ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 09/03/2012

Grantor: CDER IND/IDE Number: 49,078 Serial Number:

Evaluation of Insulin Glargine in Combination With Sitagliptin in Type 2 Diabetes Patients: EASIE Extension Trial

This study has been completed.

Sponsor:	Sanofi
Collaborators:	
Information provided by (Responsible Party):	Sanofi
ClinicalTrials.gov Identifier:	NCT00851903

Purpose

This study was the extension of the LANTU_C_02761 study named EASIE and identified as NCT00751114 (core study comparing insulin glargine versus sitagliptin in insulin-naïve patients treated with metformin and not adequately controlled).

All patients with Glycosylated Hemoglobin A1c (HbA1c) ≥ 7% at the end of the core study had the possibility to enter this extension study if they met the other inclusion criteria and did not present with any exclusion criteria.

The visit 14 of the core study (week 24) was the visit 1 (baseline, week 0) of the extension study which consisted of a 12-week treatment period.

The objectives of this extension study were:

- To assess the glycemic control (HbA1c <7%) of a 3-month combination therapy with metformin, insulin glargine and sitagliptin in patients not adequately controlled by a previous treatment with metformin plus either insulin glargine or sitagliptin.
- To assess the effect of insulin glargine in combination with sitagliptin on HbA1c level, fasting plasma glucose, 7-point glucose profile, hypoglycemia occurrence, body weight and overall safety.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: Insulin Glargine Drug: Sitagliptin Drug: Metformin	Phase 3

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Efficacy Study
Official Title: Combination Therapy of Insulin Glargine and Sitagliptin in Patients With Type 2 Diabetes Not Adequately Controlled by a Previous Treatment With Metformin and Either Insulin Glargine or Sitagliptin

Further study details as provided by Sanofi:

Primary Outcome Measure:

- HbA1c Response Rate: Percentage of Patients Achieving Glycosylated Haemoglobin A1c (HbA1c) < 7% at Study Endpoint (End of Treatment Period) [Time Frame: study endpoint: week 12 or earlier in case of premature discontinuation] [Designated as safety issue: No]

Secondary Outcome Measures:

- HbA1c: Change From Baseline to Study Endpoint [Time Frame: baseline, study endpoint: week 12 or earlier in case of premature discontinuation] [Designated as safety issue: No]
  Change = study endpoint - baseline
- Self-Monitored Fasting Plasma Glucose (SMFPG) Mean : Change From Baseline to Study Endpoint [Time Frame: baseline, study endpoint: week 12 or week 8 if value not available at week 12] [Designated as safety issue: No]
  SMFPG mean = mean of the fasting plasma glucose values recorded on the 6 consecutive days before the visit (at least 3 values needed). Change = study endpoint - baseline.
- 7-point Plasma Glucose Profile: Change From Baseline to Study Endpoint [Time Frame: baseline, study endpoint: week 12 or week 8 if value not available at week 12] [Designated as safety issue: No]
  7-point plasma glucose recorded before and after breakfast, before and after lunch, before and after dinner and at bedtime. Change = study endpoint - baseline.
- Insulin Dose [Time Frame: baseline, week 4, week 8, week 12] [Designated as safety issue: No]
  Daily dose at the face-to-face visits
- Number of Patients With at Least One Episode of Symptomatic Hypoglycemia [Time Frame: During the treatment period (12 weeks) plus 7 days after last dose] [Designated as safety issue: Yes]
  Symptomatic hypoglycemia was defined as an event with clinical symptoms that were considered to result from hypoglycemia confirmed or not by a plasma glucose measurement <= 70mg/dL [3.9 mmol/L]
- Change in Body Weight From Baseline to Study Endpoint [Time Frame: baseline, study endpoint: week 12 or week 8 or week 4 depending on last available value] [Designated as safety issue: Yes]
  Change = study endpoint - baseline

Enrollment: 112
Study Start Date: June 2009
Primary Completion Date: September 2011
Study Completion Date: September 2011

Arms	Assigned Interventions
Experimental: Combination insulin glargine and sitagliptin Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously	Drug: Insulin Glargine Subcutaneous injection. 100 Units/mL solution for injection in a prefilled SoloStar® pen (3 mL). Other Names: Lantus® Drug: Sitagliptin

Arms	Assigned Interventions
treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 < Fasting Plasma Glucose (FPG) ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.	Oral administration. 100mg film-coated tablets. Other Names: Januvia® Drug: Metformin Patients continued with metformin as usual oral anti-diabetic treatment.

