Bristol Myers Squibb™

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)	Click here to enter a date.

REPORT TYPE:	☐ SPONTANEOUS OR ☐ STUDY	COUNTRY*	
	☐ INITIAL REPORT OR ☐ FOLLOW-UP REPORT	*If UK, was Country of Incidence, Specify if Northern Ireland below? Yes ☐ No ☐	

EVENT: PREGNANCY

EXPOSURE TYPE: ☐ MATERNAL DRUG EXPOSURE OR ☐ PATERNAL DRUG EXPOSURE

FOR PATERNAL DRUG EXPOSURE ONLY: WAS PREGNANT PARTNER INFORMED CONSENT FORM SIGNED? ☐ NO ☐ YES

IF NO, DID THE MALE SUBJECT PROVIDE ALL OF THE PREGNANCY SURVEILLANCE INFORMATION BELOW? ☐ NO ☐ YES

REPORT TYPE: ☐ PROSPECTIVE REPORT OR ☐ RETROSPECTIVE REPORT

WERE THERE ANY ADDITIONAL MATERNAL/PATERNAL ADVERSE EVENTS? ☐ NO ☐ YES

IF YES, REPORT THE ADVERSE EVENTS APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)

MATERNAL INFORMATION DATE OF BIRTH:	AGE AT CONCEPTION:	HEIGHT:	WEIGHT:	RACE:
Click here to enter a date.		☐ inches ☐ cm	☐ lb ☐ kg	☐ WHITE ☐ BLACK ☐ ASIAN ☐ AMERICAN INDIAN OR ALASKAN NATIVE ☐ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ☐ Aboriginal ☐ Torres Strait Islander ☐ OTHER RACE:

NUMBER OF PREGNANCIES INCLUDING THIS ONE	NUMBER OF BIRTHS	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:	☐ SERUM ☐ URINE

ESTIMATED GESTATIONAL AGE WHEN PREGNANCY DIAGNOSED:	WEEKS	DETERMINED BY:	☐ FETAL ULTRASOUND ☐ DATE FROM LMP

CONTRACEPTION AT TIME OF CONCEPTION: ☐ NO ☐ YES ☐ UNKNOWN (IF YES, SPECIFY)

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 ____ 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. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
2. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
3. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
4. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
5. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
6. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ ongoing
7. Indication ☐ Maternal OR ☐ Paternal ☐ Non-study OR ☐ Study	☐ Not related ☐ Related					Cycle #: Cumulative dose with units	Click here to enter a date. Click here to enter a date. OR ☐ 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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PATIENT IDENTIFIER: *(FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)*	CASE # (BMS ONLY)	LOCAL COUNTRY NUMBER: (BMS ONLY)

PRENATAL DIAGNOSTIC TESTING	BASE-LINE	DATE	TEST RESULTS UNITS	NORMAL RANGE	
				LOW	HIGH
	☐	Click here to enter a date.			
	☐	Click here to enter a date.			
	☐	Click here to enter a date.			
	☐	Click here to enter a date.			
	☐	Click here to enter a date.			
	☐	Click here to enter a date.			
	☐	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) :

PRINTED NAME

SIGNATURE

DATE: Click here to enter a date.

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.

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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:

LABOR/DELIVERY COMPLICATIONS ☐ NO ☐ YES*

IF YES, SPECIFY

☐ SINGLE GESTATION ☐ MULTIPLE GESTATION (# of)

COMPLETE AN OUTCOME FORM FOR EACH FETUS/INFANT

DATE PREGNANCY ENDED: Click here to enter a date.

GESTATIONAL AGE AT OUTCOME WEEKS ☐ UNKNOWN

ASSESSED BY: ☐ OBSTETRICAL DATES ☐ FETUS/INFANT PHYSICAL EXAM

DID OBSTETRICAL COMPLICATIONS OR MATERNAL/PATERNAL MEDICAL CONDITIONS OCCUR DURING THIS PREGNANCY?

