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A Study of Purified Human Antibodies Administered Subcutaneously to Patients With Multifocal Motor Neuropathy (MMN)

This study has been completed.

Sponsor:
CSL Behring

Information provided by (Responsible Party):
CSL Behring

ClinicalTrials.gov Identifier:
NCT00701662

First received: June 18, 2008
Last updated: June 2, 2013
Last verified: June 2013
History of Changes

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

Results First Received: June 2, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Multifocal Motor Neuropathy (MMN)
Intervention:	Biological: Vivaglobin

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
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

	Vivaglobin

STARTED	**8**
COMPLETED	**7**
NOT COMPLETED	**1**
Lack of Efficacy	**1**

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
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Baseline Measures

	Vivaglobin
Overall Participants [units: participants]	**8**
Age [units: years] Mean (Standard Deviation)	**57.3 (8.78)**
Age, Customized [units: participants]	
> 18 to < 65 years	**5**
>= 65 years	**3**
Gender [units: participants]	
Female	**4**
Male	**4**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 24 in Muscle Strength [Time Frame: Baseline to week 24]

Measure Type	Primary
Measure Title	Change From Baseline to Week 24 in Muscle Strength
Measure Description	The change in Medical Research Council (MRC) score was determined at week 24 compared to baseline using descriptive statistics and nonparametric, two-sided 95% confidence intervals based on the Hodges-Lehmann method. Data for one of the eight subjects was from week 13 as week 24 data were not available. The 200-point MRC sum score is the sum of scores for 20 bilateral (left and right side) muscle groups, each rated

	between 0 (no movement) to 5 (normal movement/power). A higher MRC sum score indicates greater muscle contraction/limb movement. Positive values for change in MRC sum score indicate improvement, with a more positive value indicating greater muscle contraction/ limb movement compared with the value at baseline.
Time Frame	Baseline to week 24
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 Intention-to-Treat (ITT) data set comprised all patients treated with the study drug who had at least one post-baseline measurement for muscle strength.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Change From Baseline to Week 24 in Muscle Strength [units: score on a scale] Mean (95% Confidence Interval)	**0.4** **(-4.50 to 5.00)**

No statistical analysis provided for Change From Baseline to Week 24 in Muscle Strength

2. Primary: Mean Overall MRC Score at Baseline and Week 24 [Time Frame: Baseline and week 24]

Measure Type	Primary
Measure Title	Mean Overall MRC Score at Baseline and Week 24
Measure Description	The 200-point MRC sum score is the sum of scores for 20 bilateral (left and right side) muscle groups, each rated between 0 (no movement) to 5 (normal movement/power). A higher MRC sum score indicates greater muscle contraction/limb movement.
Time Frame	Baseline and week 24
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 ITT data set comprised all patients treated with the study drug who had at least one post-baseline measurement for muscle strength.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Mean Overall MRC Score at Baseline and Week 24 [units: score on a scale] Mean (Full Range)	
MRC score at baseline (n = 8)	**178.3 (149 to 197)**
MRC score at week 24 (n = 7)	**184.3 (171 to 198)**

No statistical analysis provided for Mean Overall MRC Score at Baseline and Week 24

3. Secondary: Change From Baseline to Week 24 in Disability [Time Frame: Baseline to week 24]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 24 in Disability
Measure Description	The change in disability score was determined at week 24 compared to baseline using descriptive statistics and nonparametric two-sided 95% confidence intervals based on the Hodges-Lehmann method. Data for one of the eight subjects was from week 13 as week 24 data were not available. Disability was measured using a modified Guy's Neurological Disability Scale, which comprises subscales for upper and lower limb disability. Both subscales comprise 6 grades, numbered from 0 (no upper limb problem/walking is not affected) to 5 (unable to use either arm for any purposeful movements/usually uses a wheelchair indoors). The disability score is calculated as the sum of both subscales, resulting in a score ranging from 0 to 10. A higher disability score indicates greater disability. Negative values for change in disability score indicate improvement, with a more negative value indicating greater improvement compared with the value at baseline.
Time Frame	Baseline to week 24
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Change From Baseline to Week 24 in Disability [units: score on a scale] Mean (95% Confidence Interval)	**0.1 (-1.00 to 1.00)**

No statistical analysis provided for Change From Baseline to Week 24 in Disability

