

Site Number: _____ Screening ID: _____ - ____

Participant Letters: _____

Complete this form for neurologic assessments performed at:

- the first visit for enrolled participants following local IRB approval to resume enrollment
- the Screening or Baseline Visit prior to randomization
- Follow-up visits at Months 6, 12, 18, and 24

A. VISIT INFORMATION

1. Was a neurologic assessment completed at this visit? Y N

If YES,

a. Date of assessment: _____ / _____ / _____
DAY MONTH YEAR

If NO, complete Section A and complete a Protocol Deviation Form (RIT21)

2. Assessment performed (*check one*):

- 1 **Initial neurologic assessment** (*performed during first visit for enrolled participants following local IRB approval to resume enrollment*)
- 2 **Baseline neurologic assessment** (*performed during Screening or Baseline Visit prior to randomization for new participants*)
- 3 **Follow-up neurologic assessment** (*performed at months 6, 12, 18, and 24*)

3. Study Visit: (*check one*)

- | | |
|--|--------------------------------------|
| <input type="checkbox"/> 2 Baseline (or Screening) | <input type="checkbox"/> 15 Month 5 |
| <input type="checkbox"/> 3 Week 1 | <input type="checkbox"/> 16 Month 6 |
| <input type="checkbox"/> 4 Week 2 | <input type="checkbox"/> 17 Month 9 |
| <input type="checkbox"/> 5 Week 3 | <input type="checkbox"/> 18 Month 12 |
| <input type="checkbox"/> 6 Week 5 | <input type="checkbox"/> 27 Month 18 |
| <input type="checkbox"/> 10 Week 10 | <input type="checkbox"/> 29 Month 24 |
| <input type="checkbox"/> 11 Month 3 | |

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 (RIT13) 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).*