



## PREGNANCY OUTCOME FORM - US Vaccines Pregnancy Registry

### Section 1 - Maternal data

<b>Initials:</b>		<b>Date of birth:</b>	<b>Date of last menstrual period:</b>
		_____	_____
		(D-M-Y)	(D-M-Y)
<b>Country:</b>		<b>Ethnic origin:</b>	<b>Estimated date of delivery:</b>
		[ ] Asian (Not Oriental)	_____
Age: [ ] Years		[ ] Black	(D-M-Y)
[ ] Months		[ ] Hispanic	
[ ] Days		[ ] Oriental	
[ ] Weeks		[ ] White/Caucasian	
<b>Weight:</b> [ ] lb	<b>Height:</b> [ ] inch	[ ] Other (specify):	<b>No. of fetuses (e.g. twins):</b>
[ ] kg	[ ] cm		_____
<b>Was this a normal conception (includes fertility drugs)?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No			<b>In-vitro fertilization?</b> <input type="checkbox"/> Yes <input type="checkbox"/> 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.

<b>Vaccine</b> (include vaccine dose number if a series) /(Generic or Trade Name)	<b>Batch/Lot No. &amp; Expiry Date</b>	<b>Formulation</b> (e.g. tablet, injection) <b>&amp; Route</b> (e.g. oral, IV)	<b>Total Doses</b>	<b>Date Vaccine was given</b> (D-M-Y)	<b>Gestation Weeks of Exposure</b> (e.g. wk 28 - wk 32)

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

**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)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Resolved with Sequelae <input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG/VACCINE</b>		<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
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)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Resolved with Sequelae <input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG/VACCINE</b>		<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
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)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Resolved with Sequelae <input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG/VACCINE</b>		<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes	<input type="checkbox"/> Almost Certain	<input type="checkbox"/> Probable
		<input type="checkbox"/> Unlikely	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

**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

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**Section 6 – Medical history details**

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

Medical history/concurrent condition/allergy	Onset date (D-M-Y)	Outcome date (D-M-Y)	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 (D-M-Y)	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**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:**

(D-M-Y)

**Gestational age at birth/  
miscarriage/termination:**

\_\_\_\_\_ weeks

### Outcome

- |   |
|---|
| <input type="checkbox"/> Ectopic pregnancy (< 22 weeks)   |
| <input type="checkbox"/> Elective termination (congenital anomaly present)                        |
| <input type="checkbox"/> Elective termination (no apparent congenital anomaly)                    |
| <input type="checkbox"/> Live infant (congenital anomaly present)                                 |
| <input type="checkbox"/> Live Infant (no apparent congenital anomaly)                             |
| <input type="checkbox"/> Lost to follow up  |
| <input type="checkbox"/> Molar pregnancy (< 22 weeks)   |
| <input type="checkbox"/> Spontaneous abortion (< 22 weeks, congenital anomaly present)            |
| <input type="checkbox"/> Spontaneous abortion (< 22 weeks, no apparent congenital anomaly)        |
| <input type="checkbox"/> Stillbirth/late fetal death (> 22 weeks, congenital anomaly present)     |
| <input type="checkbox"/> Stillbirth/late fetal death (> 22 weeks, no apparent congenital anomaly) |
| <input type="checkbox"/> 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 (D-M-Y)	Indication

**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 (D-M-Y)	End Date (D-M-Y)	Outcome	Did the event result in any of the following? (tick all that apply)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not recovered/ Not resolved <input type="checkbox"/> Recovered/ Resolved <input type="checkbox"/> Recovering/ Resolving <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG</b>	<b>ROUTE</b>	<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
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)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not recovered/ Not resolved <input type="checkbox"/> Recovered/ Resolved <input type="checkbox"/> Recovering/ Resolving <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG</b>	<b>ROUTE</b>	<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> Unknown		
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)
			<input type="checkbox"/> Fatal <input type="checkbox"/> Not recovered/ Not resolved <input type="checkbox"/> Recovered/ Resolved <input type="checkbox"/> Recovering/ Resolving <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Unknown	<input type="checkbox"/> Death? <input type="checkbox"/> Life threatening? <input type="checkbox"/> Overnight or prolonged hospitalization? <input type="checkbox"/> Congenital anomaly? <input type="checkbox"/> Severely or permanently disabling? <input type="checkbox"/> Jeopardized the patient or required significant intervention to prevent one of the other criteria listed here?
<b>DRUG</b>	<b>ROUTE</b>	<b>CAUSALITY</b>		
		<input type="checkbox"/> Yes <input type="checkbox"/> Almost Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> No <input type="checkbox"/> 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 (D-M-Y)	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)**

<b>Reporters Name:</b>		<b>Fax No.:</b>	
<b>Address:</b>		<b>Email:</b>	
<b>Country:</b>		<b>Telephone No.:</b>	

**Section 16 - Reporter information**

<b>Reporters Name:</b>		<b>Occupation:</b> (e.g. <i>Physician, Obstetrician, Nurse etc.</i> )
<b>Address:</b>		
<b>Country:</b>		
<b>Telephone No.:</b>		
<b>Fax No.:</b>		
<b>Email:</b>		
<b>Reporter's Signature:</b> _____		<b>Date:</b> _____

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*