Site Number:

Patient Number:

Pregnancy Outcome

Date of Contact

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 10 / Page Display Name = Date of Contact / Description = Date of Contact)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Neurologist ○ Other	
* Reporter of Information	○ Patient ○ Obstetrician ○ Neurologist ○ Infant HCP ○ Other	
* Other, specify		

Comorbid Conditions

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 20 / Page Display Name = Comorbid Conditions / Description = Comorbid Conditions)

Since the last review, has the patient been diagnosed or experienced worsening of any of the following

Significant Comorbidity events related to pregnancy should be entered as SAEs.

* Asthma	○ No ○ Yes ○ Unknown
* Hypertension	○ No ○ Yes ○ Unknown
* Kidney Disease	○ No ○ Yes ○ Unknown
* Thyroid Disease	○ No ○ Yes ○ Unknown
* Clotting Disorder	○ No ○ Yes ○ Unknown
* Lupus	○ No ○ Yes ○ Unknown
* Other significant comorbidity, other than non-infectious	○ No ○ Yes ○ Unknown

* Please specify	
* Please specify	
* Please specify	
* Sexually Transmitted Diseases (STDs)	○ No ○ Yes ○ Unknown
* Bacterial Vaginosis (BV)	○ No ○ Yes ○ Unknown
* Chlamydia	○ No ○ Yes ○ Unknown
* Gonorrhea	○ No ○ Yes ○ Unknown
* Hepatitis B	○ No ○ Yes ○ Unknown
* Hepatitis C	○ No ○ Yes ○ Unknown
* Herpes	○ No ○ Yes ○ Unknown
* HIV/AIDS	○ No ○ Yes ○ Unknown

* Human Papillomavirus (HPV)	○ No ○ Yes ○ Unknown
* Pelvic Inflammatory Disease (PID)	○ No ○ Yes ○ Unknown
* Other Sexually Transmitted Diseases	○ No ○ Yes ○ Unknown
* Please specify:	
* Zika Virus	○ No ○ Yes ○ Unknown
* Other significant comorbidity, other than infectious	○ No ○ Yes ○ Unknown
* Please specify	
* Please specify	
* Please specify	
* Type I diabetes	○ No ○ Yes ○ Unknown
* Type II diabetes	○ No ○ Yes ○ Unknown

* Gestational diabetes	○ No ○ Yes ○ Unknown
* Nutritional deficiencies	○ No ○ Yes ○ Unknown
* Anemia	○ No ○ Yes ○ Unknown
* Vitamin B12	○ No ○ Yes ○ Unknown
* Vitamin A	○ No ○ Yes ○ Unknown
* Calcium	○ No ○ Yes ○ Unknown
* Other Nutritional Deficiencies	○ No ○ Yes ○ Unknown
* Please specify:	

Risk Factors

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 30 / Page Display Name = Risk Factors / Description = Risk Factors)

* Has there been a change in lifestyle risk factors since the last contact?	○ No ○ Yes
* Does the patient smoke cigarettes or use tobacco?	○ Never ○ Before pregnancy ○ During pregnancy ○ Patient declined to answer ○ Unknown
* Does the patient smoke cigarettes or use tobacco?	○ Never ○ During pregnancy ○ Patient declined to answer ○ Unknown
* Does the patient consume caffeine?	○ No ○ Yes ○ Unknown
* About how many caffeinated beverages per day (on average)?	○ Less than 3 ○ 3 or more
* Does the patient consume alcohol?	○ Never ○ Before pregnancy ○ During pregnancy ○ Patient declined to answer ○ Unknown

* Does the patient consume alcohol?	○ Never ○ During pregnancy ○ Patient declined to answer ○ Unknown	
* Number of alcoholic drinks per week		(format xx)
Unknown	☐	
* Does the patient use illicit drugs?	○ No ○ Yes ○ Unknow	

Pregnancy Outcome

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 50 / Page Display Name = Pregnancy Outcome / Description = Pregnancy Outcome)

