Biogen	**Clinical Trial Serious Adverse Event (SAE) Form** **(Governed by DEV-SOP-831)**	**RD-T-144**

Subject ID #:_____	**Safety Database Tracking Number** _____ *Provided by* BIOGEN
	Protocol: 272MS401

Section A **DEMOGRAPHICS**

Year of Birth: _____ *(YYYY)*	Gender: Female	Ht:_____ ☐ cm ☐ in	Wt:_____ ☐ kg ☐ lb

Is this SAE related to pregnancy? ☐ Yes ☐ No

Is the subject currently enrolled in another Biogen Vumerity (BIIB098) clinical trial? ☐ Yes ☐ No

If yes, indicate the Protocol number of the other Biogen trial:_____

Study Subject ID in other Biogen Vumerity (BIIB098) clinical trial:_____

Section B **EVENT AND CRITERIA FOR SERIOUS CLASSIFICATION**

SAE Term: (provide medical diagnosis - not symptoms or procedure names)

Severity: *(check one)*

☐ Grade 1 ☐ Grade 4
☐ Grade 2 ☐ Grade 5
☐ Grade 3

Outcome at time of this SAE report: *(check one)*

☐ Recovered / Resolved ☐ Fatal
☐ Recovered with Sequelae ☐ Not Recovered / Not Resolved
☐ Date event resolved:_____ *(DD/MMM/YYYY)*

Date event became serious:_____ *(DD/MMM/YYYY)*

Select all that apply:

☐ Death:_____ *(DD/MMM/YYYY)*
Autopsy performed? ☐ *Yes* ☐ *No*

☐ Initial / Prolonged Hospitalization
Admission Date:_____ *(DD/MMM/YYYY)*
Discharge Date:_____ *(DD/MMM/YYYY)*

☐ Life-threatening

☐ Congenital Anomaly / Birth Defect

☐ Persistent or Significant Disability

☐ Medically Significant
Important medical events (may jeopardize the subject and may require medical/surgical intervention to prevent other outcomes)

Dechallenge:
☐ Negative
☐ Positive
☐ Unknown
☐ Not applicable

Rechallenge:
☐ Negative
☐ Positive
☐ Unknown
☐ Not applicable

Section C **STUDY DRUG**

Study drug name: Vumerity (Diroximel Fumarate)

Dose / Route / Frequency: _____

Date of first treatment:_____ *(DD/MMM/YYYY)*

Date of most recent treatment prior to event:_____ *(DD/MMM/YYYY)*

Total number of doses prior to event:_____

Report within 24 hours to QSHNSAE@iqvia.com

Subject ID #:_____	**Safety Database Tracking Number** _____ *Provided by* BIOGEN **Protocol: 272MS401**

Indicate action taken with study drug in response to this event: (check one)

☐ No action taken ☐ SAE occurred prior to first dose ☐ SAE occurred after final dose per protocol

☐ Temporarily discontinued ☐ Permanently discontinued:_____
Date of final dose (DD/MMM/YYYY)

RELATIONSHIP TO STUDY DRUG AS PROVIDED BY HEALTH CARE PROVIDER (HCP) (check one)

☐ Not related	☐ Related	State rationale for relationship to study drug:

Section D **MEDICAL HISTORY**
(Include relevant medical history)

Date of diagnosis of Multiple Sclerosis:_____
(DD/MMM/YYYY)

Disease / Diagnosis	Past or Present	Start Date *(DD/MMM/YYYY)*	Stop Date *(DD/MMM/YYYY)*

Section E **CONCOMITANT MEDICATION**
(Ongoing or completed within one week prior to onset of event)
Do not include medication(s) used as treatment(s) for this SAE.

Drug / Therapy	Indication	Dose / Route / Frequency	Start Date *(DD/MMM/YYYY)*	Stop Date *(DD/MMM/YYYY)*

Section F **SAE TREATMENTS OR MEDICATIONS**
Include all treatments or medications for the SAE.

Date *(DD/MMM/YYYY)*	Treatment or Medication	Indication

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Subject ID #:_____	Safety Database Tracking Number _____ *Provided by* BIOGEN
	Protocol: 272MS401

Section G **TEST(S) PERFORMED TO EVALUATE SERIOUS ADVERSE EVENT**

Date *(DD/MMM/YYYY)*	Test	Result	If Lab, Normal Range / Units

Section H **DESCRIPTION OF SERIOUS ADVERSE EVENT**

(In narrative form, include a description of the event, concurrent illnesses, diagnosis, clinical course, treatment for the event, and outcome, if available)

Section I **HEALTH CARE PROVIDER (HCP) INFORMATION**

HCP Name (print):_____ Title:_____

Institution:_____ Phone #: _____

Address:_____ Fax #: _____

Country:_____ Relationship to patient: _____

Section J **SIGNATURE AND COORDINATING CENTER REPRESENTATIVE INFORMATION**

Coordinating Center Representative Signature:_____ Date Signed:_____

Name (print):_____ Title:_____

Institution:_____ Phone #: _____

Address:_____ Fax #: _____

Country:_____

Report within 24 hours to QSHNSAE@iqvia.com