)	-4.5 (4.61)
DMARD Combination 1 - Month 4 (n=1681)	-6.1 (5.07)
DMARD Combination 1 - Month 6 (n=1681)	-6.9 (5.31)
DMARD Combination 2 - Month 2 (n=433)	-4.5 (4.91)
DMARD Combination 2 - Month 4 (n=433)	-6.5 (5.17)
DMARD Combination 2 - Month 6 (n=433)	-7.3 (5.35)
DMARD Combination 3 - Month 2 (n=216)	-4.6 (4.68)
DMARD Combination 3 - Month 4 (n=216)	-6.0 (5.11)
DMARD Combination 3 - Month 6 (n=216)	-6.7 (5.54)
DMARD Combination 4 - Month 2 (n=150)	-3.8 (4.58)
DMARD Combination 4 -Month 4 (n=150)	-5.9 (5.40)
DMARD Combination 4 - Month 6 (n=150)	-6.7 (6.10)
DMARD Combination 5 - Month 2 (n=106)	-4.8 (3.89)
DMARD Combination 5 - Month 4 (n=106)	-6.0 (4.96)
DMARD Combination 5 - Month 6 (n=106)	-6.2 (4.86)
DMARD Combination 6 - Month 2 (n=303)	-3.9 (4.27)
DMARD Combination 6 - Month 4 (n=303)	-5.6 (4.51)
DMARD Combination 6 - Month 6 (n=303)	-6.2 (4.90)

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Disease Modifying Antirheumatic Drug (DMARD) Background Treatment at Month 2, Month 4, and Month 6

5. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
	Mean Change From Baseline in the Number of Swollen Joints by Concomitant Corticosteroid Treatment at Month 2,

Measure Title	Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints by participant baseline concomitant corticosteroid treatment was calculated at study Month 2, Month 4, and Month 6 . A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1202)	**-4.5 (4.43)**
Did Not Receive Corticosteroids - Month 4 (n=1202)	**-6.1 (4.88)**
Did Not Receive Corticosteroids - Month 6 (n=1202)	**-6.8 (5.24)**
Received Corticosteroids - Month 2 (n=2078)	**-4.3 (4.66)**
Received Corticosteroids - Month 4 (n=2078)	**-6.1 (5.10)**
Received Corticosteroids - Month 6 (n=2078)	**-6.9 (5.33)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

6. Secondary: Mean Change From Baseline in the Number of Swollen Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
	Mean Change From Baseline in the Number of Swollen Joints by the Number of DMARD Failures at Month 2, Month 4,

Measure Title	and Month 6
Measure Description	The mean change from baseline in the mean number of swollen joints by the number of baseline participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1129)	**-4.7 (4.81)**
Failed 1 DMARD - Month 4 (n=1129)	**-6.3 (5.35)**
Failed 1 DMARD - Month 6 (n=1129)	**-7.2 (5.50)**
Failed 2 DMARDs - Month 2 (n=1176)	**-4.4 (4.54)**
Failed 2 DMARDs - Month 4 (n=1176)	**-6.0 (4.84)**
Failed 2 DMARDs - Month 6 (n=1176)	**-6.7 (5.24)**
Failed >=3 DMARDs - Month 2 (n=974)	**-4.1 (4.34)**
Failed >=3 DMARDs - Month 4 (n=974)	**-5.8 (4.83)**
Failed >=3 DMARDs - Month 6 (n=974)	**-6.6 (5.10)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6

7. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the mean number of swollen joints was calculated by the participant duration of disease at study Month 2, Month 4, and Month 6. The participant duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Duration of Disease at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=899)	**-4.4 (4.74)**
Duration < 2 years - Month 4 (n= 899)	**-5.9 (5.08)**
Duration < 2 years - Month 6 (n=899)	**-6.5 (5.26)**
Duration 2 to <5 years - Month 2 (n=764)	**-4.3 (4.63)**
Duration 2 to <5 years - Month 4 (n=764)	**-6.0 (5.04)**
Duration 2 to <5 years - Month 6 (n=764)	**-6.8 (5.41)**
Duration 5 to 10 years - Month 2 (n=692)	**-4.3 (4.49)**
Duration 5 to 10 years - Month 4 (n=692)	**-6.1 (4.96)**

Duration 5 to 10 years - Month 6 (n=692)	**-6.7 (5.40)**
Duration > 10 years - Month 2 (n=924)	**-4.6 (4.45)**
Duration > 10 years - Month 4 (n=924)	**-6.2 (4.99)**
Duration > 10 years - Month 6 (n=924)	**-7.2 (5.13)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Duration of Disease at Month 2, Month 4, and Month 6

8. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints by participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6 by the participant's level of baseline disease activity, as measured by DAS28-ESR. A total of 28 joints were evaluated. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to <=5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=698)	**-2.4 (3.33)**

DAS28 > 3.2 to <=5.1 - Month 4 (n=698)	**-3.4 (3.43)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=698)	**-3.8 (3.60)**
DAS28 > 5.1 - Month 2 (n=2572)	**-4.9 (4.73)**
DAS28 > 5.1 - Month 4 (n=2572)	**-6.8 (5.13)**
DAS28 > 5.1 - Month 6 (n=2572)	**-7.7 (5.39)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

9. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Baseline Rheumatoid Factor (RF) Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Baseline Rheumatoid Factor (RF) Level at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in the mean number of swollen joints was calculated by the participant baseline level of RF at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Baseline Rheumatoid Factor (RF) Level at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1026)	**-3.9 (4.36)**

RF <=22 IU/mL - Month 4 (n=1026)	**-5.5 (4.85)**
RF <=22 IU/mL - Month 6 (n=1026)	**-6.2 (5.07)**
RF >22 to <=146 IU/mL - Month 2 (n=1081)	**-4.2 (4.47)**
RF >22 to <=146 IU/mL - Month 4 (n=1081)	**-5.8 (4.89)**
RF >22 to <=146 IU/mL - Month 6 (n=1081)	**-6.4 (5.08)**
RF >146 IU/mL - Month 2 (n=1127)	**-5.0 (4.83)**
RF >146 IU/mL - Month 4 (n=1127)	**-6.8 (5.25)**
RF >146 IU/mL - Month 6 (n=1127)	**-7.8 (5.56)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Baseline Rheumatoid Factor (RF) Level at Month 2, Month 4, and Month 6

10. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Baseline Anti-Cyclic Citrullinated Antibody (Anti-CCP) Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Baseline Anti-Cyclic Citrullinated Antibody (Anti-CCP) Level at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in the mean number of swollen joints was calculated by the participant baseline level of anti-CCP at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in the Number of Swollen Joints by Baseline Anti-Cyclic Citrullinated Antibody (Anti-CCP) Level at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Anti-CCP <=40 U/mL - Month 2 (n=1038)	-4.0 (4.44)
Anti-CCP <=40 U/mL - Month 4 (n=1038)	-5.7 (4.89)
Anti-CCP <=40 U/mL - Month 6 (n=1038)	-6.5 (5.16)
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	-4.4 (4.41)
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	-6.1 (4.92)
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	-6.7 (5.23)
Anti-CCP >380 U/mL - Month 2 (n=1075)	-4.8 (4.86)
Anti-CCP >380 U/mL - Month 4 (n=1075)	-6.3 (5.30)
Anti-CCP >380 U/mL - Month 6 (n=1075)	-7.3 (5.51)

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Baseline Anti-Cyclic Citrullinated Antibody (Anti-CCP) Level at Month 2, Month 4, and Month 6

11. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Smoking History at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in the mean number of swollen joints was calculated by the baseline participant smoking status at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Smoking History at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
Non-Smoker - Month 2 (n=1963)	**-4.7 (4.66)**
Non-Smoker - Month 4 (n=1963)	**-6.5 (5.05)**
Non-Smoker - Month 6 (n=1963)	**-7.3 (5.35)**
Smoking history >=20 years - Month 2 (n=324)	**-4.4 (4.43)**
Smoking history >=20 years - Month 4 (n=324)	**-5.5 (5.22)**
Smoking history >=20 years - Month 6 (n=324)	**-6.5 (5.35)**
Smoking history <20 years - Month 2 (n=314)	**-4.0 (4.32)**
Smoking history <20 years - Month 4 (n=314)	**-5.4 (4.64)**
Smoking history <20 years - Month 6 (n=314)	**-6.1 (4.85)**
Currently smokes <0.5 packs/day - Month 2 (n=223)	**-4.0 (4.71)**
Currently smokes <0.5 packs/day - Month 4 (n=223)	**-6.1 (4.87)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**-6.6 (5.26)**
Currently smokes 0.5-1 pack/day - Month 2 (n=397)	**-3.6 (4.11)**
Currently smokes 0.5-1 pack/day - Month 4 (n=397)	**-5.0 (4.59)**
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	**-5.5 (4.95)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-4.0 (5.6)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-4.8 (6.25)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-5.0 (5.46)**
Pack years <7.5 - Month 2 (n=423)	**-4.2 (4.68)**
Pack years <7.5 - Month 4 (n=423)	**-6.0 (5.04)**

Pack years <7.5 - Month 6 (n=423)	**-6.5 (5.21)**
Pack years 7.5 to 20.5 - Month 2 (n=454)	**-3.8 (4.12)**
Pack years 7.5 to 20.5 - Month 4 (n=454)	**-5.3 (4.84)**
Pack years 7.5 to 20.5 - Month 6 (n=454)	**-5.9 (5.17)**
Pack years >20.5 - Month 2 (n=418)	**-3.9 (4.35)**
Pack years >20.5 - Month 4 (n=418)	**-5.0 (4.77)**
Pack years >20.5 - Month 6 (n=418)	**-5.8 (5.01)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Smoking History at Month 2, Month 4, and Month 6

12. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Eligibility for Anti-Tumor Necrosis Factor (Anti-TNF) Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Eligibility for Anti-Tumor Necrosis Factor (Anti-TNF) Treatment at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in the mean number of swollen joints was calculated by the baseline participant eligibility for anti-TNF treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Eligibility for Anti-Tumor Necrosis Factor (Anti-TNF) Treatment at Month 2, Month 4, and Month 6	

[units: Swollen Joints] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=106)	-3.1 (3.34)
Anti-TNF treatment Ineligible - Month 4 (n=106)	-4.4 (3.82)
Anti-TNF treatment Ineligible - Month 6 (n=106)	-4.5 (3.81)
Anti-TNF treatment Eligible - Month 2 (n=3174)	-4.4 (4.61)
Anti-TNF treatment Eligible - Month 4 (n=3174)	-6.1 (5.05)
Anti-TNF treatment Eligible - Month 6 (n=3174)	-6.9 (5.32)

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Eligibility for Anti-Tumor Necrosis Factor (Anti-TNF) Treatment at Month 2, Month 4, and Month 6

13. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by the participant baseline expectation of treatment outcome at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	3280

Mean Change From Baseline in the Number of Swollen Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1212)	-4.8 (4.68)
<=1.5 - Month 4 (n=1212)	-6.4 (5.14)
<=1.5 - Month 6 (n=1212)	-7.3 (5.40)
>1.5 to 1.86 - Month 2 (n=1009)	-4.4 (4.54)
>1.5 to 1.86 - Month 4 (n=1009)	-6.2 (5.09)
>1.5 to 1.86 - Month 6 (n=1009)	-6.9 (5.28)
>=1.86 - Month 2 (n=1054)	-3.9 (4.46)
>=1.86 - Month 4 (n=1054)	-5.5 (4.77)
>=1.86 - Month 6 (n=1054)	-6.3 (5.13)

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

14. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by the physician experience level at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
<=10 years - Month 2 (n=1305)	**-4.2 (4.49)**
<=10 years - Month 4 (n=1305)	**-5.8 (4.88)**
<=10 years - Month 6 (n =1305)	**-6.5 (5.13)**
>10 to 20 years - Month 2 (n=1105)	**-4.7 (4.83)**
>10 to 20 years - Month 4 (n=1105)	**-6.4 (5.35)**
>10 to 20 years - Month 6 (n=1105)	**-7.2 (5.42)**
>20 years - Month 2 (n=850)	**-4.3 (4.35)**
>20 years - Month 4 (n=850)	**-6.0 (4.77)**
>20 years - Month 6 (n=850)	**-6.8 (5.32)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level at Month 2, Month 4, and Month 6

15. Secondary: Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by the physician experience level with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1160)	**-4.2 (4.52)**
0 to 6 years - Month 4 (n=1160)	**-5.9 (5.09)**
0 to 6 years - Month 6 (n=1160)	**-6.9 (5.35)**
6 to 10 years - Month 2 (n=1745)	**-4.5 (4.63)**
6 to 10 years - Month 4 (n=1745)	**-6.2 (4.98)**
6 to 10 years - Month 6 (n=1745)	**-6.8 (5.26)**
>10 years - Month 2 (n=355)	**-4.3 (4.49)**
>10 years - Month 4 (n=355)	**-5.9 (4.98)**
>10 years - Month 6 (n=355)	**-6.6 (5.18)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

16. Secondary: Mean Change From Baseline in the Number of Swollen Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by the baseline number of patients the physician treats with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The number of patients treated with biologics is defined as the number of patients treated by the physician in the last month with

	biologics for rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1056)	**-4.3 (4.59)**
1-17 patients in prior month - Month 4 (n=1056)	**-6.2 (5.00)**
1-17 patients in prior month - Month 6 (n=1056)	**-7.4 (5.40)**
18-34 patients in prior month - Month 2 (n=1061)	**-4.5 (4.52)**
18-34 patients in prior month - Month 4 (n=1061)	**-6.1 (4.98)**
18-34 patients in prior month - Month 6 (n=1061)	**-6.8 (5.02)**
>=35 patients in prior month - Month 2 (n=1097)	**-4.5 (4.60)**
>=35 patients in prior month - Month 4 (n=1097)	**-6.1 (4.98)**
>=35 patients in prior month - Month 6 (n=1097)	**-6.8 (5.02)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

17. Secondary: Mean Change From Baseline in the Number of Swollen Joints by the the Physician Expectation of Treatment Outcome at Month 2,

Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Swollen Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of swollen joints was calculated by the physician's expectation of treatment outcome at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The physician's expectation of treatment outcomes was assessed at the start of Month 4 at which time physicians were asked to rate their expectations of treatment outcome in each participant as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Swollen Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Swollen Joints] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	**-5.5 (4.74)**
High disease activity - Month 4 (n=40)	**-7.1 (4.21)**
High disease activity - Month 6 (n=40)	**-8.2 (4.77)**
Moderate disease activity - Month 2 (n=325)	**-4.9 (4.98)**
Moderate disease activity - Month 4 (n=325)	**-6.3 (4.94)**
Moderate disease activity - Month 6 (n=325)	**-7.2 (5.75)**
Low disease activity - Month 2 (n=1932)	**-4.2 (4.53)**
Low disease activity - Month 4 (n=1932)	**-6.0 (5.12)**

Low disease activity - Month 6 (n=1932)	**-6.9 (5.23)**
Remission - Month 2 (n=966)	**-4.6 (4.50)**
Remission - Month 4 (n=966)	**-6.0 (4.84)**
Remission - Month 6 (n=966)	**-6.5 (5.24)**

No statistical analysis provided for Mean Change From Baseline in the Number of Swollen Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

18. Secondary: Mean Change From Baseline in the Number of Tender Joints by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by participant concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Concomitant MTX Dose at Month 2, Month 4, and Month 6 **[units: Tender Joints]** **Mean (Standard Deviation)**	
Low MTX Dose - Month 2 (n=142)	**-5.5 (5.82)**
	-7.9 (6.67)

Low MTX Dose - Month 4 (n=142)	
Low MTX Dose - Month 6 (n=142)	**-9.0 (6.82)**
Medium MTX Dose - Month 2 (n=526)	**-5.6 (5.76)**
Medium MTX Dose - Month 4 (n=526)	**-8.0 (6.52)**
Medium MTX Dose - Month 6 (n=526)	**-9.1 (6.57)**
High MTX Dose - Month 2 (n=1995)	**-5.5 (5.91)**
High MTX Dose - Month 4 (n=1995)	**-7.8 (6.48)**
High MTX Dose - Month 6 (n=1995)	**-8.7 (6.72)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Concomitant MTX Dose at Month 2, Month 4, and Month 6

19. Secondary: Mean Change From Baseline in the Number of Tender Joints by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by participant background DMARD treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC

Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1681)	**-5.5 (5.56)**
DMARD Combination 1 - Month 4 (n=1681)	**-7.8 (6.39)**
DMARD Combination 1 - Month 6 (n=1681)	**-8.7 (6.58)**
DMARD Combination 2 - Month 2 (n=433)	**-5.7 (6.37)**
DMARD Combination 2 - Month 4 (n=433)	**-8.0 (6.81)**
DMARD Combination 2 - Month 6 (n=433)	**-9.2 (6.46)**
DMARD Combination 3 - Month 2 (n=216)	**-5.6 (6.86)**
DMARD Combination 3 - Month 4 (n=216)	**-7.6 (6.87)**
DMARD Combination 3 - Month 6 (n=216)	**-8.2 (7.52)**
DMARD Combination 4 - Month 2 (n=150)	**-5.5 (6.11)**
DMARD Combination 4 -Month 4 (n=150)	**-8.0 (6.92)**
DMARD Combination 4 - Month 6 (n=150)	**-9.2 (7.44)**
DMARD Combination 5 - Month 2 (n=106)	**-5.4 (5.72)**
DMARD Combination 5 - Month 4 (n=106)	**-8.3 (5.81)**
DMARD Combination 5 - Month 6 (n=106)	**-8.4 (7.07)**
DMARD Combination 6 - Month 2 (n=303)	**-5.1 (5.77)**
DMARD Combination 6 - Month 4 (n=303)	**-7.5 (6.37)**
DMARD Combination 6 - Month 6 (n=303)	**-8.0 (6.68)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

20. Secondary: Mean Change From Baseline in the Number of Tender Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by participant baseline concomitant steroid treatment at study Month 2, Month 4, and Month 6. A total 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1202)	**-5.4 (5.54)**
Did Not Receive Corticosteroids - Month 4 (n=1202)	**-7.6 (6.31)**
Did Not Receive Corticosteroids - Month 6 (n=1202)	**-8.6 (6.44)**
Received Corticosteroids - Month 2 (n=2078)	**-5.6 (5.99)**
Received Corticosteroids - Month 4 (n=2078)	**-7.8 (6.61)**
Received Corticosteroids - Month 6 (n=2078)	**-8.7 (6.85)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

21. Secondary: Mean Change From Baseline in the Number of Tender Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the number of participant DMARD failures at baseline at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1129)	**-5.8 (5.74)**
Failed 1 DMARD - Month 4 (n=1129)	**-7.8 (6.65)**
Failed 1 DMARD - Month 6 (n=1129)	**-8.8 (6.94)**
Failed 2 DMARDs - Month 2 (n=1176)	**-5.5 (6.02)**
Failed 2 DMARDs - Month 4 (n=1176)	**-7.7 (6.64)**
Failed 2 DMARDs - Month 6 (n=1176)	**-8.7 (6.64)**
Failed >=3 DMARDs - Month 2 (n=974)	**-5.1 (5.68)**
Failed >=3 DMARDs - Month 4 (n=974)	**-7.6 (6.15)**
Failed >=3 DMARDs - Month 6 (n=974)	**-8.4 (6.48)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by the Number of DMARD Failures at Month 2,

Month 4, and Month 6

22. Secondary: Mean Change From Baseline in the Number of Tender Joints by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the participant duration of disease at study Month 2, Month 4, and Month 6. Duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Duration of Disease at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=899)	**-5.4 (6.03)**
Duration < 2 years - Month 4 (n=899)	**-7.4 (6.78)**
Duration < 2 years - Month 6 (n=899)	**-8.3 (6.59)**
Duration 2 to <5 years - Month 2 (n=764)	**-5.9 (5.95)**
Duration 2 to <5 years - Month 4 (n=764)	**-8.2 (6.43)**
Duration 2 to <5 years - Month 6 (n=764)	**-8.9 (6.86)**
Duration 5 to 10 years - Month 2 (n=692)	**-5.3 (5.52)**

Duration 5 to 10 years - Month 4 (n=692)	**-7.7 (6.27)**
Duration 5 to 10 years - Month 6 (n=692)	**-8.6 (6.66)**
Duration > 10 years - Month 2 (n=924)	**-5.4 (5.74)**
Duration > 10 years - Month 4 (n=924)	**-7.6 (6.45)**
Duration > 10 years - Month 6 (n=924)	**-8.7 (6.67)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Duration of Disease at Month 2, Month 4, and Month 6

23. Secondary: Mean Change From Baseline in the Number of Tender Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the participant baseline level of disease activity, as measured by DAS28, at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	

DAS28 > 3.2 to <=5.1 - Month 2 (n=698)	**-2.9 (4.10)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=698)	**-3.8 (4.42)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=698)	**-4.0 (4.59)**
DAS28 > 5.1 - Month 2 (n=2572)	**-6.2 (6.00)**
DAS28 > 5.1 - Month 4 (n=2572)	**-8.8 (6.55)**
DAS28 > 5.1 - Month 6 (n=2572)	**-9.9 (6.62)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

24. Secondary: Mean Change From Baseline in the Number of Tender Joints by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in the mean number of tender joints was calculated by the participant baseline level of RF at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Baseline RF Level at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1026)	**-5.0 (5.82)**

RF <=22 IU/mL - Month 4 (n=1026)	**-7.2 (6.60)**
RF <=22 IU/mL - Month 6 (n=1026)	**-8.1 (6.76)**
RF >22 to <=146 IU/mL - Month 2 (n=1081)	**-5.4 (5.46)**
RF >22 to <=146 IU/mL - Month 4 (n=1081)	**-7.6 (6.20)**
RF >22 to <=146 IU/mL - Month 6 (n=1081)	**-8.5 (6.36)**
RF >146 IU/mL - Month 2 (n=1127)	**-6.1 (6.16)**
RF >146 IU/mL - Month 4 (n=1127)	**-8.3 (6.69)**
RF >146 IU/mL - Month 6 (n=1127)	**-9.3 (6.97)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Baseline RF Level at Month 2, Month 4, and Month 6

25. Secondary: Mean Change From Baseline in the Number of Tender Joints by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the participant baseline level of anti-CCP at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	

[units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: Tender Joints]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1038)	**-5.0 (5.78)**
Anti-CCP <=40 U/mL - Month 4 (n=1038)	**-7.2 (6.64)**
Anti-CCP <=40 U/mL - Month 6 (n=1038)	**-8.1 (6.73)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	**-5.7 (5.73)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	**-8.0 (6.39)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	**-8.8 (6.72)**
Anti-CCP >380 U/mL - Month 2 (n=1075)	**-5.8 (5.95)**
Anti-CCP >380 U/mL - Month 4 (n=1075)	**-7.9 (6.49)**
Anti-CCP >380 U/mL - Month 6 (n=1075)	**-9.0 (6.65)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

26. Secondary: Mean Change From Baseline in the Number of Tender Joints by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Smoking History at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the baseline participant smoking status at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month

	6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Smoking History at Month 2, Month 4, and Month 6 **[units: Tender Joints]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1963)	**-5.8 (5.86)**
Non-Smoker - Month 4 (n=1963)	**-8.2 (6.49)**
Non-Smoker - Month 6 (n=1963)	**-9.2 (6.59)**
Smoking history >=20 years - Month 2 (n=324)	**-5.5 (5.97)**
Smoking history >=20 years - Month 4 (n=324)	**-7.4 (6.73)**
Smoking history >=20 years - Month 6 (n=324)	**-8.7 (6.77)**
Smoking history <20 years - Month 2 (n=314)	**-5.7 (5.74)**
Smoking history <20 years - Month 4 (n=314)	**-7.5 (6.12)**
Smoking history <20 years - Month 6 (n=314)	**-8.4 (6.51)**
Currently smokes <0.5 packs/day - Month 2 (n=223)	**-4.6 (5.11)**
Currently smokes <0.5 packs/day - Month 4 (n=223)	**-7.2 (6.67)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**-8.2 (6.84)**
Currently smokes 0.5-1 pack/day - Month 2 (n=397)	**-4.4 (5.67)**
Currently smokes 0.5-1 pack/day - Month 4 (n=397)	**-6.4 (6.36)**
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	**-6.7 (6.70)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-5.2 (6.83)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-6.9 (6.49)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-7.5 (7.64)**
Pack years <7.5 - Month 2 (n=423)	**-5.4 (5.51)**

