

Pregnancy Surveillance Form Part I (Antepartum Information)

PATIENT IDENTIFIER: (FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)		CASE # (BMS ONLY)		LOCAL COUNTRY NUMBER: (BMS ONLY)		
BMS RECEIPT DATE (BMS USE ONLY)		Click here to enter a date.		WWPS RECEIPT DATE (BMS USE ONLY)		
REPORT TYPE:		<input type="checkbox"/> SPONTANEOUS OR <input type="checkbox"/> INITIAL REPORT OR		<input type="checkbox"/> STUDY <input type="checkbox"/> FOLLOW-UP REPORT		
		COUNTRY*		*If UK, was Country of Incidence, Specify if Northern Ireland below? Yes <input type="checkbox"/> No <input type="checkbox"/>		
EVENT: PREGNANCY						
EXPOSURE TYPE: <input type="checkbox"/> MATERNAL DRUG EXPOSURE OR <input type="checkbox"/> PATERNAL DRUG EXPOSURE						
FOR PATERNAL DRUG EXPOSURE ONLY: WAS PREGNANT PARTNER INFORMED CONSENT FORM SIGNED? <input type="checkbox"/> No <input type="checkbox"/> Yes						
IF NO, DID THE MALE SUBJECT PROVIDE ALL OF THE PREGNANCY SURVEILLANCE INFORMATION BELOW? <input type="checkbox"/> No <input type="checkbox"/> Yes						
REPORT TYPE: <input type="checkbox"/> PROSPECTIVE REPORT OR <input type="checkbox"/> RETROSPECTIVE REPORT						
WERE THERE ANY ADDITIONAL MATERNAL/PATERNAL ADVERSE EVENTS? <input type="checkbox"/> No <input type="checkbox"/> Yes						
IF YES, REPORT THE ADVERSE EVENTS APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)						
MATERNAL INFORMATION		AGE AT CONCEPTION:	HEIGHT:	WEIGHT:	RACE:	
DATE OF BIRTH:		CONCEPTION:	<input type="text"/> <input type="checkbox"/> inches <input type="checkbox"/> cm	<input type="text"/> <input type="checkbox"/> lb <input type="checkbox"/> kg	<input type="checkbox"/> WHITE <input type="checkbox"/> BLACK <input type="checkbox"/> ASIAN <input type="checkbox"/> AMERICAN INDIAN OR ALASKAN NATIVE <input type="checkbox"/> NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> Aboriginal <input type="checkbox"/> Torres Strait Islander <input type="checkbox"/> OTHER RACE: <input type="text"/>	
Click here to enter a date.		<input type="text"/>				
NUMBER OF PREGNANCIES INCLUDING THIS ONE		<input type="text"/>	NUMBER OF BIRTHS		<input type="text"/>	NUMBER OF LIVING CHILDREN
ONSET DATE LAST MENSTRUAL PERIOD (LMP):		Click here to enter a date.	APPROXIMATE DATE OF CONCEPTION:	Click here to enter a date.	DATE PREGNANCY WAS CONFIRMED:	Click here to enter a date.
			ESTIMATED DATE OF DELIVERY:	Click here to enter a date.	TEST METHOD: <input type="checkbox"/> SERUM <input type="checkbox"/> URINE	
ESTIMATED GESTATIONAL AGE WHEN PREGNANCY DIAGNOSED:		<input type="text"/>	WEEKS	DETERMINED BY:		<input type="checkbox"/> FETAL ULTRASOUND <input type="checkbox"/> DATE FROM LMP
CONTRACEPTION AT TIME OF CONCEPTION: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> UNKNOWN (IF YES, SPECIFY) <input type="text"/>						
RELEVANT MATERNAL MEDICAL HISTORY/RISK FACTORS			DATE OF ONSET		IF APPLICABLE SPECIFY PERTINENT DETAILS	
			Click here to enter a date.			
			Click here to enter a date.			
			Click here to enter a date.			
			Click here to enter a date.			
PATERNAL INFORMATION:		AGE	<input type="text"/>	YEARS	DATE OF BIRTH:	Click here to enter a date.
RELEVANT PATERNAL MEDICAL HISTORY/RISK FACTORS			DATE OF ONSET		IF APPLICABLE SPECIFY PERTINENT DETAILS	
			Click here to enter a date.			
			Click here to enter a date.			
			Click here to enter a date.			
			Click here to enter a date.			

