

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE August 10, 2016

FROM Colonious King, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 240-402-8759 Fax: 301-595-1304

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch

THROUGH Gilliam Conley, Director, Division of Inspections and Surveillance

TO Jennifer Reed Chair, Review Committee
Thomas Maruna RPM
Emily Storch Clinical Reviewer

SUBJECT Bioresearch Monitoring Discipline Review Memo
BLA/STN: 125596/0
IND: 14505
Sponsor: Baxalta US Inc.
Product: Immune Globulin Subcutaneous (Human), 20% Solution

FINAL SUMMARY STATEMENT:

The Bioresearch Monitoring (BIMO) inspections of clinical investigators in support of this Biologics Licensing Application (BLA) did not reveal substantive problems that would impact the data submitted in the application.

BACKGROUND

Two clinical investigators were inspected in support of the BLA and the inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignment included specific questions related to the study protocols and verification of the study data on safety and efficacy endpoints submitted by the sponsor in the BLA. The completed inspections conducted at two clinical sites for data verification represented 27% of all the subjects studied for this new BLA application. The data audit portion of the inspection focused on the verification of the study data on safety and efficacy endpoints submitted by the sponsor in the BLA for 100% of the enrollees at site 06 and site 17.

PROTOCOL AUDITED

A clinical study of immune globulin subcutaneous (Human), 20% solution (IGSC, 20%) for the evaluation of efficacy, safety, tolerability and pharmacokinetics in subjects with primary immunodeficiency diseases. (Protocol 170904)

The table below summarizes the inspection results:

Site Number	Study Site	Location	Enrolled Subjects	483 Issued	Classification
06	Allergy, Asthma & Immunology Clinic P.A.	Irving, Texas	12	No	NAI
17	Vital Prospects Clinical Research Institute, P.C.	Tulsa, Oklahoma	9	No	NAI

NAI = No Action Indicated

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when s/he disclosed information about her/his 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. The inspected study sites had a copy of the financial disclosure forms on hand for the clinical investigator and sub-investigators.

INSPECTIONAL FINDINGS

Sponsor/Monitor Issues

There were no sponsor/monitor issues identified at the study sites audited.

Clinical Investigator (CI) Study Site Issues

Study Site 06 and 17: A Form FDA 483 was not issued at close of these inspections and the inspections were classified as No Action Indicated (NAI). A review was conducted of testing records, regulatory binders, study specific standard operating procedures, and general study conduct. In addition, source documents were reviewed and the information was compared to the data tables submitted by the sponsor in the application. No discrepancy was found between source documents at the site and the data submitted by the sponsor in the application.

BIMO ADMINISTRATIVE FOLLOW-UP

Information letters will be issued for the study sites inspected.

Please contact me should you have any questions about this memo or any aspect of Bioresearch Monitoring.

Colonious King
Consumer Safety Officer

Distribution

Electronic Copy

EDR	STN 125596/0
Jennifer Reed	Chair
Thomas Maruna	RPM
Emily Storch	Clinical Reviewer
Camille Brown	FDA Investigator
Travis Beard	FDA Investigator

Draft: King: August 9, 2016

Reviewed: Drabick: August 10, 2016