Meeting Minutes

Institution:	Retina Northwest, P.C. - Sylvan
Meeting Date:	April 24, 2026
Meeting Time	11:00 AM Pacific Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Newton, Paul	Yes	Local Unaffiliated Member

Invited Members Not in Attendance:

Member	Voting	Member Type
Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
Brickey, Debra	Yes	Local Unaffiliated Member
Johnson, Amanda	No	Site Contact

Guests:	Larsen, Cynthia (Site Representative)
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 11:01 AM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 9-25-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Patel, Apurva MD
Sponsor:	AbbVie Inc.
Protocol:	M23-415 An Operationally Seamless Phase 2b/3, Multicenter, Randomized, Masked, Sham-controlled Study to Evaluate the Efficacy and Safety of Surabgene Lomparvovec (Suravec) Delivered via Suprachoroidal Space (SCS) Injection Targeting Subjects with Diabetic Retinopathy without Center Involved-Diabetic Macular Edema (CI-DME) (NAAVIGATE)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: M23-415 is a randomized, sham-controlled, masked, Phase IIb/III study sponsored by AbbVie Inc. and designed to assess the safety and efficacy of Surabgene Lomparvovec (sura-vec; ABBV-RGX-314) in participants with diabetic retinopathy without center involved-diabetic macular edema. Sura-vec is a replication-defective, recombinant adenoassociated virus (AAV) expressing a soluble binding fragment specific to Vascular Endothelial Growth Factor (VEGF). The investigational product (IP) is administered by Suprachoroidal Space (SCS) Injection.

Biosafety Containment Level (BSL): The study agent surabgene lomparvovec is based on a Risk Group 1 (RG1) AAV vector that does not contain hazardous transgenes and is not handled or manufactured in the presence of a helper virus, thus biosafety level-1 (BSL-1) is the minimum recommended containment level for handling the study agent. The administration of this agent in a clinical setting further requires compliance with OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Site mentioned that there is another PI that may take over as Principal Investigator. The Site confirmed the proposed PI has participated as an investigator in previous clinical trials including other HGT studies approved by this IBC. The Committee agreed that once approved by Sponsor, this PI Change in Research can be approved administratively.
    - The Site confirmed that the materials of all furniture in the dosing room are easily cleanable surfaces.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:43 AM

Post-Meeting Pre-Approval Note: None