Subject Case Report Forms

272MS401_eCRF_EditChecks_Database_Validation_0.1 - All Visits

Signature Prompt: I CONFIRM THAT THE ENTRIES ON THE CASE REPORT FORM PAGES CORRESPONDING TO THIS CASEBOOK ACCURATELY AND COMPLETELY REPRESENT THE RESULTS OF THE EXAMINATIONS, TESTS, AND EVALUATIONS PERFORMED ON THE DATES SPECIFIED.

Generated By: Neha Janba

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272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Date of Visit
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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: Enrollment
Form: Informed Consent
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Protocol Version Number Under Which the Subject Entered the Study	Protocol V4 Protocol V5 Protocol V6 Protocol V7 Protocol V8 Protocol V9 Protocol V10
Informed Consent Date (dd-mon-yyyy)	
Did the subject consent to the release of medical information?	Yes No
If Yes, Release of Medical Information Consent Date (dd-mon-yyyy)	
Is the Subject a Minor?	Yes No
If Yes, Parent or Legal Guardian has Provided Informed Consent for the Subject to be Enrolled in the Biogen MS Pregnancy Exposure Registry?	Yes No
If No, Subject is not Eligible and Enrollment should be Terminated.	
Biogen Form Version	DS_IFC_FV1.0

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Inclusion Criteria Information
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Did the Subject meet Inclusion Criteria 1 Through 4?	Yes ☐ No ☐
If No, Please Choose the Criteria Unmet	_____
IC 1	_____
IC 2	_____
IC 3	_____
IC 4	_____
Did the Subject Meet any Inclusion Criteria 5 Through 7?	Yes ☐ No ☐
Participants who met one or more Criteria below may also be Enrolled in this Registry after Consultation with the HCP and Biogen Representative.	_____
If Yes, please choose the criteria	_____
IC 5	_____
IC 6	_____
Please Specify the Medical Condition Associated with Negative Pregnancy Outcomes in the Opinion of the HCP.	_____
IC 7	_____
Will the Participant Enroll in Registry Study?	Yes ☐ No ☐
Biogen Form Version	IE_FV1.0

Country	Germany ☐ Ireland ☐ France ☐ United Kingdom ☐ Spain ☐ Switzerland ☐ Australia ☐ United States of America ☐
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Sex	Female ■ Male ☐
Birth Year (yyyy)	_____
Age	_____
Age Unit	Years ■ Months ☐ Days ☐
Race (mark all that apply)	
American Indian or Alaska Native	_____
Asian	_____
Black or African American	_____
Native Hawaiian or Other Pacific Islander	_____
White	_____
Not Reported	_____
Other	_____

Race, Other Specify	_____
Asian Race Subclassification	Chinese ☐ Japanese ☐ Asian Indian ☐ Korean ☐ Taiwanese ☐ Other ☐
Asian Race Subclassification, Other Specify	_____
Biogen Form Version	DM_FV1.0

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Prior Subject Participation
Generated On: 10 Jul 2023 16:06:42

Was the subject previously screened in this study?	Yes ☐ No ☐
If Yes, Previous Subject ID (NNNN-ANA-NNNA)	_____
Did the subject participate in a previous Biogen study?	Yes ☐ No ☐ Unknown ☐
If Yes, Previous Biogen Study ID (NNNAANNN)	_____
If Yes, Previous Biogen Study Subject ID (NNN-NNN or NNNN-ANA-NNNA)	_____
Biogen Form Version	DM_PRIOR_FV1.1

Years Of Education (The Total Number of Years School Attended From Kindergarten Through any College/University)	_____
Occupation	_____
Employment Status	Not Employed ☐ Full-Time ☐ Part-Time ☐

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Vital Signs
Generated On: 10 Jul 2023 16:06:42

Vital Signs Assessment Date (dd-mon-yyyy)	_____
Vital Signs Assessment Time (24-hour clock)	_____
Height	_____
Height Unit	cm ☐ in ☐
Weight	_____
Weight Unit	kg ☐ lb ☐
Body Mass Index (BMI)	_____
Body Mass Index (BMI) Unit	KG/M2
Biogen Form Version	VS_FV2.0

