Case ID: [for GSK internal use]

PREGNANCY OUTCOME FORM - US Vaccines Pregnancy Registry

Section 1 - Maternal data

Initials:

Country:

Age: [ ] Years
[ ] Months
[ ] Days
[ ] Weeks

Weight: [ ] lb [ ] kg **Height:** [ ] inch [ ] cm

Date of birth:

_____
(Day-Month-Year)

Ethnic origin:
[ ] Asian (Not Oriental)
[ ] Black
[ ] Hispanic
[ ] Oriental
[ ] White/Caucasian
[ ] Other (specify):

Date of last menstrual period:

_____
(Day-Month-Year)

Estimated date of delivery:

_____
(Day-Month-Year)

No. of foetuses (e.g. twins):

_____

Was this a normal conception (includes fertility drugs)? ☐ Yes ☐ No

In-vitro fertilization? ☐ Yes ☐ No

If the Pregnancy Initial Notification Form was already completed, please go directly to Section 10

Section 2 - Maternal pre-natal medication/vaccine exposure

Please list all **vaccines received during pregnancy or within 28 days before becoming pregnant.**

Please list all medications (prescription and over-the-counter) received by the **mother within 3 months prior to or during pregnancy** and describe each course of therapy.

Note: For cases of paternal exposure (pregnancy in the partner of a male patient receiving GSK medication/vaccine) please describe details of GSK medication/vaccine and any other relevant information in Section 8 below.

Vaccine (include vaccine dose number if a series) **/**(Generic or Trade Name)	**Batch/Lot No. & Expiry Date**	**Formulation** (e.g. tablet, injection) **& Route** (e.g. oral, IV)	**Total Doses**	**Date Vaccine was given** (Day-Month-Year)	**Gestation Weeks of Exposure** (e.g. wk 28 - wk 32)

Drug (include dose number if a series) /(Generic or Trade Name)	**Batch/Lot No. & Expiry Date**	**Formulation** (e.g. tablet, injection) & **Route** (e.g. oral, IV)	**Total Daily Dose** (e.g. 20mg daily)	**Date Course Began** (Day-Month-Year)	**Date Course Ended** (Day-Month-Year)	**Gestation Weeks of Exposure** (e.g. wk 28 - wk 32)	**Indication for Treatment**

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Section 3 – Maternal adverse event reporting

If the patient experienced an adverse event, **please complete the following and provide a causality assessment for each suspected product** (if not applicable skip to section 6):

Adverse Event 1	**Onset Date** (D-M-Y)	**End Date** (D-M-Y)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			[ ] Fatal [ ] Not Recovered/Not Resolved [ ] Recovering/Resolving [ ] Resolved with Sequelae [ ] Recovered/Resolved [ ] Unknown	[ ] Death? [ ] Life threatening? [ ] Overnight or prolonged hospitalization? [ ] Congenital anomaly? [ ] Severely or permanently disabling? [ ] Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG/VACCINE	**CAUSALITY**			
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable

Adverse Event 2	**Onset Date** (D-M-Y)	**End Date** (D-M-Y)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			[ ] Fatal [ ] Not Recovered/Not Resolved [ ] Recovering/Resolving [ ] Resolved with Sequelae [ ] Recovered/Resolved [ ] Unknown	[ ] Death? [ ] Life threatening? [ ] Overnight or prolonged hospitalization? [ ] Congenital anomaly? [ ] Severely or permanently disabling? [ ] Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG/VACCINE	**CAUSALITY**			
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable

Adverse Event 3	**Onset Date** (D-M-Y)	**End Date** (D-M-Y)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			[ ] Fatal [ ] Not Recovered/Not Resolved [ ] Recovering/Resolving [ ] Resolved with Sequelae [ ] Recovered/Resolved [ ] Unknown	[ ] Death? [ ] Life threatening? [ ] Overnight or prolonged hospitalization? [ ] Congenital anomaly? [ ] Severely or permanently disabling? [ ] Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG/VACCINE	**CAUSALITY**			
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable
	[ ] Yes	[ ] Almost Certain	[ ] Probable	[ ] Possible
	[ ] Unlikely	[ ] No	[ ] Unknown	[ ] Not Applicable

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Section 4 - If the mother died.

