Pregnancy Reporting Form (Antepartum Information)

Please complete this form to report a pregnancy in:
- a female patient treated with pomalidomide or
- a female partner of a male patient treated with pomalidomide.
Please email immediately to Grindeks at vigilance@grindeks.com. As part of Grindeks Safety Monitoring System, we may require further information on reported pregnancies. Grindeks may therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information.

REPORT TYPE:	☐ SPONTANEOUS OR	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		

MATERNAL INFORMATION DATE OF BIRTH:	AGE AT CONCEPTION:	HEIGHT: ☐ Inches ☐ cm	WEIGHT: ☐ Lb ☐ kg	RACE: ☐ 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):	APPROXIMATE DATE OF CONCEPTION: ESTIMATED DATE OF DELIVERY:	DATE PREGNANCY WAS CONFIRMED: 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

PATERNAL INFORMATION: AGE _____ YEARS DATE OF BIRTH:

RELEVANT PATERNAL MEDICAL HISTORY/RISK FACTORS	DATE OF ONSET	IF APPLICABLE SPECIFY PERTINENT DETAILS

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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 _____	OR □ ONGOING
2. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL □ NON-STUDY OR □ STUDY	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	OR □ ONGOING
3. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL □ NON-STUDY OR □ STUDY	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	OR □ ONGOING
4. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL □ NON-STUDY OR □ STUDY	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	OR □ ONGOING
5. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	OR □ ONGOING

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
□ NON-STUDY OR □ STUDY							
6. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL □ NON-STUDY OR □ STUDY	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	OR □ ONGOING
7. _____ INDICATION _____ □ MATERNAL OR □ PATERNAL □ NON-STUDY OR □ STUDY	□ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS _____	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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PRENATAL DIAGNOSTIC TESTING	BASELINE	DATE	TEST RESULTS UNITS	NORMAL RANGE	
				LOW	HIGH
	☐				
	☐				
	☐				
	☐				
	☐				
	☐				
	☐				

DESCRIBE RESULTS IN DETAIL, IF APPLICABLE:
_____

REPORTER INFORMATION:		
QUALIFICATION: ☐ PHYSICIAN ☐ PHARMACIST ☐ NURSE/NURSE PRACTITIONER ☐ OTHER HEALTH PROFESSIONAL ☐ CONSUMER ☐ ATTORNEY ☐ OTHER NON-HEALTH PROFESSIONAL		
INSTITUTION/ORGANIZATION:		
STREET ADDRESS:	CITY: STATE/PROVINCE:	
POST CODE:	COUNTRY:	PHONE NUMBER:
Email address:		
REPORTER:		
LAST NAME:		
FIRST NAME: MIDDLE INITIAL:		
SIGNATURE: DATE:		

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