Baseline

Informed Consent

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 10 / Page Display Name = Informed Consent / Description = Informed Consent)

* Is the patient a minor?	○ No ○ Yes	
* Date of informed consent for parent/legal guardian		(DD-MMM-YYYY)
* Date of assent		(DD-MMM-YYYY)
* Date of informed consent		(DD-MMM-YYYY)
* Date of eSignature/Signature release of medical forms		(DD-MMM-YYYY)
* Protocol Version enrolled under	○ Original	
* Was this patient previously enrolled in this registry or in another AbbVie observational registry?	○ No ○ Yes - This registry ○ Yes - Another AbbVie observation registry	
* If Yes, please provide subject ID		
* Referral source	○ AbbVie observational study ○ Call center ○ HCP ○ Internet ○ Other	
* Other, specify		

Inclusion/Exclusion Criteria

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 20 / Page Display Name = Inclusion/Exclusion Criteria / Description = Inclusion/Exclusion Criteria)

* Group	○	Orilissa-exposed
	○	Internal Comparator
Inclusion Criteria		
* Patient consent to participate in the study.	○	No
	○	Yes
* Currently pregnant	○	No
	○	Yes
* Documentation that the patient was exposed to Orilissa from 14 days after LMP or at any time during pregnancy	○	No
	○	Yes
* Agrees to sign the Release of Medical Information Form permitting the study site staff to contact her HCP(s) and the pediatric HCP for medical information	○	No
	○	Yes
* Patient consent to participate in the study.	○	No
	○	Yes
* Currently pregnant women with endometriosis or other conditions based on approved indications and prescribing patterns of Orilissa	○	No
	○	Yes
* Documentation that the patient was not exposed to Orilissa from 14 days after LMP or at any time during pregnancy	○	No
	○	Yes
* Agrees to sign the Release of Medical Information Form permitting the study site staff to contact her HCP(s) and the pediatric HCP for medical information	○	No
	○	Yes

* Did the patient satisfy all eligibility criteria?

- ○ No
- ○ Yes

Demographics

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 30 / Page Display Name = Demographics / Description = Demographics)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Year of birth		(format xxxx)
Age	(auto calculated)	(format xxx)
* Ethnicity	○ Hispanic or Latino ○ Not Hispanic or Latino ○ Not Reported	
Race (check all that apply)		
White or Caucasian	☐	
Black or African American	☐	
Native Hawaiian or Other Pacific Islander	☐	
Asian	☐	
American Indian or Alaska Native	☐	
Not Reported	☐	
Other	☐	
* Other, specify		

Patient Characteristics

* Maternal education level	○ Less than 7th grade ○ Junior high school (9th grade) ○ Partial high school (10th or 11th grade) ○ High school graduate (whether private preparatory, parochial, trade, or public school) ○ Partial college (at least one year) or specialized training ○ Standard college or university graduation ○ Graduate professional training (graduate degree) ○ Not applicable
* Paternal education level	○ Less than 7th grade ○ Junior high school (9th grade) ○ Partial high school (10th or 11th grade) ○ High school graduate (whether private preparatory, parochial, trade, or public school) ○ Partial college (at least one year) or specialized training ○ Standard college or university graduation ○ Graduate professional training (graduate degree) ○ Not applicable
* Maternal employment status	○ Employed ○ Unemployed ○ Not applicable

* Paternal employment status	○ Employed ○ Unemployed ○ Not applicable
* Maternal Occupation	○ Farm laborer, day laborer ○ Unskilled worker, service worker ○ Machine operator, semiskilled worker ○ Skilled manual worker, craftsman, police ○ Clerical/sales, small farm owner ○ Technician, semiprofessional, supervisor ○ Small business owner, farm owner, teacher ○ Mid-level manager or professional ○ Senior manager or professional ○ Not applicable

* Paternal Occupation	○ Farm laborer, day laborer ○ Unskilled worker, service worker ○ Machine operator, semiskilled worker ○ Skilled manual worker, craftsman, police ○ Clerical/sales, small farm owner ○ Technician, semiprofessional, supervisor ○ Small business owner, farm owner, teacher ○ Mid-level manager or professional ○ Senior manager or professional ○ Not applicable	
* Height		(format xxx.xx)
* Height unit	○ in ○ cm	
* Pre-pregnancy body weight		(format xxx.xx)
* Weight unit	○ kg ○ lb	
Pre-Pregnancy BMI	(auto calculated)	(format xxx.xx)