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Medical History
Generated On: 10 Jul 2023 16:06:42

Does the subject have any ongoing or resolved medical or surgical history?	Yes ☐ No ☐
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Biogen Form Version	MH_FV1.0
Medical History	MEDICAL HISTORY
Medical Condition or Surgical Procedure	_____
Start Date (dd-mon-yyyy)	_____
End Date (dd-mon-yyyy)	_____
Ongoing	_____

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: MS Disease History
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Multiple Sclerosis Disease History	DISEASE HISTORY
Year of First MS Symptom(s) (yyyy)	
Year of MS Diagnosis (yyyy)	
Please Provide MS Sub-type	Relapsing Remitting MS (RRMS) ☐ Secondary Progressive MS (SPMS) ☐ Primary Progressive MS (PPMS) ☐ Unknown ☐
Onset Date of Most Recent Relapse (dd-mon-yyyy)	
Total number of relapses experienced within the past 12 months	
Total number of relapses experienced within the past 2 years	
Total number of relapses experienced within the past 3 years	
Date of most recent MRI demonstrating Gd enhancing lesions (dd-mon-yyyy)	
Biogen Form Version	MH_MSHX_FV1.0

Has the subject received any medications for the treatment of MS?	Yes ☐ No ☐
Biogen Form Version	CM_MSTHX_FV1.0
Multiple Sclerosis Treatment History, Medications	MULTIPLE SCLEROSIS TREATMENT HISTORY
Medication Name	Alemtuzumab (LEMTRADA) ☐ Azathioprine ☐ Cladribine (MAVENCLAD, MOVECTRO, LITAK) ☐ Corticotropin (ACTHAR HP, Others) ☐ Cyclophosphamide ☐ Daclizumab (ZINBRYTA, ZENAPAX) ☐ Dexamethasone IV/PO ☐ Dimethyl Fumarate (TECFIDERA) ☐ Diroximel Fumarate ☐ Fampridine (FAMPYRA, AMPYRA) ☐ Fingolimod (GILENYA) ☐ Firategrast ☐ Glatiramer Acetate (COPAXONE, GLATOPA, Others) ☐ Immunoglobulin human (IVIG) ☐ Interferon Beta-1A (AVONEX) ☐ Interferon Beta-1A (REBIF) ☐ Interferon Beta-1B (BETASERON) ☐ Interferon Beta-1B (EXTAVIA) ☐ Methotrexate ☐ Methylprednisolone IV/PO (SOLU-MEDROL, Others) ☐ Mitoxantrone (NOVANTRONE) ☐

	Mycophenolate Mofetil (CELLCEPT) ☐
	Mycophenolate Sodium (MYFORTIC) ☐
	Natalizumab (TYSABRI) ☐
	Ocrelizumab ☐
	Ofatumumab ☐
	Peginterferon Beta-1A (PLEGRIDY) ☐
	Ponvory (PONESIMOD) ☐
	Prednisolone IM/IV/PO ☐
	Prednisone PO ☐
	Rituximab ☐
	Teriflunomide (AUBAGIO) ☐
	Zeposia (Ozanimod) ☐
	Mayzent (Siponimod) ☐
	Other Medication, Specify ☐
Indication	MULTIPLE SCLEROSIS
Start Date (dd-mon-yyyy)	_____
End Date (dd-mon-yyyy)	_____
Reasons for Stopping Treatment (mark all that apply)	
Efficacy Reasons	_____
Tolerability	_____
Safety	_____
Other	_____

Has the subject received any non-drug procedures for the treatment of MS?	Yes ☐ No ☐
Biogen Form Version	PR_MSTHX_FV1.0
Multiple Sclerosis Treatment History, Procedures	MULTIPLE SCLEROSIS TREATMENT HISTORY
Procedure Name	Cytapheresis ☐ Plasmapheresis ☐ Stem Cell, Hematopoietic Transplantation (Hsct) ☐ Stem Cell, Mesenchymal ☐ Stem Cell Therapy ☐ Other Procedure, Specify ☐
Indication	MULTIPLE SCLEROSIS
Start Date (dd-mon-yyyy)	_____
End Date (dd-mon-yyyy)	_____
Reasons for Stopping Treatment (mark all that apply)	
Efficacy Reasons	_____
Tolerability	_____
Safety	_____
Other	_____

Has the Subject received any Immunomodulating/Immunosuppressing Therapies?	Yes ☐ No ☐

If Yes, Please Record the Details. Do not Record Steroids Received for Relapse.

Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Concomitant Medication	Alemtuzumab (LEMTRADA) ☐ Azathioprine ☐ Cladribine (MAVENCLAD, MOVECTRO, LITAK) ☐ Corticotropin (ACTHAR HP, Others) ☐ Cyclophosphamide ☐ Daclizumab (ZINBRYTA, ZENAPAX) ☐ Dexamethasone IV/PO ☐ Dimethyl Fumarate (TECFIDERA) ☐ Diroximel Fumarate ☐ Fampridine (FAMPYRA, AMPYRA) ☐ Fingolimod (GILENYA) ☐ Firategrast ☐ Glatiramer Acetate (COPAXONE, GLATOPA, Others) ☐ Immunoglobulin human (IVIG) ☐

- Interferon Beta-1A (AVONEX) ☐
- Interferon Beta-1A (REBIF) ☐
- Interferon Beta-1B (BETASERON) ☐
- Interferon Beta-1B (EXTAVIA) ☐
- Methotrexate ☐
- Methylprednisolone IV/PO (SOLU-MEDROL, Others) ☐
- Mitoxantrone (NOVANTRONE) ☐
- Mycophenolate Mofetil (CELLCEPT) ☐
- Mycophenolate Sodium (MYFORTIC) ☐
- Natalizumab (TYSABRI) ☐
- Ocrelizumab ☐
- Ofatumumab ☐
- Peginterferon Beta-1A (PLEGRIDY) ☐
- Ponvory (PONESIMOD) ☐
- Prednisolone IM/IV/PO ☐
- Prednisone PO ☐
- Rituximab ☐
- Teriflunomide (AUBAGIO) ☐
- Zeposia (Ozanimod) ☐
- Mayzent (Siponimod) ☐
- Other Medication, Specify ☐

Date of First Dose (dd-mon-yyyy) _____

Date of Last Dose (dd-mon-yyyy) _____

Dose _____

Unit
- Milligram (mg) ☐
- Gram (g, gm) ☐
- Tablet (tab, tbl) ☐
- Capsule (cap) ☐

- Microgram (mcg, ug) ☐
- Milliliter (mL) ☐
- Application (app) ☐
- Metric Drop (gtt) ☐
- Ampule (amp) ☐
- Drop ☐
- Inhalation (inh) ☐
- International Unit (IU) ☐
- Liter (L) ☐
- Millicurie per Kilogram (mCi/kg) ☐
- Milliequivalent (mEq) ☐
- Patch ☐
- Percentage (%) ☐
- Puff ☐
- Sachet ☐
- Spray ☐
- Suppository (supp) ☐
- Syringe ☐
- Tablespoon (Tbsp) ☐
- Teaspoon (tsp) ☐
- Unknown ☐
- Other ☐

Unit, Other Specify _____

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Pregnancy Medical History
Generated On: 10 Jul 2023 16:06:42

Was Pregnancy Medical History Reported?	Yes ☐ No ☐
Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Medical Condition	Blood Transfusions ☐ Breathing Disorders (Asthma, TB, etc) ☐ Chicken Pox ☐ Clotting Problems ☐ D(Rh) Sensitized ☐ Epilepsy (Seizures) ☐ Gestational Diabetes ☐ GYN Surgery ☐ Heart Disease ☐ Hepatitis ☐ History of Abnormal Pap ☐ HIV/AIDS ☐ Hypertension (High Blood Pressure) ☐ Kidney Disease, Urinary Tract Infection ☐ Liver or Gallbladder Disorder ☐ Malignancy (Cancer) ☐ Pre-Eclampsia ☐ Eclampsia ☐