4. Secondary: Mean Disability Score at Baseline and Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Mean Disability Score at Baseline and Week 24
Measure Description	Disability was measured using a modified Guy's Neurological Disability Scale, which comprises subscales for upper and lower limb disability. Both subscales comprise 6 grades, numbered from 0 (no upper limb problem/walking is not affected) to 5 (unable to use either arm for any purposeful movements/usually uses a wheelchair indoors). The disability score is calculated as the sum of both subscales, resulting in a score ranging from 0 to 10. A higher disability score indicates greater disability.
Time Frame	Baseline and Week 24
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Mean Disability Score at Baseline and Week 24 [units: score on a scale] Mean (Full Range)	
Disability score at baseline (n = 8)	**2.0 (1 to 3)**
Disability score at week 24 (n = 7)	**1.9 (1 to 3)**

No statistical analysis provided for Mean Disability Score at Baseline and Week 24

5. Secondary: Change From Baseline to the Completion Visit in Motor Function [Time Frame: Baseline to the completion visit (up to week 25)]

Measure Type	Secondary
Measure Title	Change From Baseline to the Completion Visit in Motor Function
Measure Description	The change in motor function was determined at the completion visit compared to baseline using descriptive statistics and nonparametric two-sided 95% confidence intervals based on the Hodges-Lehmann method. For each patient, four specific tasks were defined according to his/her weakened muscle group. The patient had to

	grade each of the tasks on a 5-point scale ranging from 0 (normal function) to 4 (not possible). The overall motor function score was calculated as the sum of the 4 grades, resulting in a score ranging from 0 (optimal) to 16 (worst). The baseline motor function score was calculated as the mean of the patient's assessments at Screening and Week 1. Negative values for change in motor function score indicate improvement, with a more negative value indicating greater improvement compared with the value at baseline.
Time Frame	Baseline to the completion visit (up to week 25)
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Change From Baseline to the Completion Visit in Motor Function [units: score on a scale] Mean (95% Confidence Interval)	**0.4** **(-1.50 to 0.75)**

No statistical analysis provided for Change From Baseline to the Completion Visit in Motor Function

6. Secondary: Mean Motor Function Score at Screening and Week 25 [Time Frame: Screening and week 25]

Measure Type	Secondary
Measure Title	Mean Motor Function Score at Screening and Week 25
Measure Description	For each patient, four specific tasks were defined according to his/her weakened muscle group. The patient had to grade each of the tasks on a 5-point scale ranging from 0 (normal function) to 4 (not possible). The overall motor function score was calculated as the sum of the 4 grades, resulting in a score ranging from 0 (optimal) to 16 (worst).
Time Frame	Screening and week 25
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description

Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Mean Motor Function Score at Screening and Week 25 [units: score on a scale] Mean (Full Range)	
Motor function score at screening (n = 8)	**5.5 (0 to 8)**
Motor function score at week 25 (n = 7)	**4.6 (0 to 8)**

No statistical analysis provided for Mean Motor Function Score at Screening and Week 25

7. Secondary: Health-Related Quality of Life at Baseline and Week 25 [Time Frame: At baseline and week 25]

Measure Type	Secondary
Measure Title	Health-Related Quality of Life at Baseline and Week 25
Measure Description	Assessed using a questionnaire on patients' satisfaction with current immunoglobulin G (IgG) treatment, treatment at home, and treatment at the hospital/doctor's office. The questions were answered by choosing a number between 1 (extremely good) and 7 (extremely bad). Note: No patients received IgG treatment at the hospital/doctor's office at Week 25.
Time Frame	At baseline and week 25
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Health-Related Quality of Life at Baseline and Week 25 [units: units on a scale] Mean (Full Range)	
Current treatment, baseline (n = 8)	**2.6 (1 to 4)**

Current treatment, week 25 (n = 7)	**1.3 (1 to 2)**
At home, baseline (n = 3)	**1.0 (1 to 1)**
At home, week 25 (n = 7)	**1.1 (1 to 2)**
In the hospital/doctor's office, baseline (n = 7)	**2.9 (1 to 5)**

No statistical analysis provided for Health-Related Quality of Life at Baseline and Week 25

