PREGNANCY / DRUG EXPOSURE VIA PARENT DATA COLLECTION FORM

Grey fields are for Sanofi use only

1- DATE REPORT RECEIVED		
COMPANY RECEIVED DATE:	☐ Initial ☐ Follow-up	
CASE NUMBER	**PRODUCT RECEIVED / PRODUCT CODE**	**SANOFI / CRO CONTACT**
LOCAL ID: GLOBAL PV ID:		NAME: TELEPHONE:
SOURCE	**STUDY INFORMATION (IF APPLICABLE)**	**WHO RECEIVED MEDICATION?**
SPONTANEOUS/UNSOLICITED ☐ (includes pregnancy registry) STUDY/SOLICITED (includes PSP/MRP ☐	STUDY ID / REGISTRY ID: CENTER ID: PATIENT ID: TREATMENT ID:	☐ MOTHER ☐ FATHER INITIALS _____ INITIALS _____ (FIRST, MIDDLE, LAST) (FIRST, MIDDLE, LAST) Initials not to be collected for case report from clinical studies

2- REPORTER INFORMATION		
NAME (first/last):	STREET:	
OCCUPATION: ☐ CONSUMER ☐ STUDY INVESTIGATOR ☐ LAWYER ☐ MEDICAL DOCTOR ☐ PHARMACIST ☐ OTHER HCP (HEALTHCARE PROFESSIONAL) ☐ OTHER	CITY/STATE/PROVINCE:	
PHONE:	POSTAL CODE:	COUNTRY:
DOES MOTHER AGREE TO PROVIDE INFORMATION? YES ☐ NO ☐ DOES FATHER AGREE TO PROVIDE INFORMATION? YES ☐ NO ☐		

3 - PARENT INFORMATION AT THE TIME OF THE PREGNANCY

	AGE/ BIRTH DATE For clinical study, Year of birth to be collected only	RH (RHESUS) FACTOR	HT / UNIT	WT / UNIT	SIGNIFICANT MEDICAL CONDITIONS*
MOTHER					SMOKING HISTORY: _____ CIGARETTES PER DAY** ALCOHOL: _____ DRINKS PER DAY SUBSTANCE ABUSE: (specify) _____ HYPERTENSION: ☐ NO ☐ YES ☐ UNK DIABETES: ☐ NO ☐ YES ☐ UNK EPILEPSY: ☐ NO ☐ YES ☐ UNK IF YES, SPECIFY THE TYPE: …. PSYCHIATRIC ILLNESS: ☐ NO ☐ YES IF YES, SPECIFY: …
					SEROLOGY: HIV: ☐ NO ☐ YES ☐ UNK HEPATITIS: ☐ NO ☐ YES ☐ UNK
					OTHER HISTORY (including thyroid disorders, asthma, allergic disease, heart disease, sexual transmitted disorder, education level, learning difficulties, congenital malformations, environmental exposures):
FATHER					SMOKING HISTORY: _____ CIGARETTES PER DAY ALCOHOL: _____ DRINKS PER DAY SUBSTANCE ABUSE: (specify): _____ HYPERTENSION: ☐ NO ☐ YES☐ UNK DIABETES: ☐ NO ☐ YES☐ UNK EPILEPSY: ☐ NO ☐ YES ☐ UNK PSYCHIATRIC ILLNESS: ☐ N☐ YES ☐ UNK
					SEROLOGY: HIV: ☐ NO ☐ YES ☐ UNK HEPATITIS: ☐ NO ☐ YES ☐ UNK

3 - PARENT INFORMATION AT THE TIME OF THE PREGNANCY

	OTHER HISTORY (including thyroid disorders, asthma, allergic disease, heart disease, sexual transmitted disorder, education level, learning difficulties, congenital malformations, environmental exposures):

*Include information on race, ethnicity, consanguinity or occupation if you consider it would contribute significantly to the investigation and evaluation of certain adverse findings in the pregnancy or its outcome or on the health of the fetus/child; per local privacy law.