Eligibility

Ages Eligible for Study: 35 Years to 71 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Patients who completed the core study LANTU_C_02761 (NCT00751114) i.e. went through the visit 14 investigation,
- HbA1c >= 7 %,
- Dose of metformin compliant with the inclusion criteria of the core study (i.e. at least 1 g/day), and maintained stable for the duration of the core study
- Ability and willingness to perform plasma blood glucose monitoring using the sponsor-provided plasma glucose meter and to complete the patient dairy,
- Signed informed consent obtained prior any study procedure,
- Willingness and ability to comply with the study protocol.

Exclusion Criteria:

- Treatment with oral antidiabetic drugs other than metformin and sitagliptin in the core study,
- Treatment with insulin other than Insulin Glargine in the core study (except in case of an emergency, for a period of time less than 7 days),
- Treatment with a non-permitted drug during the core study,
- Pregnant or lactating women,
- In-patient care,
- Active proliferative retinopathy, as defined by a photocoagulation or vitrectomy occurrence in the 6 months prior to visit 1, or any other unstable (rapidly progressing) retinopathy that may require photocoagulation or surgical treatment during the study (an optic fundus examination should have been performed within the 2 years prior to study entry in the core study),
- Impaired renal function: serum creatinine >= 1.5 mg/dL (>= 133µmol/L) or >= 1.4 mg/dL (>=124 µmol/L) in men and women, respectively,
- History of sensitivity to the study drugs or to drugs with a similar chemical structure,
- Impaired hepatic function: alanine aminotransferase (ALT), aspartate aminotransferase (AST) > 3 x upper limit of normal range,

- Alcohol or drug abuse within the last year,
- Night shift worker,
- Presence of any condition (medical, psychological, social or geographical), current or anticipated that the investigator feels would compromise the patient's safety or limit the patient successful participation in the study,
- Treatment with weight loss medications (e.g. sibutramine, orlistat, rimonabant),
- History of pancreatitis.

Contacts and Locations

Locations

United States, New Jersey
sanofi-aventis administrative office
Bridgewater, New Jersey, United States, 08807

Austria
sanofi-aventis administrative office
Vienna, Austria

Brazil
sanofi-aventis administrative office
Sao Paulo, Brazil

Colombia
sanofi-aventis administrative office
Bogota, Colombia

Egypt
sanofi-aventis administrative office
Cairo, Egypt

Greece
sanofi-aventis administrative office
Kallithea, Greece

Hong Kong
sanofi-aventis administrative office
Hong Kong, Hong Kong

India
sanofi-aventis administrative office
Mumbai, India

Israel
sanofi-aventis administrative office
Natanya, Israel

Korea, Republic of
sanofi-aventis administrative office
Seoul, Korea, Republic of

Lebanon
sanofi-aventis administrative office
Beirut, Lebanon

Mexico

sanofi-aventis administrative office
Col. Coyoacan, Mexico
Netherlands
sanofi-aventis administrative office
Gouda, Netherlands
Portugal
sanofi-aventis administrative office
Porto Salvo, Portugal
Spain
sanofi-aventis administrative office
Barcelona, Spain
United Kingdom
sanofi-aventis administrative office
Guildford Surrey, United Kingdom

Investigators

Study Director:	Clinical Sciences & Operations	sanofi-aventis

More Information

Responsible Party:	Sanofi
Study ID Numbers:	EXT_LANTU_C_02761 2008-000521-19 [EudraCT Number]
Health Authority:	United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	Among the 445 patients who completed the EASIE study, 194 had an endpoint Glycosylated Hemoglobin A1c (HbA1c) ≥ 7%. A total of 112 patients were included in the extension study: 37 uncontrolled on previous treatment with metformin and insulin glargine and 75 uncontrolled on previous treatment with metformin and sitagliptin in the EASIE study.
Pre-Assignment Details	Among the 112 included patients, two patients prematurely discontinued from the study. One of them had continued his sitagliptin treatment but never started the insulin glargine treatment.

