

Meeting Minutes



Institution:	Retinal Consultants of Arizona - North Phoenix		
Meeting Date:	April 30, 2026		
Meeting Time	12:30 PM Arizona 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
	Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Hockley, Sepideh	Yes	Local Unaffiliated Member
	Venable, Rachel	Yes	Local Unaffiliated Member
	Kalies, Celina	No	Site Contact
Invited Members Not in Attendance:	None		
Guests:	Ceballos, Anita (Affiliated, Non-voting)		
Staff:	Parrish, Wendy Payne, Kaylie		

Call to Order: The IBC Chair called the meeting to order at 12:30 PM. 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.

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Review of Prior Business: None

Previous Meeting Minutes: None

New Business:

PI:	Palejwala, Neal
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 Lomparovec (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 Lomparovec (sura-vec; ABBV-RGX-314) in participants with diabetic retinopathy without center involved-diabetic macular edema. Sura-vec is a replication-defective, recombinant adeno-associated virus (AAV) expressing a soluble binding fragment specific to Vascular Endothelial Growth Factor (VEGF). The investigational product (IP) is administered by injection into the suprachoroidal space (SCS) or sham needle-less control injection.

Biosafety Containment Level (BSL): The study agent surabgene lomparovec 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

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- 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 confirmed the carpet squares in the dosing rooms are covered with plastic/non-absorbent mats, and can be replaced as needed. The Committee acknowledged the mitigation strategies by the site and confirmed the ease of carpet square removal is sufficient, but encouraged the Site to utilize non-carpeted areas and consider removing carpet during future renovations when possible. The Committee had no concerns.
 - The Committee discussed the types of biohazardous waste containers available. The Site confirmed the photo of the biohazardous waste collection bag stand on the wall of the dosing room is for non-liquid, non-sharps waste only. It is best practice that waste be placed inside a hard-sided container, and transported inside of a hard-sided container. The Committee encouraged the Site to ensure they follow all requirements for transporting waste, and recommends the Site consider use of a hard-sided waste container for biohazardous waste collection. The Site confirmed they would utilize hard-sided biohazardous waste containers for non-liquid, non-sharps waste, and the containers will be lined with red bags prior to use. The Site Map+Photos document will be administratively revised to update this information.
 - The Site confirmed that the biohazardous waste containers are labeled with a biohazard symbol, and further confirmed the containers will be arranged in a way that ensures the biohazard labeling is visible. The Committee noted that biohazardous waste containers must have appropriate labeling, and encouraged the Site to consider adding additional biohazard stickers to the containers. The Site had no concerns.
 - The Site confirmed the hard-sided waste containers stored for Vendor pickup are sealed by the Vendor before being removed from the Site, and replaced with empty containers. No cardboard boxes are used. The Site Map+Photos document will be administratively revised to include this information.

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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 1:46 PM.

Post-Meeting Pre-Approval Note: None