**Mention if mother quit smoking or materially reduced her usage before or during pregnancy and when.

4 – SPECIFIC TO THE PREGNANCY PREVENTION PROGRAMME, IF APPLICABLE (e.g. valproate…)

WAS THERE A NEGATIVE PREGNANCY TEST AT TREATMENT INITIATION? ☐ NO ☐ YES ☐ UNK. ☐ NA*

WAS THE PATIENT GUIDE RECEIVED? ☐ NO ☐ YES ☐ UNK. ☐ NA*

WAS THE PATIENT CARD RECEIVED? ☐ NO ☐ YES ☐ UNK. ☐ NA*

WAS AN ANNUAL REVIEW COMPLETED BY A SPECIALIST? ☐ NO ☐ YES ☐ UNK ☐ NA*

WAS THE ANNUAL RISK ACKNOWLEDGMENT FORM SIGNED? ☐ NO ☐ YES ☐ UNK. ☐ NA*

*Not applicable

5- IMMUNIZATION / GYNECOLOGY

MATERNAL IMMUNIZATION				GYNECOLOGICAL DETAILS			
RUBELLA:	☐ NO	☐ YES	☐ UNK	WERE CONTRACEPTIVE METHODS USED:	☐ NO	☐ YES	☐ UNK
TOXOPLASMOSIS:	☐ NO	☐ YES	☐ UNK	IF YES, SPECIFY: CONTRACEPTION TYPE:	☐ ORAL	☐ LOCAL	☐ IUCD
CMV:	☐ NO	☐ YES	☐ UNK	:			
				CONTRACEPTION NAME:_____			
				CONTRACEPTION DOSE:_____			
				CONTRACEPTION START AND STOP DATES:_____			
				DETAILS OF POSSIBLE CAUSE TO CONTRACEPTION FAILURE:			

5- IMMUNIZATION / GYNECOLOGY

	NON COMPLIANCE WITH PRIMARY METHOD (E.G HORMONAL/IUD ☐ NO ☐ YES ☐ UNK NON COMPLIANCE WITH BARRIER METHOD ☐ NO ☐ YES ☐ UNK OTHER (EG., DRUG DRUG INTERACTION, EPISODE OF GI DISORDER, …) ☐ NO ☐ YES ☐ UNK NORMAL MENSTRUAL CYCLES ☐ NO ☐ YES ☐ UNK INFERTILITY ☐ NO ☐ YES ☐ UNK IF TREATMENT SPECIFY:

6- PREGNANCY INFORMATION

DATE OF LAST MENSTRUAL PERIOD (LMP) LMP:_____ - _____ - _____ (DD-MMM-YY)	DATE OF POSITIVE PREGNANCY TEST (IF ANY) _____ - _____ - _____ (DD-MMM-YY)
ESTIMATED DATE OF DELIVERY (EDD) EDD:_____ - _____ - _____ (DD-MMM-YY)	DATE OF PREVIOUS NEGATIVE PREGNANCY TEST (IF ANY) _____ - _____ - _____ (DD-MMM-YY)
MEDICAL ASSISTANCE / HOSPITALIZATION DURING PREGNANCY? ☐ NO ☐ YES DETAILS: _____	MULTIPLE FETUSES/CHILDREN? ☐ NO ☐ YES

IS THE OUTCOME OF CURRENT PREGNANCY KNOWN AT THE TIME OF THIS REPORT? ☐ NO ☐ YES

OBSTETRICAL HISTORY	**NUMBER/ YEAR/COMMENTS**
PREVIOUS PREGNANCIES (if ectopic or molar pregnancy or other complication, please specify):	
LIVE BIRTHS, WITHOUT CONGENITAL ANOMALIES/ MALFORMATIONS/NEURODEVELOPMENTAL DISORDERS/AUTISM SPECTRUM DISORDERS (ASD)	
LIVE BIRTHS, WITH CONGENITAL ANOMALIES/ MALFORMATIONS/NEURODEVELOPMENTAL DISORDERS/AUTISM SPECTRUM DISORDERS (specify type of congenital anomalies/developmental disorders/ASD):	