Pack years <7.5 - Month 4 (n=423)	**-7.5 (6.37)**
Pack years <7.5 - Month 6 (n=423)	**-8.4 (6.77)**
Pack years 7.5 to 20.5 - Month 2 (n=454)	**-5.2 (5.67)**
Pack years 7.5 to 20.5 - Month 4 (n=454)	**-7.6 (6.37)**
Pack years 7.5 to 20.5 - Month 6 (n=454)	**-8.1 (6.80)**
Pack years >20.5 - Month 2 (n=418)	**-4.5 (5.76)**
Pack years >20.5 - Month 4 (n=418)	**-6.1 (6.29)**
Pack years >20.5 - Month 6 (n=418)	**-7.1 (6.61)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Smoking History at Month 2, Month 4, and Month 6

27. Secondary: Mean Change From Baseline in the Number of Tender Joints by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the baseline participant eligibility for anti-TNF treatment at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in the Number of Tender Joints by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 **[units: Tender Joints]** **Mean (Standard Deviation)**	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**-4.6 (4.75)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**-7.0 (5.68)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**-7.0 (5.70)**
Anti-TNF treatment Eligible - Month 2 (n=3174)	**-5.5 (5.86)**
Anti-TNF treatment Eligible - Month 4 (n=3174)	**-7.7 (6.53)**
Anti-TNF treatment Eligible - Month 6 (n=3174)	**-8.7 (6.72)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

28. Secondary: Mean Change From Baseline in the Number of Tender Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the participant baseline expectation of treatment outcome at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC

Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1212)	**-6.1 (5.97)**
<=1.5 - Month 4 (n=1212)	**-8.2 (6.40)**
<=1.5 - Month 6 (n=1212)	**-9.2 (6.69)**
>1.5 to 1.86 - Month 2 (n=1009)	**-5.5 (5.73)**
>1.5 to 1.86 - Month 4 (n=1009)	**-7.9 (6.67)**
>1.5 to 1.86 - Month 6 (n=1009)	**-8.8 (6.77)**
>=1.86 - Month 2 (n=1054)	**-4.8 (5.67)**
>=1.86 - Month 4 (n=1054)	**-6.9 (6.39)**
>=1.86 - Month 6 (n=1054)	**-7.8 (6.58)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

29. Secondary: Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the physician experience level at study Month 2, Month 4, Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description

GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: Tender Joints]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1305)	**-5.3 (5.80)**
<=10 years - Month 4 (n=1305)	**-7.9 (6.41)**
<=10 years - Month 6 (n=1305)	**-8.7 (6.58)**
>10 to 20 years - Month 2 (n=1105)	**-5.6 (5.80)**
>10 to 20 years - Month 4 (n=1105)	**-7.7 (6.48)**
>10 to 20 years - Month 6 (n=1105)	**-8.8 (6.59)**
>20 years - Month 2 (n=850)	**-5.5 (5.89)**
>20 years - Month 4 (n=850)	**-7.6 (6.69)**
>20 years - Month 6 (n=850)	**-8.4 (7.01)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level at Month 2, Month 4, and Month 6

30. Secondary: Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the physician experience level with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1160)	**-5.5 (5.93)**
0 to 6 years - Month 4 (n=1160)	**-8.0 (6.54)**
0 to 6 years - Month 6 (n=1160)	**-8.9 (6.76)**
6 to 10 years - Month 2 (n=1745)	**-5.5 (5.78)**
6 to 10 years - Month 4 (n=1745)	**-7.6 (6.51)**
6 to 10 years - Month 6 (n=1745)	**-8.6 (6.61)**
>10 years - Month 2 (n=355)	**-5.3 (5.66)**
>10 years - Month 4 (n=355)	**-7.4 (6.34)**
>10 years - Month 6 (n=355)	**-8.0 (6.90)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

31. Secondary: Mean Change From Baseline in the Number of Tender Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints was calculated by the baseline number of patients the

	physician treats with biologics at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The number of patients treated with biologics is defined as the number of patients treated by the physician in the last month with biologics for rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1056)	**-5.5 (5.95)**
1-17 patients in prior month - Month 4 (n=1056)	**-8.0 (6.33)**
1-17 patients in prior month - Month 6 (n=1056)	**-9.2 (6.62)**
18-34 patients in prior month - Month 2 (n=1061)	**-5.7 (5.69)**
18-34 patients in prior month - Month 4 (n=1061)	**-7.8 (6.59)**
18-34 patients in prior month - Month 6 (n=1061)	**-8.6 (6.44)**
>=35 patients in prior month - Month 2 (n=1097)	**-5.3 (5.79)**
>=35 patients in prior month - Month 4 (n=1097)	**-7.5 (6.54)**
>=35 patients in prior month - Month 6 (n=1097)	**-8.2 (6.93)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

32. Secondary: Mean Change From Baseline in the Number of Tender Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Number of Tender Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the number of tender joints. was calculated by the physician's expectation of treatment outcome at study Month 2, Month 4, and Month 6. A total of 28 joints were evaluated. The physician's expectation of treatment outcomes was assessed at the start of Month 4 at which time physicians were asked to rate their expectations of treatment outcome in each participant as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Number of Tender Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Tender Joints] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	**-7.2 (5.80)**
High disease activity - Month 4 (n=40)	**-9.4 (6.32)**
High disease activity - Month 6 (n=40)	**-10.4 (6.32)**
Moderate disease activity - Month 2 (n=325)	**-5.0 (6.02)**
Moderate disease activity - Month 4 (n=325)	**-7.3 (6.83)**
Moderate disease activity - Month 6 (n=325)	**-8.3 (6.82)**
Low disease activity - Month 2 (n=1932)	**-5.5 (5.86)**

Low disease activity - Month 4 (n=1932)	**-7.9 (6.58)**
Low disease activity - Month 6 (n=1932)	**-8.9 (6.85)**
Remission - Month 2 (n=966)	**-5.6 (5.68)**
Remission - Month 4 (n=966)	**-7.5 (6.22)**
Remission - Month 6 (n=966)	**-8.3 (6.32)**

No statistical analysis provided for Mean Change From Baseline in the Number of Tender Joints by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

33. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant global assessment of disease activity was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a visual analogue scale (VAS; 0mm [best] -100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	

Low MTX Dose - Month 2 (n=142)	**-23.1 (24.89)**
Low MTX Dose - Month 4 (n=142)	**-29.3 (26.58)**
Low MTX Dose - Month 6 (n=142)	**-27.9 (29.33)**
Medium MTX Dose - Month 2 (n=526)	**-22.6 (22.99)**
Medium MTX Dose - Month 4 (n=526)	**-28.9 (24.93)**
Medium MTX Dose - Month 6 (n=526)	**-32.4 (27.85)**
High MTX Dose - Month 2 (n=1995)	**-20.3 (25.07)**
High MTX Dose - Month 4 (n=1995)	**-26.2 (27.46)**
High MTX Dose - Month 6 (n=1995)	**-30.0 (28.68)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6

34. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1681)	**-21.2 (24.61)**
DMARD Combination 1 - Month 4 (n=1681)	**-27.5 (27.23)**
DMARD Combination 1 - Month 6 (n=1681)	**-30.7 (28.48)**
DMARD Combination 2 - Month 2 (n=433)	**-19.2 (24.84)**
DMARD Combination 2 - Month 4 (n=433)	**-26.4 (27.18)**
DMARD Combination 2 - Month 6 (n=433)	**-30.8 (29.14)**
DMARD Combination 3 - Month 2 (n=216)	**-19.8 (25.82)**
DMARD Combination 3 - Month 4 (n=216)	**-23.8 (28.38)**
DMARD Combination 3 - Month 6 (n=216)	**-26.4 (28.74)**
DMARD Combination 4 - Month 2 (n=150)	**-23.3 (25.13)**
DMARD Combination 4 -Month 4 (n=150)	**-27.2 (24.16)**
DMARD Combination 4 - Month 6 (n=150)	**-32.1 (28.95)**
DMARD Combination 5 - Month 2 (n=106)	**-21.1 (23.93)**
DMARD Combination 5 - Month 4 (n=106)	**-27.3 (24.14)**
DMARD Combination 5 - Month 6 (n=106)	**-28.9 (28.75)**
DMARD Combination 6 - Month 2 (n=303)	**-21.8 (24.95)**
DMARD Combination 6 - Month 4 (n=303)	**-26.5 (28.61)**
DMARD Combination 6 - Month 6 (n=303)	**-29.5 (29.29)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

35. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1202)	**-20.5 (23.98)**
Did Not Receive Corticosteroids - Month 4 (n=1202)	**-27.0 (26.90)**
Did Not Receive Corticosteroids - Month 6 (n=1202)	**-29.2 (28.68)**
Received Corticosteroids - Month 2 (n=2078)	**-21.3 (25.04)**
Received Corticosteroids - Month 4 (n=2078)	**-26.4 (27.33)**
Received Corticosteroids - Month 6 (n=2078)	**-30.7 (28.42)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

36. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1129)	**-20.9 (23.98)**
Failed 1 DMARD - Month 4 (n=1129)	**-27.1 (28.25)**
Failed 1 DMARD - Month 6 (n=1129)	**-29.9 (29.42)**
Failed 2 DMARDs - Month 2 (n=1176)	**-20.8 (24.56)**
Failed 2 DMARDs - Month 4 (n=1176)	**-26.1 (26.67)**
Failed 2 DMARDs - Month 6 (n=1176)	**-30.1 (28.58)**
Failed >=3 DMARDs - Month 2 (n=974)	**-21.3 (23.73)**

Failed >=3 DMARDs - Month 4 (n=974)	**-26.8 (26.52)**
Failed >=3 DMARDs - Month 6 (n=974)	**-30.4 (27.43)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6

37. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=899)	**-19.4 (25.51)**
Duration < 2 years - Month 4 (n=899)	**-25.6 (28.21)**
Duration < 2 years - Month 6 (n=899)	**-29.5 (29.45)**
	-20.9

Duration 2 to <5 years - Month 2 (n=764)	**(24.33)**
Duration 2 to <5 years - Month 4 (n=764)	**-25.9 (27.38)**
Duration 2 to <5 years - Month 6 (n=764)	**-28.9 (28.26)**
Duration 5 to 10 years - Month 2 (n=692)	**-22.2 (24.76)**
Duration 5 to 10 years - Month 4 (n=692)	**-27.8 (26.51)**
Duration 5 to 10 years - Month 6 (n=692)	**-30.2 (28.36)**
Duration > 10 years - Month 2 (n=924)	**-21.8 (23.96)**
Duration > 10 years - Month 4 (n=924)	**-27.3 (26.46)**
Duration > 10 years - Month 6 (n=924)	**-31.8 (27.91)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6

38. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-

	SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=698)	**-16.0 (23.68)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=698)	**-20.0 (26.21)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=698)	**-22.6 (27.31)**
DAS28 > 5.1 - Month 2 (n=2572)	**-22.4 (24.73)**
DAS28 > 5.1 - Month 4 (n=2572)	**-28.5 (27.15)**
DAS28 > 5.1 - Month 6 (n=2572)	**-32.3 (28.47)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

39. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1026)	**18.0 (24.82)**
RF <=22 IU/mL - Month 4 (n=1026)	**-24.7 (27.89)**
RF <=22 IU/mL - Month 6 (n=1026)	**-27.6 (28.48)**
RF >22 to <=146 IU/mL - Month 2 (n=1081)	**-20.7 (24.07)**
RF >22 to <=146 IU/mL - Month 4 (n=1081)	**-25.7 (26.77)**
RF >22 to <=146 IU/mL - Month 6 (n=1081)	**-28.5 (28.15)**
RF >146 IU/mL - Month 2 (n=1127)	**-24.2 (24.81)**
RF >146 IU/mL - Month 4 (n=1127)	**-29.6 (26.72)**
RF >146 IU/mL - Month 6 (n=1127)	**-34.2 (28.54)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6

40. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-CCP <=40 U/mL - Month 2 (n=1038)	**-17.2 (24.22)**
Anti-CCP <=40 U/mL - Month 4 (n=1038)	**-23.3 (27.04)**
Anti-CCP <=40 U/mL - Month 6 (n=1038)	**-27.4 (28.21)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	**-22.6 (25.23)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	**-28.1 (27.86)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	**-29.7 (28.88)**
Anti-CCP >380 U/mL - Month 2 (n=1075)	**-23.1 (23.99)**
Anti-CCP >380 U/mL - Month 4 (n=1075)	**-28.4 (26.44)**
Anti-CCP >380 U/mL - Month 6 (n=1075)	**-33.3 (28.26)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

41. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Non-Smoker - Month 2 (n=1963)	**-20.7 (24.43)**
Non-Smoker - Month 4 (n=1963)	**-27.3 (26.73)**
Non-Smoker - Month 6 (n=1963)	**-31.5 (27.99)**
Smoking history >=20 years - Month 2 (n=324)	**-21.1 (25.34)**
Smoking history >=20 years - Month 4 (n=324)	**-26.2 (27.96)**
Smoking history >=20 years - Month 6 (n=324)	**-29.9 (28.05)**
Smoking history <20 years - Month 2 (n=314)	**-24.2 (24.92)**
Smoking history <20 years - Month 4 (n=314)	**-28.5 (27.04)**
Smoking history <20 years - Month 6 (n=314)	**-31.2 (27.73)**
Currently smokes <0.5 packs/day - Month 2 (n=223)	**-17.5 (23.82)**
Currently smokes <0.5 packs/day - Month 4 (n=223)	**-24.0 (27.76)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**-26.3 (29.99)**
Currently smokes 0.5-1 pack/day - Month 2 (n=397)	**-21.3 (24.57)**
	-24.7

Currently smokes 0.5-1 pack/day - Month 4 (n=397)	**(27.65)**
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	**-26.3 (30.57)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-21.9 (29.42)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-20.7 (31.65)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-22.8 (29.35)**
Pack years <7.5 - Month 2 (n=423)	**-21.9 (25.21)**
Pack years <7.5 - Month 4 (n=423)	**-26.4 (27.80)**
Pack years <7.5 - Month 6 (n=423)	**-29.8 (28.76)**
Pack years 7.5 to 20.5 - Month 2 (n=454)	**-21.4 (24.97)**
Pack years 7.5 to 20.5 - Month 4 (n=454)	**-27.3 (26.86)**
Pack years 7.5 to 20.5 - Month 6 (n=454)	**-28.4 (29.04)**
Pack years >20.5 - Month 2 (n=418)	**-20.6 (25.00)**
Pack years >20.5 - Month 4 (n=418)	**-23.2 (28.82)**
Pack years >20.5 - Month 6 (n=418)	**-26.3 (28.89)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6

42. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**-18.9 (21.65)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**-24.7 (24.02)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**-25.8 (27.59)**
Anti-TNF treatment Eligible - Month 2 (n=3174)	**-21.0 (24.75)**
Anti-TNF treatment Eligible - Month 4 (n=3174)	**-26.7 (27.27)**
Anti-TNF treatment Eligible - Month 6 (n=3174)	**-30.3 (28.54)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

43. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1212)	**-23.9 (25.79)**
<=1.5 - Month 4 (n=1212)	**-29.5 (28.50)**
<=1.5 - Month 6 (n=1212)	**-33.9 (28.65)**
>1.5 to 1.86 - Month 2 (n=1009)	**-21.3 (24.59)**
>1.5 to 1.86 - Month 4 (n=1009)	**-27.0 (27.03)**
>1.5 to 1.86 - Month 6 (n=1009)	**-30.3 (28.79)**
>=1.86 - Month 2 (n=1054)	**-17.3 (22.83)**
>=1.86 - Month 4 (n=1054)	**-22.8 (25.20)**
>=1.86 - Month 6 (n=1054)	**-25.6 (27.53)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

44. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6

Measure Description	The mean change from baseline in the participant global assessment of disease activity by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=10 years - Month 2 (n=1305)	**-21.0 (24.66)**
<=10 years - Month 4 (n=1305)	**-26.2 (26.73)**
<=10 years - Month 6 (n=1305)	**-29.6 (28.41)**
>10 to 20 years - Month 2 (n=1105)	**-20.8 (24.01)**
>10 to 20 years - Month 4 (n=1105)	**-27.5 (26.88)**
>10 to 20 years - Month 6 (n=1105)	**-31.1 (28.37)**
>20 years - Month 2 (n=850)	**-21.3 (25.30)**
>20 years - Month 4 (n=850)	**-26.2 (28.21)**
>20 years - Month 6 (n=850)	**-29.8 (28.72)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6

45. Secondary: mm [Best]Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	mm [Best]Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
mm [Best]Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1160)	**-21.2 (24.02)**
0 to 6 years - Month 4 (n=1160)	**-26.8 (25.74)**
0 to 6 years - Month 6 (n=1160)	**-30.4 (27.68)**
6 to 10 years - Month 2 (n=1745)	**-20.9 (24.99)**
6 to 10 years - Month 4 (n=1745)	**-26.5 (27.81)**
6 to 10 years - Month 6 (n=1745)	**-29.8 (29.06)**
	-20.5

>10 years - Month 2 (n=355)	**(24.60)**
>10 years - Month 4 (n=355)	**-27.3 (28.62)**
>10 years - Month 6 (n=355)	**-31.2 (28.22)**

No statistical analysis provided for mm [Best]Mean Change From Baseline in Participant Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

46. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1056)	**-21.0 (23.25)**
1-17 patients in prior month - Month 4 (n=1056)	**-26.3 (25.27)**

1-17 patients in prior month - Month 6 (n=1056)	**-31.4 (27.38)**
18-34 patients in prior month - Month 2 (n=1061)	**-20.8 (24.98)**
18-34 patients in prior month - Month 4 (n=1061)	**-26.7 (27.63)**
18-34 patients in prior month - Month 6 (n=1061)	**-28.8 (28.63)**
>=35 patients in prior month - Month 2 (n=1097)	**-21.2 (25.38)**
>=35 patients in prior month - Month 4 (n=1097)	**-27.0 (28.19)**
>=35 patients in prior month - Month 6 (n=1097)	**-30.3 (29.13)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

47. Secondary: Mean Change From Baseline in Participant Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Participant Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant global assessment of disease activity by the physician's expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] – 100mm [worst]) with increasing scores indicating increased level of disease. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	

[units: participants]	**3280**
Mean Change From Baseline in Participant Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
High disease activity - Month 2 (n=40)	**-25.1 (25.56)**
High disease activity - Month 4 (n=40)	**-22.4 (24.52)**
High disease activity - Month 6 (n=40)	**-30.6 (27.95)**
Moderate disease activity - Month 2 (n=325)	**-17.3 (24.53)**
Moderate disease activity - Month 4 (n=325)	**-23.4 (27.22)**
Moderate disease activity - Month 6 (n=325)	**-28.3 (27.88)**
Low disease activity - Month 2 (n=1932)	**-21.4 (24.36)**
Low disease activity - Month 4 (n=1932)	**-27.3 (27.08)**
Low disease activity - Month 6 (n=1932)	**-31.0 (28.16)**
Remission - Month 2 (n=966)	**-21.2 (25.13)**
Remission - Month 4 (n=966)	**-26.5 (27.25)**
Remission - Month 6 (n=966)	**-28.9 (29.27)**

No statistical analysis provided for Mean Change From Baseline in Participant Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

48. Secondary: Mean Change From Baseline in the Erythrocyte Sedimentation Rate (ESR) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Erythrocyte Sedimentation Rate (ESR) by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in participant serum ESR was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Erythrocyte Sedimentation Rate (ESR) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n=142)	**-9.4 (14.73)**
Low MTX Dose - Month 4 (n=142)	**-9.8 (18.98)**
Low MTX Dose - Month 6 (n=142)	**-9.2 (21.99)**
Medium MTX Dose - Month 2 (n=526)	**-11.2 (17.91)**
Medium MTX Dose - Month 4 (n=526)	**-11.5 (21.29)**
Medium MTX Dose - Month 6 (n=526)	**-12.8 (22.52)**
High MTX Dose - Month 2 (n=1995)	**-9.2 (17.85)**
High MTX Dose - Month 4 (n=1995)	**-10.3 (19.03)**
High MTX Dose - Month 6 (n=1995)	**-10.9 (20.43)**

No statistical analysis provided for Mean Change From Baseline in the Erythrocyte Sedimentation Rate (ESR) by Concomitant MTX Dose at Month 2, Month 4, and Month 6

49. Secondary: Mean Change From Baseline in ESR by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by concomitant DMARD background treatment was calculated at study Month 2, Month 4, and Month 6. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1681)	**-9.8 (17.03)**
DMARD Combination 1 - Month 4 (n=1681)	**-10.9 (18.94)**
DMARD Combination 1 - Month 6 (n=1681)	**-11.6 (20.53)**
DMARD Combination 2 - Month 2 (n=433)	**-8.1 (19.27)**
DMARD Combination 2 - Month 4 (n=433)	**-9.2 (20.60)**
DMARD Combination 2 - Month 6 (n=433)	**-10.9 (22.12)**
DMARD Combination 3 - Month 2 (n=216)	**-10.0 (20.15)**
DMARD Combination 3 - Month 4 (n=216)	**-9.9 (19.25)**
DMARD Combination 3 - Month 6 (n=216)	**-9.8 (22.15)**
DMARD Combination 4 - Month 2 (n=150)	**-10.3 (15.74)**
DMARD Combination 4 -Month 4 (n=150)	**-14.9 (23.30)**
DMARD Combination 4 - Month 6 (n=150)	**-11.9 (21.73)**
DMARD Combination 5 - Month 2 (n=106)	**-10.0 (18.88)**
DMARD Combination 5 - Month 4 (n=106)	**-8.7 (19.13)**
DMARD Combination 5 - Month 6 (n=106)	**-9.0 (20.65)**
DMARD Combination 6 - Month 2 (n=303)	**-7.6 (17.87)**

DMARD Combination 6 - Month 4 (n=303)	**-8.1 (20.40)**
DMARD Combination 6 - Month 6 (n=303)	**-8.3 (21.40)**

No statistical analysis provided for Mean Change From Baseline in ESR by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

50. Secondary: Mean Change From Baseline in ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in serum ESR by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
Did Not Receive Corticosteroids - Month 2 (n=1202)	**-9.3 (16.83)**
Did Not Receive Corticosteroids - Month 4 (n=1202)	**-10.4 (18.58)**
Did Not Receive Corticosteroids - Month 6 (n=1202)	**-10.7 (20.59)**
Received Corticosteroids - Month 2 (n=2078)	**-9.4 (18.28)**
Received Corticosteroids - Month 4 (n=2078)	**-10.1 (20.02)**
Received Corticosteroids - Month 6 (n=2078)	**-10.7 (21.36)**

No statistical analysis provided for Mean Change From Baseline in ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

51. Secondary: Mean Change From Baseline in ESR by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by the Number of DMARD Failures at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
Failed 1 DMARD - Month 2 (n=1129)	**-10.0 (17.77)**
Failed 1 DMARD - Month 4 (n=1129)	**-11.5 (20.15)**
Failed 1 DMARD - Month 6 (n=1129)	**-12.0 (21.71)**
Failed 2 DMARDs - Month 2 (n=1176)	**-9.0 (18.03)**
Failed 2 DMARDs - Month 4 (n=1176)	**-9.6 (19.25)**
Failed 2 DMARDs - Month 6 (n=1176)	**-10.3 (20.83)**
Failed >=3 DMARDs - Month 2 (n=974)	**-9.1 (17.42)**
Failed >=3 DMARDs - Month 4 (n=974)	**-9.5 (18.96)**
Failed >=3 DMARDs - Month 6 (n=974)	**-9.9 (20.61)**

No statistical analysis provided for Mean Change From Baseline in ESR by the Number of DMARD Failures at Month 2, Month 4, and Month 6

