

## Meeting Minutes

<b>Institution:</b>	Texas Retina Associates - Dallas Main		
<b>Meeting Date:</b>	June 12, 2026		
<b>Meeting Time</b>	10:00 AM Central Time		
<b>Meeting Type:</b>	Virtual Platform Teleconference (Remote) Open to the Public		
<b>Members in Attendance:</b>	<b>Member</b>	<b>Voting</b>	<b>Member Type</b>
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Berg, Rance	Yes	Local Unaffiliated Member
	Scott, Frederick	Yes	Local Unaffiliated Member
	Hughes, Ashley	No	Site Contact
<b>Invited Members Not in Attendance:</b>	<b>Member</b>	<b>Voting</b>	<b>Member Type</b>
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
<b>Guests:</b>	None		
<b>Staff:</b>	Smith, Jennifer; Hemmelgarn, Marian		

**Call to Order:** The IBC Chair called the meeting to order at 9:59 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:** None

**New Business:**

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<b>PI:</b>	Abbey, Ashkan
<b>Sponsor:</b>	AbbVie Inc.
<b>Protocol:</b>	M23-415 An Operationally Seamless Phase 2b/3, Multicenter, Randomized, Masked, Sham-controlled Study to Evaluate the Efficacy and Safety of Surabgene Lomparovec (Sura-vec) Delivered via Suprachoroidal Space (SCS) Injection Targeting Subjects with Diabetic Retinopathy without Center Involved-Diabetic Macular Edema (CI-DME) (NAAVIGATE)
<b>Review Type:</b>	Initial Review
<b>NIH Guidelines Section:</b>	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 suprachoroidal space (SCS) 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 use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

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- 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 Committee stipulated that the Site complete BBP training and send Sabai the training certificate once completed by 7/12/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Site noted that they plan to purchase a new transport container soon and the Committee stipulated that the Site send an updated photo of the container once available by 7/12/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP. The Committee reminded the Site that the transport container should be hard-sided, with a closable lid, and be marked with a biohazard symbol.
    - The Committee discussed the presence of carpeting in the exam rooms and the Site confirmed that the carpet is carpet tiles and should a carpet tile be contaminated with biohazards, the tile would be removed and replaced. The Committee recommended that the Site completely remove carpeting from spaces where study agent/biohazards are handled. If removal is not possible, the Committee recommended plastic coverings be placed over the carpet. The Site Checklist will be administratively updated to change G-II-B-4-a to "No," as there is carpet present.
    - The Committee discussed the process used to remove the needle cap from the syringe. The Site confirmed that the cap is removed in a straight down motion but was unsure of further specifics in that process. The Site indicated that they would follow up to determine the details of the cap removal.
    - The Site confirmed that eye speculums are reusable and are disinfected, then autoclaved after use.
    - The Committee reviewed the Site's biohazardous waste disposal process.
      - Currently, all biohazardous waste is collected in sharps containers. The Committee stipulated that sharps and non-sharps biohazardous waste be segregated, with non-sharps waste (e.g., PPE, contaminated gauze) disposed of

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in dedicated non-sharps biohazard waste containers. These containers should be lidded, foot-pedal operated, lined with red biohazard bags, and clearly labeled with a biohazard symbol. The Committee further stipulated that non-sharps biohazard waste containers be available in any room where study agent handling occurs.

- The Site confirmed that all biohazardous waste is subsequently transferred to cardboard biohazard waste boxes stored in the Clinical Lab for vendor pickup and that these boxes are lined with biohazard bags. The Committee recommended placing the waste boxes in leakproof trays.
- The Committee stipulated that updated photographs of the non-sharps biohazard waste containers in exam rooms be provided and recommended submitting a photograph of the waste box positioned in a leakproof tray to Sabai. All biohazardous waste-related stipulations are expected to be addressed by 7/12/26. The Committee agreed that resolution of these stipulations may be approved following review by the AP.
- The Site confirmed that they have disposable eyewash bottles throughout the facility, but do not have a plumbed eyewash station. The Committee recommended installing a plumbed eyewash if the Site works with any corrosive materials.

**Motion:** A motion of Approval with Stipulations 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:
  - The Committee stipulated that the Site complete BBP training and send Sabai the training certificate once completed by 7/12/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site send an updated photo of the new hard-sided, lidded, biohazard-labeled transport container by 7/12/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that sharps and non-sharps biohazardous waste be segregated, with non-sharps waste (e.g., PPE, contaminated gauze) disposed of in dedicated non-sharps biohazard waste containers. These containers should be lidded, foot-pedal operated, lined with red biohazard bags, and clearly labeled with a biohazard symbol. The Committee further stipulated that non-sharps biohazard waste containers be available in any room where study agent handling occurs, and that updated photographs of the non-sharps biohazard waste containers in exam rooms be provided by 7/12/26. The Committee agreed that resolution of these stipulations may be approved following review by the AP.

**Review of Incidents:** Nothing to report.

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**IBC Training:** Nothing to report.

**Reminder of IBC Approval Requirements.**

**Adjournment:** The IBC Chair adjourned the meeting at 10:44 AM.

**Post-Meeting Pre-Approval Note:** None