Pregnancy Outcome

Visit Completion

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREGOUT / PageID = 5 / Page Display Name = Visit Completion / Description = Visit Completion)

* Was a contact for this visit completed?	○ No ○ Yes
* Reason contact not completed	

Pregnancy Outcome

[Revision: Initial revision of study]

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

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		

Enter the Date of pregnancy outcome of event including; Spontaneous abortion, Elective or therapeutic termination, Live Birth (infant date of birth), Stillbirth, Ectopic pregnancy and Molar pregnancy.

* Date of pregnancy outcome		(DD-MMM-YYYY)
* Gestational age (weeks)		(format xx)
* Maternal weight at end of pregnancy		(format xxx.xx)
* Weight unit	○ kg ○ lb	
* Pregnancy Outcome	○ Spontaneous abortion ○ Elective or therapeutic termination ○ Live Birth ○ Stillbirth ○ Ectopic pregnancy ○ Molar pregnancy	

* Reason for elective or therapeutic termination	○ Prenatal testing finding ○ Maternal health ○ Psychosocial/non-medical reasons ○ Other	
* Other, specify		
* Autopsy and/or pathology reports available?	○ No ○ Yes ○ Unknown	
* 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)
* Were there any changes to comorbid conditions and/or other treatments?	○ No ○ Yes	

If yes, please enter new and/or worsening of pre-existing conditon(s) on the Adverse Events Details form and treatment(s) on the Concomitant Medications Details form. Note: Resolution of pre-existing conditions (if applicable) should only be updated on the Comorbidities Details form.

* Were there any changes to Orilissa treatment?	○ No ○ Yes	

If yes, please enter on the Orilissa Treatment Details form.

Pregnancy Outcome Multiple Births

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREGOUT / PageID = 60 (*) / Page Display Name = Pregnancy Outcome Multiple Births / Description = Pregnancy Outcome Multiple births)

Sequence number		
* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		

Enter the Date of pregnancy outcome of event including; Spontaneous abortion, Elective or therapeutic termination, Live Birth (infant date of birth), Stillbirth, Ectopic pregnancy and Molar pregnancy.

* Date of pregnancy outcome		(DD-MMM-YYYY)
* Gestational age (weeks)		(format xx)
* Maternal weight at end of pregnancy		(format xxx.xx)
* Weight units	○ kg ○ lb	

* Pregnancy Outcome	○ Spontaneous abortion ○ Elective or therapeutic termination ○ Live Birth ○ Stillbirth ○ Ectopic pregnancy ○ Molar pregnancy	
* Reason for elective or therapeutic termination	○ Prenatal testing finding ○ Maternal health ○ Psychosocial/non-medical reasons ○ Other	
* Other, specify		
* Autopsy and/or pathology reports available?	○ No ○ Yes ○ Unknown	
* 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)

* Were there any changes to comorbid conditions and/or other treatments?	○	No
	○	Yes

If yes, please enter new and/or worsening of pre-existing conditon(s) on the Adverse Events Details form and treatment(s) on the Concomitant Medications Details form. Note: Resolution of pre-existing conditions (if applicable) should only be updated on the Comorbidities Details form.

* Were there any changes to Orilissa treatment?	○	No
	○	Yes

If yes, please enter on the Orilissa Treatment Details form.

Lifestyle Risk Factors

[Revision: Initial revision of study]

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

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
Alcohol Use		
* Has the patient consumed alcohol since the last contact?	○ No ○ Yes	
Never	☐	
Before current pregnancy	☐	
* Specify alcohol use	○ light drinker (less than 8 drinks/week and less than 4 drinks on any day) ○ heavy drinker (8+ drinks/week or 4+ drinks on any day)	
During current pregnancy	☐	
* Specify alcohol use	○ light drinker (less than 8 drinks/week and less than 4 drinks on any day) ○ heavy drinker (8+ drinks/week or 4+ drinks on any day)	
Tobacco Use		

Smoking Tobacco use (cigarettes, pipes, or cigars)

* Has the patient smoked tobacco (cigarettes, pipes, or cigars) since the last contact?	○	No
	○	Yes
Never	☐	
Before current pregnancy	☐	
* Specify tobacco use	○	Some day smoker
	○	Every day smoker
During current pregnancy	☐	
* Specify tobacco use	○	Some day smoker
	○	Every day smoker

E-cigarette use

* Has the patient used e-cigarettes since the last contact?	○	No
	○	Yes
Never	☐	
Before current pregnancy	☐	
* Specify E-cigarette use	○	Some day user
	○	Every day user
During current pregnancy	☐	
* Specify E-cigarette use	○	Some day user
	○	Every day user

Recreational or illicit drug use

* Has the patient used recreational or illicit drugs since the last contact?	○	No
	○	Yes
Never	☐	
Before current pregnancy	☐	
During current pregnancy	☐	

Caffeine

Does the patient consume caffeine?