Date of death: Cause(s) of death:

Autopsy performed: [ ] Yes [ ] No [ ] Unknown
(Attach copy of report if available)

Section 5 - Could the events have been associated with any of the following (tick all that apply)

- ☐ Medical History/Concurrent Illness: _____
- ☐ Erroneous Administration: _____
- ☐ Suspected transmission of an infectious agent via a medicinal product: _____
- ☐ Lack of effect _____

Section 6 – Medical history details

Relevant medical history, concurrent illnesses, allergies (including tobacco and alcohol use)

Medical history/concurrent condition/allergy	Onset date (Day-Month-Year)	Outcome date	Continuing? (Y/N)	Notes

Additional medical history text – please include any additional relevant medical history information

Section 7 – Diagnostic details

Relevant laboratory data, investigations and procedures (including scans, X-rays, biopsy etc)

Test Name	Test date (Day-Month-Year)	Test Result	Test units	Low Norm	High Norm	Notes

Additional diagnostic text – please include any additional relevant diagnostic information.

Section 8 - MATERNAL relevant medical/family history

Please provide number of **previous pregnancies** in categories below and any additional details in space for text:

Full-term: No. and Details

- ☐ Normal birth: _____
- ☐ Still birth: _____
- ☐ Birth defect: _____
- ☐ Outcome unknown: _____

Pre-term: No. and details

- ☐ Spontaneous abortion _____
- ☐ Therapeutic abortion _____
- ☐ Pre-term labor _____
- ☐ Other (please specify) _____

Please describe any additional factors that may have had an impact on the outcome of this pregnancy, including relevant medical or family history, mother's occupation, use of recreational drugs, illnesses during pregnancy etc. Please specify other disorders including familial birth defects/genetic/chromosomal disorders, consanguinity etc.:

☐ Tobacco use ☐ Alcohol use

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Section 9 – Additional details

In the space below, please add any additional complications during pregnancy, any relevant maternal/paternal medical history and any other information you consider relevant that has not been included above. For cases of paternal exposure to GSK medication/vaccine, please specify dates of exposure, formulation, route, daily dose received:

Section 10 – Pregnancy outcome

If multiple births please duplicate Section 11 as necessary to permit separate reporting for each infant

[ ] **Multiple infants:** Number (e.g. twins): _____ Birth order (1st, 2nd, 3rd etc): _____

Delivery date:

(Day-Month-Year)

Gestational age at birth/ miscarriage/termination:

_____ weeks

Outcome
[ ] Ectopic pregnancy (< 22 weeks)
[ ] Elective termination (congenital anomaly present)
[ ] Elective termination (no apparent congenital anomaly)
[ ] Live infant (congenital anomaly present)
[ ] Live Infant (no apparent congenital anomaly)
[ ] Lost to follow up
[ ] Molar pregnancy (< 22 weeks)
[ ] Spontaneous abortion (< 22 weeks, congenital anomaly present)
[ ] Spontaneous abortion (< 22 weeks, no apparent congenital anomaly)
[ ] Stillbirth/late fetal death (> 22 weeks, congenital anomaly present)
[ ] Stillbirth/late fetal death (> 22 weeks, no apparent congenital anomaly)
[ ] Unknown

Method of delivery:

[ ] Normal vaginal [ ] Abnormal Vaginal (e.g. forceps) [ ] Cesarean section

Gender: ☐ Male ☐ Female [ ] **Full-term** (37-42 weeks) [ ] **Pre-term** (< 37 weeks) [ ] **Post-term** (> 42 weeks)

Birth weight: _____ g/Lb **Length:** _____ cm/inches **Head circumference:** _____ cm/inches

APGAR score (0-10) at 1 minute, 5 minutes and 10 minutes: _____/ _____/ _____

***If the outcome of the pregnancy was normal, please skip sections 11, 12, 13 and 14.**

Section 11 - Medications given directly to the neonate in utero or post delivery

Product	Formulation & Route	Batch no. And expiry date	Total daily dose (eg 20mg daily)	Start date/stop date (dd/mm/yyyy)	Indication

