Boostrix Pregnancy Registry Outcome Form

Patient ID or initials: 
GSK OCEANS Case No.: 

Pregnancy Status

Date of birth / miscarriage / termination (circle one) 

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 _____________________________________________________________________________

____________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

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### 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.*

<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>
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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:

<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>
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<tbody>
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<td>□ Yes  □ No □ Resolved □ Unresolved □ Sequelae □ Worse □ Improved □ Unknown □ Related □ Unrelated □ Possible □ Unknown</td>
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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