

Record of Telephone Conversation, October 15, 2012 - Q-Pan

Submission Type: BLA
Submission ID: 125419/0
Office: OVR
Product:
Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted
Applicant:
ID Biomedical Corporation of Quebec
Telecon Date/Time: 15-Oct-2012 01:57 PM Initiated by FDA? Yes
Telephone Number: michael.p.schwartz@gsk.com; robert.d.brobst@gsk.com
Communication Category(ies):
1. Information Request
Author: KIRK PRUTZMAN
Telecon Summary:
IR for clinical data clarification
FDA Participants: KIRK PRUTZMAN, CARMEN COLLAZO, JEREMY WALLY
Non-FDA Participants: MICHAEL SCHWARTZ, ROBERT BROBST
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Prutzman, Kirk C

Sent: Monday, October 15, 2012 1:57 PM

To: 'Michael Schwartz'; Robert Brobst

Cc: Collazo, Carmen; Wally, Jeremy

Subject: STN 125419 Information Request.

Dear Drs. Schwartz and Brobst,

We have the following requests for additional information regarding STN 125419 (Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted):

1. In the Q-Pan-001 CSR for Day 42, 2 subjects (1744 and 1745) were originally listed as "consent withdrawals" and 1 subject (2222) was "migration from study area". In the Day 182 Q-Pan-001 CSR annex subjects 1744 and 1745 were reclassified as "migration from the study area" and 2222 as "lost to follow-up". Please verify which is the correct reason for withdrawal for each of the subjects and provide an explanation for what occurred between the Day 42 CSR and the Day 182 CSR that lead to different reasons being applied or a reclassification of the reason for each subject withdrawal.
2. The following discrepancies appear in the Q-Pan-002 Day 42 Day 182 CSRs.

- a. In Supplement 4 of the Day 42 CSR the following subjects are listed as withdrawn for the reasons provided in the table below:

Treatment Arm	Subject #	Reason for Withdrawal
Q-Pan	3441	SAE
	1472	LTFU
	1476	LTFU
	1480	LTFU
	1497	LTFU
	1505	LTFU
	3447	AE
	3526	AE
Placebo	1471	LTFU
	3448	AE

- b. SAE=serious adverse event; LTFU = lost to follow-up; AE=adverse event
c. None of these subjects appear in the withdrawal line listings of Supplement 1 of the Day 182 CSR. Please explain.
d. In Supplement 16 of the Day 42 CSR subjects 3521 and 5134 are listed as withdrawn due to an SAE and “too far out of window...”, respectively. In Supplement 5 of the Day 182 CSR these subjects are no longer listed. Please explain.
3. Please provide or indicate where to find narratives, complete with subject identifiers and your adjudication, for all AESIs/pIMDs occurring in Q-Pan-002 through Day 364.
4. Please provide or indicate where to find individual data listings (i.e. datasets) for Q-Pan-002 unsolicited AEs (specifically SAEs and MAEs) collected through Day 364. Please submit your responses in an amendment to the BLA submission. If you have any questions about this communication, please contact Kirk Prutzman, Carmen M. Collazo, or Jeremy Wally.

Regards,

Kirk Prutzman, PhD

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