



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE July 24, 2024

FROM Triet M. Tran, PharmD, BCSCP, Regulatory Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)
Telephone: 240-425-3201

THROUGH Dennis T. Cato, Associate Director for Bioresearch Monitoring (BIMO)

THROUGH Carrie M. Mampilly, MPH, Director DIS

TO Jin Sung Hong, PhD, Chair, STN 125812.0
Prateek Shukla, MD, Clinical Reviewer
Helen Sansone, RPM

SUBJECT Bioresearch Monitoring Final Review Memo
SPONSOR Humacyte Global, Inc.
PRODUCT SYMVESS (Human Acellular Vessel (HAV))
BLA STN 125812.0

FINAL SUMMARY STATEMENT

BIMO inspections were issued for the sponsor and three domestic clinical investigator (CI) sites participating in the conduct of study Protocol CLN-PRO-V005. The inspections did not reveal significant problems impacting the data submitted in support of this Biologics License Application (BLA).

Background

BIMO inspection assignments were issued for the sponsor and three domestic CI sites that participated in the conduct of study Protocol CLN-PRO-V005. The BLA review committee concurred with the sites selected for inspection. The inspection assignments were issued for the following study protocol:

Protocol CLN-PRO-V005 - *A Phase 2/3 Study for the Evaluation of Safety and Efficacy of Humacyte's Human Acellular Vessel for Vascular Replacement or Reconstruction in Patients with Life or Limb-threatening Vascular Trauma*

BIMO CI inspections are conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for CI. BIMO sponsor inspections are conducted in accordance with CP 7348.810. The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The inspection assignment included specific questions concerning the study protocol, and information submitted in the BLA was compared to source documents at the site. Study CLN-PRO-V005 was conducted globally at 20 sites, enrolling a total of 65 subjects. The three domestic CI sites inspected in support of this BLA covered approximately 42% of the subjects enrolled in study CLN-PRO-V005.

INSPECTION SUMMARY AND FINDINGS

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, protocol deviations, study drug administration, primary efficacy endpoint, and adverse events for all subjects enrolled at the inspected clinical sites. No significant objectionable inspectional findings were observed during the inspection, and no Form FDA 483s were issued. The table below summarizes the BIMO inspections:

Site ID	Number of subjects randomized	Location	483 Issued	Final Inspection Classification
Sponsor	N/A	Humacyte Global, Inc. Durham, NC	No	No Action Indicated (NAI)
02	8	Rishi Kundi, MD, RPVI, FACS, FSVS Baltimore, MD	No	NAI
04	5	Ravi R Rajani , MD Atlanta, GA	No	NAI
06	14	Ernest Moore, MD, FACS, MAMSE, FCCM, MCCM, FACN, FISS Denver, CO	No	NAI

Noteworthy inspectional findings:

The inspections did not reveal substantive issues that impact the data submitted in the BLA.

Sponsor:

No significant sponsor issues were noted.

Clinical Investigator:

No significant objectionable inspectional findings were observed; however, the following issues were discussed during the inspections and shared with the BLA review committee. Both sites 02 and 06 were placed on enrollment hold due to compliance-related issues, requiring corrective actions and replacement of the CIs. The two inspections conducted at these sites reviewed study conduct, data integrity, and compliance with applicable regulations for the duration of the study. The inspections noted that the original CIs at both sites were replaced, and the study continued under the supervision of new CIs. The compliance issues were satisfactorily resolved under the supervision of the new CIs. The enrollment hold was lifted after staff were retrained and the new CIs took control of the study.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigators to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was last updated. The information submitted to the BLA was verified at the inspected sites, and no deviations were found in the submitted data.

ADMINISTRATIVE FOLLOW-UP

No administrative follow-up is warranted at this time. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at 240-425-3201.

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Regulatory Officer

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