☐ NO ☐ YES*

☐ UNKNOWN IF YES, SPECIFY:

*FOR ANY COMPLICATIONS NOTED ABOVE, REPORT THE ADVERSE EVENT APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)

GENDER:	BIRTH WEIGHT:	BIRTH LENGTH:	HEAD CIRCUMFERENCE:	APGAR SCORE:
☐ MALE ☐ FEMALE ☐ UNKNOWN	☐☐ / ☐☐ lbs/oz ☐☐☐☐ grams	☐ inches ☐ cm	☐ inches ☐ cm	1 MIN. 5 MIN.

☐ LIVE BIRTH NORMAL (PROCEED TO PART III)

☐ LIVE BIRTH ABNORMAL ☐ FETAL DEATH ☐ NEONATAL DEATH (IF ANY ARE CHECKED, COMPLETE SECTIONS BELOW)

☐ PRE-TERM ☐ TERM ☐ POST TERM

☐ SMALL FOR GESTATIONAL AGE

☐ INTRAUTERINE GROWTH RETARDATION

☐ DRUG WITHDRAWAL SYNDROME IN THE NEONATE

☐ MALFORMATION (SPECIFY BELOW)

☐ POST-NATAL/NEONATAL COMPLICATIONS (E.G. PERINATAL ASPHYXIA, INFECTION, RESPIRATORY DISTRESS) (SPECIFY):

FETAL DEATH

☐ ECTOPIC ☐ MISCARRIAGE/SPONTANEOUS ABORTION ☐ STILLBIRTH

☐ INDUCED ABORTION/ELECTIVE TERMINATION

AUTOPSY/PATHOLOGY REPORT ☐ NO ☐ YES ☐ UNKNOWN

NEONATAL DEATH:

CAUSE: DATE: Click here to enter a date.

PLACENTAL ABNORMALITIES ☐ NO ☐ YES ☐ UNKNOWN

IF YES, SPECIFY:

PATHOLOGY REPORT AVAILABLE ☐ NO ☐ YES ☐ UNKNOWN

FAMILY HISTORY OF CONGENITAL ABNORMALITIES/BIRTH DEFECTS:

☐ NO ☐ YES ☐ UNKNOWN

IF YES, SPECIFY:

PRIOR PREGNANCIES WITH CONGENITAL ABNORMALITIES/BIRTH DEFECTS: ☐ NO ☐ YES

IF YES, SPECIFY #/TYPE :

PRIOR STILLBIRTHS: ☐ NO ☐ YES

IF YES, SPECIFY # :

PRIOR SPONTANEOUS ABORTIONS: ☐ NO ☐ YES

IF YES, SPECIFY #:

SPECIFY ANY PRIOR PREGNANCY COMPLICATIONS:

HISTORY OF FERTILITY TREATMENTS (E.G. IVF):

☐ NO ☐ YES IF YES, SPECIFY:

DESCRIBE ANY CONGENITAL MALFORMATIONS/ABNORMALITIES, STRUCTURAL DEFECTS AND OTHER FETAL/NEONATAL COMPLICATIONS:

CAUSALITY (MANDATORY FOR STUDIES)

IN THE INVESTIGATOR'S OPINION, WAS THE DEFECT/MEDICAL PROBLEM RELATED TO MEDICATION UNDER STUDY? : ☐ NOT RELATED ☐ 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:

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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: ☐ DAYS ☐ WEEKS ☐ MONTHS

☐ NO PROBLEMS ☐ 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? ☐ NOT RELATED ☐ RELATED (PLEASE SPECIFY):

MATERNAL BREASTFEEDING: ☐ NO ☐ YES HOW LONG:

MATERNAL DRUGS TAKEN WHILE BREASTFEEDING: ☐ NO ☐ YES (IF YES, SPECIFY)

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:
PRINTED NAME	Click here to enter a date.
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 - 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.