



If the patient experienced an adverse event, please complete the following:

Adverse Event	Onset Date/ End Date (dd/mm/yy)	Is the AE a result of a suspected transmission of an infectious agent via a medicinal product?	Outcome			Relationship to GSK Product(s)	
			Resolved Unresolved	Sequelae Worse	Improved Unknown	Related Unrelated	Possible Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown
		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Resolved <input type="checkbox"/> Unresolved	<input type="checkbox"/> Sequelae <input type="checkbox"/> Worse	<input type="checkbox"/> Improved <input type="checkbox"/> Unknown	<input type="checkbox"/> Related <input type="checkbox"/> Unrelated	<input type="checkbox"/> Possible <input type="checkbox"/> Unknown

Do you consider the event(s) to be **SERIOUS**?  Yes  No

If yes, please indicate why the event is considered to be serious (tick all that apply):

Life threatening?       Severely or permanently disabling?       Required or prolonged hospitalization?

Congenital anomaly?       Jeopardised patient or required intervention?       Patient died?

If patient died, what was the cause of death? \_\_\_\_\_ Date of death (dd/mm/yy)? \_\_\_\_\_

#### Section 4 – Additional details

Please include complications during pregnancy, diagnostic results (including prenatal screening tests), any relevant maternal/paternal medical history etc. For cases of paternal exposure to GSK medication/vaccine, please specify dates of exposure, formulation, route, daily dose received:

#### Section 5 - Reporter information

Reporters Name:

Address:

Country:

Telephone No.:

Fax No.:

Title:

(e.g. Dr. Professor, Mr., Mrs., Miss, Ms etc.)

Occupation:

(e.g. Physician, Obstetrician, Nurse etc.)

Relationship to patient:

(e.g. Healthcare provider, Spouse, Relative etc.)

Reporter's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Have you reported this case to a Regulatory Agency?  Yes  No

Agency Reference No. (if known):