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PATIENT IDENTIFIER: (FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)		CASE # (BMS ONLY)				LOCAL COUNTRY NUMBER: (BMS ONLY)	
MEDICATION NAME AND INDICATION	PREGNANCY RELATED TO MEDICATION?*	DOSE AND UNITS	FREQ	ROUTE **	PERIOD(S) OF DRUG EXPOSURE ***	ONCOLOGY DRUGS ONLY	START AND STOP DATES
1. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
2. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
3. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
4. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
5. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
6. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING
7. <input style="width: 100%;" type="text"/> INDICATION <input style="width: 100%;" type="text"/> <input type="checkbox"/> MATERNAL OR <input type="checkbox"/> PATERNAL <input type="checkbox"/> NON-STUDY OR <input type="checkbox"/> STUDY	<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED	<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	CYCLE #: <input style="width: 100%;" type="text"/> CUMULATIVE DOSE WITH UNITS <input style="width: 100%;" type="text"/>	Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> Click here to enter a date. <input style="width: 100%; height: 100%;" type="text"/> OR <input type="checkbox"/> ONGOING

* MANDATORY FOR ALL STUDIES

**ROUTE:

- 1 = ORAL 2 = INTRAVENOUS 3 = SUBCUTANEOUS 4 = OTHER

***PERIOD(S) OF DRUG EXPOSURE: (INCLUDE ALL THAT APPLY)

- 0 = PRIOR TO CONCEPTION 1 = 1ST TRIMESTER 2 = 2ND TRIMESTER
 3 = 3RD TRIMESTER 4 = LABOR & DELIVERY 5 = UNKNOWN

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PRENATAL DIAGNOSTIC TESTING	BASE-LINE	DATE	TEST RESULTS UNITS	NORMAL RANGE	
				LOW	HIGH
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			
	<input type="checkbox"/>	Click here to enter a date.			

DESCRIBE RESULTS IN DETAIL, IF APPLICABLE:

REPORTER INFORMATION: BMS STUDY INVESTIGATOR NON-BMS STUDY SPONSOR OTHER*

***QUALIFICATION: (COMPLETE ONLY IF "OTHER" IS CHECKED)**

PHYSICIAN PHARMACIST NURSE/NURSE PRACTITIONER OTHER HEALTH PROFESSIONAL
 CONSUMER ATTORNEY OTHER NON-HEALTH PROFESSIONAL

PERSON COMPLETING THE FORM (IF DIFFERENT FROM INVESTIGATOR/SPONSOR) :	DATE:				
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 80%;"></td> <td style="padding: 2px 5px;">PRINTED NAME</td> </tr> <tr> <td style="border: 1px solid black;"></td> <td style="padding: 2px 5px;">SIGNATURE</td> </tr> </table>		PRINTED NAME		SIGNATURE	Click here to enter a date.
	PRINTED NAME				
	SIGNATURE				

INSTITUTION/ORGANIZATION:

STREET ADDRESS:	CITY:	
	STATE/PROVINCE:	

POST CODE:		COUNTRY:		PHONE NUMBER:	
-------------------	--	-----------------	--	----------------------	--

Email address

INVESTIGATOR/SPONSOR/OTHER:

	LAST NAME	
	FIRST NAME	MIDDLE INITIAL

SIGNATURE:	DATE:	
	Click here to enter a date.	