52. Secondary: Mean Change From Baseline in ESR by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant serum ESR by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Duration of Disease at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
Duration < 2 years - Month 2 (n=899)	**-8.6 (17.77)**
Duration < 2 years - Month 4 (n=899)	**-10.6 (20.08)**
Duration < 2 years - Month 6 (n=899)	**-11.2 (21.35)**
Duration 2 to <5 years - Month 2 (n=764)	**-9.1 (17.97)**
Duration 2 to <5 years - Month 4 (n=764)	**-9.5 (19.60)**
Duration 2 to <5 years - Month 6 (n=764)	**-9.4 (20.81)**
Duration 5 to 10 years - Month 2 (n=692)	**-9.5 (17.69)**
Duration 5 to 10 years - Month 4 (n=692)	**-10.2 (18.85)**
Duration 5 to 10 years - Month 6 (n=692)	**-11.4 (21.47)**

Duration > 10 years - Month 2 (n=924)	**-10.2 (17.63)**
Duration > 10 years - Month 4 (n=924)	**-10.5 (19.37)**
Duration > 10 years - Month 6 (n=924)	**-10.9 (20.74)**

No statistical analysis provided for Mean Change From Baseline in ESR by Duration of Disease at Month 2, Month 4, and Month 6

53. Secondary: Mean Change From Baseline in ESR by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to <=5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
DAS28 > 3.2 to <=5.1 - Month 2 (n=698)	**-3.3 (11.24)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=698)	**-2.2 (13.03)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=698)	**-2.2 (13.83)**
DAS28 > 5.1 - Month 2 (n=2572)	**-11.1 (18.76)**
DAS28 > 5.1 - Month 4 (n=2572)	**-12.4 (20.36)**

DAS28 > 5.1 - Month 6 (n=2572)	**-13.1 (22.09)**

No statistical analysis provided for Mean Change From Baseline in ESR by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

54. Secondary: Mean Change From Baseline in ESR by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Baseline RF Level at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
RF <=22 IU/mL - Month 2 (n=1026)	**-8.6 (17.12)**
RF <=22 IU/mL - Month 4 (n=1026)	**-9.2 (18.36)**
RF <=22 IU/mL - Month 6 (n=1026)	**-9.7 (19.73)**
RF >22 to <=146 IU/mL - Month 2 (n=1081)	**-9.7 (17.75)**
RF >22 to <=146 IU/mL - Month 4 (n=1081)	**-10.3 (19.18)**
RF >22 to <=146 IU/mL - Month 6 (n=1081)	**-10.3 (20.90)**
RF >146 IU/mL - Month 2 (n=1127)	**-9.8 (18.35)**
RF >146 IU/mL - Month 4 (n=1127)	**-11.1 (20.70)**

RF >146 IU/mL - Month 6 (n=1127)	**-12.2 (22.41)**

No statistical analysis provided for Mean Change From Baseline in ESR by Baseline RF Level at Month 2, Month 4, and Month 6

55. Secondary: Mean Change From Baseline in ESR by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in ESR by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1038)	**-8.6 (16.79)**
Anti-CCP <=40 U/mL - Month 4 (n=1038)	**-8.9 (17.67)**
Anti-CCP <=40 U/mL - Month 6 (n=1038)	**-9.8 (20.33)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	**-9.7 (18.17)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	**-10.7 (20.44)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	**-11.0 (20.64)**
Anti-CCP >380 U/mL - Month 2 (n=1075)	**-9.7 (18.37)**
Anti-CCP >380 U/mL - Month 4 (n=1075)	**-11.1 (20.21)**

Anti-CCP >380 U/mL - Month 6 (n=1075)	**-11.4 (22.30)**

No statistical analysis provided for Mean Change From Baseline in ESR by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

56. Secondary: Mean Change From Baseline in ESR by Smoking History at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Smoking History at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Smoking History at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1963)	**-9.7 (18.40)**
Non-Smoker - Month 4 (n=1963)	**-10.8 (20.04)**
Non-Smoker - Month 6 (n=1963)	**-11.7 (21.57)**
Smoking history >=20 years - Month 2 (n=324)	**-10.3 (18.11)**
Smoking history >=20 years - Month 4 (n=324)	**-10.6 (19.52)**
Smoking history >=20 years - Month 6 (n=324)	**-9.7 (20.95)**
Smoking history <20 years - Month 2 (n=314)	**-8.4 (17.55)**

Smoking history <20 years - Month 4 (n=314)	**-10.1 (18.24)**
Smoking history <20 years - Month 6 (n=314)	**-9.9 (20.03)**
Currently smokes <0.5 packs/day - Month 2 (n=223)	**-9.3 (17.51)**
Currently smokes <0.5 packs/day - Month 4 (n=223)	**-9.4 (19.35)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**-10.7 (22.22)**
Currently smokes 0.5-1 pack/day - Month 2 (n=397)	**-8.0 (14.88)**
Currently smokes 0.5-1 pack/day - Month 4 (n=397)	**-8.6 (18.01)**
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	**-8.0 (18.68)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-6.3 (12.82)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-4.8 (16.93)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-6.2 (20.00)**
Pack years <7.5 - Month 2 (n=423)	**-9.1 (17.40)**
Pack years <7.5 - Month 4 (n=423)	**-9.2 (18.24)**
Pack years <7.5 - Month 6 (n=423)	**-10.1 (21.17)**
Pack years 7.5 to 20.5 - Month 2 (n=454)	**-9.0 (16.61)**
Pack years 7.5 to 20.5 - Month 4 (n=454)	**-9.8 (18.60)**
Pack years 7.5 to 20.5 - Month 6 (n=454)	**-10.1 (18.73)**
Pack years >20.5 - Month 2 (n=418)	**-8.2 (16.42)**
Pack years >20.5 - Month 4 (n=418)	**-9.2 (19.44)**
Pack years >20.5 - Month 6 (n=418)	**-7.6 (20.91)**

No statistical analysis provided for Mean Change From Baseline in ESR by Smoking History at Month 2, Month 4, and Month 6

57. Secondary: Mean Change From Baseline in ESR by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**-5.6 (10.46)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**-5.0 (10.87)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**-4.7 (11.99)**
Anti-TNF treatment Eligible - Month 2 (n=3174)	**-9.5 (17.94)**
Anti-TNF treatment Eligible - Month 4 (n=3174)	**-10.4 (19.70)**
Anti-TNF treatment Eligible - Month 6 (n=3174)	**-10.9 (21.29)**

No statistical analysis provided for Mean Change From Baseline in ESR by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

58. Secondary: Mean Change From Baseline in ESR by Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month

	6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
<=1.5 - Month 2 (n=1212)	**-10.1 (18.15)**
<=1.5 - Month 4 (n=1212)	**-11.2 (19.25)**
<=1.5 - Month 6 (n=1212)	**-11.4 (21.53)**
>1.5 to 1.86 - Month 2 (n=1009)	**-9.6 (18.27)**
>1.5 to 1.86 - Month 4 (n=1009)	**-11.3 (20.44)**
>1.5 to 1.86 - Month 6 (n=1009)	**-11.8 (21.58)**
>=1.86 - Month 2 (n=1054)	**-8.2 (16.79)**
>=1.86 - Month 4 (n=1054)	**-8.0 (18.73)**
>=1.86 - Month 6 (n=1054)	**-8.9 (19.96)**

No statistical analysis provided for Mean Change From Baseline in ESR by Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

59. Secondary: Mean Change From Baseline in ESR by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Physician Experience Level at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
<=10 years - Month 2 (n=1305)	**-8.6 (17.45)**
<=10 years - Month 4 (n=1305)	**-9.4 (19.02)**
<=10 years - Month 6 (n=1305)	**-9.9 (20.85)**
>10 to 20 years - Month 2 (n=1105)	**-9.6 (18.39)**
>10 to 20 years - Month 4 (n=1105)	**-10.7 (20.44)**
>10 to 20 years - Month 6 (n=1105)	**-11.8 (22.27)**
>20 years - Month 2 (n=850)	**-10.2 (17.49)**
>20 years - Month 4 (n=850)	**-10.9 (19.13)**
>20 years - Month 6 (n=850)	**-10.6 (19.95)**

No statistical analysis provided for Mean Change From Baseline in ESR by Physician Experience Level at Month 2, Month 4, and Month 6

60. Secondary: Mean Change From Baseline in ESR by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 **[units: mm/h]** **Mean (Standard Deviation)**	
0 to 6 years - Month 2 (n=1160)	**-8.8 (18.10)**
0 to 6 years - Month 4 (n=1160)	**-10.7 (19.43)**
0 to 6 years - Month 6 (n=1160)	**-9.9 (21.87)**
6 to 10 years - Month 2 (n=1745)	**-9.7 (17.65)**
6 to 10 years - Month 4 (n=1745)	**-9.6 (19.76)**
6 to 10 years - Month 6 (n=1745)	**-11.0 (20.90)**
>10 years - Month 2 (n=355)	**-9.7 (17.44)**
>10 years - Month 4 (n=355)	**-11.5 (18.81)**
>10 years - Month 6 (n=355)	**-12.0 (19.62)**

No statistical analysis provided for Mean Change From Baseline in ESR by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

61. Secondary: Mean Change From Baseline in ESR by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1056)	**-8.9 (18.47)**
1-17 patients in prior month - Month 4 (n=1056)	**-9.2 (19.18)**
1-17 patients in prior month - Month 6 (n=1056)	**-9.5 (20.50)**
18-34 patients in prior month - Month 2 (n=1061)	**-9.8 (16.19)**
18-34 patients in prior month - Month 4 (n=1061)	**-10.9 (19.55)**
18-34 patients in prior month - Month 6 (n=1061)	**-11.5 (21.16)**
>=35 patients in prior month - Month 2 (n=1097)	**-9.2 (17.96)**
>=35 patients in prior month - Month 4 (n=1097)	**-10.0 (19.33)**
>=35 patients in prior month - Month 6 (n=1097)	**-10.9 (21.02)**

No statistical analysis provided for Mean Change From Baseline in ESR by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

62. Secondary: Mean Change From Baseline in ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum ESR by the physician's expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: mm/h] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	**-16.9 (20.16)**
High disease activity - Month 4 (n=40)	**-17.0 (23.02)**
High disease activity - Month 6 (n=40)	**-13.0 (26.66)**
Moderate disease activity - Month 2 (n=325)	**-8.8 (19.09)**
Moderate disease activity - Month 4 (n=325)	**-10.1 (20.39)**
Moderate disease activity - Month 6 (n=325)	**-11.6 (21.77)**
Low disease activity - Month 2 (n=1932)	**-9.3 (17.54)**
Low disease activity - Month 4 (n=1932)	**-10.3 (19.45)**
Low disease activity - Month 6 (n=1932)	**-10.5 (20.73)**
Remission - Month 2 (n=966)	**-9.4 (17.70)**
Remission - Month 4 (n=966)	**-10.0 (19.15)**
Remission - Month 6 (n=966)	**-10.9 (21.33)**

No statistical analysis provided for Mean Change From Baseline in ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

63. Secondary: Mean Change From Baseline in C-Reactive Protein (CRP) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in C-Reactive Protein (CRP) by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The change from baseline in participant serum CRP was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in C-Reactive Protein (CRP) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
Low MTX Dose - Month 2 (n=138)	**-6.43 (15.483)**
Low MTX Dose - Month 4 (n=138)	**-4.97 (19.260)**
Low MTX Dose - Month 6 (n=138)	**-6.61 (17.632)**
Medium MTX Dose - Month 2 (n=519)	**-7.14 (17.591)**
Medium MTX Dose - Month 4 (n=519)	**-6.54 (20.221)**
Medium MTX Dose - Month 6 (n=519)	**-5.93 (23.755)**
High MTX Dose - Month 2 (n=1967)	**-5.52 (18.452)**
High MTX Dose - Month 4 (n=1967)	**-5.46 (18.921)**
High MTX Dose - Month 6 (n=1967)	**-5.76 (19.045)**

No statistical analysis provided for Mean Change From Baseline in C-Reactive Protein (CRP) by Concomitant MTX Dose at Month 2, Month 4, and Month 6

64. Secondary: Mean Change From Baseline in CRP by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by concomitant DMARD background treatment was calculated at study Month 2, Month 4, and Month 6. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1662)	**-6.02 (16.365)**
DMARD Combination 1 - Month 4 (n=1662)	**-5.74 (18.459)**
DMARD Combination 1 - Month 6 (n=1662)	**-5.91 (19.101)**
DMARD Combination 2 - Month 2 (n=424)	**-6.14 (16.979)**
DMARD Combination 2 - Month 4 (n=424)	**-5.07 (21.648)**
DMARD Combination 2 - Month 6 (n=424)	**-6.43 (18.324)**

DMARD Combination 3 - Month 2 (n=211)	**-2.56 (22.236)**
DMARD Combination 3 - Month 4 (n=211)	**-3.32 (19.341)**
DMARD Combination 3 - Month 6 (n=211)	**-2.37 (16.441)**
DMARD Combination 4 - Month 2 (n=147)	**-7.57 (22.433)**
DMARD Combination 4 -Month 4 (n=147)	**-9.61 (22.126)**
DMARD Combination 4 - Month 6 (n=147)	**-9.54 (22.444)**
DMARD Combination 5 - Month 2 (n=104)	**-4.42 (28.394)**
DMARD Combination 5 - Month 4 (n=104)	**-4.49 (16.258)**
DMARD Combination 5 - Month 6 (n=104)	**-3.62 (36.080)**
DMARD Combination 6 - Month 2 (n=301)	**-3.90 (16.817)**
DMARD Combination 6 - Month 4 (n=301)	**-4.70 (17.356)**
DMARD Combination 6 - Month 6 (n=301)	**-4.08 (19.620)**

No statistical analysis provided for Mean Change From Baseline in CRP by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

65. Secondary: Mean Change From Baseline in CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in serum CRP by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month

	6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
Did Not Receive Corticosteroids - Month 2 (n=1187)	**-5.14 (15.017)**
Did Not Receive Corticosteroids - Month 4 (n=1187)	**-4.90 (15.643)**
Did Not Receive Corticosteroids - Month 6 (n=1187)	**-5.00 (18.391)**
Received Corticosteroids - Month 2 (n=2048)	**-6.04 (19.355)**
Received Corticosteroids - Month 4 (n=2048)	**-5.98 (20.850)**
Received Corticosteroids - Month 6 (n=2048)	**-6.20 (20.738)**

No statistical analysis provided for Mean Change From Baseline in CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

66. Secondary: Mean Change From Baseline in CRP by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1118)	**-6.38 (18.525)**
Failed 1 DMARD - Month 4 (n=1118)	**-6.23 (20.809)**
Failed 1 DMARD - Month 6 (n=1118)	**-6.06 (21.514)**
Failed 2 DMARDs - Month 2 (n=1158)	**-5.20 (17.550)**
Failed 2 DMARDs - Month 4 (n=1158)	**-4.89 (18.155)**
Failed 2 DMARDs - Month 6 (n=1158)	**-5.54 (18.247)**
Failed >=3 DMARDs - Month 2 (n=958)	**-5.56 (17.533)**
Failed >=3 DMARDs - Month 4 (n=958)	**-5.69 (18.158)**
Failed >=3 DMARDs - Month 6 (n=958)	**-5.69 (19.959)**

No statistical analysis provided for Mean Change From Baseline in CRP by the Number of DMARD Failures at Month 2, Month 4, and Month 6

67. Secondary: Mean Change From Baseline in CRP by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the participant serum CRP by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Duration of Disease at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=885)	**-5.84 (18.067)**
Duration < 2 years - Month 4 (n=885)	**-5.40 (21.661)**
Duration < 2 years - Month 6 (n=885)	**-6.03 (21.956)**
Duration 2 to <5 years - Month 2 (n=756)	**-6.42 (20.069)**
Duration 2 to <5 years - Month 4 (n=756)	**-6.23 (19.018)**
Duration 2 to <5 years - Month 6 (n=756)	**-6.15 (20.592)**
Duration 5 to 10 years - Month 2 (n=681)	**-4.73 (15.933)**
Duration 5 to 10 years - Month 4 (n=681)	**-4.49 (18.010)**
Duration 5 to 10 years - Month 6 (n=681)	**-5.15 (16.892)**
Duration > 10 years - Month 2 (n=912)	**-5.73 (17.183)**
Duration > 10 years - Month 4 (n=912)	**-6.05 (17.284)**
Duration > 10 years - Month 6 (n=912)	**-5.63 (19.402)**

No statistical analysis provided for Mean Change From Baseline in CRP by Duration of Disease at Month 2, Month 4, and Month 6

68. Secondary: Mean Change From Baseline in CRP by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. DAS28-ESR scores of > 3.2 to <=5.1 indicate moderate disease activity and DAS28-ESR scores of > 5.1 indicate high disease activity.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
DAS28 > 3.2 to <=5.1 - Month 2 (n=687)	**-3.07 (11.053)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=687)	**-1.61 (13.582)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=687)	**-1.57 (13.418)**
DAS28 > 5.1 - Month 2 (n=2538)	**-6.43 (19.287)**
DAS28 > 5.1 - Month 4 (n=2538)	**-6.67 (20.241)**
DAS28 > 5.1 - Month 6 (n=2538)	**-6.89 (21.215)**

No statistical analysis provided for Mean Change From Baseline in CRP by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

69. Secondary: Mean Change From Baseline in CRP by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Baseline RF Level at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1025)	**-5.18 (16.961)**
RF <=22 IU/mL - Month 4 (n=1025)	**-4.63 (18.781)**
RF <=22 IU/mL - Month 6 (n=1025)	**-5.19 (18.356)**
RF >22 to <=146 IU/mL - Month 2 (n=1079)	**-6.12 (15.703)**
RF >22 to <=146 IU/mL - Month 4 (n=1079)	**-5.89 (17.219)**
RF >22 to <=146 IU/mL - Month 6 (n=1079)	**-5.46 (21.063)**
RF >146 IU/mL - Month 2 (n=1125)	**-5.85 (20.488)**
RF >146 IU/mL - Month 4 (n=1125)	**-6.21 (21.056)**
RF >146 IU/mL - Month 6 (n=1125)	**-6.59 (20.170)**

No statistical analysis provided for Mean Change From Baseline in CRP by Baseline RF Level at Month 2, Month 4, and Month 6

70. Secondary: Mean Change From Baseline in CRP by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in CRP by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1027)	**-5.16 (17.703)**
Anti-CCP <=40 U/mL - Month 4 (n=1027)	**-4.79 (19.454)**
Anti-CCP <=40 U/mL - Month 6 (n=1027)	**-5.03 (18.512)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1101)	**-5.95 (17.423)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1101)	**-5.73 (18.955)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1101)	**-5.60 (18.699)**
Anti-CCP >380 U/mL - Month 2 (n=1070)	**-6.00 (18.651)**
Anti-CCP >380 U/mL - Month 4 (n=1070)	**-6.22 (19.067)**
Anti-CCP >380 U/mL - Month 6 (n=1070)	**-6.60 (22.345)**

No statistical analysis provided for Mean Change From Baseline in CRP by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

71. Secondary: Mean Change From Baseline in CRP by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in CRP by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Smoking Status at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1941)	**-6.00 (18.946)**
Non-Smoker - Month 4 (n=1941)	**-5.96 (20.052)**
Non-Smoker - Month 6 (n=1941)	**-6.27 (21.278)**
Smoking history >=20 years - Month 2 (n=318)	**-5.33 (13.490)**
Smoking history >=20 years - Month 4 (n=318)	**-4.42 (18.329)**
Smoking history >=20 years - Month 6 (n=318)	**-3.70 (16.922)**
Smoking history <20 years - Month 2 (n=312)	**-5.88 (19.794)**
Smoking history <20 years - Month 4 (n=312)	**-6.50 (17.869)**
Smoking history <20 years - Month 6 (n=312)	**-7.38 (19.301)**
Currently smokes <0.5 packs/day - Month 2 (n=218)	**-4.28 (16.141)**
Currently smokes <0.5 packs/day - Month 4 (n=218)	**-4.85 (18.384)**

Currently smokes <0.5 pack/day - Month 6 (n=218)	**-4.72 (15.013)**
Currently smokes 0.5-1 pack/day - Month 2 (n=388)	**-5.61 (13.870)**
Currently smokes 0.5-1 pack/day - Month 4 (n=388)	**-4.88 (15.045)**
Currently smokes 0.5-1 pack/day - Month 6 (n=388)	**-4.57 (18.217)**
Currently smokes >1 packs/day - Month 2 (n=58)	**-3.44 (21.229)**
Currently smokes >1 packs/day - Month 4 (n=58)	**-1.86 (23.322)**
Currently smokes >1 packs/day - Month 6 (n=58)	**-2.76 (19.927)**
Pack years <7.5 - Month 2 (n=418)	**-6.13 (18.761)**
Pack years <7.5 - Month 4 (n=418)	**-5.91 (18.169)**
Pack years <7.5 - Month 6 (n=418)	**-6.75 (18.752)**
Pack years 7.5 to 20.5 - Month 2 (n=450)	**-4.73 (13.845)**
Pack years 7.5 to 20.5 - Month 4 (n=450)	**-4.63 (16.089)**
Pack years 7.5 to 20.5 - Month 6 (n=450)	**-4.60 (15.440)**
Pack years >20.5 - Month 2 (n=405)	**-4.92 (15.558)**
Pack years >20.5 - Month 4 (n=405)	**-4.40 (18.166)**
Pack years >20.5 - Month 6 (n=405)	**-3.48 (18.229)**

No statistical analysis provided for Mean Change From Baseline in CRP by Smoking Status at Month 2, Month 4, and Month 6

72. Secondary: Mean Change From Baseline in CRP by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
Anti-TNF treatment Ineligible - Month 2 (n=105)	**-2.92 (10.633)**
Anti-TNF treatment Ineligible - Month 4 (n=105)	**-2.74 (11.237)**
Anti-TNF treatment Ineligible - Month 6 (n=105)	**-3.16 (10.453)**
Anti-TNF treatment Eligible - Month 2 (n=3130)	**-5.81 (18.078)**
Anti-TNF treatment Eligible - Month 4 (n=3130)	**-5.68 (19.314)**
Anti-TNF treatment Eligible - Month 6 (n=3130)	**-5.85 (20.146)**

No statistical analysis provided for Mean Change From Baseline in CRP by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

73. Secondary: Mean Change From Baseline in CRP by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1201)	**-5.83 (15.963)**
<=1.5 - Month 4 (n=1201)	**-5.58 (17.902)**
<=1.5 - Month 6 (n=1201)	**-5.83 (17.496)**
>1.5 to 1.86 - Month 2 (n=995)	**-6.61 (18.586)**
>1.5 to 1.86 - Month 4 (n=995)	**-6.66 (21.059)**
>1.5 to 1.86 - Month 6 (n=995)	**-6.47 (22.984)**
>=1.86 - Month 2 (n=1034)	**-4.69 (19.286)**
>=1.86 - Month 4 (n=1034)	**-4.51 (18.487)**
>=1.86 - Month 6 (n=1034)	**-5.00 (19.364)**

No statistical analysis provided for Mean Change From Baseline in CRP by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

74. Secondary: Mean Change From Baseline in CRP by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: mg/L]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1284)	**-5.17 (17.628)**
<=10 years - Month 4 (n=1284)	**-5.29 (17.491)**
<=10 years - Month 6 (n=1284)	**-5.77 (20.401)**
>10 to 20 years - Month 2 (n=1094)	**-5.60 (19.412)**
>10 to 20 years - Month 4 (n=1094)	**-5.58 (20.544)**
>10 to 20 years - Month 6 (n=1094)	**-5.65 (20.715)**
>20 years - Month 2 (n=837)	**-6.71 (16.262)**
>20 years - Month 4 (n=837)	**-6.03 (19.794)**
>20 years - Month 6 (n=837)	**-5.96 (18.132)**

No statistical analysis provided for Mean Change From Baseline in CRP by Physician Experience Level at Month 2, Month 4, and Month 6

75. Secondary: Mean Change From Baseline in CRP by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in CRP by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1147)	**-5.40 (16.834)**
0 to 6 years - Month 4 (n=1147)	**-5.53 (18.865)**
0 to 6 years - Month 6 (n=1147)	**-6.38 (18.656)**
6 to 10 years - Month 2 (n=1717)	**-5.95 (18.516)**
6 to 10 years - Month 4 (n=1717)	**-5.59 (19.658)**
6 to 10 years - Month 6 (n=1717)	**-5.42 (20.802)**
>10 years - Month 2 (n=351)	**-5.58 (18.496)**
>10 years - Month 4 (n=351)	**-5.68 (17.691)**
>10 years - Month 6 (n=351)	**-5.60 (19.623)**