	Sexual Transmitted Disease ☐
	Thyroid Disease ☐
	Tissue Disorder ☐
	Uterine Anomaly/DES Exposure ☐
	Varicosities/Phlebitis (Swelling of Veins) ☐
	Other ☐
If Other Medical Condition, Please Specify	_____
Category	Family History ☐
	Adverse Pregnancy Outcomes ☐
	Developmental Abnormalities ☐
	Other ☐
If Other Category, Please Specify	_____
Start Date (dd-mon-yyyy)	_____
Ongoing	_____
Stop Date (dd-mon-yyyy)	_____

Did Subject have any Family History of Risk Factors?	Yes ☐ No ☐
Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Has the Baby's Father ever Personally Fathered Other Pregnancies/Children?	Yes ☐ No ☐ Unknown ☐
If Yes, Check all that Apply	
Multiple Births (Twins, Triplets, etc)	_____
Spontaneous Abortions (Miscarriages)	_____
Congenital Anomalies, Malformations or Birth Defects	_____
Developmental Delays (Physical and/or Mental)	_____
Has anyone in the Baby's Mother's Family ever had Pregnancies or Babies?	Yes ☐ No ☐ Unknown ☐
If Yes, Check all that Apply	
Multiple Births (Twins, Triplets, etc)	_____
Relation	Parent ☐ Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ Other ☐
If Other Relation, Please Specify	_____
Spontaneous Abortions (Miscarriages)	_____

Relation	Parent ☐ Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ Other ☐
If Other Relation, Please Specify	_____
Congenital Anomalies, Malformations or Birth Defects	_____
Relation	Parent ☐ Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ Other ☐
If Other Relation, Please Specify	_____
Developmental Delays (Physical and/or Mental)	_____
Relation	Parent ☐ Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ Other ☐
If Other Relation, Please Specify	_____

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Past Pregnancy / Obstetrical History
Generated On: 10 Jul 2023 16:06:42

Did Subject have any Past Pregnancy/Obstetrical History?	Yes ☐ No ☐
Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Total Number of Pregnancies (not Including the Pregnancy Currently being Reported)	_____
If Twin or Multiple Birth, Please Complete Separate Line for each Outcome	
Pregnancy Number (e.g. P1, P2, etc)	_____
Twin or Multiple Birth?	Yes ☐ No ☐
Birth Order	1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐
MS Status at time of Pregnancy Outcome(Active, Relapse, Progressing, Other specify)	Active ☐ Relapse ☐ Progressing ☐ Other ☐
If Other MS Status, Please Specify	_____
Gestational Age at Time of Pregnancy Outcome - Weeks	_____
Live Birth	Yes ☐ No ☐

If Outcome was a Live Birth, did Neonatal Death occur afterwards?	Yes ☐ No ☐
If Not Live Birth, Please Provide Birth Outcome	
Spontaneous Abortion	_____
Still Birth	_____
Medical Abortion	_____
Surgical Abortion	_____
Molar Pregnancy	_____
Ectopic pregnancy	_____
If Other, Please Specify	_____
Birth Defect/Abnormality	Congenital Anomalies ☐ Malformation ☐ Birth Defects ☐ Not Applicable ☐ Other ☐
If Other, Please Specify	_____
Enter Developmental Delays (Physical or Mental) or enter NA	Physical ☐ Mental ☐ Not Applicable ☐ Other ☐
If Other, Please Specify	_____
Has the Subject ever had a Cesarean Delivery?	Yes ☐ No ☐
If Yes, for Medical need?	Yes ☐ No ☐
If Yes, Please Specify	_____
Has the Subject had any or the following Pregnancy/Obstetric complications with Previous Pregnancies?	Yes ☐ No ☐ Unknown ☐
If Yes, Check all that Apply	
Early Labour	_____
Placenta Problems/Vaginal Bleeding	_____

Other	_____
If Other Complication, Please Specify	_____

272MS401_eCRF_EditChecks_Database_Validation_0.1: All Visits
Project Name: 272MS401
Folder: Enrollment
Form: Current Pregnancy
Generated On: 10 Jul 2023 16:06:42

