



**U.S. FOOD & DRUG**  
ADMINISTRATION

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DATE: July 16, 2025

FROM: Char-Dell K. Edwards BS, MT (ASCP), Consumer Safety Officer (CSO)  
Bioresearch Monitoring Branch (BMB)  
Division of Inspections and Surveillance (DIS)  
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Kanaeko R. Sharp, MS, SBB (ASCP), Branch Chief, BMB

THROUGH: Carrie M. Mampilly, MPH, Director DIS

TO: Sukyoung Sohn, PhD, Committee Chair  
Prateek Shukla, MD, Clinical Reviewer  
Helen Sansone, RPM

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo  
SPONSOR: Precigen Inc.  
PRODUCT: PAPZIMEOS (zopapogene imadenovec (PRGN-2012))  
BLA STN: 125832/0

**REVIEW SUMMARY:**

Bioresearch Monitoring (BIMO) inspection assignments were issued for the sponsor, and one clinical investigator (CI) site that participated in the conduct of study protocol PRGN-2012-201: A Phase 1/2 Study of Adjuvant PRGN-2012 in Adult Participants with Recurrent Respiratory Papillomatosis. The inspections did not reveal substantive issues that impact the data submitted in this original Biologics License Application (BLA).

**BACKGROUND:**

The sponsor and one domestic CI site for protocol PRGN-2012-201 were identified for BIMO inspections. The BLA review committee concurred with the proposed sites. The sites were selected based upon sponsor-reported deaths, adverse events, protocol deviations, number of subjects enrolled, and previous BIMO inspection histories.

The inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for CI and CP 7348.810, Sponsors, Contract Research Organizations and Monitors. Information submitted in the BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical studies.

**PROTOCOL**

PRGN-2012-201: A Phase 1/2 Study of Adjuvant PRGN-2012 in Adult Participants with Recurrent Respiratory Papillomatosis

**BIMO INSPECTIONS SUMMARY:**

No significant BIMO inspectional findings were noted. The below table summarizes site information and outcomes from the BIMO inspections:

<b>Site ID</b>	<b>Firm Name and Location</b>	<b>FDA Form 483 Issued?</b>	<b>Final Inspection Classification</b>
Sponsor	Precigen, Inc. Germantown, Maryland	No	No Action Indicated (NAI)
001	Scott M. Norberg, DO Bethesda, Maryland	No	NAI

**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. The information submitted to the BLA was verified for each of the inspected clinical study sites, no deviations were found in the submitted data.

**ADMINISTRATIVE FOLLOW-UP:**

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact Char-Dell Edwards at 240-402-2859 or [Char-Dell.Edwards@fda.hhs.gov](mailto:Char-Dell.Edwards@fda.hhs.gov).

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Consumer Safety Officer

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