Pregnancy Surveillance Form Part II (Pregnancy Outcome)

PATIENT IDENTIFIER: (FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)		CASE # (BMS ONLY)		LOCAL COUNTRY NUMBER: (BMS ONLY)	
PREGNANCY OUTCOME:		MODE OF DELIVERY: <input type="text"/>		LABOR/DELIVERY COMPLICATIONS <input type="checkbox"/> No <input type="checkbox"/> Yes* IF YES, SPECIFY <input type="text"/>	
<input type="checkbox"/> SINGLE GESTATION <input type="checkbox"/> MULTIPLE GESTATION (# <input type="text"/> of <input type="text"/>) COMPLETE AN OUTCOME FORM FOR EACH FETUS/INFANT DATE PREGNANCY ENDED: GESTATIONAL AGE AT OUTCOME <input type="text"/> WEEKS <input type="checkbox"/> UNKNOWN Click here to enter a date. ASSESSED BY: <input type="checkbox"/> OBSTETRICAL DATES <input type="checkbox"/> FETUS/INFANT PHYSICAL EXAM				DID OBSTETRICAL COMPLICATIONS OR MATERNAL/PATERNAL MEDICAL CONDITIONS OCCUR DURING THIS PREGNANCY? <input type="checkbox"/> No <input type="checkbox"/> Yes* <input type="checkbox"/> UNKNOWN IF YES, SPECIFY: <input type="text"/>	
*FOR ANY COMPLICATIONS NOTED ABOVE, REPORT THE ADVERSE EVENT APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)					
GENDER: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE <input type="checkbox"/> UNKNOWN		BIRTH WEIGHT: <input type="text"/> / <input type="text"/> lbs/oz <input type="text"/> / <input type="text"/> grams		BIRTH LENGTH: <input type="text"/> <input type="checkbox"/> inches <input type="checkbox"/> cm	
		HEAD CIRCUMFERENCE: <input type="text"/> <input type="checkbox"/> inches <input type="checkbox"/> cm		APGAR SCORE: 1 MIN. <input type="text"/> 5 MIN. <input type="text"/>	
<input type="checkbox"/> LIVE BIRTH NORMAL (PROCEED TO PART III)					
<input type="checkbox"/> LIVE BIRTH ABNORMAL <input type="checkbox"/> FETAL DEATH <input type="checkbox"/> NEONATAL DEATH (IF ANY ARE CHECKED, COMPLETE SECTIONS BELOW)					
<input type="checkbox"/> PRE-TERM <input type="checkbox"/> TERM <input type="checkbox"/> POST TERM <input type="checkbox"/> SMALL FOR GESTATIONAL AGE <input type="checkbox"/> INTRAUTERINE GROWTH RETARDATION <input type="checkbox"/> DRUG WITHDRAWAL SYNDROME IN THE NEONATE <input type="checkbox"/> MALFORMATION (SPECIFY BELOW) <input type="checkbox"/> POST-NATAL/NEONATAL COMPLICATIONS (E.G. PERINATAL ASPHYXIA, INFECTION, RESPIRATORY DISTRESS) (SPECIFY): <input type="text"/>				FAMILY HISTORY OF CONGENITAL ABNORMALITIES/BIRTH DEFECTS: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> UNKNOWN IF YES, SPECIFY: <input type="text"/>	
FETAL DEATH <input type="checkbox"/> ECTOPIC <input type="checkbox"/> MISCARRIAGE/SPONTANEOUS ABORTION <input type="checkbox"/> STILLBIRTH <input type="checkbox"/> INDUCED ABORTION/ELECTIVE TERMINATION AUTOPSY/PATHOLOGY REPORT <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> UNKNOWN				PRIOR PREGNANCIES WITH CONGENITAL ABNORMALITIES/BIRTH DEFECTS: DEFECTS: <input type="checkbox"/> No <input type="checkbox"/> Yes IF YES, SPECIFY #/TYPE : <input type="text"/>	
NEONATAL DEATH: CAUSE: <input type="text"/> DATE: <input type="text"/> <small>Click here to enter a date.</small>				PRIOR STILLBIRTHS: <input type="checkbox"/> No <input type="checkbox"/> Yes IF YES, SPECIFY # : <input type="text"/>	
PLACENTAL ABNORMALITIES <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> UNKNOWN IF YES, SPECIFY: <input type="text"/>				PRIOR SPONTANEOUS ABORTIONS: <input type="checkbox"/> No <input type="checkbox"/> Yes IF YES, SPECIFY #: <input type="text"/>	
PATHOLOGY REPORT AVAILABLE <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> UNKNOWN				SPECIFY ANY PRIOR PREGNANCY COMPLICATIONS: <input type="text"/>	
HISTORY OF FERTILITY TREATMENTS (E.G. IVF): <input type="checkbox"/> No <input type="checkbox"/> Yes IF YES, SPECIFY: <input type="text"/>					
DESCRIBE ANY CONGENITAL MALFORMATIONS/ABNORMALITIES, STRUCTURAL DEFECTS AND OTHER FETAL/NEONATAL COMPLICATIONS: <input style="width: 100%; height: 40px;" type="text"/>					
CAUSALITY (MANDATORY FOR STUDIES) IN THE INVESTIGATOR'S OPINION, WAS THE DEFECT/MEDICAL PROBLEM RELATED TO MEDICATION UNDER STUDY? : <input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED IF RELATED, PLEASE COMMENT ON SPECIFIC EVENT(S) AND MEDICATION(S) BELOW: IF NOT RELATED, INDICATE WHAT THE DEFECT/MEDICAL PROBLEM WAS ATTRIBUTED TO: <input style="width: 100%; height: 30px;" type="text"/>					