Date of Assessment (dd-mon-yyyy)	
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	
First Date of Last Menstrual Period (LMP) (dd-mon-yyyy)	
Estimated Date of Delivery (EDD) (dd-mon-yyyy)	
How was Current Pregnancy Confirmed? (Check all that Apply)	
Urine Pregnancy Test	
Date of Test (dd-mon-yyyy)	
Pelvic/Abdominal Physical Exam	
Date of Test (dd-mon-yyyy)	
Laboratory Blood Test	
Date of Test (dd-mon-yyyy)	
Ultrasound	
Date of Test (dd-mon-yyyy)	
Fetal Heart Tones by Auscultation or Doppler	
Date of Test (dd-mon-yyyy)	
Other Test	
If Other Test, Please Specify	
Date of Test (dd-mon-yyyy)	

Was there any change in the Prenatal Testing since previous assessment?	Yes ☐ No ☐
Has any Prenatal Testing beyond Confirmatory Tests of Pregnancy been Completed?	Yes ☐ No ☐ Unknown ☐
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
If Other Source of Information, Please Specify	_____
If more than one test is performed, add multiple rows	
Test	Ultrasound ☐ Amniocentesis ☐ MSAFP/Serum ☐ Other ☐
Date of Test (dd-mon-yyyy)	_____
Date of Test Results(dd-mon-yyyy)	_____
Evidence of Abnormality	Yes ☐ No ☐ Unknown ☐
If Yes, Please Specify	_____

Did the Subject have any Other Pregnancy Risk Factors?	Yes ☐ No ☐
Date of Assessment (dd-mon-yyyy)	_____
Source of Information	Subject ☐ Neurologist ☐ Pediatrician ☐ Obstetrician ☐ Gynaecologist ☐ General Medicine Physician/Internist ☐ Medical Records ☐ Other ☐
Other Source of Information	_____
Alcohol Use	Yes ☐ No ☐
Alcohol Use History	Before Pregnancy ☐ During Pregnancy ☐
Type of Beverage	Beer ☐ Wine ☐ Liquor/Spirits ☐ Other ☐
If Other, Please Specify	_____
Volume	_____
Unit	mL ☐ oz ☐
Frequency	Daily ☐ Weekly ☐ Monthly ☐
Tobacco Use	Yes ☐ No ☐
Type of Product	Cigarettes ☐ Cigars ☐

	Pipes ☐ Smokeless Tobacco ☐ eCigarette/Vaporizer ☐ Hookah ☐ Other ☐
If Other, Please Specify	_____
Average Quantity	_____
Unit	Number of Cigarettes ☐ Number of Cigars ☐ Number of Pipes ☐ Pinch/Snuff ☐ Number of Inhalations ☐ Number of Bowls ☐ Other ☐
If Other, Please Specify	_____
Frequency	Daily ☐ Weekly ☐ Monthly ☐
Does the Subject use Tobacco/ENDS (Electronic Nicotine Delivery Systems)?	Yes ☐ No ☐
Tobacco/ ENDS (Electronic Nicotine Delivery Systems) Use History	Before Pregnancy ☐ During Pregnancy ☐
Year of Subject Started using Tobacco/ ENDS (yyyy)	_____
Year of Subject Stopped using Tobacco/ENDS (Before Pregnancy Only) (yyyy)	_____
Does the Subject use Caffeine?	Yes ☐ No ☐
Caffeine Use History	Before Pregnancy ☐ During Pregnancy ☐
Year of Subject Started using Caffeine (yyyy)	_____
About how many Caffeinated Beverages per day (on Average)?	Less Than 8 oz ☐ More Than 8 oz ☐

	Other ☐
Year of Subject Stopped using Caffeine (Before Pregnancy Only) (yyyy)	_____
Does the Subject use Recreational Drug?	Yes ☐ No ☐
Recreational Drug Use History	Before Pregnancy ☐ During Pregnancy ☐
If Before Pregnancy/During Pregnancy, Please Specify Drug Name	_____
Year of Subject Started using Recreational Drugs (yyyy)	_____
Year of Subject Stopped using Recreational Drug (Before Pregnancy Only) (yyyy)	_____