* Date of pregnancy outcome	(DD-MMM-YYYY)	
Gestational age (weeks)	(auto calculated)	(format xx)
* Pregnancy Outcome	○ Spontaneous abortion ○ Elective or therapeutic termination ○ Live Birth ○ Stillbirth	
* Reason for elective or therapeutic termination	○ Prenatal testing finding ○ Maternal health ○ Psychosocial/non-medical reasons ○ Other	
* Other, specify		
* Congenital malformations identified?	○ No ○ Yes ○ Unknown	
* Autopsy and/or pathology reports available?	○ No ○ Yes	
* Mode of delivery	○ Vaginal delivery ○ Assisted delivery ○ Cesarean section	
* Was anesthesia used?	○ No ○ Yes	

* If yes, what type?	○ Local Anesthesia ○ Spinal Anesthesia ○ Epidural Anesthesia	
* Were there multiple live births?	○ No ○ Yes	
* If yes, how many?		(format x)

Infant Characteristics

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 60 / Page Display Name = Infant Characteristics / Description = Infant Characteristics - Single)

* Date of Birth		(DD-MMM-YYYY)
Gestational age at birth	(auto calculated)	(format xx)
Infant age	(auto calculated)	(format xx)
* Sex	○ Male ○ Female	

At birth:

Infant's current:

* Date of measurement collection		(DD-MMM-YYYY)
* Weight		(format xxx.xx)
* Weight Unit	○ lb ○ kg	
* Length		(format xxx.xx)
* Length Unit	○ in ○ cm	
* Head circumference		(format xx.xx)
* Head circumference Unit	○ in ○ cm	
* Are laboratory values available (CD19, neutrophil, lymphocyte, white blood cell, immunoglobulin, platelet counts)?	○ No ○ Yes	

If Yes, please complete the Infant Laboratory form.

Apgar Scores:

* 1 minute		(format xx)
* 5 minutes		(format xx)
* 10 minutes		(format xx)
* Congenital malformations noted?	○ No ○ Yes	
If Yes, please select all that apply:		
Chromosomal defects, known mendelian inherited disorders, Syndromes and DiGeorge Sequence	☐	
Amniotic bands	☐	
Metabolic disorders (e.g. phenylketonuria, G6PD deficiency)	☐	
Structural malformations	☐	
CENTRAL NERVOUS SYSTEM		
Anencephaly	☐	
Encephalocele	☐	
Neural tube defects	☐	
Spina bifida	☐	
Other	☐	
* Other, specify		
CARDIOVASCULAR		
Coarctation of the aorta	☐	
Endocardial cushion defect	☐	
Ventricular septal defect	☐	
Other	☐	
* Other, specify		
ORAL CLEFTS		
Cleft palate only	☐	

Cleft lip with or without cleft palate	☐
Other	☐
* Other, specify	
GENITAL ORGANS	
Hypospadias	☐
Undescended testicle	☐
Other	☐
* Other, specify	
UPPER ALIMENTARY TRACT & GASTROINTESTINAL SYSTEM	
Anal atresia/stenosis	☐
Pyloric stenosis	☐
Small intestine atresia/stenosis	☐
Tracheo-esophageal fistula	☐
Other	☐
* Other, specify	
URINARY SYSTEM	
Cystic kidney disease	☐
Extra or horseshoe kidney	☐
Renal agenesis & dysgenesis	☐
Renal collecting system anomalies	☐
Other	☐
* Other, specify	
MUSCULOSKELETAL SYSTEM	
Clubfoot	☐
Craniosynostosis	☐
Diaphragmatic hernia	☐
Gastroschisis	☐

Limb reduction defects	☐	
Omphalocele	☐	
Polydactyly	☐	
Other	☐	
* Other, specify		
OTHER		
Inguinal hernia	☐	
Other	☐	
* Other, specify		
* Any change in infant feeding since last contact?	○ No ○ Yes	
* Infant feeding	○ Breastfed ○ Formula ○ Combination breastfed/formula ○ Other	
* Other, specify		
* Start Date of breastfeeding		(UNK-UNK-UNK)
* Breastfeeding ongoing	☐	
* Stop Date of breastfeeding		(UNK-UNK-UNK)
Number of weeks exclusively breasted since birth	(auto calculated)	(format xxx)

Infant Characteristics - Multiple Births

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 70 (*) / Page Display Name = Infant Characteristics - Multiple Births / Description = Infant Characteristics - Multiple)