6- PREGNANCY INFORMATION

SPONTANEOUS ABORTIONS PRIOR TO 20 WEEKS GESTATION (specify gestational age):	
ELECTIVE TERMINATION (FETAL DEFECTS) (specify gestational age):	
ELECTIVE TERMINATION (NO FETAL DEFECTS OR UNKNOWN) (specify gestational age):	
FETAL DEATHS (>20 WEEKS GESTATION) (specify gestational age, cause(s)/Post Mortem findings):	

MATERNAL/PATERNAL/RELATIVES (including grand-parents) **HISTORY**:

CONGENITAL MALFORMATION	☐ NO	☐ YES, SPECIFY RELATION/DETAILS: _____
CHILDREN DYING YOUNG	☐ NO	☐ YES, SPECIFY RELATION/DETAILS: _____
CHROMOSOMAL ABNORMALITY	☐ NO	☐ YES, SPECIFY RELATION/DETAILS: _____
DEVELOPMENTAL DELAY	☐ NO	☐ YES, SPECIFY RELATION/DETAILS: _____
HEREDITARY DISEASE	☐ NO	☐ YES, SPECIFY RELATION/DETAILS: _____
PERTINENT GYNECOLOGIC INFORMATION	☐ NO	☐ YES, SPECIFY RELATION / DETAILS: _____
CONSANGUINITY BETWEEN PARENTS	☐ NO	☐ YES, SPECIFY RELATION / DETAILS: _____
OTHER	☐ NO	☐ YES, SPECIFY: _____

7- ADVERSE EVENT (OTHER THAN ABNORMAL PREGNANCY OUTCOMES) INVOLVED DURING THE PREGNANCY ?

☐ NO ☐ YES (please complete corresponding AE form(s))

THE AE OCCURRED IN THE ☐ MOTHER ☐ CHILD	GLOBAL PV DATABASE NUMBER FOR CHILD REPORT # _____

DESCRIBE ADVERSE EVENT(S):

8- MEDICATIONS: (include prescription & OTC medicines and pregnancy/food supplements e.g. folic acid and other vitamins, iron)

PRODUCTS* (LIST SANOFI-DRUG(S) FIRST)	CAUSAL RELATION-SHIP (YES/NO)	FETAL / NEONATAL EXPOSURE **	INDICATION	DOSE/ SCHEDULE/DOSE NUMBER	ROUTE	START DATE+ (DD-MMM-YY)	STOP DATE+ (DD-MMM-YY)	DURATION (DAYS)	BATCH NUMBER (MANDATORY. IF NOT AVAILABLE, ENTER NA/ IF NOT OBTAINABLE AT ALL ENTER NO)	SITE OF ADMIN	SIDE OF ADMIN

*If any medications were possibly involved in the occurrence of the reported disorder; specify action taken & outcome **Fetal Exposure: Select All the Numbers (below) that apply for Fetal Exposure

+Stop And Start Dates: If exact dates are unavailable, provide gestation weeks of exposure or trimesters of exposure.

1. PRIOR TO OR AT TIME OF CONCEPTION
2. DURING PREGNANCY
3. LABOR AND DELIVERY
4. BREAST FEEDING

9- ADDITIONAL MEDICAL DATA

COMMENTS REGARDING MATERNAL HEALTH OR COMPLICATIONS DURING PREGNANCY,

10- PRENATAL TESTING

Specify below or check if none ☐

EXAMINATION	DATE (DD-MMM-YY)	NORMAL ✓	ABNORMAL ✓	SPECIFY ABNORMALITIES
AMNIOCENTESIS				
ALPHA FETAL PROTEIN (AND OTHER SERUM MARKERS)				
CHORIONIC VILLI SAMPLING				
FETAL STRESS TEST				
UTERINE ULTRASOUND (please describe)				
GENETIC SCREENING (specify:_____)				
OTHER (specify:_____)				

11- PREGNANCY OUTCOME

CHILDREN/FETUSES: ☐ SINGLE ☐ MULTI (#_____)

CHILD/ FETUS/	SEX	DATE OF DELIVERY, ABORTION, TERMINATION OR FETAL DEATH (DD-MMM-YY)	APGAR SCORE		DELIVERY MODE (✓)		WEEK OF GESTATION	BIRTH WEIGHT & LENGTH	HEAD CIRCUM (CMS)	*OUTCOME	CONGENITAL ANOMALY		NEONATE DEATH (age at death, specify cause)
			1 MIN	5 MIN	VAG	C-SECT					YES**	NO	
								g cm					
								g cm					
								g cm					