* Has the patient consumed caffeine since the last contact?	○ No ○ Yes	
Never	☐	
Before current pregnancy	☐	
* About how many caffeinated beverages per day (on average)?		(format xx)
During current pregnancy	☐	
* About how many caffeinated beverages per day (on average)?		(format xx)

* Is there any known exposure to another human teratogen?	○ No ○ Yes	
* If yes, please specify		

Infant Characteristics

[Revision: Initial revision of study]

(Visit ID = 50 / Visit Display Name = Pregnancy Outcome / Visit Abbrev = PREGOUT / PageID = 40 / Page Display Name = Infant Characteristics / Description = Infant Characteristics)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
Other, Specify		
* Birth order	○ Birth Order 1	
* Infant vital status	○ Alive ○ Deceased	
* Date of Death		(DD-MMM-YYYY)
* Primary cause of Death		
* Autopsy and/or pathology reports available?	○ No ○ Yes ○ Unknown	
* Infant Age (months)		(format xx)
* Sex	○ Male ○ Female	

At delivery

* Weight		(format xxxxx.xx)

* Weight unit	○ g ○ lb	
* Length		(format xxx.xx)
* Length unit	○ in ○ cm	
* Head circumference		(format xx.xx)
* Head circumference unit	○ in ○ cm	
* Head circumference unknown	☐	
Apgar Scores:		
Not Done/Unknown	☐	
1 minute		(format xx)
1 minute unknown	☐	
5 minutes		(format xx)
5 minutes unknown	☐	
10 minutes		(format xx)
10 minutes unknown	☐	
* Has the child met normal developmental milestones in relation to age?	○ No ○ Yes	
If No, Specify (Check all that apply):		
Social/Emotional	☐	
Language/Communication	☐	
Cognitive	☐	
Movement/Physical	☐	
Other	☐	
* Other, specify		

* Was Infant diagnosed with Failure to thrive?	○ No ○ Yes
* If Yes, please specify	
* Congenital malformations noted?	○ No ○ Yes
* Any new congenital malformations noted?	○ No ○ Yes
CENTRAL NERVOUS SYSTEM	
Anencephaly	☐
Encephalocele	☐
Other Neural tube defect	☐
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 Congenital malformations related to Chromosomal Anomaly?	○ No ○ Yes	
* If Yes, specify		
* Any Congenital malformations related to Amniotic bands?	○ No ○ Yes	
* If Yes, specify		
Hospitalization		
* Any Infant Hospitalization (Other than standard post-birth stay)?	○ No ○ Yes	
* Any Infant Hospitalization since the last contact?	○ No ○ Yes	
* Reason for Hospitalizations		
* Length of Stay (days)		(format xxx)
Infant Feeding **Infant Feeding since last contact**		
* Infant feeding	○ Breastfed ○ Formula ○ Combination breastfed/formula ○ Other	
* Other, specify		
* Start Date of breastfeeding		(UNK-UNK-UNK)

* Breastfeeding ongoing	○ No ○ Yes	
* Stop Date of breastfeeding		(UNK-UNK-UNK)
* Number of weeks exclusively breastfed since birth		(format xxx)

Vaccination

* Did the infant have any vaccinations?	○ No ○ Yes	
* Did the infant have any vaccinations since the last contact?	○ No ○ Yes	
If Yes, select all that apply		
Diphtheria (D)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Diphtheria, tetanus, & acellular pertussis (DTaP)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Haemophilus influenzae type b infection (HiB)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Hepatitis A (HepA)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Hepatitis B (HepB)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Influenza (IIV)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Measles (MEAS)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Measles, mumps, rubella (MMR)	☐	

