PREGNANCY INITIAL NOTIFICATION FORM

GSK Reference No:

GSK Receipt Date:

Section 1 - Maternal data

Initials:

Age: years

Weight: ☐ Kg ☐ lb

Height: ☐ cm ☐ inches

Date of birth:
_____
Day Month Year

Patient I.D. / medical records number:
_____

Ethnic origin:
☐ Black
☐ Hispanic
☐ White
☐ Asian
☐ Oriental
☐ 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 medications (prescription and over-the-counter) and vaccines, taken by the **mother within 3 months prior to or during pregnancy**. Please list GSK medication(s)/vaccine(s) first.

Describe each course of therapy or change in route or dose 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 4 below.

Drug / Vaccine / OTC Name (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** (dd/mm/yy)	**Date Course Ended** (dd/mm/yy)	**Gestation Weeks of Exposure** (e.g. wk 28 - wk 32)	**Indication for Treatment**

Note: Please indicate with an asterix ***** the medication(s)/vaccine(s) that were considered suspect (if applicable)

Section 3 – Adverse event reporting

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)	
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ Unknown
		☐ Yes ☐ No	☐ Resolved ☐ Unresolved	☐ Sequelae ☐ Worse	☐ Improved ☐ Unknown	☐ Related ☐ Unrelated	☐ Possible ☐ 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):