

Record of Telephone Conversation - Cervarix, August 26, 2009

- System Info - 103686 SHONE, DEANNA 28-Aug-2009 17:13:57 SHONEDE
RECORD OF TELEPHONE CONVERSATION
Submission Type: Original Application Submission ID: 125259/0 Office: OVRR
Product:
Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant
Applicant:
GlaxoSmithKline Biologicals
Telecon Date/Time: 26-AUG-2009 12:34 PM Initiated by FDA? Yes
Telephone Number:
Communication Category(ies):
Information Request
Author: HELEN GEMIGNANI
Telecon Summary:
Information Request for Results in TVC cohort
FDA Participants:
Non-FDA Participants:
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Gemignani, Helen S
Sent: Wednesday, August 26, 2009 12:34 PM
To: 'Matt.Whitman@gsk.com'
Cc: 'nicholas.perombelon@gsk.com'; 'Cynthia.A.D'Ambrosio@gsk.com'
Subject: Cervarix - Request for Results in TVC cohort

To assist Dr. Miller with her VRBPAC slides, could you please fill in the table below for the TVC cohort (irrespective of baseline PCR and serostatus) or indicate location in BLA or study HPV-008.
HPV-008: Efficacy against incident infection, and persistent infection (6- and 12-months) related to
HPV 16 and/or 18 irrespective of baseline PCR and serostatus (TVC cohort)

	Cervarix		Havrix		Efficacy (96.1% CI)
Endpoint	N	Number of cases	N	Number of cases	
Incident infection					
6-month persistent					

	Cervarix		Havrix		Efficacy (96.1% CI)
infection					
12-month persistent infection					