No statistical analysis provided for Mean Change From Baseline in CRP by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

76. Secondary: Mean Change From Baseline in CRP by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1043)	**-5.61 (17.530)**
1-17 patients in prior month - Month 4 (n=1043)	**-5.51 (19.219)**
1-17 patients in prior month - Month 6 (n=1043)	**-6.01 (17.911)**
18-34 patients in prior month - Month 2 (n=1049)	**-5.31 (18.054)**
18-34 patients in prior month - Month 4 (n=1049)	**-5.24 (20.441)**
18-34 patients in prior month - Month 6 (n=1049)	**-5.49 (21.234)**
>=35 patients in prior month - Month 2 (n=1077)	**-6.18 (18.134)**
	-5.92

>=35 patients in prior month - Month 4 (n=1077)	**(17.615)**
>=35 patients in prior month - Month 6 (n=1077)	**-5.81 (20.194)**

No statistical analysis provided for Mean Change From Baseline in CRP by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

77. Secondary: Mean Change From Baseline in CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in participant serum CRP by the physician's expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: mg/L] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	**-12.35 (19.948)**
High disease activity - Month 4 (n=40)	**-11.02 (23.210)**
High disease activity - Month 6 (n=40)	**-11.41 (20.392)**
Moderate disease activity - Month 2 (n=313)	**-6.74 (19.737)**
Moderate disease activity - Month 4 (n=313)	**-8.72 (20.915)**

Moderate disease activity - Month 6 (n=313)	**-8.97 (22.089)**
Low disease activity - Month 2 (n=1906)	**-5.82 (19.413)**
Low disease activity - Month 4 (n=1906)	**-5.70 (19.519)**
Low disease activity - Month 6 (n=1906)	**-5.86 (20.553)**
Remission - Month 2 (n=959)	**-4.80 (13.488)**
Remission - Month 4 (n=959)	**-4.13 (17.227)**
Remission - Month 6 (n=959)	**-4.32 (17.589)**

No statistical analysis provided for Mean Change From Baseline in CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

78. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in physician global assessment of disease activity was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n=142)	**-24.6**

	(19.80)
Low MTX Dose - Month 4 (n=142)	**-32.1 (21.50)**
Low MTX Dose - Month 6 (n=142)	**-35.8 (22.02)**
Medium MTX Dose - Month 2 (n=523)	**-25.9 (21.29)**
Medium MTX Dose - Month 4 (n=523)	**-34.4 (21.19)**
Medium MTX Dose - Month 6 (n=523)	**-38.2 (22.63)**
High MTX Dose - Month 2 (n=1987)	**-24.1 (20.53)**
High MTX Dose - Month 4 (n=1987)	**-32.9 (21.47)**
High MTX Dose - Month 6 (n=1987)	**-37.3 (22.93)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant MTX Dose at Month 2, Month 4, and Month 6

79. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease by concomitant DMARD background treatment was evaluated at Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide only.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1674)	**-24.7 (20.42)**
DMARD Combination 1 - Month 4 (n=1674)	**-33.0 (21.63)**
DMARD Combination 1 - Month 6 (n=1674)	**-36.5 (23.22)**
DMARD Combination 2 - Month 2 (n=432)	**-23.5 (21.44)**
DMARD Combination 2 - Month 4 (n=432)	**-33.5 (21.15)**
DMARD Combination 2 - Month 6 (n=432)	**-40.5 (21.00)**
DMARD Combination 3 - Month 2 (n=215)	**-23.9 (20.91)**
DMARD Combination 3 - Month 4 (n=215)	**-31.8 (21.43)**
DMARD Combination 3 - Month 6 (n=215)	**-37.1 (22.84)**
DMARD Combination 4 - Month 2 (n=149)	**-25.1 (20.53)**
DMARD Combination 4 -Month 4 (n=149)	**-34.5 (20.87)**
DMARD Combination 4 - Month 6 (n=149)	**-39.7 (22.46)**
DMARD Combination 5 - Month 2 (n=105)	**-26.1 (21.63)**
DMARD Combination 5 - Month 4 (n=105)	**-33.5 (21.17)**
DMARD Combination 5 - Month 6 (n=105)	**-35.7 (22.58)**
DMARD Combination 6 - Month 2 (n=302)	**-25.4 (21.24)**
DMARD Combination 6 - Month 4 (n=302)	**-33.3 (22.52)**
DMARD Combination 6 - Month 6 (n=302)	**-37.3 (23.02)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

80. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1197)	**-23.6 (20.09)**
Did Not Receive Corticosteroids - Month 4 (n=1197)	**-32.3 (21.55)**
Did Not Receive Corticosteroids - Month 6 (n=1197)	**-35.9 (23.12)**
Received Corticosteroids - Month 2 (n=2069)	**-25.0 (21.08)**
Received Corticosteroids - Month 4 (n=2069)	**-33.3 (21.66)**
Received Corticosteroids - Month 6 (n=2069)	**-37.8 (22.77)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

81. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1124)	**-24.7 (20.96)**
Failed 1 DMARD - Month 4 (n=1124)	**-32.8 (22.34)**
Failed 1 DMARD - Month 6 (n=1124)	**-36.1 (23.85)**
Failed 2 DMARDs - Month 2 (n=1171)	**-24.5 (21.20)**
Failed 2 DMARDs - Month 4 (n=1171)	**-32.8 (20.79)**
Failed 2 DMARDs - Month 6 (n=1171)	**-37.7 (21.69)**
Failed >=3 DMARDs - Month 2 (n=970)	**-24.2**

	(19.89)
Failed >=3 DMARDs - Month 4 (n=970)	**-33.2 (21.91)**
Failed >=3 DMARDs - Month 6 (n=970)	**-37.6 (23.24)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6

82. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=895)	**-23.5 (21.06)**
Duration < 2 years - Month 4 (n=895)	**-31.7 (22.44)**
Duration < 2 years - Month 6 (n=895)	**-35.3 (23.98)**

Duration 2 to <5 years - Month 2 (n=761)	**-25.0 (20.76)**
Duration 2 to <5 years - Month 4 (n=761)	**-33.4 (21.79)**
Duration 2 to <5 years - Month 6 (n=761)	**-37.5 (22.13)**
Duration 5 to 10 years - Month 2 (n=688)	**-23.6 (2128)**
Duration 5 to 10 years - Month 4 (n=688)	**-32.4 (21.00)**
Duration 5 to 10 years - Month 6 (n=688)	**-36.7 (22.90)**
Duration > 10 years - Month 2 (n=921)	**-25.7 (19.92)**
Duration > 10 years - Month 4 (n=921)	**-34.2 (21.10)**
Duration > 10 years - Month 6 (n=921)	**-38.7 (22.39)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Duration of Disease at Month 2, Month 4, and Month 6

83. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=696)	**-21.3 (19.24)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=696)	**-27.4 (20.01)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=696)	**-30.5 (20.35)**
DAS28 > 5.1 - Month 2 (n=2560)	**-25.4 (21.00)**
DAS28 > 5.1 - Month 4 (n=2560)	**-34.4 (21.81)**
DAS28 > 5.1 - Month 6 (n=2560)	**-38.9 (23.24)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

84. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1023)	**-21.9 (20.57)**
RF <=22 IU/mL - Month 4 (n=1023)	**-29.9 (21.63)**
RF <=22 IU/mL - Month 6 (n=1023)	**-34.2 (22.90)**
RF >22 to <=146 IU/mL - Month 2 (n=1077)	**-23.9 (20.35)**
RF >22 to <=146 IU/mL - Month 4 (n=1077)	**-32.4 (21.51)**
RF >22 to <=146 IU/mL - Month 6 (n=1077)	**-36.5 (22.72)**
RF >146 IU/mL - Month 2 (n=1120)	**-27.5 (20.91)**
RF >146 IU/mL - Month 4 (n=1120)	**-36.3 (21.17)**
RF >146 IU/mL - Month 6 (n=1120)	**-40.5 (22.58)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline RF Level at Month 2, Month 4, and Month 6

85. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR or at least one post-baseline measurement of DAS28-

ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-CCP <=40 U/mL - Month 2 (n=1035)	**-21.6 (20.82)**
Anti-CCP <=40 U/mL - Month 4 (n=1035)	**-30.4 (22.23)**
Anti-CCP <=40 U/mL - Month 6 (n=1035)	**-34.6 (23.64)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1105)	**-24.6 (20.60)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1105)	**-33.0 (21.29)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1105)	**-36.7 (22.92)**
Anti-CCP >380 U/mL - Month 2 (n=1071)	**-27.1 (20.62)**
Anti-CCP >380 U/mL - Month 4 (n=1071)	**-35.2 (21.23)**
Anti-CCP >380 U/mL - Month 6 (n=1071)	**-40.2 (21.96)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

86. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by participant baseline smoking status was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant

	smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Non-Smoker - Month 2 (n=1954)	**-25.0 (20.86)**
Non-Smoker - Month 4 (n=1954)	**-33.9 (21.26)**
Non-Smoker - Month 6 (n=1954)	**-38.3 (22.38)**
Smoking history >=20 years - Month 2 (n=323)	**-26.5 (19.97)**
Smoking history >=20 years - Month 4 (n=323)	**-34.3 (21.45)**
Smoking history >=20 years - Month 6 (n=323)	**-38.7 (21.91)**
Smoking history <20 years - Month 2 (n=313)	**-25.3 (20.78)**
Smoking history <20 years - Month 4 (n=313)	**-33.1 (21.79)**
Smoking history <20 years - Month 6 (n=313)	**-37.1 (24.62)**
Currently smokes <0.5 packs/day - Month 2 (n=222)	**-22.0 (19.85)**
Currently smokes <0.5 packs/day - Month 4 (n=222)	**-31.0 (22.71)**
Currently smokes <0.5 pack/day - Month 6 (n=222)	**-34.8 (24.11)**
	-21.6

Currently smokes 0.5-1 pack/day - Month 2 (n=395)	**(20.33)**
Currently smokes 0.5-1 pack/day - Month 4 (n=395)	**-28.6 (22.11)**
Currently smokes 0.5-1 pack/day - Month 6 (n=395)	**-31.6 (23.62)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-22.7 (24.16)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-28.9 (22.61)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-34.2 (21.29)**
Pack years <7.5 - Month 2 (n=422)	**-24.8 (20.94)**
Pack years <7.5 - Month 4 (n=422)	**-32.8 (22.77)**
Pack years <7.5 - Month 6 (n=422)	**-36.7 (24.61)**
Pack years 7.5 to 20.5 - Month 2 (n=451)	**-23.2 (19.99)**
Pack years 7.5 to 20.5 - Month 4 (n=451)	**-31.5 (20.84)**
Pack years 7.5 to 20.5 - Month 6 (n=451)	**-34.8 (23.22)**
Pack years >20.5 - Month 2 (n=417)	**-23.7 (20.75)**
Pack years >20.5 - Month 4 (n=417)	**-30.3 (22.73)**
Pack years >20.5 - Month 6 (n=417)	**-34.6 (22.86)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Smoking Status at Month 2, Month 4, and Month 6

87. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=105)	**-22.0 (18.89)**
Anti-TNF treatment Ineligible - Month 4 (n=105)	**-27.9 (19.21)**
Anti-TNF treatment Ineligible - Month 6 (n=105)	**-31.6 (20.66)**
Anti-TNF treatment Eligible - Month 2 (n=3161)	**-24.6 (20.79)**
Anti-TNF treatment Eligible - Month 4 (n=3161)	**-33.1 (21.68)**
Anti-TNF treatment Eligible - Month 6 (n=3161)	**-37.3 (22.96)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

88. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] -100mm [worst]) with increasing scores indicating increased level of disease. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1208)	**-26.4 (21.50)**
<=1.5 - Month 4 (n=1208)	**-34.7 (22.21)**
<=1.5 - Month 6 (n=1208)	**-39.2 (23.01)**
>1.5 to 1.86 - Month 2 (n=1005)	**-25.2 (20.46)**
>1.5 to 1.86 - Month 4 (n=1005)	**-34.3 (21.06)**
>1.5 to 1.86 - Month 6 (n=1005)	**-38.0 (22.25)**
>=1.86 - Month 2 (n=1049)	**-21.6 (19.79)**
>=1.86 - Month 4 (n=1049)	**-29.6 (21.11)**
>=1.86 - Month 6 (n=1049)	**-33.8 (23.13)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

89. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the treating physician level of experience was evaluated at study Month 2, Month 4, and Month 6. The participant global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=10 years - Month 2 (n=1305)	**-23.7 (21.25)**
<=10 years - Month 4 (n=1305)	**-33.2 (21.86)**
<=10 years - Month 6 (n=1305)	**-37.0 (23.43)**
>10 to 20 years - Month 2 (n=1101)	**-25.6 (20.53)**
>10 to 20 years - Month 4 (n=1101)	**-33.6 (21.50)**
>10 to 20 years - Month 6 (n=1101)	**-38.8 (22.62)**
>20 years - Month 2 (n=846)	**-24.5 (20.05)**
>20 years - Month 4 (n=846)	**-31.9 (21.41)**
>20 years - Month 6 (n=846)	**-35.1 (22.25)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level at Month 2, Month 4, and Month 6

90. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by physician experience level with biologics was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1159)	**-23.5 (20.84)**
0 to 6 years - Month 4 (n=1159)	**-32.5 (21.94)**
0 to 6 years - Month 6 (n=1159)	**-37.3 (23.13)**
6 to 10 years - Month 2 (n=1740)	**-24.9 (20.80)**
6 to 10 years - Month 4 (n=1740)	**-33.2 (21.50)**
	-37.1

6 to 10 years - Month 6 (n=1740)	**(22.86)**
>10 years - Month 2 (n=353)	**-26.4 (19.63)**
>10 years - Month 4 (n=353)	**-33.3 (21.24)**
>10 years - Month 6 (n=353)	**-36.6 (22.29)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

91. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the number of patients treated with biologics by the treating physician was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1053)	**-23.1 (19.37)**

1-17 patients in prior month - Month 4 (n=1053)	**-32.4 (20.04)**
1-17 patients in prior month - Month 6 (n=1053)	**-38.3 (21.95)**
18-34 patients in prior month - Month 2 (n=1060)	**-25.5 (21.04)**
18-34 patients in prior month - Month 4 (n=1060)	**-33.7 (21.96)**
18-34 patients in prior month - Month 6 (n=1060)	**-37.0 (23.00)**
>=35 patients in prior month - Month 2 (n=1095)	**-25.0 (21.38)**
>=35 patients in prior month - Month 4 (n=1095)	**-32.7 (22.79)**
>=35 patients in prior month - Month 6 (n=1095)	**-36.0 (23.67)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

92. Secondary: Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the physician global assessment of disease activity by the baseline physician expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The physician global assessment of disease activity was evaluated using a VAS (0mm [best] - 100mm [worst]) with increasing scores indicating increased level of disease. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-

	SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
High disease activity - Month 2 (n=39)	**-28.5 (18.27)**
High disease activity - Month 4 (n=39)	**-37.3 (24.56)**
High disease activity - Month 6 (n=39)	**-38.9 (28.37)**
Moderate disease activity - Month 2 (n=325)	**-24.1 (20.53)**
Moderate disease activity - Month 4 (n=325)	**-32.6 (22.50)**
Moderate disease activity - Month 6 (n=325)	**-37.4 (23.94)**
Low disease activity - Month 2 (n=1927)	**-24.8 (20.72)**
Low disease activity - Month 4 (n=1927)	**-33.6 (21.18)**
Low disease activity - Month 6 (n=1927)	**-38.0 (22.40)**
Remission - Month 2 (n=966)	**-24.0 (20.84)**
Remission - Month 4 (n=966)	**-31.6 (21.96)**
Remission - Month 6 (n=966)	**-35.1 (23.21)**

No statistical analysis provided for Mean Change From Baseline in the Physician Global Assessment of Disease Activity by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

93. Secondary: Mean Change From Baseline in DAS28-ESR Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n=142)	**-1.40 (1.060)**
Low MTX Dose - Month 4 (n=142)	**-1.97 (1.271)**
Low MTX Dose - Month 6 (n=142)	**-2.23 (1.358)**
Medium MTX Dose - Month 2 (n=526)	**-1.43 (1.037)**
Medium MTX Dose - Month 4 (n=526)	**-2.01 (1.252)**
Medium MTX Dose - Month 6 (n=526)	**-2.35 (1.400)**
High MTX Dose - Month 2 (n=1995)	**-1.42 (1.131)**
High MTX Dose - Month 4 (n=1995)	**-2.00 (1.275)**
High MTX Dose - Month 6 (n=1995)	**-2.29 (1.376)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6

94. Secondary: Mean Change From Baseline in DAS28-ESR Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

Measure Description	The DAS28-ESR measures disease burden using patient global health (self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX+sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1681)	**-1.44 (1.092)**
DMARD Combination 1 - Month 4 (n=1681)	**-2.03 (1.279)**
DMARD Combination 1 - Month 6 (n=1681)	**-2.32 (1.386)**
DMARD Combination 2 - Month 2 (n=433)	**-1.35 (1.163)**
DMARD Combination 2 - Month 4 (n=433)	**-1.94 (1.274)**
DMARD Combination 2 - Month 6 (n=433)	**-2.32 (1.329)**
DMARD Combination 3 - Month 2 (n=216)	**-1.42 (1.208)**
DMARD Combination 3 - Month 4 (n=216)	**-1.85 (1.280)**
DMARD Combination 3 - Month 6 (n=216)	**-2.10 (1.441)**
DMARD Combination 4 - Month 2 (n=150)	**-1.39 (1.059)**

DMARD Combination 4 -Month 4 (n=150)	**-2.12 (1.334)**
DMARD Combination 4 - Month 6 (n=150)	**-2.46 (1.493)**
DMARD Combination 5 - Month 2 (n=106)	**-1.46 (1.099)**
DMARD Combination 5 - Month 4 (n=106)	**-2.09 (1.148)**
DMARD Combination 5 - Month 6 (n=106)	**-2.18 (1.329)**
DMARD Combination 6 - Month 2 (n=303)	**-1.40 (1.098)**
DMARD Combination 6 - Month 4 (n=303)	**-1.90 (1.288)**
DMARD Combination 6 - Month 6 (n=303)	**-2.13 (1.352)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

95. Secondary: Mean Change From Baseline in DAS28-ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR <3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC

Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Did Not Receive Corticosteroids - Month 2 (n=1202)	**-1.41 (1.079)**
Did Not Receive Corticosteroids - Month 4 (n=1202)	**-2.00 (1.233)**
Did Not Receive Corticosteroids - Month 6 (n=1202)	**-2.30 (1.380)**
Received Corticosteroids - Month 2 (n=2078)	**-1.41 (1.123)**
Received Corticosteroids - Month 4 (n=2078)	**-1.95 (1.291)**
Received Corticosteroids - Month 6 (n=2078)	**-2.24 (1.376)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

96. Secondary: Mean Change From Baseline in DAS28-ESR Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed on a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Failed 1 DMARD - Month 2 (n=1129)	**-1.47 (1.142)**
Failed 1 DMARD - Month 4 (n=1129)	**-2.05 (1.361)**
Failed 1 DMARD - Month 6 (n=1129)	**-2.32 (1.471)**
Failed 2 DMARDs - Month 2 (n=1176)	**-1.41 (1.117)**
Failed 2 DMARDs - Month 4 (n=1176)	**-1.93 (1.254)**
Failed 2 DMARDs - Month 6 (n=1176)	**-2.26 (1.347)**
Failed >=3 DMARDs - Month 2 (n=974)	**-1.35 (1.050)**
Failed >=3 DMARDs - Month 4 (n=974)	**-1.92 (1.175)**
Failed >=3 DMARDs - Month 6 (n=974)	**-2.20 (1.301)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6

97. Secondary: Mean Change From Baseline in DAS28-ESR Score by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed on a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR >5.1 = high disease activity, DAS28-ESR <3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Duration of Disease at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=899)	**-1.39 (1.172)**
Duration < 2 years - Month 4 (n=899)	**-1.97 (1.380)**
Duration < 2 years - Month 6 (n=899)	**-2.25 (1.453)**
Duration 2 to <5 years - Month 2 (n=764)	**-1.43 (1.100)**
Duration 2 to <5 years - Month 4 (n=764)	**-1.97 (1.214)**
Duration 2 to <5 years - Month 6 (n=764)	**-2.23 (1.361)**
Duration 5 to 10 years - Month 2 (n=692)	**-1.40 (1.069)**
Duration 5 to 10 years - Month 4 (n=692)	**-1.97 (1.204)**
Duration 5 to 10 years - Month 6 (n=692)	**-2.25 (1.385)**
Duration > 10 years - Month 2 (n=924)	**-1.44 (1.076)**
Duration > 10 years - Month 4 (n=924)	**-1.97 (1.256)**
Duration > 10 years - Month 6 (n=924)	**-2.30 (1.311)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Duration of Disease at Month 2, Month 4, and Month 6

98. Secondary: Mean Change From Baseline in DAS28-ESR Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in DAS28-ESR Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR with increasing scores indicating increased level of disease burden. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
DAS28 > 3.2 to <=5.1 - Month 2 (n=698)	**-1.10 (1.001)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=698)	**-1.43 (1.085)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=698)	**-1.61 (1.184)**
DAS28 > 5.1 - Month 2 (n=2572)	**-1.50 (1.111)**
DAS28 > 5.1 - Month 4 (n=2572)	**-2.12 (1.272)**
DAS28 > 5.1 - Month 6 (n=2572)	**-2.45 (1.368)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

99. Secondary: Mean Change From Baseline in DAS28-ESR Score by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. Increasing scores indicate increased burden of disease. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Baseline RF Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
RF <=22 IU/mL - Month 2 (n=1026)	**-1.34 (1.140)**
RF <=22 IU/mL - Month 4 (n=1026)	**-1.90 (1.284)**
RF <=22 IU/mL - Month 6 (n=1026)	**-2.19 (1.427)**
RF >22 to <=146 IU/mL - Month 2 (n=1081)	**-1.41 (1.077)**
RF >22 to <=146 IU/mL - Month 4 (n=1081)	**-1.95 (1.249)**
RF >22 to <=146 IU/mL - Month 6 (n=1081)	**-2.21 (1.362)**
RF >146 IU/mL - Month 2 (n=1127)	**-1.49 (1.106)**
RF >146 IU/mL - Month 4 (n=1127)	**-2.06 (1.282)**
RF >146 IU/mL - Month 6 (n=1127)	**-2.38 (1.347)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Baseline RF Level at Month 2, Month 4, and Month 6

100. Secondary: Mean Change From Baseline in DAS28-ESR Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. Increasing scores indicate increased burden of disease. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1038)	**-1.30 (1.120)**
Anti-CCP <=40 U/mL - Month 4 (n=1038)	**-1.85 (1.277)**
Anti-CCP <=40 U/mL - Month 6 (n=1038)	**-2.17 (1.424)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	**-1.46 (1.071)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	**-2.04 (1.274)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	**-2.27 (1.371)**

Anti-CCP >380 U/mL - Month 2 (n=1075)	**-1.48 (1.127)**
Anti-CCP >380 U/mL - Month 4 (n=1075)	**-2.01 (1.261)**
Anti-CCP >380 U/mL - Month 6 (n=1075)	**-2.35 (1.343)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

101. Secondary: Mean Change From Baseline in DAS28-ESR Score by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Smoking Status at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1963)	**-1.44 (1.111)**
Non-Smoker - Month 4 (n=1963)	**-2.04 (1.260)**

