

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 neurological 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).*