



Pregnancy Form

Send to: connectsafety.sm@thermofisher.com and pv@connectpharm.com

Report Information	
Date Investigator became Aware: ____ / ____ / ____ DD / MMM / YYYY	Report type: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up version #: _____
Date of report: ____ / ____ / ____ DD / MMM / YYYY	Protocol No.:
Participant Information	
Participant ID: _____	Date of Birth: ____ / ____ / ____ DD / MMM / YYYY
	Height: <input type="checkbox"/> inches <input type="checkbox"/> cm Weight: <input type="checkbox"/> lbs <input type="checkbox"/> kg
Medical history	
<input type="checkbox"/> none <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Seizures <input type="checkbox"/> Thyroid disorder <input type="checkbox"/> Allergic disease <input type="checkbox"/> Heart disease <input type="checkbox"/> Depression <input type="checkbox"/> Other psychiatric disorder <input type="checkbox"/> Sexual transmitted disease <input type="checkbox"/> Hepatitis <input type="checkbox"/> HIV/AIDS <input type="checkbox"/> Other, specify _____	
Family history	
<input type="checkbox"/> none <input type="checkbox"/> history of congenital abnormality <input type="checkbox"/> psychomotor retardation in family <input type="checkbox"/> Other, specify _____	
Pregnancy Information	
Date of last menstrual period (LMP): ____ / ____ / ____ DD / MMM / YYYY	
Gestational age at the time of last study drug intake: ____ weeks ____ days based on <input type="checkbox"/> ultrasound <input type="checkbox"/> LMP	
Expected date of delivery: ____ / ____ / ____ DD / MMM / YYYY	Date of blood or serum β -hCG test positive: ____ / ____ / ____ DD / MMM / YYYY
Date of ultrasound examination positive: ____ / ____ / ____ DD / MMM / YYYY	If positive, gestational age at ultrasound examination: _____

Method of contraception: <input type="checkbox"/> None <input type="checkbox"/> Hormonal <input type="checkbox"/> Surgical <input type="checkbox"/> Barrier <input type="checkbox"/> Intrauterine device <input type="checkbox"/> Other _____			
Concomitant medications:			
Fertility History			
<input type="checkbox"/> Number of previous pregnancies _____ <input type="checkbox"/> Number of full-term births _____ <input type="checkbox"/> Number of premature births _____ <input type="checkbox"/> Number of ectopic pregnancies _____ <input type="checkbox"/> Number of spontaneous abortions _____ <input type="checkbox"/> Number of fetal deaths/stillbirths _____ <input type="checkbox"/> Complications during previous pregnancies and birth? Please specify _____ <input type="checkbox"/> Birth defects in previous pregnancies? Please specify _____			
Did the Participant Withdraw from the Trial?			
<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, please specify the date of withdrawal: _____ / _____ / _____ <div style="text-align: center;">DD / MMM / YYYY</div> And tick the reason for withdrawal: <input type="checkbox"/> Pregnancy <input type="checkbox"/> Other reasons, please specify _____			
Investigational Product			
Date of informed consent: _____ / _____ / _____ <div style="text-align: center;">DD / MMM / YYYY</div>			
Design: <input type="checkbox"/> Open-label <input type="checkbox"/> Blind		If it is blinded, did the blind breaking occur? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, date: _____ / _____ / _____ <div style="text-align: right;">DD / MMM / YYYY</div>	
Date of last study drug administration before pregnancy confirmed: _____ / _____ / _____ <div style="text-align: center;">DD / MMM / YYYY</div>			
Relevant Laboratory and Non-laboratory Tests (eg, prenatal tests e.g. blood or serum β-hCG, ultrasound, amniocentesis):			
Date (DD / MMM / YYYY)	Tests	Results (Unit)	Reference Range (Unit)

Pregnancy Outcomes <input type="checkbox"/> Not applicable (Complete this section for pregnancy outcomes)	
Pregnant outcome:	<input type="checkbox"/> Method of delivery _____ <input type="checkbox"/> Stillbirth <input type="checkbox"/> Dead fetus
	<input type="checkbox"/> Spontaneous abortion Date: _____ <input type="checkbox"/> Elective abortion Date: _____ <input type="checkbox"/> Other _____
Newborn Information <input type="checkbox"/> Not applicable (Complete when newborn information is available)	
Date of Birth: _____ / _____ / _____ DD / MMM / YYYY	Fetal/newborn status: <input type="checkbox"/> Normal <input type="checkbox"/> foetal distress <input type="checkbox"/> Birth defects, please specify _____ <input type="checkbox"/> Other abnormality _____
Gestational age at birth _____ weeks	Newborn gender <input type="checkbox"/> Male <input type="checkbox"/> Female
Body length (unit)	Weight (unit)
Apgar score: APGAR Score 1 (Min 1) _____ APGAR Score 2 (Min 5) _____	Whether there is significant medical condition: <input type="checkbox"/> No <input type="checkbox"/> Yes, if yes, please specify it below.
Describe relevant results, assessments (eg, diagnostic tests, consultations), abnormal amniotic fluid, abnormal placenta, or other information relevant to the newborn medical condition.	



Pregnancy Form

--

Additional Information, if any

--

Investigator/Reporter Information



Pregnancy Form

Site Address:	Investigator name: Phone: Email:	Reporter name: Phone: Email:
I, the undersigned investigator, attest that I have reviewed this Safety Report and agree with the content.		
Investigator Signature:		Date: ____ / ____ / ____ DD / MMM / YYYY