## 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