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Section 12 – Infant/Foetal adverse events

Provide a causality assessment for each suspect product (including products received directly to baby before or after birth, products received transplacentally and via breastfeeding **)**

Adverse Event 1	**Onset Date** (dd/mm/yyyy)	**End Date** (dd/mm/yyyy)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			☐ Fatal ☐ Not recovered/ Not resolved ☐ Recovered/ Resolved ☐ Recovering/ Resolving ☐ Resolved with sequelae ☐Unknown	☐ Death? ☐ Life threatening? ☐ Overnight or prolonged hospitalization? ☐ Congenital anomaly? ☐ Severely or permanently disabling? ☐ Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG	**ROUTE**	**CAUSALITY**
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown

Adverse Event 2	**Onset Date** (dd/mm/yyyy)	**End Date** (dd/mm/yyyy)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			☐ Fatal ☐ Not recovered/ Not resolved ☐ Recovered/ Resolved ☐ Recovering/ Resolving ☐ Resolved with sequelae ☐Unknown	☐ Death? ☐ Life threatening? ☐ Overnight or prolonged hospitalization? ☐ Congenital anomaly? ☐ Severely or permanently disabling? ☐ Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG	**ROUTE**	**CAUSALITY**
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown

Adverse Event 3	**Onset Date** (dd/mm/yyyy)	**End Date** (dd/mm/yyyy)	**Outcome**	**Did the event result in any of the following?** (tick all that apply)
			☐ Fatal ☐ Not recovered/ Not resolved ☐ Recovered/ Resolved ☐ Recovering/ Resolving ☐ Resolved with sequelae ☐Unknown	☐ Death? ☐ Life threatening? ☐ Overnight or prolonged hospitalization? ☐ Congenital anomaly? ☐ Severely or permanently disabling? ☐ Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?

DRUG	**ROUTE**	**CAUSALITY**
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown

		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown	
		☐ Yes ☐ Almost Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ No ☐ Unknown	

Section 13 - If the INFANT died.

Date of death of neonate/foetus:

Cause(s) of death:_____

Autopsy performed: ☐Yes ☐No ☐Unknown
(Attach copy of report if available)

Section 14 - Additional information for the infant/fetus

If any birth defects (structural/chromosomal disorder) were noted, please describe (please include severity of malformation, surgery planned, conclusions of genetic counseling etc):

Was the defect evident from a prenatal test (e.g. amniocentesis, ultrasound, MS/AFP)? ☐ Yes ☐ No
(If yes please provide details in investigations section below)

Relevant laboratory tests & procedures. (In case of an abnormal evolution or outcome, please send a copy of all relevant laboratory tests and procedures e.g. autopsy results on fetus/neonate):

Test Name	Test Date (dd/mm/yyyy)	Test Result	Test Units	Low Norm	High Norm

Additional details on fetus/infant not included above including details of resuscitation, ICU admission, reason for termination etc. Describe any immediate postnatal problems/neonatal illnesses (e.g. jaundice, respiratory distress). (Please attach copy of examination report/discharge summary if available):

Section 15 - Details of the Health Care Provider or specialist expected to supervise health of the newborn (e.g. Pediatrician)

Reporters Name:		**Fax No.:**
Address:		**Email:**
Country:		**Telephone No.:**

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Section 16 - Reporter information		
Reporters Name:		**Occupation:** (*e.g. Physician, Obstetrician, Nurse etc.)*
Address:		
Country:		
Telephone No.:		
Fax No.:		
Email:		
Reporter's Signature: _____		**Date: _____**

By signing above you acknowledge that the information provided in this form is accurate to the best of your knowledge and that you have any necessary authorization to share this information.

The identity of the patient and all health care reporters will be kept confidential, except to fulfill regulatory reporting obligations.

This form is intended to document the experience of one patient only. If your information relates to more than one patient, please duplicate the form as necessary to permit separate reporting for each patient.

THANK YOU FOR COMPLETING THIS FORM

Please return in the enclosed envelope.