272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Pregnancy Outcome Follow-Up (EDD + 4 Weeks OR at any time prior as reported)
Form: Date of Visit
Generated On: 10 Jul 2023 16:06:42

Visit Not Done	_____
Visit Not Done Reason	Not Collected Due to the Impact of Covid-19 Pandemic ☐ Inadvertently Omitted ☐ Visit Scheduling Time Constraints ☐ Subject Non-Compliant/Refusal ☐ Caregiver Non-Compliant/Refusal ☐ Subject Discontinued from Study ☐
Visit Date (dd-mon-yyyy)	_____
Type of Visit Performed	Study Site (Assigned or Alternate) In-Person ☐ Home Health In-Person ☐ Remote - Audio Only (e.g. Telephone) ☐ Remote - Audio and Video (e.g. Telemedicine) ☐
In addition to completing the forms for this visit, please add and/or update log records (Adverse Events, Concomitant Medications/Treatments, etc.), as appropriate	
Biogen Form Version	VISIT_FV2.1

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Pregnancy Outcome Follow-Up (EDD + 4 Weeks OR at any time prior as reported)
Form: Vital Signs Follow-Up
Generated On: 10 Jul 2023 16:06:42

Vital Signs Assessment Date (dd-mon-yyyy)	_____
Weight	_____
Weight Unit	kg ☐ lb ☐
Weight Difference Since Last Visit	_____
Weight Unit	KG
Biogen Form Version	VS_FV1.0

Birth Order	1 Male ☐ 1 Female ☐ 2 Male ☐ 2 Female ☐ 3 Male ☐ 3 Female ☐ 4 Male ☐ 4 Female ☐ 5 Male ☐ 5 Female ☐
Vital Signs Assessment Date (dd-mon-yyyy)	_____
Weight	_____
Weight Unit	lb ☐ oz ☐ gm ☐ kg ☐
Length	_____
Length Unit	cm ☐ in ☐
Head Circumference	_____
Head Circumference Unit	cm ☐ in ☐

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Pregnancy Outcome Follow-Up (EDD + 4 Weeks OR at any time prior as reported)
Form: MS Disease Changes Since Last Contact
Generated On: 10 Jul 2023 16:06:42

Has the Subject's MS Disease Course Changed or has the Subject had a Relapse Since Last Contact?	Yes ☐ No ☐
Please Indicate the Number of MS Relapses Since the Last Contact	_____
Current MS Status	Active ☐ Relapse ☐ Progressing ☐ Other ☐
If Other MS Status, Please Specify	_____

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Pregnancy Outcome Follow-Up (EDD + 4 Weeks OR at any time prior as reported)
Form: Pregnancy Outcome
Generated On: 10 Jul 2023 16:06:42

Was the Pregnancy Outcome Assessment Performed?	Yes ☐ No ☐
Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
If Other Source of Information, Please Specify	_____
Twin or Multiple Pregnancy	Yes ☐ No ☐
If Twin or Multiple Birth, Please Complete Separate Line for each Outcome	
Birth Order	1 Male ☐ 1 Female ☐ 2 Male ☐ 2 Female ☐ 3 Male ☐ 3 Female ☐ 4 Male ☐ 4 Female ☐ 5 Male ☐ 5 Female ☐
Date of Pregnancy Outcome (dd-mon-yyyy)	_____
Gestational Age at Time of Pregnancy Outcome - Weeks	_____
Live Birth?	Yes ☐ No ☐
If Live Birth is No, Please Provide the Outcome	Spontaneous Abortion ☐

	Fetal Death/Stillbirth ☐ Elective/Therapeutic Abortion ☐ Other ☐
If Other, Please specify	_____
If Live Birth is No, Please complete Adverse Event Form	
Mode of Delivery at Live Birth (Check One):	
Mode of Delivery	Vaginal Delivery ☐ Cesarean Delivery ☐
Suction or Forceps Delivery?	Yes ☐ No ☐
For Medical Need?	Yes ☐ No ☐
If Yes, Please Specify	_____
Did Neonatal Death occur afterwards? (If an Infant Death was noted, the Infant Record of Death must be Complete)	Yes ☐ No ☐
Was Pregnancy a Molar Pregnancy?	Yes ☐ No ☐
Was Pregnancy an Ectopic Pregnancy?	Yes ☐ No ☐
Mode of Delivery of Nonviable Products of Conception (Check all that apply):	
Medical Abortion	_____
Surgical Abortion	_____
Abdominal/Pelvic Laparotomy	_____
Vaginal Delivery	_____
Suction or Forceps Delivery?	Yes ☐ No ☐
Cesarean Delivery	_____
For Medical Need?	Yes ☐ No ☐
If Yes, Please Specify	_____

Were Products of Conception Examined?	Yes ☐ No ☐ Unknown ☐
If Yes, were any Abnormalities Identified?	Yes ☐ No ☐ Unknown ☐
If Yes, Please Describe	_____
Has the Subject Recovered?	Yes ☐ No ☐
MS Status at Time of Pregnancy Outcome	Active ☐ Relapse ☐ Progressing ☐ Other ☐
If Other MS Status, Please Specify	_____
Date when MS Treatment is Re-instated (dd-mon-yyyy)	_____
If New MS Treatment	Yes ☐ No ☐
Date of New MS Treatment (dd-mon-yyyy)	_____
Please Indicate the Number of MS Relapses Since the Last Contact	_____
Was there a Maternal Death? (If a Maternal Death was noted, the Maternal Record of Death must be Completed)	Yes ☐ No ☐

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Pregnancy Outcome Follow-Up (EDD + 4 Weeks OR at any time prior as reported)
Form: Neonatal Characteristics
Generated On: 10 Jul 2023 16:06:42

Was a Neonatal Characteristics Assessment Performed?	Yes ☐ No ☐
Date of Office Visit (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Birth Order	1 Male ☐ 1 Female ☐ 2 Male ☐ 2 Female ☐ 3 Male ☐ 3 Female ☐ 4 Male ☐ 4 Female ☐ 5 Male ☐ 5 Female ☐
If Live Birth, APGAR Score	
APGAR Score - 1 minute	_____
APGAR Score - 5 minutes	_____
APGAR Score - 10 minutes	_____
Did the Newborn have any Birth Defects/Abnormalities?	Yes ☐ No ☐
Birth Defect/Abnormality	_____
Attributable to Biogen MS Treatment	Yes ☐ No ☐

	Unknown ☐ Other ☐
If Other Attributable Factors (e.g. Maternal Age, etc), Please Specify	_____
Was the Child Breastfeeding at any time after Birth?	Yes ☐ No ☐
If Yes, Provide Start Date of Breastfeeding (dd-mon-yyyy)	_____
Is Child still Breastfeeding?	Yes ☐ No ☐
Date of Breastfeeding Discontinued (dd-mon-yyyy)	_____
Was there an Infant Death?	Yes ☐ No ☐
If an Infant Death was Noted, the Infant Record of Death must be Completed.	