Cervarix Pregnancy Registry Outcome Form

Patient ID or initials:	GSK OCEANS Case No.:

Pregnancy Status

Date of birth / miscarriage / termination *(circle one)* ☐☐☐ ☐☐ ☐☐

M M M DD YR

OUTCOME

☐ Healthy infant

☐ Spontaneous abortion (< 20 weeks gestation)

☐ Stillbirth/Fetal death (≥ 20 weeks gestation)

☐ Induced abortion

☐ Other, specify _____

Method of delivery:

☐ Spontaneous vaginal

☐ Induced vaginal

☐ Cesarean section

☐ Forceps/suction assisted

☐ Other, specify _____

FETAL/NEONATAL STATUS

☐ Normal

☐ Birth defect (i.e. structural/chromosomal disorder), specify _____

_____

_____

_____

_____

Was the defect evident from a prenatal test (e.g. amniocentesis, ultrasound, MS/AFP)? ☐ Yes ☐ No

Specify _____

_____

_____

_____

_____

INFANT INFORMATION

Gestational weeks at birth / miscarriage / termination ☐☐ weeks

Infant's gender ☐ Male ☐ Female ☐ Unknown

Length ☐☐.☐ cm or ☐☐.☐ inches

Weight ☐☐☐☐ grams or ☐☐ pounds ☐☐ ounces

Apgar score (0 – 10): 1 minute: ☐☐ 5 minutes: ☐☐ 10 minutes: ☐☐

Additional Drug/Vaccine Exposures

Complete drug section for all drugs and vaccines taken by the mother during pregnancy. ***Do not include drugs or vaccines that have already been included on the Pregnancy Notification Form.***

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

Additional details on **fetus/infant** including any adverse events, physical examination, 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):

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

☐ **Life threatening**	☐ **Severely or permanently disabling**	☐ **Required or prolonged hospitalization**
☐ **Jeopardized infant or required intervention**	☐ **Infant died: Cause of death__________________**	**Date of death (dd/mm/yy): _____________**

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

OR

Call 0800 221441
GlaxoSmithKline UK
Stockley Park West, Uxbridge,
Middlesex, UB11 1BT
Telephone: +44 (0)800 221 441
Fax: +44 (0)208 990 4328