Pregnancy Surveillance Form Part III (Infant Follow-up)

PATIENT IDENTIFIER: (FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)		CASE # (BMS ONLY)		LOCAL COUNTRY NUMBER: (BMS ONLY)	
CURRENT INFANT AGE:		AGE UNITS: <input type="checkbox"/> DAYS <input type="checkbox"/> WEEKS <input type="checkbox"/> MONTHS			
<input type="checkbox"/> NO PROBLEMS <input type="checkbox"/> MEDICAL PROBLEMS NOTED (SPECIFY AND DESCRIBE FINDINGS AND/OR PLANNED EVALUATIONS; E.G. DIAGNOSTIC TESTING, CONSULTATIONS, ETC)					
CAUSALITY (MANDATORY FOR ALL STUDIES): IN THE INVESTIGATOR'S OPINION WERE ANY PROBLEMS NOTED ABOVE RELATED TO THE MEDICATION UNDER STUDY?					
<input type="checkbox"/> NOT RELATED <input type="checkbox"/> RELATED (PLEASE SPECIFY):					
MATERNAL BREASTFEEDING:		<input type="checkbox"/> No <input type="checkbox"/> Yes		HOW LONG: <input style="width: 100px;" type="text"/>	
MATERNAL DRUGS TAKEN WHILE BREASTFEEDING:		<input type="checkbox"/> No <input type="checkbox"/> Yes		(IF YES, SPECIFY)	
REPORTER INFORMATION:					
<input type="checkbox"/> BMS STUDY INVESTIGATOR <input type="checkbox"/> NON-BMS STUDY SPONSOR <input type="checkbox"/> OTHER*					
*QUALIFICATION: (COMPLETE ONLY IF "OTHER" IS CHECKED)					
<input type="checkbox"/> PHYSICIAN <input type="checkbox"/> PHARMACIST <input type="checkbox"/> NURSE/NURSE PRACTITIONER <input type="checkbox"/> OTHER HEALTH PROFESSIONAL <input type="checkbox"/> CONSUMER <input type="checkbox"/> ATTORNEY <input type="checkbox"/> OTHER NON-HEALTH PROFESSIONAL					
PERSON COMPLETING THE FORM (IF DIFFERENT FROM INVESTIGATOR/SPONSOR) :					DATE:
<input style="width: 100%;" type="text"/>			PRINTED NAME		Click here to enter a date.
<input style="width: 100%;" type="text"/>			SIGNATURE		
INSTITUTION/ORGANIZATION: <input style="width: 100%;" type="text"/>					
STREET ADDRESS: <input style="width: 100%;" type="text"/>			CITY: <input style="width: 100%;" type="text"/>		STATE/PROVINCE: <input style="width: 100%;" type="text"/>
POST CODE: <input style="width: 100%;" type="text"/>		COUNTRY: <input style="width: 100%;" type="text"/>		PHONE NUMBER: <input style="width: 100%;" type="text"/>	
Email address <input style="width: 100%;" type="text"/>					
INVESTIGATOR/SPONSOR/OTHER:					
<input style="width: 100%;" type="text"/>			LAST NAME		
<input style="width: 100%;" type="text"/>			FIRST NAME		MIDDLE INITIAL
<input style="width: 100%;" type="text"/>					DATE:
<input style="width: 100%;" type="text"/>					Click here to enter a date.

