



Memorandum

DATE: June 24, 2025

TO: Wen Seeto, BLA Committee Chair, PhD
Ying Geng, Clinical Reviewer, MD, PhD
Mike Singer, Clinical Reviewer, MD, PhD

FROM: Malcolm Nasirah, PharmD, MS, Regulatory Reviewer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality

THROUGH: Kanaeko R. Ravenell, Chief, BMB

THROUGH: Carrie M. Mampilly, MPH, Director, DIS

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo

PRODUCT: Allogeneic Peripheral Nerve Graft

SPONSOR: AxoGen Corporation
BLA STN: 125816/0

REVIEW SUMMARY

BIMO inspection assignments were issued for the sponsor and three clinical study sites that participated in the conduct of study Protocol No. ANG-CP-007/ RECON. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

BACKGROUND

The Sponsor and three domestic clinical study sites, conducting the study Protocol No. ANG-CP-007/RECON were identified for BIMO inspections. The sites were selected for inspection based upon previous BIMO inspection history, enrollment numbers, review committee concern, sponsor-reported adverse events, and protocol deviations.

The inspected sites comprised of approximately 25% of the total subjects randomized into ANG-CP-007/RECON.

The inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for Clinical Investigators (CI) and (CP) 7348.810, Inspection Program for Sponsors, Contract Research Organizations and Monitors. Information submitted www.fda.gov

in the BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical study Protocol No. ANG-CP-007/RECON.

PROTOCOL

Protocol ANG-CP-007: *A Multicenter, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance® Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities (RECON)*

BIMO INSPECTIONS SUMMARY

The below table summarizes site information and outcomes from the BIMO inspections:

Site ID	Firm Name	Location	FDA Form 483 Issued?	Final Inspectional Classification
01	David Bozentka	Philadelphia, PA	No	No Action Indicated (NAI)
02	Jonathan Isaacs	Richmond, VA	Yes	Voluntary Action Indicated (VAI)
12	Gregory Merrell	Indianapolis, IN	No	NAI
Sponsor	Axogen Corporation LLC	Tampa, FL	No	NAI

INSPECTIONAL FINDINGS:

Site 01:

No significant objectionable inspectional findings were observed at this study site and the inspection did not reveal substantive issues that impact the data submitted in the BLA.

Site 02:

Objectionable conditions were observed during the inspection at this study site and a Form FDA 483 was issued at close of the inspection. Specifically:

- Temperature log documentation for the investigational product was not maintained on site for the entire duration of the trial.
- One serious adverse event (SAE) was not reported to the sponsor within the required timeframe outlined in the protocol.

The CI submitted a response to the Form FDA 483 issued with a Corrective Action and Preventative Action (CAPA) plan inclusive of addressing the missing temperature log documentation from an offsite storage facility.

The corrective action plan submitted by the clinical investigator in response to the FDA 483 was reviewed and appear adequate, if successfully implemented.

Site 12:

No significant objectionable inspectional findings were observed at this study site and the inspection did not reveal substantive issues that impact the data submitted in the BLA.

Sponsor:

No significant objectionable inspectional findings were observed at the sponsor inspection and no substantive issues were revealed that impact the data submitted in the BLA.

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the above inspections.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigator 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, spouse(s) and dependent children, as well as if and when the information was last updated.

Financial disclosure inconsistencies were observed for site 02. However, the observations were dated prior to the start of the trial and the financial disclosures were properly accounted for in an Institutional Review Board (IRB) approved Informed Consent Form.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 301-796-6667 or Malcolm.Nasirah@fda.hhs.gov.

Malcolm Nasirah, PharmD
Consumer Safety Officer