

Bioresearch Monitoring Summary Memo, October 3, 2012 - Q-Pan

DATE October 3, 2012

FROM Anthony Hawkins, Bioresearch Monitoring, HFM-664

Division of Inspections and Surveillance

Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO Carmen Collazo-Custudio, BLA Committee Chair, HFM-481

Andrea James, Clinical Reviewer, HFM-485

Kirk Prutzman, Co-RPM, HFM-481

Jeremy Wally, Lead RPM, HFM-478

SUBJECT Bioresearch Monitoring Summary

STN: 125419-0

IND: 13413

Product: Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

Sponsor: ID Biomedical Corporation of Quebec

(dba GlaxoSmithKline Biologicals)

SUMMARY

Bioresearch monitoring inspection results from four clinical study sites did not reveal problems that impact the data submitted in the application.

BACKGROUND

The Bioresearch Monitoring Branch issued inspection assignments on April 16, 2012 covering four Protocol 110464 clinical investigators and study sites.

Inspections of Clinical Sites and Outcome

Study site #	Location	Enrolled subjects	Form FDA 483 issued?	Final inspection classification
049675	Edison, NJ	138	No	NAI
049686	Chicago, IL	114	No	NAI
049697	Anaheim, CA	133	No	VAI
049705	Erie, PA	141	No	NAI

NAI = No Action Indicated VAI = Voluntary Action Indicated

STUDY TITLE:

A Phase 3, observer-blind, randomized, placebo controlled multi-center trial to evaluate the safety and immunogenicity of a two-dose series of monovalent A/Indonesia/5/05 (H5N1) vaccine antigen in association with AS03 adjuvant in adults aged ≥18 years
[Protocol 110464 (FLU Q-PAN-002 PRI)]

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when he/she disclosed information about his/her financial

interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children including if and when the information was updated. Each inspected study site had a copy of the financial disclosure forms on hand for clinical investigators and sub-investigators.

SPONSOR ISSUES

No sponsor or monitoring issues were noted.

INSPECTIONAL FINDINGS

The FDA investigators noted a few minor problems during the inspections.

Study Records:

The clinical study site had no documentation showing a contractual agreement between itself and the clinical investigator, and inadequate documentation showing prohibited medication use by various subjects. (Edison, NJ)

The clinical investigator had incomplete or missing documentation concerning vaccine administration, informed consent prior to study drug administration to subjects, blood sample preparation steps, and also delayed SAE reporting for one subject. (Erie, PA)

The FDA investigator observed subject number discrepancies between study documents used to report one subject's SAEs and another subject's death to the IRB and the sponsor. (Anaheim, CA)

Study Protocol Adherence, Clinical Investigator Responsibilities:

The FDA investigator observed several instances during the inspection whereby study staff left a storage room containing clinical study records unlocked and opened. Study staff signed the Principal Unblinded Study Staff document which outlined their responsibilities approximately seven months after initiation of the study. (Edison, NJ)

The clinical investigator did not follow the protocol including one subject's missed pregnancy testing; a wrong second dose of study drug was given to one subject; a subject received both doses of study drug in the same arm; one subject had enrolled in another clinical study; and 30 minute post-vaccination observations were missed for three subjects. The site already investigated these items and implemented changes prior to the FDA inspection. (Chicago, IL)

BIMO ADMINISTRATIVE FOLLOW-UP

We issued information letters to each of the clinical investigators. Please contact me at (301) 827-6338 if you have any questions about this memo or any aspect of bioresearch monitoring.

Anthony Hawkins
Consumer Safety Officer