Pregnancy Surveillance Form - Quick Reference Guide

The Pregnancy Surveillance Form will be completed for all prospective (confirmed pregnancy, prior to delivery or confirmation of congenital anomaly) and retrospective (when congenital anomaly/malformation is confirmed or after delivery has occurred) reports of pregnancy and pregnancy outcomes (live births: normal or abnormal, fetal death, neonatal death etc.) It functions as a data collection and query tool to report pregnancies and related pregnancy information. AE/SAEs for all subjects/patients reported in association with the pregnancy (obstetric complications, maternal medical complications, etc.) are to be reported separately on the clinical or non-interventional SAE form or spontaneous AE/SAE form.

Pregnancy Surveillance Form Part I	Pregnancy Surveillance Form Part II	Pregnancy Surveillance Form Part III
When a pregnancy is confirmed	When the pregnancy outcome is known	When the infant outcome is known.

Site Monitor: When a pregnancy is confirmed, collaborate with the site manager or clinical scientist to ensure that the Investigator has notified the IRB/IEC or Health Authority (if required by local law).

- Ensure that documentation of pregnancy notifications sent by the Investigator to the IRB/IEC are filed in the On-site Investigator File (OSIF) and R&D Study File.
- In countries where notification of the IRB/IEC is handled by the sponsor, the site manager is responsible for ensuring that the documentation of all pregnancy notifications sent to the IRB/IEC are filed within the R&D Study File.
- **Note:** for Paternal Drug Exposure in Interventional Study Reports: If pregnant partner informed consent is not signed, Part I, Part II and Part III information needs to come from the male subject, and not from the female partner herself.

All Pages Header Information

- For studies the “Patient Identifier” is the same as that used throughout the CRF, and populated with the protocol, site and subject numbers i.e. CV131-345-234-1134
- For spontaneous reports, enter local country number (if applicable) at the top left and/or enter a patient identifier (i.e. initials) if available or leave blank
- Parts I, II and III will be completed with all appropriate identifying header information on each page

Part I - Page 1

Complete all questions for “PREGNANCY” as the only adverse event; other SAEs reported in association with the pregnancy (obstetric complications, maternal medical complications etc.) are reported separately either on the clinical/non-interventional study SAE form or the Spontaneous AE/SAE forms.

Part I - Page 2: Medication:

- Include each medication reported as a separate entry.
- Indicate if the drug was associated with maternal or paternal exposure.
- Indicate if the drug was identified as a non - study medication or study medication by the investigator or reporter. Study medications include the medications under study (for non-interventional studies), the Investigational Medicinal Product (IMP), comparator medications and background therapy identified in the protocol.

“Pregnancy Related to Medication” Column: Check whether or not the pregnancy was related to the medication.

Dosing Information: For route and period(s) of drug exposure, use the codes indicated at the bottom of the page.

For period(s) of drug exposure, include all that apply.

Part I - Page 3: Prenatal Diagnostic Testing: Indicate if the results are baseline by checking under “baseline”; otherwise leave this box blank when providing the relevant details. Specify the test results (including any relevant units or other data), use the space below this section to describe results in more detail if needed.

Part II - Pregnancy Outcome: Complete delivery and outcome data as requested at the top of the page. If the outcome involved multiple gestations, please complete a separate outcome form for each fetus/infant. If the pregnancy/outcome involved labor or delivery complications, obstetric complications, or maternal medical conditions, briefly specify them.

NOTE: If any complications reported above meet the definition of an SAE (or an AE for non-study patients) they should be reported separately on either the clinical or non-interventional SAE form or the spontaneous AE/SAE form. If the outcome is “live birth- normal” check this box, and proceed to the next page or any adverse outcome (live birth abnormal, fetal or neonatal death) complete all requested information to the fullest extent

For any adverse outcome (live birth abnormal, fetal or neonatal death) complete all requested information to the fullest extent possible. A detailed causality assessment by the investigator is required for any reports from trials and must be provided as noted at the bottom of this page.