Sequence Number		
* Birth Order	○ Birth Order 1 ○ Birth Order 2 ○ Birth Order 3 ○ Birth Order 4 ○ Birth Order 5	
* Date of Birth		(DD-MMM-YYYY)
Gestational age at birth	(auto calculated)	(format xx)
Infant age	(auto calculated)	(format xx)
* Sex	○ Male ○ Female	
At birth:		
Infant's current:		
* Date of measurement collection		(DD-MMM-YYYY)
* Weight		(format xxx.xx)
* Weight Unit	○ lb ○ kg	
* Length		(format xxx.xx)
* Length Unit	○ in ○ cm	
* Head circumference		(format xx.xx)

* Head circumference Unit	○ in ○ cm	
* Are laboratory values available (CD19, neutrophil, lymphocyte, white blood cell, immunoglobulin, platelet counts)?	○ No ○ Yes	
If Yes, please complete the Infant Laboratory form.		
Apgar Scores:		
* 1 minute		(format xx)
* 5 minutes		(format xx)
* 10 minutes		(format xx)
* Congenital malformations noted?	○ No ○ Yes	
If Yes, please select all that apply:		
Chromosomal defects, known mendelian inherited disorders, Syndromes and DiGeorge Sequence	☐	
Amniotic bands	☐	
Metabolic disorders (e.g. phenylketonuria, G6PD deficiency)	☐	
Structural malformations	☐	
CENTRAL NERVOUS SYSTEM		
Anencephaly	☐	
Encephalocele	☐	
Neural tube defects	☐	
Spina bifida	☐	
Other	☐	
* Other, specify		
CARDIOVASCULAR		
Coarctation of the aorta	☐	

Endocardial cushion defect	☐
Ventricular septal defect	☐
Other	☐
* Other, specify	
ORAL CLEFTS	
Cleft palate only	☐
Cleft lip with or without cleft palate	☐
Other	☐
* Other, specify	
GENITAL ORGANS	
Hypospadias	☐
Undescended testicle	☐
Other	☐
* Other, specify	
UPPER ALIMENTARY TRACT & GASTROINTESTINAL SYSTEM	
Anal atresia/stenosis	☐
Pyloric stenosis	☐
Small intestine atresia/stenosis	☐
Tracheo-esophageal fistula	☐
Other	☐
* Other, specify	
URINARY SYSTEM	
Cystic kidney disease	☐
Extra or horseshoe kidney	☐
Renal agenesis & dysgenesis	☐
Renal collecting system anomalies	☐
Other	☐

* Other, specify		
MUSCULOSKELETAL SYSTEM		
Clubfoot	☐	
Craniosynostosis	☐	
Diaphragmatic hernia	☐	
Gastroschisis	☐	
Limb reduction defects	☐	
Omphalocele	☐	
Polydactyly	☐	
Other	☐	
* Other, specify		
OTHER		
Inguinal hernia	☐	
Other	☐	
* Other, specify		
* Any change in infant feeding since last contact?	○ No ○ Yes	
* Infant feeding	○ Breastfed ○ Formula ○ Combination breastfed/formula ○ Other	
* Other, specify		
* Start Date of breastfeeding		(UNK-UNK-UNK)
Breastfeeding ongoing	☐	
* Stop Date of breastfeeding		(UNK-UNK-UNK)
Number of weeks exclusively breasted since birth	(auto calculated)	(format xxx)

Infant Labs

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 100 / Page Display Name = Infant Labs / Description = Infant Labs)

* Date of sample collection (DD-MMM-YYYY)

Test Name	Not Done	Result	Units	Other, specify	Low	High	Clinically Significant
CD19	☐	(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other		(xxxxx.xx)	(xxxxx.xx)	☐
Neutrophil	☐	(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other		(xxxxx.xx)	(xxxxx.xx)	☐
Lymphocyte	☐	(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other		(xxxxx.xx)	(xxxxx.xx)	☐

White Blood Cell	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Immunoglobulin	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Platelet counts	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Blood Lead Concentration Test	☐		(xx.xx)	○ µl/dL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐

Infant Labs - Multiple Births

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 110 (*) / Page Display Name = Infant Labs - Multiple Births / Description = Infant Labs - Multiple)

Sequence Number	
* Birth Order	○ Birth Order 1 ○ Birth Order 2 ○ Birth Order 3 ○ Birth Order 4 ○ Birth Order 5
* Date of sample collection	(DD-MMM-YYYY)

