Pregnancy FU 3

Visit Completion

[Revision: Initial revision of study]

(Visit ID = 40 / Visit Display Name = Pregnancy FU 3 / Visit Abbrev = PREGFU3 / PageID = 5 / Page Display Name = Visit Completion / Description = Visit Completion)

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

Pregnancy status

[Revision: Initial revision of study]

(Visit ID = 40 / Visit Display Name = Pregnancy FU 3 / Visit Abbrev = PREGFU3 / PageID = 20 / Page Display Name = Pregnancy status / Description = Pregnancy Status)

* Date of Contact		(DD-MMM-YYYY)
* Reporter of Information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, Specify		
* Gestational age (weeks)		(format xx)
* Number of fetuses		(format x)
* Maternal weight		(format xxx)
* Weight unit	○ kg ○ lb	
* Were there any obstetrical complications since last contact?	○ No ○ Yes	
If Yes, check all that apply		
Gestational diabetes	☐	
Preeclampsia	☐	
Pregnancy-induced hypertension (PIH)	☐	
Toxoplasmosis	☐	
Oligohydramnios	☐	

Polyhydramnios	☐
Cervical incompetence	☐
Preterm labor	☐
Rh incompatibility	☐
Placenta previa	☐
Placenta abruption	☐
Antepartum hemorrhage	☐
Premature membrane rupture	☐
Chorioamnionitis	☐
Thromboembolism (deep vein thrombosis, pulmonary embolism)	☐
Eclampsia	☐
Viral infection (check all that apply):	☐
Cytomegalovirus	☐
Herpes	☐
Measles	☐
Parvovirus B19	☐
Rubella	☐
Other	☐
* Other, specify	
Bacterial infection (check all that apply):	☐
Chlamydia	☐
Group B strep	☐
Listeriosis	☐
Syphilis	☐
Other	☐
* Other, specify	

* Other obstetrical complication	○	No
	○	Yes
* Other obstetrical complication, specify		
* Were there any changes in supplement usage?	○	No
	○	Yes

If Yes, please report on the Concomitant Medication Details form.

* 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.

* Has there been a pregnancy outcome since the last contact?	○	No
	○	Yes

If Yes, please complete the Pregnancy Outcome visit.

* Were any prenatal tests performed?	○	No
	○	Yes
	○	Unknown

If Yes, please enter on the Prenatal Testing form.

Prenatal Testing

[Revision: Initial revision of study]

(Visit ID = 40 / Visit Display Name = Pregnancy FU 3 / Visit Abbrev = PREGFU3 / PageID = 30 (*) / 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 = 40 / Visit Display Name = Pregnancy FU 3 / Visit Abbrev = PREGFU3 / PageID = 40 / 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		