Case ID: [for GSK internal use]

INITIAL NOTIFICATION 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

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**

Section 3 – 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	**Pre-term:**	No. and details
☐ Normal birth:	____________	☐ Spontaneous abortion	____________
☐ Still birth:	____________	☐ Therapeutic abortion	____________
☐ Birth defect:	____________	☐ Pre-term labor	____________
☐ Outcome unknown:	____________	☐ 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 - Details of the Health Care Provider expected to supervise health of the newborn (e.g. Pediatrician)

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

Section 11 - 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.