

Site Number: _____ Screening ID: _____ - ____

Participant Letters: _____

Complete this form for neurologic assessments performed at:

- the next visit for participants enrolled prior to the addition of the neurologic assessment
- the Screening or Baseline Visit prior to randomization
- the end of treatment (Visit 27)

A. VISIT INFORMATION

1. Was a neurologic assessment completed at this visit?

Y N

If YES,

a. Date of assessment:

____ / ____ / ____
DAY MONTH YEAR

2. Assessment performed (*check one*):

- ☐ 1 **Initial neurologic assessment** (*performed during next visit for participants enrolled prior to the addition of the neurological assessment*)
- ☐ 2 **Baseline neurologic assessment** (*performed during the Screening or Baseline Visit prior to randomization for new participants*)
- ☐ 3 **End of treatment neurologic assessment** (*performed at Visit 27*)

3. Study Visit: (*check one*)

- | | | | |
|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> -1 Screening | <input type="checkbox"/> 8 Visit 8 | <input type="checkbox"/> 17 Visit 17 | <input type="checkbox"/> 26 Visit 26 |
| <input type="checkbox"/> 0 Baseline | <input type="checkbox"/> 9 Visit 9 | <input type="checkbox"/> 18 Visit 18 | <input type="checkbox"/> 27 Visit 27 |
| <input type="checkbox"/> 1 Visit 1 | <input type="checkbox"/> 10 Visit 10 | <input type="checkbox"/> 19 Visit 19 | |
| <input type="checkbox"/> 2 Visit 2 | <input type="checkbox"/> 11 Visit 11 | <input type="checkbox"/> 20 Visit 20 | |
| <input type="checkbox"/> 3 Visit 3 | <input type="checkbox"/> 12 Visit 12 | <input type="checkbox"/> 21 Visit 21 | |
| <input type="checkbox"/> 4 Visit 4 | <input type="checkbox"/> 13 Visit 13 | <input type="checkbox"/> 22 Visit 22 | |
| <input type="checkbox"/> 5 Visit 5 | <input type="checkbox"/> 14 Visit 14 | <input type="checkbox"/> 23 Visit 23 | |
| <input type="checkbox"/> 6 Visit 6 | <input type="checkbox"/> 15 Visit 15 | <input type="checkbox"/> 24 Visit 24 | |
| <input type="checkbox"/> 7 Visit 7 | <input type="checkbox"/> 16 Visit 16 | <input type="checkbox"/> 25 Visit 25 | |

B. ASSESSMENT INFORMATION

1. Were there any clinically significant abnormalities?

Y N

If YES,

- If baseline assessment and clinically significant abnormalities noted, participant is **NOT ELIGIBLE** for study participation.
- If initial or follow-up assessment and clinically significant abnormalities noted, complete Adverse Event Report Form (**CTL13**) and refer to Neurologist for further evaluation.

Initials (first, middle, last) of person completing this form:

F M L

Date form completed:

____ / ____ / ____
DAY MONTH YEAR

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*