8. Secondary: Treatment Satisfaction at Baseline and Week 25 [Time Frame: At baseline and week 25]

Measure Type	Secondary
Measure Title	Treatment Satisfaction at Baseline and Week 25
Measure Description	Treatment satisfaction was assessed using the Life Quality Index, which comprises 15 items rated on a 7-point scale (1 = worst rating, 7 = best rating) with a possible maximum score of 105. The highest score indicates the highest satisfaction with the impact of treatment on social factors. The 15 items were summarized to 4 scales: treatment interference, therapy-related problems, therapy setting, and treatment costs. The raw scores for these scales were transformed to a score ranging from 0 to 100, with 100 being the best score achievable.
Time Frame	At baseline and week 25
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Treatment Satisfaction at Baseline and Week 25 [units: units on a scale] Mean (Full Range)	
Treatment interference, baseline (n = 8)	**60.76 (8.3 to 97.2)**
Treatment interference, week 25 (n = 6)	**91.67 (75.0 to 100.0)**
Therapy-related problems, baseline (n = 8)	**70.30 (8.3 to 91.7)**
Therapy-related problems, week 25 (n = 7)	**89.29 (66.7 to 100.0)**

Therapy setting, baseline (n = 8)	**75.01 (5.6 to 100.0)**
Therapy setting, week 25 (n = 6)	**96.28 (83.3 to 100.0)**
Treatment costs, baseline (n = 8)	**70.84 (0.0 to 100.0)**
Treatment costs, week 25 (n = 6)	**86.10 (50.0 to 100.0)**

No statistical analysis provided for Treatment Satisfaction at Baseline and Week 25

9. Secondary: Overall Health Status at Baseline and Week 25 [Time Frame: Baseline and week 25]

Measure Type	Secondary
Measure Title	Overall Health Status at Baseline and Week 25
Measure Description	Overall Health Status was assessed using a Visual Analogue Scale (VAS). Patients were asked to rate their overall health status by placing a mark on a 100 mm VAS, with 0 being the worst imaginable state and 100 being the best imaginable state.
Time Frame	Baseline and week 25
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 analysis population comprised the subjects in the ITT data set (ie, all patients treated with the study drug) who had at least one post-baseline value (and if necessary a baseline value).

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Overall Health Status at Baseline and Week 25 [units: units on a scale] Mean (Full Range)	
Baseline (n = 8)	**72.1 (52 to 96)**
Week 25 (n = 7)	**73.9 (50 to 98)**

No statistical analysis provided for Overall Health Status at Baseline and Week 25

10. Secondary: Number of Patients With Adverse Events (AEs) by Severity and Relatedness [Time Frame: For the duration of the study, up to Week 25]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events (AEs) by Severity and Relatedness
Measure Description	Included all AEs that occurred during the entire study period. Mild AE: Did not interfere with routine activities; Moderate AE: Interfered somewhat with routine activities; Severe AE: Impossible to perform routine activities.
Time Frame	For the duration of the study, up to Week 25
Safety Issue	Yes

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 safety data set (SDS) comprised all treated patients.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Number of Patients With Adverse Events (AEs) by Severity and Relatedness [units: participants]	
All AEs	**4**
Mild AEs	**3**
Moderate AEs	**2**
Severe AEs	**0**
Not related AEs	**4**
Possibly related AEs	**0**
Probably related AEs	**0**
Related AEs	**1**

No statistical analysis provided for Number of Patients With Adverse Events (AEs) by Severity and Relatedness

11. Secondary: Rate of AEs by Severity and Relatedness [Time Frame: For the duration of the study, up to Week 25]

Measure Type	Secondary
Measure Title	Rate of AEs by Severity and Relatedness
Measure Description	The rate was the number of AEs over the number of infusions administered. Included all AEs that occurred during the entire study period. Mild AE: Did not interfere with routine activities; Moderate AE: Interfered somewhat with routine activities; Severe AE: Impossible to perform routine activities.
Time Frame	For the duration of the study, up to Week 25

Safety Issue	Yes

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 SDS comprised all treated patients.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Overall Units Analyzed [units: Infusions]	**183**
Rate of AEs by Severity and Relatedness [units: AEs per infusion]	
All AEs	**0.104**
Mild AEs	**0.093**
Moderate AEs	**0.011**
Severe AEs	**0.000**
Not related AEs	**0.038**
Possibly related AEs	**0.000**
Probably related AEs	**0.000**
Related AEs	**0.066**

No statistical analysis provided for Rate of AEs by Severity and Relatedness

12. Secondary: Number of Patients With Local/Injection Site Reactions [Time Frame: For the duration of the study, up to Week 25]

Measure Type	Secondary
Measure Title	Number of Patients With Local/Injection Site Reactions
Measure Description	All AEs arising from local/injection site reactions.
Time Frame	For the duration of the study, up to Week 25
Safety Issue	Yes

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 SDS comprised all treated patients.

