Biogen	**Clinical Trial Pregnancy Notification and Outcome Form** **(Governed by DEV-SOP-831)**	**RD-T-147**

Subject ID #:_____

Safety Database Tracking Number

_____

Provided by BIOGEN

Protocol: 272MS401

DEMOGRAPHICS

SUBJECT DEMOGRAPHICS

Subject Year of Birth:_____ *(YYYY)*

Study subject is the: Mother

Date of last menstrual period:_____ *(DD/MMM/YYYY)*

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: _____

PREGNANCY CONFIRMATION

Date pregnancy was confirmed:_____ *(DD/MMM/YYYY)*

How was the pregnancy confirmed?

☐ Urine hCG

☐ Serum hCG

☐ Ultrasound

☐ Other _____

OUTCOME OF PREGNANCY

Date of outcome: _____ *(DD/MMM/YYYY)*

Weeks of gestation at outcome: _____

Select one:

☐ Outcome pending EDC / Due date: _____ *(DD/MMM/YYYY)*

☐ Live birth without congenital anomaly

☐ Live birth with congenital anomaly*

Specify:_____

☐ Ectopic pregnancy*

☐ Spontaneous abortion / miscarriage*

☐ Elective termination without foetal defects

☐ Elective termination with foetal defects*

Specify:_____

☐ Stillbirth with foetal defects* Specify: _____

☐ Stillbirth without foetal defects*

☐ Lost to follow-up / Unknown

***Complete SAE Form and fax/email within 24 hours.**

Any other complications with the pregnancy? ☐ No ☐ Yes, *if yes provide details below:*

STUDY DRUG

Study drug name: ☐ Vumerity (Diroximel Fumarate) or ☐ Other Disease Modifying Therapy (DMT): _____

Dose / Route /Frequency:_____

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

Total number of doses prior to pregnancy confirmation:_____

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

☐ No action taken ☐ Temporarily discontinued ☐ Permanently discontinued:_____ *Date of final dose (DD/MMM/YYYY)*

COMMENTS

Report within 24 hours to QSHNSAE@iqvia.com

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

HEALTH CARE PROVIDER (HCP) INFORMATION

HCP Name (print):_____ Title:_____

Institution:_____ Phone #: _____

Address:_____ Fax #: _____

Country:_____ Relationship to patient:_____

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