

**RECORD OF TELEPHONE CONVERSATION**

Submission Type: BLA Submission ID: 125419/0 Office: OVRR

Product:

Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

Applicant:

ID Biomedical Corporation of Quebec (dba GlaxoSmithKline Biologicals)

Telecon Date/Time: 21-Feb-2013 12:08 PM Initiated by FDA? No

Telephone Number: 610-787-3435

Communication Category(ies):

1. Other - GSK informed CBER that dataset in the BLA was not final

Author: CARMEN COLLAZO-CUSTODIO

Telecon Summary:

The Q-Pan-002 WUNSOL dataset submitted with the original BLA (125419/0, submitted Feb 22, 2012) was not the final cleaned dataset.

FDA Participants: Carmen Collazo, Jeremy Wally, Kirk Prutzman

Non-FDA Participants: Michael Schwartz

Telecon Body:

The following was communicated to CBER via e-mail correspondence:

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**From:** Michael Schwartz [michael.p.schwartz@gsk.com]  
**Sent:** Thursday, February 21, 2013 12:07 PM  
**To:** Collazo, Carmen  
**Cc:** Wally, Jeremy; Prutzman, Kirk C; Michael Schwartz  
**Subject:** RE: STN 125419 - please provide the following information

Dear Carmen,

The information being requested is not located in the Clinical Study Reports (CSR) since the contents of the CSRs reflect available diagnoses at the time of database freeze for results reported in the corresponding CSRs, and thus does not reflect updates/changes that occur during the study. However, GSK's system allows for tracking changes to these diagnoses, though not easily, in the Case Report Forms (CRF) and Statistical Analysis System (SAS) files that we previously provided.

**Subject 5677**

On page 49 of the CRF, "Pyoderma Streptococcal" is listed as AE #1, with an onset date of Feb 26, 2008. However, in the audit trail on page 50 (next page) of the CRF "vasculitis" is listed as AE #1, also with an onset date of Feb 26, 2008. Vasculitis appears in the audit trail because the diagnosis was

subsequently changed to Pyoderma Streptococcal based upon new information received from the PI. The same AE number and onset date is further demonstration of the change in diagnosis.

The Q-Pan-002 WUNSOL dataset submitted with the original BLA (125419/0, submitted Feb 22, 2012) was not the final cleaned dataset and thus vasculitis is listed in this dataset. However, if you refer to the Q - Pan - 002 WUNSOL dataset submitted on Nov 6, 2012, which is the final data set, vasculitis is not listed any longer since the AE #1 diagnosis was changed from vasculitis to Streptococcal dermatitis (Pyoderma Streptococcal).

Below is a copy of the clinical data correction form supporting the change of the diagnosis. Per the data correction request, initiated by the Investigator on Aug 20, 2008, the diagnosis of "vasculitis" for subject 5677 was changed to "Pyoderma Streptococcal."

CLINICAL DATA CORRECTION FORM							
e-Track Number	: 110464			Contact	: CHAES RINEHART		
Center Number	: 49692			FAX nbr	: 913-925-4402		
Investigator Name	: DR. CASEY JOHNSON			Printed on	: <i>Casey Johnson</i>		
Subject Number	: 005677			Investigator signature and date	: <i>Casey Johnson</i> 20 Aug 2008		
Visit	Module Name	Field	Old data	Copy attached	New data	Date entered	Processed by
UNSCOLLECTED AE 1	NON-SERIOUS AE	# 1	DESCRIPTION: <sup>CM</sup> VASCULITIS		DESCRIPTION: STREPTOCOCCAL DERMATITIS		
UNSCOLLECTED AE 1	NON-SERIOUS AE	# 1			STOP DATE: 01 JUN 2008		
UNSCOLLECTED AE 1	NON-SERIOUS AE	# 1	OUTCOME: NOT RECOVERED / NOT RESOLVED		OUTCOME: RECOVERED WITH SEQUELAE / RESOLVED WITH SEQUELAE		

SOP-BIO-01-WACB-4595 V02  
CRK SOP Title: SOP-BIO-01-WACB-4595 V02  
Effect: 17 Sep 2007

050072008  
MVM

Database Change Request Form - Version 05 Oct 2007  
Printed on 16/08/2008

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## Subject 1666

On page 145 of the CRF, "LUPUS" is listed in the audit trail as AE #51, with an onset date of Jul 7, 2008. However, in the CRF you will also note that this subject experienced four AEs (AE #1 diarrhea; #53 osteoporosis; #54 hypothyroidism; #71 edema). AE #51 **lupus** was no longer listed as an AE in the clean listings because the diagnosis of lupus was withdrawn (incorrect data entry) by the PI, thus no AE is listed on page 143 (2 pages prior) of the CRF.

Again, the Q-Pan-002 WUNSOL dataset submitted with the original BLA (125419/0, submitted Feb 22, 2012) was not the final cleaned data set and thus Lupus is listed in this dataset. However, if you refer to the Q-Pan-002 WUNSOL dataset submitted on Nov 6, 2012, which is the final dataset, Lupus is not listed since that AE was withdrawn.

Below is a copy of the clinical data correction form supporting that the diagnosis was withdrawn following the documentation of an **incorrect data entry** by the investigator. Per the data correction request, initiated by the investigator on Nov 27, 2008, the event of "Lupus" for Subject 1666 was deleted; the correction request form indicates that this event was entered into the database in error.

CLINICAL DATA CORRECTION FORM						
Visit	Module Name	Field	Old data	Copy attached	New data	For Data Management only
	UNSOLICITED AEs 2	AE	#1 LUPUS DATED STARTED: 07 JUL 2008 INTENSITY: MODERATE NO OUTCOME: NOT RECOVERED/ NOT RESOLVED MEDICAL ATTENDED VISIT: YES TYPE: MEDICAL PERSONNEL		PLEASE DELETE AE #1 LUPUS AND ENTRIES FOR AE #1 DATA ENTERED BY MISTAKE	Date entered: 4 Dec 2008 Processed by: aw
/						

PCRA-823-WRCD-0021-01 v-02  
CRF SOP Reference: SOP-400-WRCD-0001 v-02  
Effective 28 Sep 2007

*PD [Signature]*  
03/12/2008

Database Change Review Form - Version 09 Feb 2007  
Printed on 07/15/2008

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I hope this helps bring the clarification requested by CBER. Please let me know of any further questions. Regards,  
Mike

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**From:** Collazo, Carmen [mailto:Carmen.Collazo@fda.hhs.gov]  
**Sent:** Tuesday, February 19, 2013 2:17 PM  
**To:** Michael Schwartz; Jillian Horvath  
**Cc:** Wally, Jeremy; Prutzman, Kirk C; Collazo, Carmen  
**Subject:** STN 125419 - please provide the following information  
**Importance:** High

Dear Mike,

Reference is made to the response provided in Amendment 25, Module 1.11.2, submitted on February 1, 2013. Regarding subjects 1666 and 5677 from study Q-Pan-H5N1-002, please identify the page numbers in the Day 182 Annex report (or any other report in the BLA submission) where these diagnoses were reconsidered/reclassified. Also, please indicate where the Case Report Forms for these subjects were submitted. Please provide the requested information as soon as possible. Thank you!

*Carmen M. Collazo-Custodio, Ph.D.*

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Research and Review  
Center for Biologics  
Evaluation and Research  
U.S. Food and Drug  
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