## To Be Filled out by the Treating Clinician

1. Is the participant/subject having new neurologic symptom(s) or an acute worsening of preexisting neurologic symptoms?\*\*  Yes  No (STOP)  Unknown
   1. If Yes, Date of onset: // mm/dd/yyyy
      1. Did the symptoms last more than 24 hours?  Yes  No (Skip to Q7)  Unknown
2. Did the participant/subject have a fever due to intercurrent illness? Yes (Skip to Q7)  No
3. Prior to the onset of this event, were the participant’s/subject’s MS symptom(s) stable or improving over the last 30 days?  Yes  No  Unknown
   1. If Yes, was onset within the last 24 hours? Yes  No  Unknown
   2. If No, was the onset within the last 7 days?  Yes  No  Unknown
4. Are the symptom(s) associated with new neurologic findings?  Yes  No  Unknown
   1. If Yes, was the [specify system] system involved in the relapse? (Choose all that apply)
      1. Pyramidal  Yes No
      2. Sensory  Yes  No
      3. Cerebellar  Yes  No
      4. Bowel and/or Bladder  Yes  No
      5. Brainstem  Yes  No
      6. Mental  Yes  No
      7. Visual  Yes  No
5. Are the participant’s/subject’s symptom(s) ongoing?  Yes  No  Unknown
   1. If No, End Date: // mm/dd/yyyy
6. Please describe event, symptom(s) and treatment that occurred with the participant/subject:
7. If applicable, is this a protocol defined qualifying relapse according to the definition set in the study protocol?

Yes  No  Unknown

* 1. If No, please indicate why the event is not a qualifying relapse as defined in the protocol:

## General Instructions

All elements on this form are classified as Supplemental (unless otherwise specified) and should only be collected if the research team considers them appropriate for their study.

\*\*This element is classified as Supplemental-Highly Recommended for clinical trial designs.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Visit Date – The preferred format for recording date is DD/MMM/YYYY. 99/99/9999 can be used to indicate an unknown date.
* New neurologic symptoms –If No, do not complete the remainder of the form
* Symptoms Onset Date – Record the date of relapse onset to the level of certainty available (mm/dd/yyyy). Onset is the time of onset at which the patient initially reports the new neurological symptom consistent with MS or worsening/recurrence of prior MS symptoms
* Did the symptoms last more than 24 hours? *–* If no, skip to question 7
* Fever due to incurrent illness –If yes, skip to question 7
* MS symptoms – No additional instructions
* Was onset within the last 24 hours? – Only answered if "Yes" was answered for "Prior to the onset of this event, were the participant's/subject's MS symptom(s) stable or improving over the last 30 days?"
* Was onset within the last 7 days? – Only answered if "No" was answered for "Prior to the onset of this event, were the participant's/subject's MS symptom(s) stable or improving over the last 30 days?"
* Neurologic findings – No additional instructions
* Deficit present? *–* Answer All
* Symptoms ongoing? – No additional instructions
* Symptoms end date –Only answered if "No" was answered for "Are the participant's/subject's symptom(s) ongoing?" The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
* Description of Event – No additional instructions
* Protocol defined relapse – Modify as needed based on protocol specifications