* Vaccination Date		(UNK-UNK-UNK)
Meningococcal disease (MenC, MenACWY-D, MenACWY-CRM)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Mumps (MUMPS)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Pertussis (acp)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Pneumococcal disease (PCV, PCV13)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Poliomyelitis (IPV)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Rotavirus (RV, ROTA)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Rubella (RUBE)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Tetanus (TT)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Varicella (VAR)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Other	☐	
* Other, specify		
* Vaccination Date		(UNK-UNK-UNK)

Infant Characteristics Multiple Births

[Revision: Initial revision of study]

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

Sequence number		
* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Birth order	○ Birth order 1 ○ Birth order 2 ○ Birth order 3 ○ Birth order 4 ○ Birth order 5	
* Infant vital status	○ Alive ○ Deceased	
* Date of Death		(DD-MMM-YYYY)
* Primary cause of Death		
* Autopsy and/or pathology reports available?	○ No ○ Yes ○ Unknown	

* Infant Age (months)		(format xx)
* Sex	○ Male ○ Female	
At delivery		
* Weight		(format xxxxx.xx)
* Weight unit	○ g ○ lb	
* Length		(format xxx.xx)
* Length unit	○ in ○ cm	
* Head circumference		(format xx.xx)
* Head circumference unit	○ in ○ cm	
* Head circumference unknown	☐	
Apgar Scores:		
Not Done/Unknown	☐	
1 minute		(format xx)
1 minute unknown	☐	
5 minutes		(format xx)
5 minutes unknown	☐	
10 minutes		(format xx)
10 minutes unknown	☐	
* Has the child met normal developmental milestones in relation to age?	○ No ○ Yes	
If No, Specify (Check all that apply):		
Social/Emotional	☐	

Language/Communication	☐
Cognitive	☐
Movement/Physical	☐
Other	☐
* Other, specify	
* Was Infant diagnosed with Failure to thrive?	○ No ○ Yes
* If Yes, please specify	
* Congenital malformations noted?	○ No ○ Yes
* Any new congenital malformations noted?	○ No ○ Yes
CENTRAL NERVOUS SYSTEM	
Anencephaly	☐
Encephalocele	☐
Other Neural tube defect	☐
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 Congenital malformations related to Chromosomal Anomaly?	○ No ○ Yes
* If Yes, specify	
* Any Congenital malformations related to Amniotic bands?	○ No ○ Yes
* If Yes, specify	
Hospitalization	
* Any Infant Hospitalization (Other than standard post-birth stay)?	○ No ○ Yes
* Any Infant Hospitalization since the last contact?	○ No ○ Yes
* Reason for Hospitalizations	
* Length of Stay (days)	(format xxx)
Infant Feeding **Infant Feeding since last contact**	

* Infant feeding	○ Breastfed ○ Formula ○ Combination breastfed/formula ○ Other	
* Other, specify		
* Start Date of breastfeeding		(UNK-UNK-UNK)
* Breastfeeding ongoing	○ No ○ Yes	
* Stop Date of breastfeeding		(UNK-UNK-UNK)
* Number of weeks exclusively breastfed since birth		(format xxx)

Vaccination

* Did the infant have any vaccinations?	○ No ○ Yes	
* Did the infant have any vaccinations since the last contact?	○ No ○ Yes	
If Yes, select all that apply		
Diphtheria (D)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Diphtheria, tetanus, & acellular pertussis (DTaP)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Haemophilus influenzae type b infection (HiB)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Hepatitis A (HepA)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Hepatitis B (HepB)	☐	

* Vaccination Date		(UNK-UNK-UNK)
Influenza (IIV)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Measles (MEAS)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Measles, mumps, rubella (MMR)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Meningococcal disease (MenC, MenACWY-D, MenACWY-CRM)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Mumps (MUMPS)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Pertussis (acp)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Pneumococcal disease (PCV, PCV13)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Poliomyelitis (IPV)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Rotavirus (RV, ROTA)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Rubella (RUBE)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Tetanus (TT)	☐	
* Vaccination Date		(UNK-UNK-UNK)

Varicella (VAR)	☐	
* Vaccination Date		(UNK-UNK-UNK)
Other	☐	
* Other, specify		
* Vaccination Date		(UNK-UNK-UNK)