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 < Fasting Plasma Glucose (FPG) ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Overall Study

	Combination Insulin Glargine and Sitagliptin
Started	112
Safety Population	112 [1]
Treated by Combination	111 [2]
Modified Intent-To-Treat Population	111 [3]
Completed	110
Not Completed	2
Withdrawal by Subject	2

[1] patients treated with at least one dose of insulin glargine OR one dose of sitagliptin
[2] patients treated with at least one dose of insulin glargine AND one dose of sitagliptin
[3] mITT population: patients treated by combination with at least 1 on-treatment efficacy measure

Baseline Characteristics

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Baseline Measures

	Combination Insulin Glargine and Sitagliptin
Number of Participants	111
Age, Continuous [1] [units: years] Mean (Standard Deviation)	52.4 (9.3)
Gender, Male/Female [2] [units: participants]	
Female	56
Male	55
Body Weight [2] [units: kg] Mean (Standard Deviation)	84.6 (21.0)
Body Mass Index [2] [units: kg/m²] Mean (Standard Deviation)	31.3 (5.2)
Systolic Blood Pressure [2] [units: mmHg] Mean (Standard Deviation)	129.9 (15.5)
Diastolic Blood Pressure [2] [units: mmHg] Mean (Standard Deviation)	80.1 (7.3)
Heart Rate [2] [units: beats/min] Mean (Standard Deviation)	76.9 (9.1)
Duration of diabetes [3] [units: years] Median (Inter-Quartile Range)	4.1 (2.0 to 8.3)
At least one diabetic late complication [4] [units: participants]	
Yes	23
No	88
Glycosylated Hemoglobin A1c (HbA1c) [2]	8.0 (1.0)

	Combination Insulin Glargine and Sitagliptin
[units: percent] Mean (Standard Deviation)	
Fasting Plasma Glucose [5] [units: mg/dL] Mean (Standard Deviation)	151.5 (46.9)
Self-Monitored Fasting Plasma Glucose [6] [units: mg/dL] Mean (Standard Deviation)	144.4 (38.2)

[1] mITT population

Age collected at EASIE study entry (24 weeks before baseline)

[2] mITT population

[3] mITT population

Duration of diabetes collected at EASIE study entry (24 weeks before baseline)

[4] mITT population

Diabetic late complications: myocardial infarction, angina pectoris, coronary artery disease, heart failure, stroke, transient ischemic attack, peripheral vascular disease, diabetic neuropathy, diabetic nephropathy, diabetic retinopathy

Information collected at EASIE study entry (24 weeks before baseline)

[5] mITT population but due to missing values N=110

[6] mITT population but due to missing values N=104

Outcome Measures

1. Primary Outcome Measure:

Measure Title	HbA1c Response Rate: Percentage of Patients Achieving Glycosylated Haemoglobin A1c (HbA1c) < 7% at Study Endpoint (End of Treatment Period)
Measure Description	
Time Frame	study endpoint: week 12 or earlier in case of premature discontinuation
Safety Issue?	No

Analysis Population Description

The population analyzed consisted of the subset of mITT patients who had HbA1c value at study endpoint.

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	106
HbA1c Response Rate: Percentage of Patients Achieving Glycosylated Haemoglobin A1c (HbA1c) < 7% at Study Endpoint (End of Treatment Period) [units: percentage of participants] Number (95% Confidence Interval)	51.9 (41.97 to 61.70)

2. Secondary Outcome Measure:

Measure Title	HbA1c: Change From Baseline to Study Endpoint
Measure Description	Change = study endpoint - baseline
Time Frame	baseline, study endpoint: week 12 or earlier in case of premature discontinuation
Safety Issue?	No

Analysis Population Description

The population analyzed consisted of the subset of mITT patients who had both baseline and endpoint for this outcome measure

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	106
HbA1c: Change From Baseline to Study Endpoint [units: percent] Mean (Standard Deviation)	-0.80 (1.05)

3. Secondary Outcome Measure:

Measure Title	Self-Monitored Fasting Plasma Glucose (SMFPG) Mean : Change From Baseline to Study Endpoint
Measure Description	SMFPG mean = mean of the fasting plasma glucose values recorded on the 6 consecutive days before the visit (at least 3 values needed). Change = study endpoint - baseline.
Time Frame	baseline, study endpoint: week 12 or week 8 if value not available at week 12
Safety Issue?	No

Analysis Population Description

The population analyzed consisted of the subset of mITT patients who had both baseline and endpoint for this outcome measure

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	104
Self-Monitored Fasting Plasma Glucose (SMFPG) Mean : Change From Baseline to Study Endpoint [units: mg/dL] Mean (Standard Deviation)	-35.43 (39.61)

4. Secondary Outcome Measure:

Measure Title	7-point Plasma Glucose Profile: Change From Baseline to Study Endpoint
Measure Description	7-point plasma glucose recorded before and after breakfast, before and after lunch, before and after dinner and at bedtime. Change = study endpoint - baseline.
Time Frame	baseline, study endpoint: week 12 or week 8 if value not available at week 12
Safety Issue?	No

Analysis Population Description

The population analyzed consisted of the subset of mITT patients who had valid 7-point plasma glucose profiles (4 points needed for a valid profile) both at baseline and endpoint.

