



DATE: April 16, 2019

FROM: Haecin Chun, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH: Dennis Cato, Branch Chief, Bioresearch Monitoring Branch

THROUGH: Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance

TO: Jennifer Reed, PhD, Chair
Deborah Belsky, MD, MPH, Clinical Reviewer
Alicia Candido, PhD, RPM
Patrick Riggins, PhD, RPM

SUBJECT: Bioresearch Monitoring Final Review Memo
SPONSOR: Grifols Therapeutics, LLC
PRODUCT: Immune Globulin Subcutaneous (Human), 20% Solution
BLA: STN 125683/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring inspections of four clinical investigators did not reveal substantive issues that impact the data submitted in this application.

BACKGROUND

Four Bioresearch Monitoring (BIMO) clinical investigator inspection assignments were issued in support of this Biologics License Application (BLA). The clinical sites were selected based on subject enrollment, previous inspectional history and information and data submitted in the application. The members in this BLA review committee concurred with the selected study sites.

Protocol GTI1502 entitled, “*An open-label, multi-center study to evaluate the safety and pharmacokinetics of IGSC 20% administered for 6 months in subjects with primary immunodeficiency,*” was a phase III clinical study that involved a total of 61 adult and pediatric subjects. The study was conducted at 18 sites in the United States and three (3) sites in Canada. The four domestic sites selected for BIMO inspection represented approximately 38% (23) of the study subjects.

The inspections were conducted in accordance with FDA’s Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators, and the inspection assignment included specific questions concerning the clinical study. In addition, information submitted in the BLA was compared to source documents at each selected study site.

BIMO INSPECTION

The table below summarizes the site information and the outcome of the BIMO inspections conducted for Protocol GTI1502:

Site #	Study Site Name and Location	Form FDA 483 Issued?	Final Classification
105	Duke University Medical Center Durham, NC	No	No Action Indicated
114	Oklahoma Institute of Allergy and Asthma Clinical Research, LLC Oklahoma City, OK	No	No Action Indicated
116	Washington University School of Medicine St. Louis, MO	No	No Action Indicated
119	The South Bend Clinic, LLP South Bend, IN	No	No Action Indicated

INSPECTIONAL FINDINGS

No significant inspectional findings were identified.

SPONSOR/MONITORING ISSUES

No sponsor or monitoring issues were identified during the clinical study site inspections.

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, and if and when the information was updated. The information submitted to the BLA was verified for each of the inspected clinical sites.

ADMINISTRATIVE FOLLOW-UP:

Information letters were issued to the clinical investigators at all inspected study sites.

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at (240) 402-8038.

Haecin Chun
Consumer Safety Officer

Distribution

Electronic Copy:

EDR BLA 125683/0

Jennifer Reed, Chair, STN 125683/0

Deborah Belsky, Clinical Reviewer

Patrick Riggins, RPM

Alicea Candido, RPM

Carrie Mampilly

Dennis Cato

Bhanu Kannon

Chron

Cberbimonotification@fda.hhs.gov

ORA BIMOE Correspondence

ORA BIMOW Correspondence

Eileen J. Bannerman, FDA Investigator

Corrine M. Carter, FDA Investigator

Johann M. Fitch, FDA Investigator

Karen Montgomery, FDA Investigator

History:

Draft: Chun: 3/28/19

Review: Cato: 4/15/19