Protocol #: 272MS401

COMPLETE THE PREGNANCY NOTIFICATION AND OUTCOME FORM FOR ALL FEMALE SUBJECTS ENROLLED IN THIS STUDY WHO WERE EXPOSED TO MS DMT.

Provide follow-up information on a new Pregnancy Notification and Outcome Form. Do not modify previously submitted Pregnancy Forms with follow-up data.

Report all pregnancy complications that meet any of the serious outcomes provided in the protocol on a Serious Adverse Event (SAE) form within 24 hours of awareness (RD-T-144).

GENERAL INSTRUCTIONS FOR COMPLETING PREGNANCY FORMS

- Write legibly using a black or blue indelible ink pen.
- If a correction is required, draw a single line through the error, so that it remains legible, write in the correct data, then initial and date the changes (e.g., ~~placbo~~ placebo EAL 01/JAN/2022).
- Use the date format of DD/MMM/YYYY (e.g., 12/JAN/2022). Partial dates are acceptable by entering a hyphen for unknown data (e.g., -/-/2022).
- Use the appropriate medical terminology; be concise.
- Remember to redact the subject's identifying information (e.g. name, initials, day/month of birth, hospital number etc.) on all source documents.
- Be sure to write the subject ID number on each page of all forms and source documents.

INVESTIGATOR RESPONSIBILITIES

- Fax or email the Pregnancy Form to IQVIA Lifecycle Safety **within 24 hours** of knowledge of event.
- Do not wait for the complete information before faxing or emailing the form. Follow up with the reporting HCP to provide additional information and documents needed to support the assessment of the Pregnancy **as requested** (e.g., e.g., pregnancy serum test, etc.).

DEMOGRAPHICS

Subject ID#: Record the Subject ID.

Subject Demographics:

- Record the subject's year of birth (YYYY).
- The subject is the mother (Pre-populated).
- Record the start date of the pregnant female's last menstrual period.

Current enrollment in another Biogen Vumerity (BIIB098) Clinical Trial: Check the appropriate box and provide information as applicable.

Pregnancy Confirmation:

- Record the date the pregnancy was confirmed.
- Record how the pregnancy was confirmed.

OUTCOME OF PREGNANCY

Record the date of the pregnancy outcome.

Record the number of weeks of gestation at the time out the outcome.

Select one outcome of the pregnancy:

- If the outcome is pending, record the expected due date or date of cesarean section.
- If there was a congenital anomaly, then specify.
- If there were foetal defects, then specify.
- If the option selected has a "*", then complete an SAE form and fax or email within 24 hours to IQVIA Lifecycle Safety.

Check the box if there were any other complications with the pregnancy. If yes, then provide details. Indicate any defects, infections or other complications.

Report within 24 hours to QSHNSAE@iqvia.com

STUDY DRUG

Study drug name: Select Vumerity or other Disease Modifying Therapy (DMT) that the subject received. If "Other DMT" was selected, provide the name of the other DMT.

Dose / Route / Frequency: Enter the dose, route, and frequency of the study drug administration (e.g., 80 mg, Orally, QW).

Date of first treatment: Enter the date of the initial dose of study drug.

Total number of doses: Enter the total number of doses prior to pregnancy confirmation.

Action taken with study drug: Indicate the action taken with the study drug in the response to pregnancy; check one of the options. If the study drug was permanently discontinued, enter the date of the final dose.

COMMENTS

Record any relevant comments or provide any relevant details that were not included in the sections above.

HCP AND COORDINATING CENTER REPRESENTATIVE INFORMATION

- HCP: Provide the name, title, institution, address, country, phone #, fax #, relationship to patient
- The Coordination Center Representative **MUST SIGN** to acknowledge completeness and accuracy of the SAE Form.
- Print the full name and title of the Coordinating Center Representative, sign, the date signed, the name, institution, address, country, phone, and fax number.