Non-Smoker - Month 6 (n=1963)	-2.36 (1.341)
Smoking history >=20 years - Month 2 (n=324)	-1.44 (1.096)
Smoking history >=20 years - Month 4 (n=324)	-1.88 (1.227)
Smoking history >=20 years - Month 6 (n=324)	-2.23 (1.355)
Smoking history <20 years - Month 2 (n=314)	-1.47 (1.18)
Smoking history <20 years - Month 4 (n=314)	-1.99 (1.312)
Smoking history <20 years - Month 6 (n=314)	-2.28 (1.399)
Currently smokes <0.5 packs/day - Month 2 (n=223)	-1.26 (1.111)
Currently smokes <0.5 packs/day - Month 4 (n=223)	-1.87 (1.309)
Currently smokes <0.5 pack/day - Month 6 (n=223)	-2.17 (1.522)
Currently smokes 0.5-1 pack/day - Month 2 (n=397)	-1.30 (1.032)
Currently smokes 0.5-1 pack/day - Month 4 (n=397)	-1.76 (1.234)
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	-1.90 (1.376)
Currently smokes >1 packs/day - Month 2 (n=59)	-1.31 (1.369)
Currently smokes >1 packs/day - Month 4 (n=59)	-1.57 (1.465)
Currently smokes >1 packs/day - Month 6 (n=59)	-1.77 (1.521)
Pack years <7.5 - Month 2 (n=423)	-1.42 (1.158)
Pack years <7.5 - Month 4 (n=423)	-1.94 (1.316)
Pack years <7.5 - Month 6 (n=423)	-2.24 (1.463)
Pack years 7.5 to 20.5 - Month 2 (n=454)	-1.41 (1.049)
Pack years 7.5 to 20.5 - Month 4 (n=454)	-1.94 (1.247)
Pack years 7.5 to 20.5 - Month 6 (n=454)	-2.16 (1.386)
Pack years >20.5 - Month 2 (n=418)	-1.29 (1.071)
Pack years >20.5 - Month 4 (n=418)	-1.69 (1.227)
Pack years >20.5 - Month 6 (n=418)	-1.93 (1.380)

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Smoking Status at Month 2, Month 4, and Month 6

102. Secondary: Mean Change From Baseline in DAS28-ESR Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**-1.29 (0.881)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**-1.87 (1.051)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**-1.86 (1.117)**
Anti-TNF treatment Eligible - Month 2 (n=3174)	**-1.42 (1.114)**
Anti-TNF treatment Eligible - Month 4 (n=3174)	**-1.97 (1.277)**

Anti-TNF treatment Eligible - Month 6 (n=3174)	**-2.27 (1.383)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

103. Secondary: Mean Change From Baseline in DAS28-ESR Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-ESR score by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1212)	**-1.56 (1.132)**
<=1.5 - Month 4 (n=1212)	**-2.11 (1.283)**
<=1.5 - Month 6 (n=1212)	**-2.43**

	(1.377)
>1.5 to 1.86 - Month 2 (n=1009)	**-1.40 (1.094)**
>1.5 to 1.86 - Month 4 (n=1009)	**-2.01 (1.288)**
>1.5 to 1.86 - Month 6 (n=1009)	**-2.28 (1.386)**
>=1.86 - Month 2 (n=1054)	**-1.25 (1.063)**
>=1.86 - Month 4 (n=1054)	**-1.75 (1.208)**
>=1.86 - Month 6 (n=1054)	**-2.04 (1.344)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

104. Secondary: Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level at Month 2, Month 4, and Month 6	

[units: Score on a Scale] Mean (Standard Deviation)	
<=10 years - Month 2 (n=1305)	**-1.35 (1.073)**
<=10 years - Month 4 (n=1305)	**-1.93 (1.240)**
<=10 years - Month 6 (n=1305)	**-2.20 (1.342)**
>10 to 20 years - Month 2 (n=1105)	**-1.46 (1.126)**
>10 to 20 years - Month 4 (n=1105)	**-2.03 (1.313)**
>10 to 20 years - Month 6 (n=1105)	**-2.38 (1.423)**
>20 years - Month 2 (n=850)	**-1.45 (1.127)**
>20 years - Month 4 (n=850)	**-1.95 (1.261)**
>20 years - Month 6 (n=850)	**-2.22 (1.359)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level at Month 2, Month 4, and Month 6

105. Secondary: Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description

GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1160)	**-1.36 (1.063)**
0 to 6 years - Month 4 (n=1160)	**-1.94 (1.237)**
0 to 6 years - Month 6 (n=1160)	**-2.22 (1.359)**
6 to 10 years - Month 2 (n=1745)	**-1.44 (1.124)**
6 to 10 years - Month 4 (n=1745)	**-1.97 (1.293)**
6 to 10 years - Month 6 (n=1745)	**-2.28 (1.385)**
>10 years - Month 2 (n=355)	**-1.46 (1.151)**
>10 years - Month 4 (n=355)	**-2.05 (1.269)**
>10 years - Month 6 (n=355)	**-2.33 (1.389)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

106. Secondary: Mean Change From Baseline in DAS28-ESR Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1056)	**-1.34 (1.034)**
1-17 patients in prior month - Month 4 (n=1056)	**-1.89 (1.154)**
1-17 patients in prior month - Month 6 (n=1056)	**-2.26 (1.269)**
18-34 patients in prior month - Month 2 (n=1061)	**-1.46 (1.095)**
18-34 patients in prior month - Month 4 (n=1061)	**-2.01 (1.291)**
18-34 patients in prior month - Month 6 (n=1061)	**-2.26 (1.392)**
>=35 patients in prior month - Month 2 (n=1097)	**-1.44 (1.177)**
>=35 patients in prior month - Month 4 (n=1097)	**-2.00 (1.350)**
>=35 patients in prior month - Month 6 (n=1097)	**-2.27 (1.449)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

107. Secondary: Mean Change From Baseline in DAS28-ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

Measure Description	The DAS28-ESR measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the ESR. The DAS28-ESR is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 = low disease activity, and DAS28-ESR <2.6 = remission. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	**-1.84 (1.388)**
High disease activity - Month 4 (n=40)	**-2.28 (1.359)**
High disease activity - Month 6 (n=40)	**-2.54 (1.638)**
Moderate disease activity - Month 2 (n=325)	**-1.24 (1.067)**
Moderate disease activity - Month 4 (n=325)	**-1.72 (1.160)**
Moderate disease activity - Month 6 (n=325)	**-2.06 (1.339)**
Low disease activity - Month 2 (n=1932)	**-1.37 (1.070)**
Low disease activity - Month 4 (n=1932)	**-1.95 (1.252)**
Low disease activity - Month 6 (n=1932)	**-2.24 (1.361)**
Remission - Month 2 (n=966)	**-1.54 (1.161)**

Remission - Month 4 (n=966)	**-2.09 (1.322)**
Remission - Month 6 (n=966)	**-2.37 (1.400)**

No statistical analysis provided for Mean Change From Baseline in DAS28-ESR by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

108. Secondary: Mean Change From Baseline in DAS28-CRP Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Low MTX Dose - Month 2 (n=138)	**-1.34 (1.014)**
Low MTX Dose - Month 4 (n=138)	**-1.87 (1.184)**
Low MTX Dose - Month 6 (n=138)	**-2.18 (1.266)**

Medium MTX Dose - Month 2 (n=519)	**-1.38 (1.011)**
Medium MTX Dose - Month 4 (n=519)	**-1.94 (1.178)**
Medium MTX Dose - Month 6 (n=519)	**-2.23 (1.339)**
High MTX Dose - Month 2 (n=1967)	**-1.34 (1.067)**
High MTX Dose - Month 4 (n=1967)	**-1.87 (1.215)**
High MTX Dose - Month 6 (n=1967)	**-2.16 (1.286)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6

109. Secondary: Mean Change From Baseline in DAS28-CRP Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts & swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP >5.1 =high disease activity, DAS28-CRP <3.2=low disease activity, and DAS28-CRP <2.6=remission. DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 =leflunomide.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6	

[units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1662)	-1.36 (1.032)
DMARD Combination 1 - Month 4 (n=1662)	-1.90 (1.216)
DMARD Combination 1 - Month 6 (n=1662)	-2.18 (1.305)
DMARD Combination 2 - Month 2 (n=424)	-1.32 (1.123)
DMARD Combination 2 - Month 4 (n=424)	-1.86 (1.252)
DMARD Combination 2 - Month 6 (n=424)	-2.21 (1.254)
DMARD Combination 3 - Month 2 (n=211)	-1.31 (1.168)
DMARD Combination 3 - Month 4 (n=211)	-1.76 (1.203)
DMARD Combination 3 - Month 6 (n=211)	-1.94 (1.308)
DMARD Combination 4 - Month 2 (n=147)	-1.33 (1.022)
DMARD Combination 4 -Month 4 (n=147)	-1.92 (1.153)
DMARD Combination 4 - Month 6 (n=147)	-2.33 (1.361)
DMARD Combination 5 - Month 2 (n=104)	-1.39 (1.019)
DMARD Combination 5 - Month 4 (n=104)	-1.95 (1.127)
DMARD Combination 5 - Month 6 (n=104)	-2.10 (1.303)
DMARD Combination 6 - Month 2 (n=301)	-1.35 (1.029)
DMARD Combination 6 - Month 4 (n=301)	-1.86 (1.216)
DMARD Combination 6 - Month 6 (n=301)	-2.06 (1.279)

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

110. Secondary: Mean Change From Baseline in DAS28-CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month

	6
Measure Description	The mean change from baseline in the DAS28-CRP by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Did Not Receive Corticosteroids - Month 2 (n=1187)	**-1.34 (1.013)**
Did Not Receive Corticosteroids - Month 4 (n=1187)	**-1.86 (1.152)**
Did Not Receive Corticosteroids - Month 6 (n=1187)	**-2.16 (1.289)**
Received Corticosteroids - Month 2 (n=2048)	**-1.35 (1.072)**
Received Corticosteroids - Month 4 (n=2048)	**-1.86 (1.237)**
Received Corticosteroids - Month 6 (n=2048)	**-2.14 (1.297)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

111. Secondary: Mean Change From Baseline in DAS28-CRP Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Failed 1 DMARD - Month 2 (n=1118)	**-1.39 (1.082)**
Failed 1 DMARD - Month 4 (n=1118)	**-1.91 (1.288)**
Failed 1 DMARD - Month 6 (n=1118)	**-2.19 (1.366)**
Failed 2 DMARDs - Month 2 (n=1158)	**-1.35 (1.064)**
Failed 2 DMARDs - Month 4 (n=1158)	**-1.83 (1.186)**
Failed 2 DMARDs - Month 6 (n=1158)	**-2.13 (1.271)**
Failed >=3 DMARDs - Month 2 (n=958)	**-1.30 (0.993)**
Failed >=3 DMARDs - Month 4 (n=958)	**-1.84 (1.128)**
Failed >=3 DMARDs - Month 6 (n=958)	**-2.12 (1.234)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by the Number of DMARD Failures at Month 2, Month 4, and Month 6

112. Secondary: Mean Change From Baseline in DAS28-CRP Score by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Duration of Disease at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Duration < 2 years - Month 2 (n=885)	**-1.31 (1.113)**
Duration < 2 years - Month 4 (n=885)	**-1.82 (1.296)**
Duration < 2 years - Month 6 (n=885)	**-2.10 (1.353)**
Duration 2 to <5 years - Month 2 (n=756)	**-1.38 (1.042)**
Duration 2 to <5 years - Month 4 (n=756)	**-1.90 (1.169)**

Duration 2 to <5 years - Month 6 (n=756)	**-2.16 (1.278)**
Duration 5 to 10 years - Month 2 (n=681)	**-1.33 (1.022)**
Duration 5 to 10 years - Month 4 (n=681)	**-1.87 (1.148)**
Duration 5 to 10 years - Month 6 (n=681)	**-2.12 (1.298)**
Duration > 10 years - Month 2 (n=912)	**-1.37 (1.016)**
Duration > 10 years - Month 4 (n=912)	**-1.87 (1.188)**
Duration > 10 years - Month 6 (n=912)	**-2.20 (1.243)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Duration of Disease at Month 2, Month 4, and Month 6

113. Secondary: Mean Change From Baseline in DAS28-CRP Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP with increasing scores indicating increased burden of disease. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). DAS28-CRP > 5.1 = high disease activity, DAS28-CRP < 3.2 to < =5.1 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in DAS28-CRP Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=687)	-1.06 (0.931)
DAS28 > 3.2 to <=5.1 - Month 4 (n=687)	-1.37 (1.025)
DAS28 > 3.2 to <=5.1 - Month 6 (n=687)	-1.55 (1.088)
DAS28 > 5.1 - Month 2 (n=2538)	-1.43 (1.063)
DAS28 > 5.1 - Month 4 (n=2538)	-2.00 (1.216)
DAS28 > 5.1 - Month 6 (n=2538)	-2.31 (1.296)

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

114. Secondary: Mean Change From Baseline in DAS28-CRP Score by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	

[units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Baseline RF Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
RF <=22 IU/mL - Month 2 (n=1025)	**-1.23 (1.057)**
RF <=22 IU/mL - Month 4 (n=1025)	**-1.75 (1.200)**
RF <=22 IU/mL - Month 6 (n=1025)	**-2.02 (1.294)**
RF >22 to <=146 IU/mL - Month 2 (n=1079)	**-1.34 (1.017)**
RF >22 to <=146 IU/mL - Month 4 (n=1079)	**-1.85 (1.170)**
RF >22 to <=146 IU/mL - Month 6 (n=1079)	**-2.12 (1.280)**
RF >146 IU/mL - Month 2 (n=1125)	**-1.45 (1.067)**
RF >146 IU/mL - Month 4 (n=1125)	**-1.98 (1.238)**
RF >146 IU/mL - Month 6 (n=1125)	**-2.29 (1.295)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Baseline RF Level at Month 2, Month 4, and Month 6

115. Secondary: Mean Change From Baseline in DAS28-CRP Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-CCP <=40 U/mL - Month 2 (n=1027)	**-1.22 (1.048)**
Anti-CCP <=40 U/mL - Month 4 (n=1027)	**-1.73 (1.200)**
Anti-CCP <=40 U/mL - Month 6 (n=1027)	**-2.02 (1.285)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1101)	**-1.38 (1.022)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1101)	**-1.92 (1.208)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1101)	**-2.16 (1.301)**
Anti-CCP >380 U/mL - Month 2 (n=1070)	**-1.43 (1.072)**
Anti-CCP >380 U/mL - Month 4 (n=1070)	**-1.92 (1.204)**
Anti-CCP >380 U/mL - Month 6 (n=1070)	**-2.26 (1.284)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

116. Secondary: Mean Change From Baseline in DAS28-CRP Score by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Smoking Status at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Non-Smoker - Month 2 (n=1941)	**-1.38 (1.054)**
Non-Smoker - Month 4 (n=1941)	**-1.94 (1.195)**
Non-Smoker - Month 6 (n=1941)	**-2.26 (1.257)**
Smoking history >=20 years - Month 2 (n=318)	**-1.36 (1.036)**
Smoking history >=20 years - Month 4 (n=318)	**-1.74 (1.190)**
Smoking history >=20 years - Month 6 (n=318)	**-2.11 (1.309)**
Smoking history <20 years - Month 2 (n=312)	**-1.41 (1.068)**
Smoking history <20 years - Month 4 (n=312)	**-1.88 (1.266)**
Smoking history <20 years - Month 6 (n=312)	**-2.15 (1.325)**
Currently smokes <0.5 packs/day - Month 2 (n=218)	**-1.15 (1.037)**
Currently smokes <0.5 packs/day - Month 4 (n=218)	**-1.76 (1.241)**
Currently smokes <0.5 pack/day - Month 6 (n=218)	**-2.04 (1.364)**
Currently smokes 0.5-1 pack/day - Month 2 (n=388)	**-1.22 (0.984)**
Currently smokes 0.5-1 pack/day - Month 4 (n=388)	**-1.63 (1.155)**
Currently smokes 0.5-1 pack/day - Month 6 (n=388)	**-1.77 (1.289)**

Currently smokes >1 packs/day - Month 2 (n=58)	**-1.33 (1.246)**
Currently smokes >1 packs/day - Month 4 (n=58)	**-1.55 (1.248)**
Currently smokes >1 packs/day - Month 6 (n=58)	**-1.63 (1.386)**
Pack years <7.5 - Month 2 (n=418)	**-1.34 (1.088)**
Pack years <7.5 - Month 4 (n=418)	**-1.82 (1.239)**
Pack years <7.5 - Month 6 (n=418)	**-2.12 (1.346)**
Pack years 7.5 to 20.5 - Month 2 (n=450)	**-1.32 (1.021)**
Pack years 7.5 to 20.5 - Month 4 (n=450)	**-1.83 (1.195)**
Pack years 7.5 to 20.5 - Month 6 (n=450)	**-2.03 (1.319)**
Pack years >20.5 - Month 2 (n=405)	**-1.22 (0.989)**
Pack years >20.5 - Month 4 (n=405)	**-1.57 (1.148)**
Pack years >20.5 - Month 6 (n=405)	**-1.81 (1.294)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Smoking Status at Month 2, Month 4, and Month 6

117. Secondary: Mean Change From Baseline in DAS28-CRP Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=105)	**-1.17 (0.867)**
Anti-TNF treatment Ineligible - Month 4 (n=105)	**-1.75 (0.982)**
Anti-TNF treatment Ineligible - Month 6 (n=105)	**-1.81 (1.086)**
Anti-TNF treatment Eligible - Month 2 (n=3130)	**-1.35 (1.056)**
Anti-TNF treatment Eligible - Month 4 (n=3130)	**-1.87 (1.213)**
Anti-TNF treatment Eligible - Month 6 (n=3130)	**-2.16 (1.299)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

118. Secondary: Mean Change From Baseline in DAS28-CRP Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the DAS28-CRP score by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1201)	**-1.48 (1.081)**
<=1.5 - Month 4 (n=1201)	**-1.97 (1.225)**
<=1.5 - Month 6 (n=1201)	**-2.31 (1.285)**
>1.5 to 1.86 - Month 2 (n=995)	**-1.35 (1.031)**
>1.5 to 1.86 - Month 4 (n=995)	**-1.92 (1.212)**
>1.5 to 1.86 - Month 6 (n=995)	**-2.16 (1.294)**
>=1.86 - Month 2 (n=1034)	**-1.19 (1.006)**
>=1.86 - Month 4 (n=1034)	**-1.67 (1.153)**
>=1.86 - Month 6 (n=1034)	**-1.94 (1.278)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

119. Secondary: Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the

	minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1284)	**-1.30 (1.026)**
<=10 years - Month 4 (n=1284)	**-1.83 (1.171)**
<=10 years - Month 6 (n=1284)	**-2.12 (1.274)**
>10 to 20 years - Month 2 (n=1094)	**-1.39 (1.051)**
>10 to 20 years - Month 4 (n=1094)	**-1.93 (1.242)**
>10 to 20 years - Month 6 (n=1094)	**-2.23 (1.305)**
>20 years - Month 2 (n=837)	**-1.36 (1.082)**
>20 years - Month 4 (n=837)	**-1.83 (1.208)**
>20 years - Month 6 (n=837)	**-2.09 (1.301)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level at Month 2, Month 4, and Month 6

120. Secondary: Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1147)	**-1.31 (1.028)**
0 to 6 years - Month 4 (n=1147)	**-1.83 (1.179)**
0 to 6 years - Month 6 (n=1147)	**-2.16 (1.281)**
6 to 10 years - Month 2 (n=1717)	**-1.37 (1.047)**
6 to 10 years - Month 4 (n=1717)	**-1.87 (1.220)**
6 to 10 years - Month 6 (n=1717)	**-2.14 (1.292)**
>10 years - Month 2 (n=351)	**-1.40 (1.126)**

>10 years - Month 4 (n=351)	**-1.93 (1.225)**
>10 years - Month 6 (n=351)	**-2.16 (1.337)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

121. Secondary: Mean Change From Baseline in DAS28-CRP Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in DAS28-CRP Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1043)	**-1.31 (1.001)**
1-17 patients in prior month - Month 4 (n=1043)	**-1.81 (1.111)**
1-17 patients in prior month - Month 6 (n=1043)	**-2.21**

	(1.228)
18-34 patients in prior month - Month 2 (n=1049)	**-1.36 (1.040)**
18-34 patients in prior month - Month 4 (n=1049)	**-1.88 (1.228)**
18-34 patients in prior month - Month 6 (n=1049)	**-2.13 (1.297)**
>=35 patients in prior month - Month 2 (n=1077)	**-1.38 (1.100)**
>=35 patients in prior month - Month 4 (n=1077)	**-1.90 (1.269)**
>=35 patients in prior month - Month 6 (n=1077)	**-2.11 (1.339)**

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP Score by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

122. Secondary: Mean Change From Baseline in DAS28-CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in DAS28-CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The DAS28-CRP measures disease burden using patient global health (patient self-assessment), tender joint-counts and swollen joint-counts (up to 28), and the CRP. The DAS28-CRP is expressed as a score on a scale with the minimum score=0 (best) to maximum score=10 (worst). Increasing scores indicate increased burden of disease with DAS28-CRP> 5.1 = high disease activity, DAS28-CRP < 3.2 = low disease activity, and DAS28-CRP <2.6 = remission. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in DAS28-CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
High disease activity - Month 2 (n=40)	-1.68 (1.084)
High disease activity - Month 4 (n=40)	-2.10 (1.190)
High disease activity - Month 6 (n=40)	-2.57 (1.485)
Moderate disease activity - Month 2 (n=313)	-1.19 (0.992)
Moderate disease activity - Month 4 (n=313)	-1.67 (1.104)
Moderate disease activity - Month 6 (n=313)	-1.96 (1.265)
Low disease activity - Month 2 (n=1906)	-1.32 (1.037)
Low disease activity - Month 4 (n=1906)	-1.85 (1.207)
Low disease activity - Month 6 (n=1906)	-2.14 (1.300)
Remission - Month 2 (n=959)	-1.44 (1.083)
Remission - Month 4 (n=959)	-1.94 (1.224)
Remission - Month 6 (n=959)	-2.20 (1.271)

No statistical analysis provided for Mean Change From Baseline in DAS28-CRP by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

123. Secondary: Mean Change From Baseline in the Simplified Disease Activity Index (SDAI) Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Simplified Disease Activity Index (SDAI) Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10cm [worst]) and level of C-reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Simplified Disease Activity Index (SDAI) Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n=138)	**-15.55 (11.605)**
Low MTX Dose - Month 4 (n=138)	**-20.69 (13.346)**
Low MTX Dose - Month 6 (n=138)	**-23.81 (14.063)**
Medium MTX Dose - Month 2 (n=516)	**-15.74 (11.579)**
Medium MTX Dose - Month 4 (n=516)	**-21.38 (12.872)**
Medium MTX Dose - Month 6 (n=516)	**-24.01 (13.992)**
High MTX Dose - Month 2 (n=1959)	**-14.99 (11.920)**
High MTX Dose - Month 4 (n=1959)	**-20.52 (13.061)**
High MTX Dose - Month 6 (n=1959)	**-23.00 (13.743)**

No statistical analysis provided for Mean Change From Baseline in the Simplified Disease Activity Index (SDAI) Score by Concomitant MTX Dose at Month 2, Month 4, and Month 6

124. Secondary: Mean Change From Baseline in SDAI Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein

	(mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1655)	**-15.22 (11.434)**
DMARD Combination 1 - Month 4 (n=1655)	**-20.59 (12.977)**
DMARD Combination 1 - Month 6 (n=1655)	**-23.07 (13.766)**
DMARD Combination 2 - Month 2 (n=423)	**-15.16 (12.811)**
DMARD Combination 2 - Month 4 (n=423)	**-21.02 (13.780)**
DMARD Combination 2 - Month 6 (n=423)	**-24.31 (13.540)**
DMARD Combination 3 - Month 2 (n=210)	**-14.64 (13.206)**
DMARD Combination 3 - Month 4 (n=210)	**-19.84 (13.763)**
DMARD Combination 3 - Month 6 (n=210)	**-21.41 (14.685)**
DMARD Combination 4 - Month 2 (n=146)	**-14.86 (11.590)**
DMARD Combination 4 -Month 4 (n=146)	**-21.52 (12.601)**

DMARD Combination 4 - Month 6 (n=146)	**-24.45 (14.879)**
DMARD Combination 5 - Month 2 (n=103)	**-15.63 (11.838)**
DMARD Combination 5 - Month 4 (n=103)	**-20.71 (11.925)**
DMARD Combination 5 - Month 6 (n=103)	**-21.67 (13.876)**
DMARD Combination 6 - Month 2 (n=300)	**-14.11 (11.443)**
DMARD Combination 6 - Month 4 (n=300)	**-19.70 (12.639)**
DMARD Combination 6 - Month 6 (n=300)	**-21.41 (13.670)**

