



Memorandum

DATE: September 13, 2017

TO: Caren Chancey, BLA Committee Chair
Julia Lathrop, Clinical Reviewer
Vasanth Kumar, RPM

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

THROUGH: Dennis Cato, Branch Chief, Bioresearch Monitoring

Carrie Mampilly, Director, Division of Inspections and Surveillance

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo
BLA: STN 125653/0
PRODUCT: cobas® Zika test
SPONSOR: Roche Molecular Systems, Inc

REVIEW SUMMARY

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

BACKGROUND

Protocol cX8-ZIKA-412, *A Prospective Study to Evaluate the Specificity of the cobas® Zika Test for use on the cobas® 6800/8800 System for Screening of Blood Donations for the Presence of Zika Virus RNAB10241* was designed to evaluate the clinical specificity of the cobas Zika test for donor plasma samples.

The Bioresearch Monitoring Branch member and the review committee selected three clinical investigators to evaluate their conduct of Protocol cX8-ZIKA-412. The clinical sites selected had no previous history of CBER BIMO inspection.

The BIMO inspections were conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators.

Information submitted in the BLA was compared to source documents at each clinical site. The inspection assignments also included specific questions concerning the clinical study.

Protocol cX8-ZIKA-412 was conducted at five study sites in the United States. A total of 358,266 donations were collected in U.S. from donors enrolled in the study, of which the data from 358,038 donations were evaluable for the study. The three sites selected for BIMO inspections represented approximately 17% of the total donations.

INSPECTION SITES and FINDINGS

No significant inspectional findings were noted. The following table summarizes BIMO inspections conducted at three domestic study sites for Protocol cX8-ZIKA-412:

| Site ID | Site Location | Form FDA 483 Issued | Final Classification |
|---------|---------------|---------------------|----------------------|
| 3 (QTX) | Norcross, GA | No | No Action Indicated |
| 4 (BLC) | Piedmont, SC | No | No Action Indicated |
| 5 (BCT) | Hammond, LA | No | No Action Indicated |

SPONSOR ISSUE

No significant sponsor issues were noted at the inspected sites. However, BIMO noted in the original BLA submission that the sponsor provided copies of the “Conflict of Interest Disclosure Form for Investigative Sites” completed for the Institution Review Board (IRB) for each clinical investigator conducting study Protocol cX8-ZIKA-412. This issue was discussed with the review committee. BIMO was not able to locate the FDA financial disclosure forms, Form FDA 3454 and/or 3455, with authorized signature in the BLA. Additional discussion about the financial disclosure information is found in the next section of this memo.

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program (CPGM 7348.811) directs the FDA investigator to ask the clinical investigator if and when she/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 FDA investigators reported that financial disclosure information was present at each inspected study site. However, the FDA investigator who inspected Site# 5 reported in the establishment inspection report that the clinical investigator did not complete a financial disclosure form for the Sponsor and only completed the “Conflict of Interest Disclosure Form for Investigative Sites” from the IRB.

ADMINISTRATIVE FOLLOW-UP

Information letters were issued to the three clinical investigators who were inspected to support this BLA.

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

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Caren Chancey, Chair, STN 125653/0
Julia Lathrop, Clinical Reviewer
Vasantha Kumar, RPM
Carrie Mampilly
Dennis Cato
Colonious King
CBERBIMONOTIFICATION@fda.hhs.gov
[ORAHQ BIMO Inspection POC](#)
Division of Bioresearch Monitoring Operations East (BIMOE)
Tracy R. Ball, FDA Investigator
Dana Daigle, FDA Investigator
William Tonkins, FDA Investigator

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