Meeting Minutes

Institution:	Maine Eye Center
Meeting Date:	April 08, 2026
Meeting Time	1:30 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Pennoyer, Kelly	Yes	Local Unaffiliated Member
Manter, Heather	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Forrette, Lindsay	Yes	Local Unaffiliated Member

Guests:	Parenteau, Alec Erickson, Lillian
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 1:30 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.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 10-20-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Moore, Jeffrey MD
Sponsor:	AbbVie Inc.
Protocol:	M24-528 A Randomized, Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age-Related Macular Degeneration (nAMD)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: M24-528 is a randomized, partially masked Phase 3b clinical trial sponsored by AbbVie Inc. and designed to assess the injection burden and long-term efficacy of surabgene lomparvovec (ABBV-RGX-314) in adult participants with neovascular age-related macular degeneration (nAMD). Surabgene lomparvovec is a replication-defective adeno-associated viral (AAV) vector expressing a soluble binding fragment against Vascular Endothelial Growth Factor (VEGF). The investigational product (IP) is administered by subretinal injection.

Biosafety Containment Level (BSL): The study agent surabgene lomparvovec consists of a replication-defective AAV vector that does not contain hazardous transgenes and is not handled or manufactured in the presence of a helper virus and so qualifies as a Risk Group 1 (RG1) vector for which Biosafety Level 1 (BSL-1) is the minimum recommended containment level. 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 Committee stipulated that the Site provides a photo of the red biohazard bags used in the biohazardous waste bins.
  - The Committee recommended that the Site add a biohazard symbol to the black waste container if this is used to dispose of biohazardous waste from this study agent in the OR.
  - The Site confirmed that the preparation of study agent is done once the participant has been brought into the OR.
  - The Site confirmed that study staff perform a glove change between study agent preparation and administration. The Facility Details form will be administratively updated to reflect this practice.

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 Site provide a photo of the red biohazard bags used in the biohazardous waste bins to Sabai by 5/7/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

New Business:

PI:	Moore, Jeffrey 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 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 Committee stipulated that the Site provides a photo of the red biohazard bags used in the biohazardous waste bins.
  - The Site confirmed that study staff perform a glove change between study agent preparation and administration. The Facility Details form will be administratively updated to reflect this practice.
  - The Committee discussed the use of a thermal camera during the administration of the study agent. The Site confirmed that the individual who will be filming during the administration will be in the appropriate PPE, as described for the staff administering the agent, while in the administration rooms.

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 Site provide a photo of the red biohazard bags used in the biohazardous waste bins to Sabai by 5/7/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:05 PM

Post-Meeting Pre-Approval Note: After the meeting, the Chair requested that the study agent name on the Biohazard Sign be updated to include "Surabgene lomparvovec (ABBV-RGX-314)".