

EXPOSURE IN UTERO REPORT FORM

Protocol Identification acronym/code: _____

All 3 pages to be transmitted to FROM within 24 hours of knowledge of pregnancy

1. PATIENT (MOTHER) INFORMATION					
SITE (NR AND NAME) _____	PATIENT ID _ _	DATE OF BIRTH _ _ / _ _ / _ _ (dd/mm/yy)	WEIGHT kg	HEIGHT cm	SEX
CONTRACEPTION USED <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	TYPE		DATE OF LAST MENSTRUATION _ _ / _ _ / _ _ <input type="checkbox"/> Unknown (dd/mm/yy)		
2. IMP INFORMATION					
IMP NAME, ROUTE, and SCHEDULE	Batch No	Tumor Type or Other Indication	Date of Last IMP Dose Before Pregnancy Assessment (dd/mm/yy)	IMP Start Date IMP Stop Date (dd/mm/yy)	
<IMP NAME>			_ _ / _ _ / _ _ : (if SAE onset on same day)	First Dose: _ _ / _ _ / _ _ Last Dose: _ _ / _ _ / _ _ or Ongoing <input type="checkbox"/>	
			Cycle# _____ Day# _____		
<IMP NAME>			_ _ / _ _ / _ _ : (if SAE onset on same day)	First Dose: _ _ / _ _ / _ _ Last Dose: _ _ / _ _ / _ _ or Ongoing <input type="checkbox"/>	
			Cycle# _____ Day# _____		
3. PREGNANCY-ASSOCIATED SERIOUS ADVERSE EVENTS					
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown					
If the mother experiences any SAE during pregnancy, please complete a SAE form					
SITE Nr		PATIENT ID		Initial: <input type="checkbox"/>	Follow up #: _____

4. PREGNANCY OUTCOME

DELIVERY / ABORTION

DATE OF DELIVERY / ABORTION |_|_|/|_|_|/|_|_| (dd/mm/yy)

Specify if normal delivery, caesarean section, planned / spontaneous abortion:

Reason for abortion (if applicable):

Is there a reasonable possibility that delivery complications / spontaneous abortion were caused by the IMP(s)?

☐ Yes ☐ No

Maternal complications related to birth:

Is there a reasonable possibility that maternal complications were caused by the IMP(s)?

☐ Yes ☐ No

5. CHILD INFORMATION

☐ Normal

☐ Abnormal, specify: _____

☐ Stillbirth

☐ Neonate died, date of death: |_|_|/|_|_|/|_|_| (dd/mm/yy)

Did the child experience any Serious Adverse Event?

☐ Yes ☐ No ☐ Unknown

If yes, SAE Term _____ CTCAE V..... Grade _____

SERIOUSNESS CRITERIA

(check all appropriate to event)

- ☐ LIFE-THREATENING
☐ DEATH
☐ INVOLVED OR PROLONGED HOSPITALIZATION
☐ DISABILITY
☐ CONGENITAL ANOMALY/BIRTH DEFECT
☐ IMPORTANT MEDICAL EVENT (E.G., INTERVENTION REQUIRED TO PREVENT ONE OF THE ABOVE)

OUTCOME

- ☐ RESOLVED
☐ RESOLVED WITH SEQUELAE
☐ UNRESOLVED / ONGOING
☐ DEATH
☐ UNKNOWN / LOST TO FOLLOW-UP

Resolution Date

|_|_|/|_|_|/|_|_|
(dd/mm/yy)

IMP RELATIONSHIP ASSESSMENT

Is there a reasonable possibility that the SAE was caused by the IMP(s)?

☐ Yes ☐ No

SITE Nr

PATIENT ID

Initial: ☐

Follow up #: _____

6. NARRATIVE

8. PRIMARY SOURCE OF INFORMATION

REPORTER:

INVESTIGATOR SIGNATURE:

PRINT NAME: _____

TITLE : _____

DATE : |__|/|__|/|__| (dd/mm/yy)

INSTITUTION, DEPARTMENT, AND TELEPHONE NUMBER :

DATE OF TRANSMISSION : |__|/|__|/|__| (dd/mm/yy)