Pregnancy History

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 60 / Page Display Name = Pregnancy History / Description = Pregnancy History)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Has the patient ever been pregnant in the past?	○ No ○ Yes	
* Number of past pregnancies		(format xx)
Number of term live births (≥ 37 weeks gestation)		(format xx)
Number of term live births unknown	☐	
Number of preterm live births (< 37 weeks gestation)		(format xx)
Number of preterm live births unknown	☐	
Number of spontaneous abortions (< 20 weeks)		(format xx)
Number of spontaneous abortions unknown	☐	
Number of stillbirths (≥ 20 weeks gestation)		(format xx)
Number of stillbirths unknown	☐	
Number of ectopic pregnancies		(format xx)
Number of ectopic pregnancies unknown	☐	

Number of molar pregnancies		(format xx)
Number of molar pregnancies unknown	☐	
Number of pregnancies ending in small for gestational age infants		(format xx)
Number of pregnancies ending in small for gestational age infants unknown	☐	
Number of pregnancies ending with a child with a birth defect		(format xx)
Number of pregnancies ending with a child with a birth defect unknown	☐	
Number of elective or therapeutic terminations		(format xx)
Number of elective or therapeutic terminations unknown	☐	
Did any prior pregnancies have the following diagnosis		
* Intrauterine growth restriction (IUGR)	○ No ○ Yes ○ Unknown	
* Other adverse fetal outcomes	○ No ○ Yes ○ Unknown	
* If yes, please specify		
* Congenital abnormalities	○ No ○ Yes ○ Unknown	
* Specify abnormalities		

Disease History

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 70 / Page Display Name = Disease History / Description = Disease History)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Does the patient have a confirmed diagnosis of Endometriosis?	○ No ○ Yes	
* Date of Endometriosis diagnosis		(UNK-UNK-UNK)
* Stage of Endometriosis	○ Stage I ○ Stage II ○ Stage III ○ Stage IV ○ Unknown	
* Does the patient have a confirmed diagnosis of Uterine Fibroids?	○ No ○ Yes	
* Date of Uterine Fibroids diagnosis		(UNK-UNK-UNK)

* Severity of bleeding	○ Mild ○ Moderate ○ Severe ○ Very severe	
* Does the patient have a diagnosis of another condition based on approved indications and prescribing patterns of Orilissa?	○ No ○ Yes	
* If Yes, specify condition		
* Date of diagnosis		(UNK-UNK-UNK)

Please complete the Orilissa Treatment form if patient has taken Orilissa 14 days after LMP or any time during pregnancy

Please complete the Comorbidity form and Concomitant Medications form to indicate whether the patient has any comorbid conditions and other medication use, respectively.

Current Pregnancy

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 80 / Page Display Name = Current Pregnancy / Description = Current Pregnancy)

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

* Was this a planned pregnancy?	○ No ○ Yes

What form(s) of birth control was the pregnant women using in the year before this pregnancy? (check all that apply)

No Contraceptive used	☐
Tubal ligation/occlusion	☐
Hormonal contraception	☐
IUD	☐
Contraceptive sponge	☐
Diaphragm or cervical cap plus spermicide	☐
Condom +/- spermicide	☐
Partner vasectomy	☐
Rhythm method	☐
Other	☐
Other, specify	

* Were any assisted reproductive techniques used for treatment of infertility?	○ No ○ Yes	
If yes, check all that apply		
Intrauterine insemination (IUI)	☐	
In vitro fertilization (IVF)	☐	
Other	☐	
* Other, specify		
* Start date of last menstrual period (LMP)		(UNK-UNK-UNK)
* Gestational age (weeks)		(format xx)
* Expected Date of Delivery (EDD)		(UNK-UNK-UNK)
* Number of prenatal visits prior to enrollment		(format xx)
* Were any prenatal tests performed?	○ No ○ Yes ○ Unknown	
If Yes, please enter on the Prenatal Testing form.		

Supplement taken

Please enter supplements on the Concomitant Medications Details form.

* Prenatal vitamin	○ Prior to conception ○ Post-conception only ○ Not taken at all
* Multivitamin	○ Prior to conception ○ Post-conception only ○ Not taken at all
* Folic acid	○ Prior to conception ○ Post-conception only ○ Not taken at all

Prenatal Testing

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 90 (*) / Page Display Name = Prenatal Testing / Description = Prenatal Testing)

Sequence number		
* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Prenatal test	○ NT scan ○ Ultrasound level 1 ○ Ultrasound level 2 ○ Chorionic villus sampling ○ Amniocentesis ○ Rubella Titer ○ Toxoplasmosis ○ Venereal disease research laboratory test ○ Hepatitis Screen ○ Maternal serum alpha-fetoprotein screen ○ Glucose screen ○ Other	

* Other, Specify		
* Date of test		(UNK-UNK-UNK)
* Result		
* Number of fetuses		(format x)

Lifestyle Risk Factors

[Revision: Initial revision of study]

(Visit ID = 10 / Visit Display Name = Baseline / Visit Abbrev = BL / PageID = 100 / 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		