Twinrix Pregnancy Registry Registration Form

Patient ID or initials:	GSK OCEANS Case No.:

Mother's Relevant Medical/Family History

Mother's Date of Birth ☐☐☐ ☐☐ ☐☐ (M M M / DD / YR) or age ☐☐ years

Date of last menstrual period ☐☐☐ ☐☐ ☐☐ (M M M / DD / YR)

Estimated Date of Delivery ☐☐☐ ☐☐ ☐☐ (M M M / DD / YR)

Race ☐ White ☐ Black ☐ Asian ☐ Hispanic ☐ Other or mixed _____

Was the mother using contraception?

☐ Yes, specify _____ ☐ No

Type of conception

☐ Normal ☐ IVF (in vitro fertilization) ☐ Other assisted fertility methods (e.g. drugs)

Is there evidence of a defect from prenatal testing: ☐ Yes ☐ No

Indicate tests performed and date(s) done:

☐ ultrasound _____ ☐ amniocentesis _____

☐ (MS)AFP _____ ☐ other, specify _____

Number of previous pregnancies ☐☐ Pre-term ☐☐ Full-term

If applicable, record numbers in categories below:

Outcomes:

☐☐ Normal births ☐☐ Stillbirths ☐☐ Spontaneous abortion(s) -- <20 weeks gestation

☐☐ Children born with defects ☐☐ Fetal demise (≥20 weeks gestation) ☐☐ Elective abortion(s)

Record details of children born with defects

Describe any maternal history which may have an impact on the outcome of this pregnancy

Father's Relevant Medical/Family History

Describe any paternal history which may have an impact on the outcome of this pregnancy

Drug/Vaccine Exposures

Drug/ Vaccine Name	Route or formulation	Dose	Lot Number/ Expiration Date	Start Date	Stop Date	Ongoing Y/N	Indication
Twinrix	**IM**					☐Y ☐N	
						☐Y ☐N	
						☐Y ☐N	
						☐Y ☐N	
						☐Y ☐N	
						☐Y ☐N	

If the mother 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? ☐ **Jeopardized mother or required intervention?** ☐ **Mother died?** ☐

If mother died, what was the cause of death? ____________________________ **Date of death (dd/mm/yy)?** ______________

REPORTER INFORMATION

Name: _____

Degree: ☐ MD ☐ DO ☐ RN ☐ Other _____

Specialty: _____

Address: _____

City and State: _____ Zip code: _____

Telephone no: | | | | | | | | | | |

Fax no: | | | | | | | | | | |

Reporter's signature: _____ Date: | | | | | | | | |

M M M DD YR

RETURN FORM TO GLAXOSMITHKLINE

Fax: 610-787-7083
Mailing address:
NAVD-BCSP
GlaxoSmithKline
2301 Renaissance Boulevard
Building 510, MC-RN0220
King of Prussia, PA 19406