11- PREGNANCY OUTCOME

1.	* OUTCOME: ENTER THE NUMBER APPROPRIATE TO THE PREGNANCY OUTCOME (ENTER ALL THAT APPLY) 2. LIVE BIRTH (NORMAL) 3. LIVE BIRTH (ABNORMAL)** 4. SPONTANEOUS ABORTION (<20 WEEKS GESTATION) 5. EARLY FETAL DEATH (20-27 WEEKS GESTATION) 6. LATE FETAL DEATH (AT LEAST 28 WEEKS GESTATION) 7. ELECTIVE TERMINATION 8. STILLBIRTH 9. MATERNAL DEATH (IF RESULTING IN FETAL DEATH, ADD APPROPRIATE NUMBER) 10. ECTOPIC PREGNANCY 11. LIVE BIRTH (NORMAL) – DEVELOPMENTAL DISORDERS**
	OF NOTE, CONGENITAL ANOMALIES INCLUDE MALFORMATIONS AND ABNORMAL FUNCTIONS EITHER BEING OBSERVABLE AT BIRTH OR LATER DURING THE CHILD DEVELOPMENT. IF PREGNANCY OUTCOME INVOLVES CONGENITAL ANOMALY **AT BIRTH OR DEVELOPMENTAL DISORDERS, SPECIFY (SEE SECTION 12 FOR NEURO DEVELOPMENT DISORDERS):
	IN CASE OF ABORTION, STILLBIRTHS, FETAL DEATH OR MATERNAL DEATH, WAS AN AUTOPSY PERFORMED? ☐ NO ☐ YES ☐ UNK IF YES, PROVIDE RESULTS FOR EACH WHERE APPLICABLE:
	LABOR/DELIVERY: MODE OF DELIVERY: ANY COMPLICATIONS OF LABOR AND/OR DELIVERY ☐ NO ☐ YES, SPECIFY:
	MEDICATION DURING LABOR ☐ NO ☐ YES, SPECIFY:
	CLEAR AMNIOTIC FLUID ☐ NO ☐ YES NORMAL PLACENTA ☐ NO ☐ YES

11- PREGNANCY OUTCOME

ADDITIONAL INFORMATION ABOUT THE NEWBORN CONDITION:

BREAST FEEDING ☐ NO ☐ YES

NEONATAL ILLNESS ☐ NO ☐ YES, SPECIFY: _____

NEED FOR RESUSCITATION ☐ NO ☐ YES INTRAUTERINE GROWTH RESTRICTION OR IMMATURITY ☐ NO ☐ YES, SPECIFY:

CORRECTIVE TREATMENT RECEIVED BY NEWBORN ☐ NO ☐ YES, SPECIFY: _____

INTENSIVE CARE ☐ NO ☐ YES

TRANSFERRED TO INTENSIVE CARE UNIT OR PEDIATRIC DEPARTMENT ☐ NO ☐ YES DURATION: ___

ADDRESS OF DEPARTMENT _____

INFANT TO BE FOLLOWED UP BY (DOCTOR'S NAME AND ADDRESS)

12- PEDIATRIC ASSESSMENT

CHILD #	CHILD AGE AT THE TIME OF ASSESSMENT	MOTOR DEVELOPMENT		NEUROLOGICAL AND BEHAVIOURAL DEVELOPMENT		GROWTH WEIGHT & LENGTH*	OTHER TYPE OF CONGENITAL ANOMALY*		IF * SPECIFY .
		NORMAL	DELAYED*	NORMAL	DELAYED*		YES*	NO	
						g cm			
						g cm			
						g cm			

*SPECIFY **MEDICAL EVENTS THAT LED TO MEDICAL OFFICE/ER VISIT OR HOSPITALIZATION** OR CONGENITAL ANOMALY **NOT IDENTIFIED AT BIRTH** OR DEVELOPMENTAL DISORDERS/AUTISM SPECTRUM DISORDERS,

PRINTED NAME:_____

SIGNATURE: _____ **DATE:**_____