Depending on the time point, few values were missing.

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	104
7-point Plasma Glucose Profile: Change From Baseline to Study Endpoint [units: mg/dL] Mean (Standard Deviation)	
Before breakfast (N=104)	-34.2 (38.1)
After breakfast (N=103)	-34.1 (48.1)
Before lunch (N=104)	-26.6 (48.2)
After lunch (N=104)	-26.5 (43.7)
Before dinner (N=103)	-25.1 (43.0)
After dinner (N=100)	-24.9 (46.7)
At bedtime (N=93)	-35.2 (51.7)

5. Secondary Outcome Measure:

Measure Title	Insulin Dose
Measure Description	Daily dose at the face-to-face visits
Time Frame	baseline, week 4, week 8, week 12
Safety Issue?	No

Analysis Population Description

mITT population

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	111
Insulin Dose [units: unit per kg body weight] Mean (Standard Deviation)	
Baseline	0.28 (0.18)
Week 4 N=110	0.37 (0.16)
Week 8 N=110	0.42 (0.18)
Week 12	0.46 (0.20)

6. Secondary Outcome Measure:

Measure Title	Number of Patients With at Least One Episode of Symptomatic Hypoglycemia
Measure Description	Symptomatic hypoglycemia was defined as an event with clinical symptoms that were considered to result from hypoglycemia confirmed or not by a plasma glucose measurement <= 70mg/dL [3.9 mmol/L]
Time Frame	During the treatment period (12 weeks) plus 7 days after last dose
Safety Issue?	Yes

Analysis Population Description

The population analyzed for this outcome measure was the safety population

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	112
Number of Patients With at Least One Episode of Symptomatic Hypoglycemia [units: participants]	40

7. Secondary Outcome Measure:

Measure Title	Change in Body Weight From Baseline to Study Endpoint
Measure Description	Change = study endpoint - baseline
Time Frame	baseline, study endpoint: week 12 or week 8 or week 4 depending on last available value
Safety Issue?	Yes

Analysis Population Description

The population analyzed was the safety population with both baseline and endpoint values available

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Measured Values

	Combination Insulin Glargine and Sitagliptin
Number of Participants Analyzed	111
Change in Body Weight From Baseline to Study Endpoint [units: kg] Mean (Standard Deviation)	1.15 (2.24)

Reported Adverse Events

Time Frame	Adverse events were assessed throughout the extension study (12 weeks). Only adverse events starting from inclusion in the extension study were taken into account.
Additional Description	[Not specified]

Reporting Groups

	Description
Combination Insulin Glargine and Sitagliptin	Insulin glargine administered once a day, in the evening, at dinner or at bedtime. Starting dose: - last dose administered in the core study for patients previously treated with insulin glargine, - 0.2 U/Kg of body weight for patients previously treated with sitagliptin. Monitoring of blood glucose and titration: all patients, irrespective of their previous treatment group in the core study were empowered to adjust their insulin doses, under strict investigator's supervision. The goal was to achieve through a force titration 70 <FPG ≤ 100 mg/dL (3.9 <FPG ≤ 5.5 mmol/L). Sitagliptin: stable dose of 100 mg once a day administered with or without food.

Serious Adverse Events

	Combination Insulin Glargine and Sitagliptin
	Affected/At Risk (%)
Total	2/112 (1.79%)
Cardiac disorders	
Right ventricular failure [A] *	1/112 (0.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

	Combination Insulin Glargine and Sitagliptin
	Affected/At Risk (%)
Endometrial cancer [A] *	1/112 (0.89%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDra

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Combination Insulin Glargine and Sitagliptin
	Affected/At Risk (%)
Total	0/112 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:
Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
If no publication has occurred within 12 months of the completion of the study, the Investigator shall have the right to publish/present independently the results of the study. The Investigator shall provide the Sponsor with a copy of any such presentation/publication for comment at least 45 days before any presentation/submission for publication. If requested by the Sponsor, any presentation/submission shall be delayed up to 90 days, to allow the Sponsor to preserve its proprietary rights.

Results Point of Contact:
Name/Official Title: Trial Transparency Team
Organization: sanofi-aventis
Phone:
Email: Contact-US@sanofi.com