Test Name	Not Done	Result	Units	Other, specify	Low	High	Clinically Significant
CD19	☐	(xxxxx.xx)	10^9/L 10^3/µL 10^6/mL cells/mcL Other		(xxxxx.xx)	(xxxxx.xx)	☐
Neutrophil	☐	(xxxxx.xx)	10^9/L 10^3/µL 10^6/mL cells/mcL Other		(xxxxx.xx)	(xxxxx.xx)	☐
Lymphocyte	☐	(xxxxx.xx)	10^9/L 10^3/µL 10^6/mL cells/mcL Other		(xxxxx.xx)	(xxxxx.xx)	☐

White Blood Cell	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Immunoglobulin	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Platelet counts	☐		(xxxxx.xx)	○ 10^9/L ○ 10^3/µL ○ 10^6/mL ○ cells/mcL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐
Blood Lead Concentration Test	☐		(xx.xx)	○ µl/dL ○ Other			(xxxxx.xx)		(xxxxx.xx)	☐

Infant Vaccinations

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 80 (*) / Page Display Name = Infant Vaccinations / Description = Infant Vaccinations)

Sequence Number	
* Birth Order	○ Birth Order 1 ○ Birth Order 2 ○ Birth Order 3 ○ Birth Order 4 ○ Birth Order 5

* Vaccination Name	○ Diphtheria (D) ○ Diphtheria, tetanus, & acellular pertussis (DTaP) ○ Haemophilus influenzae type b infection (HiB) ○ Hepatitis A (HepA) ○ Hepatitis B (HepB) ○ Influenza (IIV) ○ Measles (MEAS) ○ Measles, mumps, rubella (MMR) ○ Meningococcal disease (MenC, MenACWY-D, MenACWY-CRM) ○ Mumps (MUMPS) ○ Pertussis (acp) ○ Pneumococcal disease (PCV, PCV13) ○ Poliomyelitis (IPV) ○ Rotavirus (RV, ROTA) ○ Rubella (RUBE) ○ Tetanus (TT) ○ Varicella (VAR) ○ Other	
* Other, specify		
* Vaccination Date		(UNK-UNK-UNK)

MS Disease Status

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREG / PageID = 90 / Page Display Name = MS Disease Status / Description = MS Disease Status)

* Since the last visit, has the patient experienced a relapse(s)?	○ No ○ Yes
* If Yes, total number of relapses:	(format xx)

Start date of relapse	End date of relapse
(UNK-UNK-UNK)	(UNK-UNK-UNK)
(UNK-UNK-UNK)	(UNK-UNK-UNK)
(UNK-UNK-UNK)	(UNK-UNK-UNK)
(UNK-UNK-UNK)	(UNK-UNK-UNK)
(UNK-UNK-UNK)	(UNK-UNK-UNK)
(UNK-UNK-UNK)	(UNK-UNK-UNK)

* Current type of MS

- ○ Relapsing Remitting MS (RRMS)
- ○ Secondary Progressive MS (SPMS)
- ○ Primary Progressive MS (PPMS)
- ○ Clinically Isolated Syndrome (CIS)
- ○ Radiologically Isolated Syndrome (RIS)
- ○ Unknown

* Date of most recent Expanded Disability Status Scale (EDSS) score		(DD-MMM-YYYY)
* EDSS score:	(format xx.x)	
Not available	☐	
* Any recent MRI results since last visit?	○ No ○ Yes	

Date of MRI	Results:	Number of Gadolinium-enhancing (Gd+) lesions identified on T1 weighted MRI of the brain	Non	Min_One	Number of new or newly enlarged hyperintense lesions on T2-weighted MRI of the brain.	Zero (0)	One_Two (1-2)	Three_Eight (3-8)	Nine_Plus (9+)
(DD-MMM-YYYY)			☐	☐		☐	☐	☐	☐
(DD-MMM-YYYY)			☐	☐		☐	☐	☐	☐
(DD-MMM-YYYY)			☐	☐		☐	☐	☐	☐
(DD-MMM-YYYY)			☐	☐		☐	☐	☐	☐
(DD-MMM-YYYY)			☐	☐		☐	☐	☐	☐