No statistical analysis provided for Mean Change From Baseline in SDAI Score by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

125. Secondary: Mean Change From Baseline in SDAI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0 cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in SDAI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1182)	-14.86 (11.130)
Did Not Receive Corticosteroids - Month 4 (n=1182)	-20.20 (12.452)
Did Not Receive Corticosteroids - Month 6 (n=1182)	-22.50 (13.513)
Received Corticosteroids - Month 2 (n=2039)	-15.12 (12.102)
Received Corticosteroids - Month 4 (n=2039)	-20.54 (13.367)
Received Corticosteroids - Month 6 (n=2039)	-23.12 (13.962)

No statistical analysis provided for Mean Change From Baseline in SDAI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

126. Secondary: Mean Change From Baseline in SDAI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	

[units: participants]	**3280**
Mean Change From Baseline in SDAI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Failed 1 DMARD - Month 2 (n=1113)	**-15.69 (11.955)**
Failed 1 DMARD - Month 4 (n=1113)	**-20.82 (13.873)**
Failed 1 DMARD - Month 6 (n=1113)	**-23.31 (14.472)**
Failed 2 DMARDs - Month 2 (n=1153)	**-14.97 (11.902)**
Failed 2 DMARDs - Month 4 (n=1153)	**-20.26 (12.712)**
Failed 2 DMARDs - Month 6 (n=1153)	**-22.74 (13.451)**
Failed >=3 DMARDs - Month 2 (n=954)	**-14.33 (11.303)**
Failed >=3 DMARDs - Month 4 (n=954)	**-20.12 (12.421)**
Failed >=3 DMARDs - Month 6 (n=954)	**-22.60 (13.430)**

No statistical analysis provided for Mean Change From Baseline in SDAI by the Number of DMARD Failures at Month 2, Month 4, and Month 6

127. Secondary: Mean Change From Baseline in SDAI by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Duration of Disease at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Duration < 2 years - Month 2 (n=881)	**-14.62 (12.465)**
Duration < 2 years - Month 4 (n=881)	**-19.74 (13.904)**
Duration < 2 years - Month 6 (n=881)	**-22.04 (14.136)**
Duration 2 to <5 years - Month 2 (n=753)	**-15.37 (11.745)**
Duration 2 to <5 years - Month 4 (n=753)	**-20.84 (12.672)**
Duration 2 to <5 years - Month 6 (n=753)	**-23.12 (13.619)**
Duration 5 to 10 years - Month 2 (n=677)	**-14.75 (11.368)**
Duration 5 to 10 years - Month 4 (n=677)	**-20.50 (12.587)**
Duration 5 to 10 years - Month 6 (n=677)	**-22.63 (13.893)**
Duration > 10 years - Month 2 (n=909)	**-15.35 (11.331)**
Duration > 10 years - Month 4 (n=909)	**-20.65 (12.804)**
Duration > 10 years - Month 6 (n=909)	**-23.71 (13.516)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Duration of Disease at Month 2, Month 4, and Month 6

128. Secondary: Mean Change From Baseline in SDAI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of five outcome parameters: tender and swollen joint count (based on a 28 joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased

	level of disease with increasing scores indicating increased burden of disease. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
DAS28 > 3.2 to <=5.1 - Month 2 (n=685)	**-9.34 (8.351)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=685)	**-12.20 (8.638)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=685)	**-13.42 (8.997)**
DAS28 > 5.1 - Month 2 (n=2526)	**-16.61 (12.035)**
DAS28 > 5.1 - Month 4 (n=2526)	**-22.66 (13.121)**
DAS28 > 5.1 - Month 6 (n=2526)	**-25.48 (13.745)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

129. Secondary: Mean Change From Baseline in SDAI by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Baseline RF Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
RF <=22 IU/mL - Month 2 (n=1022)	**-13.31 (11.369)**
RF <=22 IU/mL - Month 4 (n=1022)	**-18.68 (12.690)**
RF <=22 IU/mL - Month 6 (n=1022)	**-21.03 (13.335)**
RF >22 to <=146 IU/mL - Month 2 (n=1075)	**-14.73 (11.288)**
RF >22 to <=146 IU/mL - Month 4 (n=1075)	**-19.89 (12.479)**
RF >22 to <=146 IU/mL - Month 6 (n=1075)	**-22.09 (13.315)**
RF >146 IU/mL - Month 2 (n=1118)	**-16.88 (12.288)**
RF >146 IU/mL - Month 4 (n=1118)	**-22.53 (13.618)**
RF >146 IU/mL - Month 6 (n=1118)	**-25.38 (14.328)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Baseline RF Level at Month 2, Month 4, and Month 6

130. Secondary: Mean Change From Baseline in SDAI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in SDAI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1024)	**-13.40 (11.370)**
Anti-CCP <=40 U/mL - Month 4 (n=1024)	**-18.92 (12.860)**
Anti-CCP <=40 U/mL - Month 6 (n=1024)	**-21.41 (13.526)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1094)	**-15.39 (11.601)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1094)	**-21.01 (12.787)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1094)	**-22.89 (13.718)**
Anti-CCP >380 U/mL - Month 2 (n=1066)	**-16.23 (12.156)**
Anti-CCP >380 U/mL - Month 4 (n=1066)	**-21.23 (13.436)**
Anti-CCP >380 U/mL - Month 6 (n=1066)	**-24.38 (14.046)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

131. Secondary: Mean Change From Baseline in SDAI by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Smoking Status at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1932)	**-15.64 (11.959)**
Non-Smoker - Month 4 (n=1932)	**-21.45 (13.082)**
Non-Smoker - Month 6 (n=1932)	**-24.25 (13.565)**
Smoking history >=20 years - Month 2 (n=317)	**-15.10 (11.260)**
Smoking history >=20 years - Month 4 (n=317)	**-19.34 (13.177)**
Smoking history >=20 years - Month 6 (n=317)	**-22.54 (14.104)**
Smoking history <20 years - Month 2 (n=311)	**-15.16 (11.477)**

Smoking history <20 years - Month 4 (n=311)	**-19.81 (12.777)**
Smoking history <20 years - Month 6 (n=311)	**-22.09 (13.648)**
Currently smokes <0.5 packs/day - Month 2 (n=217)	**-13.29 (11.523)**
Currently smokes <0.5 packs/day - Month 4 (n=217)	**-19.75 (12.965)**
Currently smokes <0.5 pack/day - Month 6 (n=217)	**-21.63 (13.986)**
Currently smokes 0.5-1 pack/day - Month 2 (n=386)	**-12.85 (10.766)**
Currently smokes 0.5-1 pack/day - Month 4 (n=386)	**-17.31 (12.300)**
Currently smokes 0.5-1 pack/day - Month 6 (n=386)	**-18.53 (13.500)**
Currently smokes >1 packs/day - Month 2 (n=58)	**-14.23 (14.048)**
Currently smokes >1 packs/day - Month 4 (n=58)	**-17.48 (13.194)**
Currently smokes >1 packs/day - Month 6 (n=58)	**-17.91 (14.453)**
Pack years <7.5 - Month 2 (n=417)	**-15.03 (11.772)**
Pack years <7.5 - Month 4 (n=417)	**-20.22 (13.138)**
Pack years <7.5 - Month 6 (n=417)	**-22.30 (14.299)**
Pack years 7.5 to 20.5 - Month 2 (n=447)	**-14.06 (11.024)**
Pack years 7.5 to 20.5 - Month 4 (n=447)	**-19.43 (12.462)**
Pack years 7.5 to 20.5 - Month 6 (n=447)	**-20.97 (13.912)**
Pack years >20.5 - Month 2 (n=404)	**-13.27 (10.943)**
Pack years >20.5 - Month 4 (n=404)	**-17.00 (12.278)**
Pack years >20.5 - Month 6 (n=404)	**-19.27 (13.313)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Smoking Status at Month 2, Month 4, and Month 6

132. Secondary: Mean Change From Baseline in SDAI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in SDAI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-TNF treatment Ineligible - Month 2 (n=104)	**-12.10 (9.033)**
Anti-TNF treatment Ineligible - Month 4 (n=104)	**-17.08 (10.679)**
Anti-TNF treatment Ineligible - Month 6 (n=104)	**-17.50 (11.278)**
Anti-TNF treatment Eligible- Month 2 (n=3117)	**-15.12 (11.823)**
Anti-TNF treatment Eligible - Month 4 (n=3117)	**-20.52 (13.094)**
Anti-TNF treatment Eligible - Month 6 (n=3117)	**-23.07 (13.841)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

133. Secondary: Mean Change From Baseline in SDAI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4,

	and Month 6
Measure Description	The mean change from baseline in the SDAI by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1197)	**-16.51 (12.063)**
<=1.5 - Month 4 (n=1197)	**-21.74 (13.182)**
<=1.5 - Month 6 (n=1197)	**-24.42 (13.894)**
>1.5 to 1.86 - Month 2 (n=991)	**-15.24 (11.600)**
>1.5 to 1.86 - Month 4 (n=991)	**-21.04 (13.244)**
>1.5 to 1.86 - Month 6 (n=991)	**-23.20 (13.816)**
>=1.86 - Month 2 (n=1029)	**-13.09 (11.276)**
>=1.86 - Month 4 (n=1029)	**-18.24 (12.411)**
>=1.86 - Month 6 (n=1029)	**-20.76 (13.431)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

134. Secondary: Mean Change From Baseline in SDAI by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1284)	**-14.49 (11.734)**
<=10 years - Month 4 (n=1284)	**-20.20 (12.818)**
<=10 years - Month 6 (n=1284)	**-22.60 (13.587)**
>10 to 20 years - Month 2 (n=1090)	**-15.62 (11.857)**
>10 to 20 years - Month 4 (n=1090)	**-20.95 (13.465)**
>10 to 20 years - Month 6 (n=1090)	**-23.71 (13.926)**

>20 years - Month 2 (n=833)	**-15.10 (11.571)**
>20 years - Month 4 (n=833)	**-20.13 (12.810)**
>20 years - Month 6 (n=833)	**-22.32 (13.857)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Physician Experience Level at Month 2, Month 4, and Month 6

135. Secondary: Mean Change From Baseline in SDAI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
0 to 6 years - Month 2 (n=1146)	**-14.71 (11.851)**
0 to 6 years - Month 4 (n=1146)	**-20.41 (13.109)**
0 to 6 years - Month 6 (n=1146)	**-23.43 (13.784)**

6 to 10 years - Month 2 (n=1712)	**-15.25 (11.694)**
6 to 10 years - Month 4 (n=1712)	**-20.50 (13.078)**
6 to 10 years - Month 6 (n=1712)	**-22.75 (13.831)**
>10 years - Month 2 (n=349)	**-14.99 (11.616)**
>10 years - Month 4 (n=349)	**-20.17 (12.644)**
>10 years - Month 6 (n=349)	**-21.93 (13.491)**

No statistical analysis provided for Mean Change From Baseline in SDAI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

136. Secondary: Mean Change From Baseline in SDAI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6	

[units: Score on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1040)	-14.80 (11.566)
1-17 patients in prior month - Month 4 (n=1040)	-20.65 (12.437)
1-17 patients in prior month - Month 6 (n=1040)	-24.32 (13.447)
18-34 patients in prior month - Month 2 (n=1048)	-15.32 (11.736)
18-34 patients in prior month - Month 4 (n=1048)	-20.51 (13.421)
18-34 patients in prior month - Month 6 (n=1048)	-22.65 (13.603)
>=35 patients in prior month - Month 2 (n=1075)	-15.05 (11.797)
>=35 patients in prior month - Month 4 (n=1075)	-20.19 (13.201)
>=35 patients in prior month - Month 6 (n=1075)	-21.88 (14.015)

No statistical analysis provided for Mean Change From Baseline in SDAI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

137. Secondary: Mean Change From Baseline in SDAI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in SDAI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The SDAI is the numerical sum of 5 outcome parameters: tender and swollen joint count (28-joint assessment), patient and physician global assessment of disease activity (VAS 0cm [best] – 10 cm [worst]) and level of C reactive protein (mg/dL, normal <1 mg/dL) with increasing scores indicating increased level of disease. The SDAI is expressed as a score on a scale with the minimum score=0 (best) to maximum score=86 (worst). The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description

GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in SDAI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
High disease activity - Month 2 (n=39)	**-19.26 (11.686)**
High disease activity - Month 4 (n=39)	**-23.66 (11.626)**
High disease activity - Month 6 (n=39)	**-27.55 (13.633)**
Moderate disease activity - Month 2 (n=313)	**-14.78 (11.904)**
Moderate disease activity - Month 4 (n=313)	**-20.39 (12.757)**
Moderate disease activity - Month 6 (n=313)	**-23.22 (14.029)**
Low disease activity - Month 2 (n=1901)	**-14.93 (11.812)**
Low disease activity - Month 4 (n=1901)	**-20.65 (13.258)**
Low disease activity - Month 6 (n=1901)	**-23.33 (13.892)**
Remission - Month 2 (n=959)	**-15.16 (11.560)**
Remission - Month 4 (n=959)	**-19.91 (12.675)**
Remission - Month 6 (n=959)	**-21.79 (13.418)**

No statistical analysis provided for Mean Change From Baseline in SDAI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

138. Secondary: Number of Participants Who Achieved DAS28-ESR EULAR Response [Time Frame: Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved DAS28-ESR EULAR Response
Measure Description	EULAR response was assessed at the end of Month 2, Month 4, and Month 6 by the Disease Activity Score using the 28 tender and swollen joint count calculated with erythrocyte sedimentation rate values (DAS28-ESR). A good response would was defined as a decrease >1.2 units and a final DAS28-ESR < 3.2 units, while a moderate response was defined as a decrease > 1.2 units and final DAS28-ESR >= 3.2 units, OR a decrease of 0.6 to 1.2.
Time Frame	Month 2, Month 4, Month 6

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	In Part 1 of the trial, participants received subcutaneous golimumab 50 mg once monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants Who Achieved DAS28-ESR EULAR Response [units: Participants]	
Study Month 2	**2127**
Study Month 4	**2522**
Study Month 6	**2692**

No statistical analysis provided for Number of Participants Who Achieved DAS28-ESR EULAR Response

139. Secondary: Number of Participants Who Achieved DAS28-CRP EULAR Response [Time Frame: Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved DAS28-CRP EULAR Response
Measure Description	DAS28-CRP EULAR response is defined as a good or moderate response that results in a DAS28-CRP >=0.6.
Time Frame	Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR.

Reporting Groups

	Description
GLM50-SC	In Part 1 of the trial, participants received subcutaneous golimumab 50 mg once

	monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants Who Achieved DAS28-CRP EULAR Response [units: Participants]	
Study Month 2	**2199**
Study Month 4	**2530**
Study Month 6	**2667**

No statistical analysis provided for Number of Participants Who Achieved DAS28-CRP EULAR Response

140. Secondary: Number of Participants Achieving Low Disease Activity and Remission at Month 2, Month 4, and Month 6 [Time Frame: Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Number of Participants Achieving Low Disease Activity and Remission at Month 2, Month 4, and Month 6
Measure Description	The number of participants achieving low disease activity or remission was calculated by the DAS28-ESR, DAS28-CRP, and SDAI at study Month 2, Month 4, and Month 6. Low disease activity by DAS28-ESR was defined as >= 2.6 to 3.2, and remission was defined as a DAS28-ESR <2.6. Low disease activity by DAS28-CRP was defined as DAS28-CRP >=2.6 to 3.2, and remission was defined as DAS28-CRP >2.6. Low disease activity by SDAI was defined as SDAI >5.0 to <=20, and remission was defined as SDAI <=5.0.
Time Frame	Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants Achieving Low Disease Activity and Remission at Month 2, Month 4, and Month 6	

[units: Participants]	
Low Disease Activity by DAS28-ESR - Month 2	545
Low Disease Activity by DAS28-ESR - Month 4	923
Low Disease Activity by DAS28-ESR - Month 6	1228
Low Disease Activity by DAS28-CRP - Month 2	805
Low Disease Activity by DAS28-CRP - Month 4	1268
Low Disease Activity by DAS28-CRP - Month 6	1624
Low Disease Activity by SDAI - Month 2	671
Low Disease Activity by SDAI - Month 4	1205
Low Disease Activity by SDAI - Month 6	1585
Remission by DAS28-ESR - Month 2	251
Remission by DAS28-ESR - Month 4	527
Remission by DAS28-ESR - Month 6	784
Remission by DAS28-CRP - Month 2	380
Remission by DAS28-CRP - Month 4	765
Remission by DAS28-CRP - Month 6	1065
Remission by SDAI - Month 2	88
Remission by SDAI - Month 4	285
Remission by SDAI - Month 6	464

No statistical analysis provided for Number of Participants Achieving Low Disease Activity and Remission at Month 2, Month 4, and Month 6

141. Secondary: Mean Change From Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline the disability index of the HAQ was calculated by concomitant MTX dose (low < 10mg/wk, medium >= 10 to < 15 mg/week, and high >=15 mg/week) at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst)with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Low MTX Dose - Month 2 (n=142)	**-0.35 (0.521)**
Low MTX Dose - Month 4 (n=142)	**-0.50 (0.547)**
Low MTX Dose - Month 6 (n=142)	**-0.58 (0.631)**
Medium MTX Dose - Month 2 (n=526)	**-0.41 (0.533)**
Medium MTX Dose - Month 4 (n=526)	**-0.54 (0.598)**
Medium MTX Dose - Month 6 (n=526)	**-0.61 (0.651)**
High MTX Dose - Month 2 (n=1993)	**-0.37 (0.528)**
High MTX Dose - Month 4 (n=1993)	**-0.50 (0.613)**
High MTX Dose - Month 6 (n=1993)	**-0.56 (0.649)**

No statistical analysis provided for Mean Change From Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) by Concomitant MTX Dose at Month 2, Month 4, and Month 6

142. Secondary: Mean Change From Baseline in HAQ-DI by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). DMARD Combination 1 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2 = MTX + leflunomide; Combination 3 = MTX + sulfasalazine; Combination 4 = MTX + hydrochloroquine, chloroquine, chloroquine phosphate + sulfasalazine; Combination 5 = leflunomide.

Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1679)	**-0.37 (0.521)**
DMARD Combination 1 - Month 4 (n=1679)	**-0.50 (0.607)**
DMARD Combination 1 - Month 6 (n=1679)	**-0.56 (0.651)**
DMARD Combination 2 - Month 2 (n=433)	**-0.40 (0.574)**
DMARD Combination 2 - Month 4 (n=433)	**-0.55 (0.633)**
DMARD Combination 2 - Month 6 (n=433)	**-0.62 (0.671)**
DMARD Combination 3 - Month 2 (n=216)	**-0.34 (0.531)**
DMARD Combination 3 - Month 4 (n=216)	**-0.43 (0.624)**
DMARD Combination 3 - Month 6 (n=216)	**-0.53 (0.588)**
DMARD Combination 4 - Month 2 (n=150)	**-0.36 (0.490)**
DMARD Combination 4 -Month 4 (n=150)	**-0.45 (0.523)**
DMARD Combination 4 - Month 6 (n=150)	**-0.55 (0.627)**
DMARD Combination 5 - Month 2 (n=106)	**-0.38 (0.501)**

DMARD Combination 5 - Month 4 (n=106)	**-0.67 (0.599)**
DMARD Combination 5 - Month 6 (n=106)	**-0.63 (0.709)**
DMARD Combination 6 - Month 2 (n=303)	**-0.33 (0.490)**
DMARD Combination 6 - Month 4 (n=303)	**-0.43 (0.540)**
DMARD Combination 6 - Month 6 (n=303)	**-0.47 (0.579)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

143. Secondary: Mean Change From Baseline in HAQ-DI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Did Not Receive Corticosteroids - Month 2 (n=1201)	**-0.32 (0.476)**

Did Not Receive Corticosteroids - Month 4 (n=1201)	**-0.47 (0.582)**
Did Not Receive Corticosteroids - Month 6 (n=1201)	**-0.51 (0.612)**
Received Corticosteroids - Month 2 (n=2076)	**-0.39 (0.542)**
Received Corticosteroids - Month 4 (n=2076)	**-0.51 (0.604)**
Received Corticosteroids - Month 6 (n=2076)	**-0.58 (0.653)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

144. Secondary: Mean Change From Baseline in HAQ-DI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by the Number of DMARD Failures at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Failed 1 DMARD - Month 2 (n=1128)	**-0.39 (0.545)**

Failed 1 DMARD - Month 4 (n=1128)	**-0.54 (0.630)**
Failed 1 DMARD - Month 6 (n=1128)	**-0.60 (0.679)**
Failed 2 DMARDs - Month 2 (n=1175)	**-0.37 (0.533)**
Failed 2 DMARDs - Month 4 (n=1175)	**-0.48 (0.605)**
Failed 2 DMARDs - Month 6 (n=1175)	**-0.55 (0.644)**
Failed >=3 DMARDs - Month 2 (n=973)	**-0.33 (0.470)**
Failed >=3 DMARDs - Month 4 (n=973)	**-0.46 (0.541)**
Failed >=3 DMARDs - Month 6 (n=973)	**-0.51 (0.580)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by the Number of DMARD Failures at Month 2, Month 4, and Month 6

145. Secondary: Mean Change From Baseline in HAQ-DI by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**

Mean Change From Baseline in HAQ-DI by Duration of Disease at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=897)	-0.36 (0.547)
Duration < 2 years - Month 4 (n=897)	-0.50 (0.619)
Duration < 2 years - Month 6 (n=897)	-0.57 (0.669)
Duration 2 to <5 years - Month 2 (n=763)	-0.38 (0.532)
Duration 2 to <5 years - Month 4 (n=763)	-0.49 (0.621)
Duration 2 to <5 years - Month 6 (n=763)	-0.56 (0.662)
Duration 5 to 10 years - Month 2 (n=692)	-0.40 (0.531)
Duration 5 to 10 years - Month 4 (n=692)	-0.54 (0.602)
Duration 5 to 10 years - Month 6 (n=692)	-0.58 (0.642)
Duration > 10 years - Month 2 (n=924)	-0.33 (0.470)
Duration > 10 years - Month 4 (n=924)	-0.45 (0.545)
Duration > 10 years - Month 6 (n=924)	-0.52 (0.582)

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Duration of Disease at Month 2, Month 4, and Month 6

146. Secondary: Mean Change From Baseline in HAQ-DI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of

DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=697)	**-0.25 (0.430)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=697)	**-0.33 (0.512)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=697)	**-0.37 (0.525)**
DAS28 > 5.1 - Month 2 (n=2570)	**-0.40 (0.537)**
DAS28 > 5.1 - Month 4 (n=2570)	**-0.54 (0.609)**
DAS28 > 5.1 - Month 6 (n=2570)	**-0.61 (0.658)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

147. Secondary: Mean Change From Baseline in HAQ-DI by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Baseline RF Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1025)	**-0.28 (0.486)**
RF <=22 IU/mL - Month 4 (n=1025)	**-0.41 (0.580)**
RF <=22 IU/mL - Month 6 (n=1025)	**-0.45 (0.599)**
RF >22 to <=146 IU/mL - Month 2 (n=1080)	**-0.36 (0.496)**
RF >22 to <=146 IU/mL - Month 4 (n=1080)	**-0.48 (0.563)**
RF >22 to <=146 IU/mL - Month 6 (n=1080)	**-0.52 (0.602)**
RF >146 IU/mL - Month 2 (n=1126)	**-0.46 (0.559)**
RF >146 IU/mL - Month 4 (n=1126)	**-0.60 (0.630)**
RF >146 IU/mL - Month 6 (n=1126)	**-0.70 (0.686)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Baseline RF Level at Month 2, Month 4, and Month 6

148. Secondary: Mean Change From Baseline in HAQ-DI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1036)	**-0.28 (0.475)**
Anti-CCP <=40 U/mL - Month 4 (n=1036)	**-0.41 (0.567)**
Anti-CCP <=40 U/mL - Month 6 (n=1036)	**-0.45 (0.587)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1112)	**-0.40 (0.527)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1112)	**-0.52 (0.607)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1112)	**-0.58 (0.641)**
Anti-CCP >380 U/mL - Month 2 (n=1074)	**-0.43 (0.535)**
Anti-CCP >380 U/mL - Month 4 (n=1074)	**-0.55 (0.604)**
Anti-CCP >380 U/mL - Month 6 (n=1074)	**-0.63 (0.666)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

149. Secondary: Mean Change From Baseline in HAQ-DI by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and

	3=unable to do for a combined total score of 0 (best) to 32 (worst). Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Smoking Status at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Non-Smoker - Month 2 (n=1960)	**-0.38 (0.540)**
Non-Smoker - Month 4 (n=1960)	**-0.52 (0.615)**
Non-Smoker - Month 6 (n=1960)	**-0.59 (0.652)**
Smoking history >=20 years - Month 2 (n=324)	**-0.35 (0.462)**
Smoking history >=20 years - Month 4 (n=324)	**-0.49 (0.552)**
Smoking history >=20 years - Month 6 (n=324)	**-0.52 (0.600)**
Smoking history <20 years - Month 2 (n=314)	**-0.43 (0.505)**
Smoking history <20 years - Month 4 (n=314)	**-0.51 (0.572)**
Smoking history <20 years - Month 6 (n=314)	**-0.57 (0.625)**
Currently smokes <0.5 packs/day - Month 2 (n=223)	**-0.30 (0.480)**
Currently smokes <0.5 packs/day - Month 4 (n=223)	**-0.44 (0.562)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**-0.52 (0.628)**

Currently smokes 0.5-1 pack/day - Month 2 (n=397)	**-0.32 (0.490)**
Currently smokes 0.5-1 pack/day - Month 4 (n=397)	**-0.42 (0.571)**
Currently smokes 0.5-1 pack/day - Month 6 (n=397)	**-0.45 (0.616)**
Currently smokes >1 packs/day - Month 2 (n=59)	**-0.37 (0.517)**
Currently smokes >1 packs/day - Month 4 (n=59)	**-0.34 (0.539)**
Currently smokes >1 packs/day - Month 6 (n=59)	**-0.42 (0.584)**
Pack years <7.5 - Month 2 (n=423)	**-0.38 (0.513)**
Pack years <7.5 - Month 4 (n=423)	**-0.49 (0.580)**
Pack years <7.5 - Month 6 (n=423)	**-0.58 (0.642)**
Pack years 7.5 to 20.5 - Month 2 (n=454)	**-0.37 (0.494)**
Pack years 7.5 to 20.5 - Month 4 (n=454)	**-0.48 (0.567)**
Pack years 7.5 to 20.5 - Month 6 (n=454)	**-0.52 (0.622)**
Pack years >20.5 - Month 2 (n=418)	**-0.31 (0.455)**
Pack years >20.5 - Month 4 (n=418)	**-0.40 (0.547)**
Pack years >20.5 - Month 6 (n=418)	**-0.42 (0.572)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Smoking Status at Month 2, Month 4, and Month 6

150. Secondary: Mean Change From Baseline in HAQ-DI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**-0.27 (0.406)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**-0.44 (0.565)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**-0.47 (0.576)**
Anti-TNF treatment Eligible- Month 2 (n=3171)	**-0.37 (0.523)**
Anti-TNF treatment Eligible - Month 4 (n=3171)	**-0.50 (0.597)**
EligAnti-TNF treatment Eligible - Month 6 (n=3171)	**-0.56 (0.641)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

151. Secondary: Mean Change From Baseline in HAQ-DI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the HAQ-DI by the participant baseline expectation of treatment outcome was evaluated at study Month 2, Month 4, and Month 6. The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1211)	**-0.46 (0.557)**
<=1.5 - Month 4 (n=1211)	**-0.59 (0.634)**
<=1.5 - Month 6 (n=1211)	**-0.65 (0.691)**
>1.5 to 1.86 - Month 2 (n=1009)	**-0.34 (0.488)**
>1.5 to 1.86 - Month 4 (n=1009)	**-0.48 (0.580)**
>1.5 to 1.86 - Month 6 (n=1009)	**-0.55 (0.610)**
>=1.86 - Month 2 (n=1053)	**-0.29 (0.490)**
>=1.86 - Month 4 (n=1053)	**-0.39 (0.549)**
>=1.86 - Month 6 (n=1053)	**-0.44 (0.583)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

152. Secondary: Mean Change From Baseline in HAQ-DI by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and

	common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1304)	**-0.37 (0.515)**
<=10 years - Month 4 (n=1304)	**-0.48 (0.573)**
<=10 years - Month 6 (n=1304)	**-0.55 (0.627)**
>10 to 20 years - Month 2 (n=1104)	**-0.35 (0.511)**
>10 to 20 years - Month 4 (n=1104)	**-0.48 (0.611)**
>10 to 20 years - Month 6 (n=1104)	**-0.54 (0.644)**
>20 years - Month 2 (n=850)	**-0.39 (0.535)**
>20 years - Month 4 (n=850)	**-0.53 (0.607)**
>20 years - Month 6 (n=850)	**-0.59 (0.650)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Physician Experience Level at Month 2, Month 4, and Month 6

153. Secondary: Mean Change From Baseline in HAQ-DI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time

Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
0 to 6 years - Month 2 (n=1160)	**-0.39 (0.533)**
0 to 6 years - Month 4 (n=1160)	**-0.51 (0.596)**
0 to 6 years - Month 6 (n=1160)	**-0.60 (0.631)**
6 to 10 years - Month 2 (n=1744)	**-0.35 (0.511)**
6 to 10 years - Month 4 (n=1744)	**-0.49 (0.593)**
6 to 10 years - Month 6 (n=1744)	**-0.53 (0.650)**
>10 years - Month 2 (n=354)	**-0.37 (0.512)**
>10 years - Month 4 (n=354)	**-0.48 (0.602)**
	-0.54 (0.607)

>10 years - Month 6 (n=354)	

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

154. Secondary: Mean Change From Baseline in HAQ-DI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a scores ranging from 0 (best) to 3 (best) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1055)	**-0.39 (0.529)**
1-17 patients in prior month - Month 4 (n=1055)	**-0.51 (0.594)**
1-17 patients in prior month - Month 6 (n=1055)	**-0.59 (0.625)**
18-34 patients in prior month - Month 2 (n=1060)	**-0.35 (0.501)**

18-34 patients in prior month - Month 4 (n=1060)	**-0.48 (0.580)**
18-34 patients in prior month - Month 6 (n=1060)	**-0.53 (0.627)**
>=35 patients in prior month - Month 2 (n=1097)	**-0.36 (0.529)**
>=35 patients in prior month - Month 4 (n=1097)	**-0.50 (0.609)**
>=35 patients in prior month - Month 6 (n=1097)	**-0.55 (0.664)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

155. Secondary: Mean Change From Baseline in HAQ-DI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in HAQ-DI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The HAQ-DI assesses 8 categories of daily activity including dressing, arising, eating, walking, hygiene, reach, grip, and common activities with a score 0 (best) to 3 (worst) with 0=able to do, 1=with some difficulty, 2=with much difficulty, and 3=unable to do for a combined total score of 0 (best) to 32 (worst). The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in HAQ-DI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
	-0.36 (0.563)

High disease activity - Month 2 (n=40)	
High disease activity - Month 4 (n=40)	**-0.49 (0.536)**
High disease activity - Month 6 (n=40)	**-0.54 (0.593)**
Moderate disease activity - Month 2 (n=325)	**-0.29 (0.482)**
Moderate disease activity - Month 4 (n=325)	**-0.43 (0.529)**
Moderate disease activity - Month 6 (n=325)	**-0.49 (0.575)**
Low disease activity - Month 2 (n=1930)	**-0.38 (0.526)**
Low disease activity - Month 4 (n=1930)	**-0.51 (0.610)**
Low disease activity - Month 6 (n=1930)	**-0.57 (0.642)**
Remission - Month 2 (n=966)	**-0.38 (0.515)**
Remission - Month 4 (n=966)	**-0.49 (0.587)**
Remission - Month 6 (n=966)	**-0.54 (0.653)**

No statistical analysis provided for Mean Change From Baseline in HAQ-DI by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

156. Secondary: Number of Participants Who Achieved Minimal or Absence of Functional Impairment [Time Frame: Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved Minimal or Absence of Functional Impairment
Measure Description	The number of participants that achieved minimal or absence of functional impairment as assessed by the HAQ at study Month 2, Month 4, and Month 6 was calculated. Minimal or absence of functional impairment was defined as a HAQ score of <=0.5. The HAQ evaluates participants on a scale of 0 to 3, with 0=with no difficulty, 1=with some difficulty, 2=with much difficulty, and 3=unable to do.
Time Frame	Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR.

Reporting Groups

	Description

GLM50-SC	In Part 1 of the trial, participants received subcutaneous golimumab 50 mg once monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants Who Achieved Minimal or Absence of Functional Impairment [units: Participants]	
Study Month 2	**865**
Study Month 4	**1087**
Study Month 6	**1226**

No statistical analysis provided for Number of Participants Who Achieved Minimal or Absence of Functional Impairment

157. Secondary: Mean Change From Baseline in the EuroQOL (EQ-5D) Quality-of-Life Questionnaire by Concomitant MTX Dose at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in the EuroQOL (EQ-5D) Quality-of-Life Questionnaire by Concomitant MTX Dose at Month 2, Month 4, and Month 6
Measure Description	Concomitant MTX dose was defined as low < 10mg/wk, medium >= 10 to < 15 mg/week, and and high >=15 mg/week. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	**3280**

[units: participants]	
Mean Change From Baseline in the EuroQOL (EQ-5D) Quality-of-Life Questionnaire by Concomitant MTX Dose at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Low MTX Dose - Month 2 (n=142)	**0.20 (0.331)**
Low MTX Dose - Month 4 (n=142)	**0.25 (0.318)**
Low MTX Dose - Month 6 (n=142)	**0.26 (0.312)**
Medium MTX Dose - Month 2 (n=526)	**0.20 (0.325)**
Medium MTX Dose - Month 4 (n=526)	**0.24 (0.338)**
Medium MTX Dose - Month 6 (n=526)	**0.27 (0.332)**
High MTX Dose - Month 2 (n=1985)	**0.20 (0.311)**
High MTX Dose - Month 4 (n=1985)	**0.23 (0.336)**
High MTX Dose - Month 6 (n=1985)	**0.26 (0.346)**

No statistical analysis provided for Mean Change From Baseline in the EuroQOL (EQ-5D) Quality-of-Life Questionnaire by Concomitant MTX Dose at Month 2, Month 4, and Month 6

158. Secondary: Mean Change From Baseline in EQ-5D by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. DMARD Combination 1=MTX + hydrochloroquine, chloroquine, chloroquine phosphate; Combination 2=MTX + leflunomide; Combination 3=MTX +sulfasalazine; Combination 4=MTX + hydrochloroquine, chloroquine, chloroquine phosphate+sulfasalazine; Combination 5=leflunomide.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DMARD Combination 1 - Month 2 (n=1672)	**0.21 (0.313)**
DMARD Combination 1 - Month 4 (n=1672)	**0.24 (0.336)**
DMARD Combination 1 - Month 6 (n=1672)	**0.26 (0.341)**
DMARD Combination 2 - Month 2 (n=432)	**0.19 (0.316)**
DMARD Combination 2 - Month 4 (n=432)	**0.23 (0.337)**
DMARD Combination 2 - Month 6 (n=432)	**0.27 (0.346)**
DMARD Combination 3 - Month 2 (n=216)	**0.16 (0.343)**
DMARD Combination 3 - Month 4 (n=216)	**0.18 (0.355)**
DMARD Combination 3 - Month 6 (n=216)	**0.21 (0.325)**
DMARD Combination 4 - Month 2 (n=150)	**0.25 (0.307)**
DMARD Combination 4 -Month 4 (n=150)	**0.24 (0.316)**
DMARD Combination 4 - Month 6 (n=150)	**0.26 (0.349)**
DMARD Combination 5 - Month 2 (n=105)	**0.22 (0.273)**
DMARD Combination 5 - Month 4 (n=105)	**0.28 (0.302)**
DMARD Combination 5 - Month 6 (n=105)	**0.29 (0.374)**
DMARD Combination 6 - Month 2 (n=303)	**0.17 (0.284)**
DMARD Combination 6 - Month 4 (n=303)	**0.21 (0.306)**

DMARD Combination 6 - Month 6 (n=303)	**0.19 (.341)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Concomitant DMARD Background Treatment at Month 2, Month 4, and Month 6

159. Secondary: Mean Change From Baseline in EQ-5D by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by participant concomitant corticosteroid use was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Did Not Receive Corticosteroids - Month 2 (n=1199)	**0.17 (0.291)**
Did Not Receive Corticosteroids - Month 4 (n=1199)	**0.21 (0.306)**
Did Not Receive Corticosteroids - Month 6 (n=1199)	**0.22 (0.329)**
Received Corticosteroids - Month 2 (n=2069)	**0.21 (0.322)**
	0.24 (0.343)

Received Corticosteroids - Month 4 (n=2069)	
Received Corticosteroids - Month 6 (n=2069)	**0.27 (0.348)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Concomitant Corticosteroid Treatment at Month 2, Month 4, and Month 6

160. Secondary: Mean Change From Baseline in EQ-5D by the Number of DMARD Failures at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by the Number of DMARD Failures at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the number of participant DMARD failures was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by the Number of DMARD Failures at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Failed 1 DMARD - Month 2 (n=1124)	**0.21 (0.324)**
Failed 1 DMARD - Month 4 (n=1124)	**0.24 (0.338)**
Failed 1 DMARD - Month 6 (n=1124)	**0.27 (0.347)**

Failed 2 DMARDs - Month 2 (n=1173)	**0.19 (0.312)**
Failed 2 DMARDs - Month 4 (n=1173)	**0.22 (0.329)**
Failed 2 DMARDs - Month 6 (n=1173)	**0.24 (0.346)**
Failed >=3 DMARDs - Month 2 (n=970)	**0.19 (0.298)**
Failed >=3 DMARDs - Month 4 (n=970)	**0.22 (0.323)**
Failed >=3 DMARDs - Month 6 (n=970)	**0.24 (0.331)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by the Number of DMARD Failures at Month 2, Month 4, and Month 6

161. Secondary: Mean Change From Baseline in EQ-5D by Duration of Disease at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Duration of Disease at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant duration of disease was calculated at study Month 2, Month 4, and Month 6. The duration of disease is defined as the time since the diagnosis of rheumatoid arthritis. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Duration of Disease at Month 2, Month 4, and Month 6 [units: Score on a Scale]	

Mean (Standard Deviation)	
Duration < 2 years - Month 2 (n=893)	0.18 (0.315)
Duration < 2 years - Month 4 (n=893)	0.21 (0.339)
Duration < 2 years - Month 6 (n=893)	0.24 (0.342)
Duration 2 to <5 years - Month 2 (n=760)	0.21 (0.311)
Duration 2 to <5 years - Month 4 (n=760)	0.23 (0.319)
Duration 2 to <5 years - Month 6 (n=760)	0.24 (0.339)
Duration 5 to 10 years - Month 2 (n=691)	0.22 (0.315)
Duration 5 to 10 years - Month 4 (n=691)	0.24 (0.341)
Duration 5 to 10 years - Month 6 (n=691)	0.26 (0.357)
Duration > 10 years - Month 2 (n=923)	0.19 (0.307)
Duration > 10 years - Month 4 (n=923)	0.23 (0.323)
Duration > 10 years - Month 6 (n=923)	0.25 (0.334)

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Duration of Disease at Month 2, Month 4, and Month 6

162. Secondary: Mean Change From Baseline in EQ-5D by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant baseline level of disease activity was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. DAS28-ESR > 5.1 = high disease activity, DAS28-ESR < 3.2 to < =5.1 = low disease activity, and DAS28-ESR <2.6 = remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of

DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
DAS28 > 3.2 to <=5.1 - Month 2 (n=695)	**0.10 (0.232)**
DAS28 > 3.2 to <=5.1 - Month 4 (n=695)	**0.12 (0.253)**
DAS28 > 3.2 to <=5.1 - Month 6 (n=695)	**0.13 (0.267)**
DAS28 > 5.1 - Month 2 (n=2563)	**0.22 (0.325)**
DAS28 > 5.1 - Month 4 (n=2563)	**0.26 (0.343)**
DAS28 > 5.1 - Month 6 (n=2563)	**0.28 (0.353)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Baseline Level of Disease Activity at Month 2, Month 4, and Month 6

163. Secondary: Mean Change From Baseline in EQ-5D by Baseline RF Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Baseline RF Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant baseline RF level was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Baseline RF Level at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
RF <=22 IU/mL - Month 2 (n=1020)	**0.16 (0.296)**
RF <=22 IU/mL - Month 4 (n=1020)	**0.19 (0.322)**
RF <=22 IU/mL - Month 6 (n=1020)	**0.21 (0.314)**
RF >22 to <=146 IU/mL - Month 2 (n=1079)	**0.19 (0.305)**
RF >22 to <=146 IU/mL - Month 4 (n=1079)	**0.22 (0.324)**
RF >22 to <=146 IU/mL - Month 6 (n=1079)	**0.23 (0.339)**
RF >146 IU/mL - Month 2 (n=1123)	**0.25 (0.328)**
RF >146 IU/mL - Month 4 (n=1123)	**0.27 (0.338)**
RF >146 IU/mL - Month 6 (n=1123)	**0.30 (0.365)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Baseline RF Level at Month 2, Month 4, and Month 6

164. Secondary: Mean Change From Baseline in EQ-5D by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant baseline serum level of anti-CCP was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be

	used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-CCP <=40 U/mL - Month 2 (n=1033)	**0.15 (0.297)**
Anti-CCP <=40 U/mL - Month 4 (n=1033)	**0.19 (0.324)**
Anti-CCP <=40 U/mL - Month 6 (n=1033)	**0.21 (0.319)**
Anti-CCP >40 to <=380 U/mL - Month 2 (n=1109)	**0.21 (0.313)**
Anti-CCP >40 to <=380 U/mL - Month 4 (n=1109)	**0.24 (0.328)**
Anti-CCP >40 to <=380 U/mL - Month 6 (n=1109)	**0.25 (0.343)**
Anti-CCP >380 U/mL - Month 2 (n=1071)	**0.23 (0.321)**
Anti-CCP >380 U/mL - Month 4 (n=1071)	**0.25 (0.336)**
Anti-CCP >380 U/mL - Month 6 (n=1071)	**0.28 (0.28)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Baseline Anti-CCP Level at Month 2, Month 4, and Month 6

165. Secondary: Mean Change From Baseline in EQ-5D by Smoking Status at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary

Measure Title	Mean Change From Baseline in EQ-5D by Smoking Status at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Pack years smoked is defined as the total number of packs smoked per day multiplied by the number of years the participant smoked.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Smoking Status at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Non-Smoker - Month 2 (n=1957)	**0.21 (0.319)**
Non-Smoker - Month 4 (n=1957)	**0.24 (0.334)**
Non-Smoker - Month 6 (n=1957)	**0.27 (0.339)**
Smoking history >=20 years - Month 2 (n=322)	**0.18 (0.300)**
Smoking history >=20 years - Month 4 (n=322)	**0.20 (0.304)**
Smoking history >=20 years - Month 6 (n=322)	**0.21 (0.324)**
Smoking history <20 years - Month 2 (n=312)	**0.19 (0.315)**
Smoking history <20 years - Month 4 (n=312)	**0.22 (0.334)**
Smoking history <20 years - Month 6 (n=312)	**0.24 (0.351)**
	0.16 (0.301)

Currently smokes <0.5 packs/day - Month 2 (n=223)	
Currently smokes <0.5 packs/day - Month 4 (n=223)	**0.20 (0.338)**
Currently smokes <0.5 pack/day - Month 6 (n=223)	**0.24 (0.344)**
Currently smokes 0.5-1 pack/day - Month 2 (n=395)	**0.20 (0.296)**
Currently smokes 0.5-1 pack/day - Month 4 (n=395)	**0.20 (0.327)**
Currently smokes 0.5-1 pack/day - Month 6 (n=395)	**0.21 (0.363)**
Currently smokes >1 packs/day - Month 2 (n=59)	**0.14 (0.269)**
Currently smokes >1 packs/day - Month 4 (n=59)	**0.15 (0.292)**
Currently smokes >1 packs/day - Month 6 (n=59)	**0.19 (0.325)**
Pack years <7.5 - Month 2 (n=421)	**0.21 (0.314)**
Pack years <7.5 - Month 4 (n=421)	**0.22 (0.333)**
Pack years <7.5 - Month 6 (n=421)	**0.26 (0.357)**
Pack years 7.5 to 20.5 - Month 2 (n=453)	**0.17 (0.284)**
Pack years 7.5 to 20.5 - Month 4 (n=453)	**0.20 (0.310)**
Pack years 7.5 to 20.5 - Month 6 (n=453)	**0.335 (0.19)**
Pack years >20.5 - Month 2 (n=415)	**0.17 (0.301)**
Pack years >20.5 - Month 4 (n=415)	**0.19 (0.325)**
Pack years >20.5 - Month 6 (n=415)	**0.19 (0.342)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Smoking Status at Month 2, Month 4, and Month 6

166. Secondary: Mean Change From Baseline in EQ-5D by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant eligibility for anti-TNF treatment was calculated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 =

	some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
Anti-TNF treatment Ineligible - Month 2 (n=106)	**0.15 (0.298)**
Anti-TNF treatment Ineligible - Month 4 (n=106)	**0.18 (0.305)**
Anti-TNF treatment Ineligible - Month 6 (n=106)	**0.19 (0.305)**
Anti-TNF treatment Eligible - Month 2 (n=3162)	**0.20 (0.312)**
Anti-TNF treatment Eligible - Month 4 (n=3162)	**0.23 (0.331)**
Anti-TNF treatment Eligible - Month 6 (n=3162)	**0.25 (0.343)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Eligibility for Anti-TNF Treatment at Month 2, Month 4, and Month 6

167. Secondary: Mean Change From Baseline in EQ-5D by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The mean change from baseline in the EQ-5D by the participant baseline expectation of treatment outcome was

	evaluated at study Month 2, Month 4, and Month 6. The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The participant expectation scale was evaluated by questionnaire for a categorical score of 1 (best) to 5 (worst).
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline. Participants were grouped by participant expectation score into 3 groups: <=1.5, >1.5 to <1.86, and >=1.86.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Score on a Scale] Mean (Standard Deviation)	
<=1.5 - Month 2 (n=1208)	**0.22 (0.323)**
<=1.5 - Month 4 (n=1208)	**0.26 (0.337)**
<=1.5 - Month 6 (n=1208)	**0.28 (0.349)**
>1.5 to 1.86 - Month 2 (n=1006)	**0.20 (0.304)**
>1.5 to 1.86 - Month 4 (n=1006)	**0.23 (0.319)**
>1.5 to 1.86 - Month 6 (n=1006)	**0.25 (0.331)**
>=1.86 - Month 2 (n=1050)	**0.17 (0.304)**
>=1.86 - Month 4 (n=1050)	**0.19 (0.329)**
>=1.86 - Month 6 (n=1050)	**0.21 (0.341)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Participant Baseline Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

168. Secondary: Mean Change From Baseline in EQ-5D by Physician Experience Level at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Physician Experience Level at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Physician experience is defined as the number of years the treating physician has experience managing patients with rheumatoid arthritis.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Physician Experience Level at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
<=10 years - Month 2 (n=1300)	**0.20 (0.311)**
<=10 years - Month 4 (n=1300)	**0.23 (0.335)**
<=10 years - Month 6 (n=1300)	**0.25 (0.352)**
>10 to 20 years - Month 2 (n=1103)	**0.18 (0.316)**
>10 to 20 years - Month 4 (n=1103)	**0.22 (0.331)**
>10 to 20 years - Month 6 (n=1103)	**0.24 (0.340)**

>20 years - Month 2 (n=847)	**0.21 (0.309)**
>20 years - Month 4 (n=847)	**0.25 (0.322)**
>20 years - Month 6 (n=847)	**0.26 (0.330)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Physician Experience Level at Month 2, Month 4, and Month 6

169. Secondary: Mean Change From Baseline in EQ-5D by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. Physician experience is defined as the number of years the treating physician has experience managing rheumatoid arthritis with biologics.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6 **[units: Score on a Scale]** **Mean (Standard Deviation)**	
0 to 6 years - Month 2 (n=1154)	**0.21 (0.319)**
0 to 6 years - Month 4 (n=1154)	**0.24 (0.347)**
0 to 6 years - Month 6 (n=1154)	**0.26 (0.356)**

6 to 10 years - Month 2 (n=1743)	**0.19 (0.310)**
6 to 10 years - Month 4 (n=1743)	**0.23 (0.324)**
6 to 10 years - Month 6 (n=1743)	**0.24 (0.338)**
>10 years - Month 2 (n=353)	**0.18 (0.300)**
>10 years - Month 4 (n=353)	**0.21 (0.309)**
>10 years - Month 6 (n=353)	**0.24 (0.318)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by Physician Experience Level With Biologics at Month 2, Month 4, and Month 6

170. Secondary: Mean Change From Baseline in EQ-5D by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant is asked to indicate their health state by ticking the box against the most appropriate statement in each of the 5 dimensions. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The number of patients treated with biologics is defined as the number of patients with rheumatoid arthritis treated by the physician in the last month with biologic agents.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed	

[units: participants]	**3280**
Mean Change From Baseline in EQ-5D by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
1-17 patients in prior month - Month 2 (n=1052)	**0.21 (0.307)**
1-17 patients in prior month - Month 4 (n=1052)	**0.24 (0.326)**
1-17 patients in prior month - Month 6 (n=1052)	**0.26 (0.339)**
18-34 patients in prior month - Month 2 (n=1059)	**0.18 (0.312)**
18-34 patients in prior month - Month 4 (n=1059)	**0.21 (0.327)**
18-34 patients in prior month - Month 6 (n=1059)	**0.24 (0.338)**
>=35 patients in prior month - Month 2 (n=1093)	**0.20 (0.319)**
>=35 patients in prior month - Month 4 (n=1093)	**0.24 (0.340)**
>=35 patients in prior month - Month 6 (n=1093)	**0.25 (0.350)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by the Number of Patients Treated by the Physician With Biologics at Month 2, Month 4, and Month 6

171. Secondary: Mean Change From Baseline in EQ-5D by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [Time Frame: Baseline, Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in EQ-5D by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6
Measure Description	The EQ-5D assesses the 5 domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The participant indicates their health state by ticking the box against the most appropriate statement. The digits (1 [best] to 3 [worst]; with 0= no problems, 1 = some problems, 2 = some problems, and 3= severe problems) for the 5 dimensions can be combined in a 5-digit number describing the participant's health state. The numerals 1 to 3 have no arithmetic properties and should not be used as a cardinal score. The physician's expectation of treatment outcome was assessed at the start of Month 4, when physicians were asked to rate their expectations of treatment outcome as: high disease activity, moderate disease activity, low disease activity, or remission.
Time Frame	Baseline, Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR. n values represent the number of participants at baseline.