Reporting Groups

	Description

Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Number of Patients With Local/Injection Site Reactions [units: participants]	
Total	**1**
Injection site oedema	**1**
Injection site pruritis	**1**
Skin reaction	**1**

No statistical analysis provided for Number of Patients With Local/Injection Site Reactions

13. Secondary: Number of Patients With Clinically Relevant Changes in Laboratory Parameters [Time Frame: Baseline to Week 25]

Measure Type	Secondary
Measure Title	Number of Patients With Clinically Relevant Changes in Laboratory Parameters
Measure Description	Laboratory parameters included hematology, serum chemistry, and urinalysis parameters.
Time Frame	Baseline to Week 25
Safety Issue	Yes

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 SDS comprised all treated patients.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Number of Patients With Clinically Relevant Changes in Laboratory Parameters [units: participants]	**0**

No statistical analysis provided for Number of Patients With Clinically Relevant Changes in Laboratory Parameters

14. Secondary: Number of Patients With Clinically Relevant Changes in Vital Signs [Time Frame: Baseline to Week 25]

Measure Type	Secondary
Measure Title	Number of Patients With Clinically Relevant Changes in Vital Signs
Measure Description	Vital signs included heart rate, systolic blood pressure, diastolic blood pressure, and body temperature.
Time Frame	Baseline to Week 25
Safety Issue	Yes

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 SDS comprised all treated patients.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Measured Values

	Vivaglobin
Overall Participants [units: participants]	**8**
Number of Patients With Clinically Relevant Changes in Vital Signs [units: participants]	**0**

No statistical analysis provided for Number of Patients With Clinically Relevant Changes in Vital Signs

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	For the duration of the study, up to Week 25.
Additional Description	The SDS comprised all treated patients. "General disorders" were collected under the Medical Dictionary for Regulatory Activities System organ class (MedDRA SOC) General disorders and administration site conditions.

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Serious Adverse Events

	Vivaglobin
Total, serious adverse events	
# participants affected / at risk	**0/8 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	For the duration of the study, up to Week 25.
Additional Description	The SDS comprised all treated patients. "General disorders" were collected under the Medical Dictionary for Regulatory Activities System organ class (MedDRA SOC) General disorders and administration site conditions.

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
Vivaglobin	Human normal immunoglobulin, 0.1 to 0.5 g/kg body weight per week.

Other Adverse Events

	Vivaglobin
Total, other (not including serious) adverse events	
# participants affected / at risk	**4/8 (50.00%)**
Blood and lymphatic system disorders	
Spontaneous haematoma † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
General disorders	
Asthenia † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Injection-site oedema † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**4**
Injection-site pruritus † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**4**
Infections and infestations	
Influenza † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Orchitis † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Nervous system disorders	
Hemicephalalgia † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Multifocal motor neuropathy † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Skin and subcutaneous tissue disorders	
† 1	

Erythema	
# participants affected / at risk	**1/8 (12.50%)**
# events	**1**
Skin reaction † 1	
# participants affected / at risk	**1/8 (12.50%)**
# events	**4**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (11.1)

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: CSL agreements and restrictions on publishing may vary with individual investigators; however, CSL will not prohibit any investigator from publishing. CSL supports the publication of results from all centers of a multi-center trial and generally requires that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Clinical Trial Disclosure Manager
Organization: CSL Behring
phone: Use email contact
e-mail: clinicaltrials@cslbehring.com

Publications of Results:

Misbah S, et al. Efficacy and safety of subcutaneous immunoglobulin, Vivaglobin, in patients with multifocal motor neuropathy. Journal of Neurology 257(Suppl 1):S105-S106, 2010.

Misbah SA, Baumann A, Fazio R, Dacci P, Schmidt DS, Burton J, Sturzenegger M. A smooth transition protocol for patients with multifocal motor neuropathy going from intravenous to subcutaneous immunoglobulin therapy: an open-label proof-of-concept study. J Peripher Nerv Syst. 2011 Jun;16(2):92-7. doi: 10.1111/j.1529-8027.2011.00330.x.

Responsible Party:	CSL Behring
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Last Updated:	June 2, 2013
Health Authority:	Switzerland: Swissmedic Germany: Paul-Ehrlich-Institut Italy: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency