Cervarix Pregnancy Registry Registration Form

**Patient ID or initials:**

**GSK OCEANS Case No.:**

**Mother's Relevant Medical/Family History**

Mother's Date of Birth

<table>
<thead>
<tr>
<th>M M M</th>
<th>DD</th>
<th>YR</th>
</tr>
</thead>
</table>

or age  

years

Date of last menstrual period

<table>
<thead>
<tr>
<th>M M M</th>
<th>DD</th>
<th>YR</th>
</tr>
</thead>
</table>

Estimated Date of Delivery

<table>
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<tr>
<th>M M M</th>
<th>DD</th>
<th>YR</th>
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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**

<table>
<thead>
<tr>
<th>Pre-term</th>
<th>Full-term</th>
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</thead>
</table>

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

<table>
<thead>
<tr>
<th>Drug/ Vaccine Name</th>
<th>Route or formulation</th>
<th>Dose</th>
<th>Lot Number/ Expiration Date</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing Y/N</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervarix</td>
<td>IM</td>
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</tbody>
</table>
If the mother experienced an adverse event, please complete the following:

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Onset Date/ End Date (dd/mm/yy)</th>
<th>Is the AE a result of a suspected transmission of an infectious agent via a medicinal product?</th>
<th>Outcome</th>
<th>Relationship to GSK Product(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>☐ Yes ☐ No</td>
<td>☐ Resolved ☐ Unresolved</td>
<td>☐ Sequelae ☐ Worse ☐ Improved ☐ Unknown</td>
</tr>
<tr>
<td></td>
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<td>☐ Yes ☐ No</td>
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<td>☐ Sequelae ☐ Worse ☐ Improved ☐ Unknown</td>
</tr>
</tbody>
</table>

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: ____________________________

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