Reporting Groups

	Description
GLM50-SC	Participants received subcutaneous golimumab 50 mg once monthly for 6 months (study Month 1 to Month 6).

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Mean Change From Baseline in EQ-5D by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6 [units: Units on a Scale] Mean (Standard Deviation)	
High disease activity - Month 2 (n=38)	**0.24 (0.315)**
High disease activity - Month 4 (n=38)	**0.20 (0.355)**
High disease activity - Month 6 (n=38)	**0.20 (0.352)**
Moderate disease activity - Month 2 (n=325)	**0.18 (0.298)**
Moderate disease activity - Month 4 (n=325)	**0.23 (0.320)**
Moderate disease activity - Month 6 (n=325)	**0.25 (0.320)**
Low disease activity - Month 2 (n=1926)	**0.20 (0.323)**
Low disease activity - Month 4 (n=1926)	**0.23 (0.335)**
Low disease activity - Month 6 (n=1926)	**0.25 (0.349)**
Remission - Month 2 (n=964)	**0.19 (0.295)**
Remission - Month 4 (n=964)	**0.22 (0.323)**
Remission - Month 6 (n=964)	**0.23 (0.335)**

No statistical analysis provided for Mean Change From Baseline in EQ-5D by the the Physician Expectation of Treatment Outcome at Month 2, Month 4, and Month 6

172. Secondary: Number of Participants With a Participant Acceptable Symptom State (PASS) at Month 4, Month 6, and Month 8 [Time Frame: Month 2, Month 4, Month 6]

Measure Type	Secondary
Measure Title	Number of Participants With a Participant Acceptable Symptom State (PASS) at Month 4, Month 6, and Month 8

Measure Description	The number of participants achieving PASS was evaluated at study Month 2, Month 4, and Month 6 was calculated. PASS is participant self-evaluation tool that uses a VAS 0mm (best) - 100mm (worst), with a score <=31 representing an acceptable PASS.
Time Frame	Month 2, Month 4, Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The efficacy evaluable population comprised all participants with a baseline DAS28-ESR and at least one post-baseline measurement of DAS28-ESR.

Reporting Groups

	Description
GLM50-SC	In Part 1 of the trial, participants received subcutaneous golimumab 50 mg once monthly.

Measured Values

	GLM50-SC
Number of Participants Analyzed [units: participants]	**3280**
Number of Participants With a Participant Acceptable Symptom State (PASS) at Month 4, Month 6, and Month 8 [units: Participants]	
Study Month 2	**1578**
Study Month 4	**1889**
Study Month 6	**2164**

No statistical analysis provided for Number of Participants With a Participant Acceptable Symptom State (PASS) at Month 4, Month 6, and Month 8

173. Secondary: Mean Area Under the DAS28-ESR Curve From Study Month 6 to Month 12 [Time Frame: End of Month 6, End of Month 12]

Measure Type	Secondary
Measure Title	Mean Area Under the DAS28-ESR Curve From Study Month 6 to Month 12
Measure Description	The DAS28-ESR is a continuous disease measure which is a composite of 4 variables: the 28 tender joint count, the 28 swollen joint count, ESR, and participant assessment of disease activity measure on a visual analogue scale. The DAS28-ESR has numeric thresholds that define high disease activity (> 5.1), low disease activity (< 3.2) and remission (< 2.6). Minimum score=0 (best) to maximum score=10 (worst). The DAS28-ESR area under the curve can be calculated from the DAS28-ESR score versus time curve to provide an assessment of changes in disease activity over time. The area under the DAS28-ESR score versus time curve was computed using the trapezoidal rule and using raw DAS28-ESR score values at Part-2 Baseline, end of Month 12, and at least 2 intermediate time points. The DAS28-ESR area under the curve was then averaged over the total duration (months) and expressed as units on a scale.
Time Frame	End of Month 6, End of Month 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
8 participants (3 poor quality data, 4 without a post-baseline DAS28-ESR, and 1 did not take Part 2 medication) and 7 participants (5 poor data quality, 1 without a DAS28-ESR at baseline, 1 without post-baseline DAS28-ESR) were excluded from the efficacy evaluable population for the IV-GLM 2mg/kg + SC GLM 50 mg and SC-GLM50 arms, respectively.

Reporting Groups

	Description
IV-GLM 2 mg/kg + SC GLM 50 mg	Participants received IV-GLM at a dose of 2 mg/kg at the start of Month 7, start of Month 8, and start of Month 10 if remission was not achieved at any of these IV administration visits. If remission was achieved, participants were switched to subcutaneous golimumab at a dose of 50 mg once monthly.
SC-GLM50	Participants received SC GLM at a dose of 50 mg once monthly.

Measured Values

	IV-GLM 2 mg/kg + SC GLM 50 mg	**SC-GLM50**
Number of Participants Analyzed [units: participants]	**242**	**248**
Mean Area Under the DAS28-ESR Curve From Study Month 6 to Month 12 [units: Units on a Scale] Mean (Standard Deviation)	**3.67 (0.992)**	**3.67 (0.924)**

No statistical analysis provided for Mean Area Under the DAS28-ESR Curve From Study Month 6 to Month 12

174. Secondary: Percentage of Participants Achieving Remission [Time Frame: Start of Month 8, Start of Month 9, Start of Month 10, Start of Month 11, End of Month 12]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Remission
Measure Description	Remission was defined as achievement of a DAS28-ESR < 2.6.
Time Frame	Start of Month 8, Start of Month 9, Start of Month 10, Start of Month 11, End of Month 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
8 participants (3 poor quality data, 4 without a post-baseline DAS28-ESR, and 1 did not take Part 2 medication) and 7 participants (5 poor data quality, 1 without a DAS28-ESR at baseline, 1 without post-baseline DAS28-ESR) were excluded from the efficacy evaluable population for the IV-GLM 2mg/kg + SC GLM 50 mg and SC-GLM50 arms, respectively.

Reporting Groups

	Description
IV-GLM 2 mg/kg + SC GLM 50 mg	Participants received IV GLM at a dose of 2 mg/kg until remission is achieved at which time they were

	switched to SC GLM at a dose of 50 mg once monthly.
SC-GLM50	Participants received SC GLM at a dose of 50 mg once monthly.

Measured Values

	IV-GLM 2 mg/kg + SC GLM 50 mg	SC-GLM50
Number of Participants Analyzed [units: participants]	**242**	**248**
Percentage of Participants Achieving Remission **[units: Percentage of Participants] Number (95% Confidence Interval)**		
Start of Month 8	**19.8 (15.3 to 25.4)**	**13.7 (10.0 to 18.7)**
Start of Month 9	**28.2 (23.0 to 34.4)**	**20.1 (15.7 to 25.)**
Start of Month 10	**34.2 (28.6 to 40.6)**	**29.5 (24. to 35.6)**
Start of Month 11	**40.3 (34.3 to 46.8)**	**39.3 (33.5 to 45.7)**
End of Month 12	**44.3 (38.2 to 50.9)**	**45.1 (39.1 to 51.5)**

No statistical analysis provided for Percentage of Participants Achieving Remission

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Golimumab 50 mg Subcutaneous (GLM50-SC)	Participants received GLM50-SC once monthly for a period of 6 months.
Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	Participants received IV-GLM at a dose of 2 mg/kg at the start of Month 7, start of Month 8, and start of Month 10 if remission was not achieved at any of these IV administration visits. If remission was achieved, participants were switched subcutaneous golimumab at a dose of 50 mg once monthly.
SC-GLM50	Participants received subcutaneous golimumab at a dose of 50 mg once monthly for a period of 6 months in Part 2 of the study.

Serious Adverse Events

	Golimumab 50 mg Subcutaneous (GLM50-SC)	Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	SC-GLM50
Total, serious adverse events			
# participants affected / at risk	**203/3357 (6.05%)**	**17/245 (6.94%)**	**7/255 (2.75%)**
Blood and lymphatic system disorders			
Leukopenia † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Lymphadenopathy † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Thrombocytopenia † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Cardiac disorders			
Atrial fibriliation † 1			
# participants affected / at risk	**3/3357 (0.09%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**4**	**1**	**0**
Acute myocardial infarction † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Angina pectoris † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Myocardial infarction † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Angina unstable † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Arrhythmia † 1			

# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Cardiac failure congestive † 1			
# participants affected / at risk	1/3357 (0.03%)	1/245 (0.41%)	0/255 (0.00%)
# events	1	1	0
Cardiopulmonary failure † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Palpitations † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Tachyarrhythmia † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Congenital, familial and genetic disorders			
Pyloric stenosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Ear and labyrinth disorders			
Conductive deafness † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Eye disorders			
Cataract † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Open angle glaucoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Gastrointestinal disorders			
Abdominal pain † 1			
# participants affected / at risk	3/3357 (0.09%)	1/245 (0.41%)	0/255 (0.00%)

# events	**4**	**1**	**0**
Gastritis † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Gastrointestinal haemorrhage † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Gastrooesophageal reflux disease † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Appendix disorder † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Diarrhoea † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Dyspepsia † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Enterocolitis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Gastritis atrophic † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Gastritis erosive † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Lumbar hernia † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**

Mouth ulceration † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Oesophageal varicies hemorrhage † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Oesophagitis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Rectal hemorrhage † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Small intestine obstruction † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Vomiting † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Colitis ulcerative † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**0**	**1**	**0**
General disorders			
Pyrexia † 1			
# participants affected / at risk	**3/3357 (0.09%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**3**	**0**	**0**
Malaise † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Calcinosis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**

Chest pain † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**1**	**1**	**0**
General physical health deterioration † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Impaired healing † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Multi-organ failure † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Oedema peripheral † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Pain † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Hepatobiliary disorders			
Cholecystitis † 1			
# participants affected / at risk	**3/3357 (0.09%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**3**	**0**	**0**
Liver disorder † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Cholestasis † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**0**	**1**	**0**
Immune system disorders			
Drug hypersensitivity † 1			
# participants affected / at risk	**3/3357 (0.09%)**	**0/245 (0.00%)**	**0/255 (0.00%)**

# events	3	0	0
Infections and infestations			
Pneumonia † 1			
# participants affected / at risk	9/3357 (0.27%)	2/245 (0.82%)	1/255 (0.39%)
# events	10	2	1
Arthritis bacterial † 1			
# participants affected / at risk	5/3357 (0.15%)	0/245 (0.00%)	0/255 (0.00%)
# events	5	0	0
Sepsis † 1			
# participants affected / at risk	5/3357 (0.15%)	1/245 (0.41%)	0/255 (0.00%)
# events	5	1	0
Tuberculosis † 1			
# participants affected / at risk	4/3357 (0.12%)	0/245 (0.00%)	0/255 (0.00%)
# events	5	0	0
Respiratory tract infection † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Urinary Tract Infection † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Cellulitis † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Gastroenteritis † 1			
# participants affected / at risk	2/3357 (0.06%)	1/245 (0.41%)	0/255 (0.00%)
# events	2	1	0
Peritonsillar abcess † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Rotavirus infection † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)

# events	2	0	0
Viral infection † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Abcess oral † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Bacterial pyelonephritis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Beta haemolytic streptococcal infection † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Bronchitis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Erysipelas † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Groin abcess † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Helicobacter gastritis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Herpes zoster † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	1/255 (0.39%)
# events	1	0	1
Herpes zoster oticus † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
† 1			

Infected skin ulcer			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Listeria sepsis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Lower respiratory tract infection † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Ludwig angina † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Lung infection † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Lymph node tuberculosis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Paronychia † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**0**	**1**	**0**
Pyelonephritis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**1/255 (0.39%)**
# events	**1**	**0**	**1**
Oral candidiasis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Osteomyelitis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Otitis media acute † 1			

# participants affected / at risk	1/3357 (0.03%)	1/245 (0.41%)	0/255 (0.00%)
# events	1	1	0
Pharyngitis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Pneumocystis jiroveci pneumonia † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Rash pustular † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Salmonellosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Septic shock † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Sinusitis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Syphillis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Tonsillitis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Tracheitis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Injury, poisoning and procedural complications			
Overdose † 1			

# participants affected / at risk	5/3357 (0.15%)	2/245 (0.82%)	1/255 (0.39%)
# events	5	2	1
Alcohol poisoning † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Fall † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Femur fracture † 1			
# participants affected / at risk	2/3357 (0.06%)	1/245 (0.41%)	0/255 (0.00%)
# events	2	1	0
Joint injury † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Face injury † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Femoral neck fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Forearm fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hip fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Joint dislocation † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Multiple fractures † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)

# events	1	0	0
Rib fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Spinal compression fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Spinal fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Synovial rupture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Thermal burn † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Tibia fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Upper limb fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Wound † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Investigations			
Blood pressure increased † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Body temperature increased † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)

# events	1	0	0
Transaminases increased † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Weight increased † 1			
# participants affected / at risk	0/3357 (0.00%)	0/245 (0.00%)	1/255 (0.39%)
# events	0	0	1
Metabolism and nutrition disorders			
Diabetes mellitus † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Dehydration † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hypoglycaemia † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hypokalaemia † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hyponatraemia † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Musculoskeletal and connective tissue disorders			
Fibromyalgia † 1			
# participants affected / at risk	0/3357 (0.00%)	1/245 (0.41%)	0/255 (0.00%)
# events	0	1	0
Rheumatoid arthritis † 1			
# participants affected / at risk	9/3357 (0.27%)	1/245 (0.41%)	0/255 (0.00%)
# events	9	1	0
Back pain † 1			

# participants affected / at risk	4/3357 (0.12%)	0/245 (0.00%)	0/255 (0.00%)
# events	4	0	0
Arthralgia † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Intervertebral disc protrusion † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Osteoarthritis † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Arthritis † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Arthropathy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Intervertebral disc disorder † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Lumbar spine stenosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Meniscal degeneration † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Osteonecrosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Polychondritis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)

# events	1	0	0
Synovial cyst † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Rotator cuff syndrome † 1			
# participants affected / at risk	0/3357 (0.00%)	1/245 (0.41%)	0/255 (0.00%)
# events	0	1	0
Ankle fracture † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer † 1			
# participants affected / at risk	4/3357 (0.12%)	0/245 (0.00%)	0/255 (0.00%)
# events	4	0	0
Basal cell carcinoma † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Cervix carcinoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Colon cancer † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Diffuse large B-cell carcinoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Lung adenocarcinoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Lung neoplasm malignant † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)

# events	1	0	0
Malignant melanoma † 1			
# participants affected / at risk	1/3357 (0.03%)	1/245 (0.41%)	0/255 (0.00%)
# events	1	1	0
Metastases to central nervous system † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Metastatic gastric cancer † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Multiple myeloma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Pancreatic carcinoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Squamous cell carcinoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Uterine leiomyoma † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Vulval cancer † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Breast cancer in situ † 1			
# participants affected / at risk	0/3357 (0.00%)	0/245 (0.00%)	1/255 (0.39%)
# events	0	0	1
Cervix carcinoma stage 0 † 1			
# participants affected / at risk	0/3357 (0.00%)	0/245 (0.00%)	1/255 (0.39%)
# events	0	0	1

Thyroid cancer † 1			
# participants affected / at risk	0/3357 (0.00%)	0/245 (0.00%)	1/255 (0.39%)
# events	0	0	1
Nervous system disorders			
Cerebral infarction † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Sciatica † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0
Carpal tunnel syndrome † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Cerebrovascular accident † 1			
# participants affected / at risk	1/3357 (0.03%)	1/245 (0.41%)	0/255 (0.00%)
# events	1	1	0
Convulsion † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Epilepsy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hemiparesis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Polyneuropathy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Syncope † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
† 1			

Transient ischaemic attack			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Vertebrobasilar insufficiency † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**1/245 (0.41%)**	**0/255 (0.00%)**
# events	**0**	**1**	**0**
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**2/3357 (0.06%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**2**	**0**	**0**
Panic attack † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Renal and urinary disorders			
Renal failure acute † 1			
# participants affected / at risk	**3/3357 (0.09%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**3**	**0**	**0**
Calculus bladder † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Nephrolithiases † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Renal amyloidosis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Renal failure † 1			

# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Reproductive system and breast disorders			
Endometrial hypertrophy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Endometriosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Fibrocystic breast disease † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Ovarian cyst † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea † 1			
# participants affected / at risk	4/3357 (0.12%)	1/245 (0.41%)	0/255 (0.00%)
# events	4	1	0
Pneumonitis † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	3	0	0
Respiratory failure † 1			
# participants affected / at risk	3/3357 (0.09%)	0/245 (0.00%)	0/255 (0.00%)
# events	4	0	0
Acute respiratory distress syndrome † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Bronchopneumopathy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Bronchospasm † 1			

# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Haemoptysis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Interstitial lung disease † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Lung cyst † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Pleurisy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Pulmonary fibrosis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Pulmonary hypertension † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	0/3357 (0.00%)	1/245 (0.41%)	0/255 (0.00%)
# events	0	2	0
Pulmonary oedema † 1			
# participants affected / at risk	0/3357 (0.00%)	1/245 (0.41%)	0/255 (0.00%)
# events	0	1	0
Skin and subcutaneous tissue disorders			
Angioedema † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Dermatitis allergic † 1			

# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Dermatitis exfoliative † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Dermatitis psoriasiform † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Erythema † 1			
# participants affected / at risk	0/3357 (0.00%)	0/245 (0.00%)	1/255 (0.39%)
# events	0	0	1
Surgical and medical procedures			
Arterial bypass operation † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Arthrodesis † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Hysterectomy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Lymphadenectomy † 1			
# participants affected / at risk	1/3357 (0.03%)	0/245 (0.00%)	0/255 (0.00%)
# events	1	0	0
Vascular disorders			
Deep vein thrombosis † 1			
# participants affected / at risk	4/3357 (0.12%)	0/245 (0.00%)	0/255 (0.00%)
# events	4	0	0
Circulatory collapse † 1			
# participants affected / at risk	2/3357 (0.06%)	0/245 (0.00%)	0/255 (0.00%)
# events	2	0	0

Arteriosclerosis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Hypertension † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Hypertensive crisis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**
Thrombophlebitis † 1			
# participants affected / at risk	**1/3357 (0.03%)**	**0/245 (0.00%)**	**0/255 (0.00%)**
# events	**1**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (10.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Golimumab 50 mg Subcutaneous (GLM50-SC)	Participants received GLM50-SC once monthly for a period of 6 months.
Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg	Participants received IV-GLM at a dose of 2 mg/kg at the start of Month 7, start of Month 8, and start of Month 10 if remission was not achieved at any of these IV administration visits. If remission was achieved, participants were switched subcutaneous golimumab at a dose of 50 mg once monthly.
SC-GLM50	Participants received subcutaneous golimumab at a dose of 50 mg once monthly for a period of 6 months in Part 2 of the study.

Other Adverse Events

	Golimumab 50 mg Subcutaneous (GLM50-SC)	**Intravenous GLM (IV-GLM) 2 mg/kg + SC GLM 50 mg**	**SC-GLM50**

Total, other (not including serious) adverse events			
# participants affected / at risk	**0/3357 (0.00%)**	**28/245 (11.43%)**	**24/255 (9.41%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**13/245 (5.31%)**	**18/255 (7.06%)**
# events	**0**	**15**	**19**
Upper respiratory tract infection † 1			
# participants affected / at risk	**0/3357 (0.00%)**	**15/245 (6.12%)**	**6/255 (2.35%)**
# events	**0**	**17**	**9**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (10.0)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Investigator is granted the right to use the results of all work under this study including but not limited to, the results of tests and any raw data and statistical data generated for investigator's own teaching, research, and publication purposes only. Investigator/Institution agrees, on behalf of itself and its employees, officers, trustees, and agents, not to cause said results to be knowingly used for any commercial purpose whatsoever except as authorized by the sponsor in writing.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development

Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Combe B, Dasgupta B, Louw I, Pal S, Wollenhaupt J, Zerbini CA, Beaulieu AD, Schulze-Koops H, Durez P, Yao R, Vastesaeger N, Weng HH; GO-MORE Investigators. Efficacy and safety of golimumab as add-on therapy to disease-modifying antirheumatic drugs: results of the GO-MORE study. Ann Rheum Dis. 2014 Aug;73(8):1477-86. doi: 10.1136/annrheumdis-2013-203229. Epub 2013 Jun 5.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Schulze-Koops H, Giacomelli R, Samborski W, Rednic S, Herold M, Yao R, Govoni M, Vastesaeger N, Weng HH. Factors influencing the patient evaluation of injection experience with the SmartJect autoinjector in rheumatoid arthritis. Clin Exp Rheumatol. 2015 Mar-Apr;33(2):201-8. Epub 2015 Jan 29.

Dasgupta B, Combe B, Louw I, Wollenhaupt J, Zerbini CA, Beaulieu A, Schulze-Koops H, Durez P, Wolff V, Yao R, Weng HH, Govoni M, Vastesaeger N. Patient and physician expectations of add-on treatment with golimumab for rheumatoid arthritis: relationships between expectations and clinical and quality of life outcomes. Arthritis Care Res (Hoboken). 2014 Dec;66(12):1799-807. doi: 10.1002/acr.22371.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00975130 History of Changes
Other Study ID Numbers:	P06129 2009-011137-26 (EudraCT Number) CTRI/2009/091/000883 (Registry Identifier: CTRI)
Study First Received:	August 20, 2009
Results First Received:	July 18, 2012
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Health Authority:	Canada: Health Canada

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