

Meeting Minutes

Institution:	Southeastern Retina Associates		
Meeting Date:	December 04, 2025		
Meeting Time	1:00 PM Eastern 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
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Schratter, KaSandra	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Murphy, Cheryl	Yes	Local Unaffiliated Member
	Dabney, Michael	Yes	Local Unaffiliated Member
Guests:	Deyhle, Rebekah		
Staff:	Payne, Kaylie		

Call to Order: The IBC Chair called the meeting to order at 1:01 PM. A quorum was present as defined in the Sabai IBC Charter. The Chair noted there was quorum with the current attendance and the review could proceed without local members present. The Chair also noted that the NIH Office of Science Policy considers local member attendance to be a strong recommendation and best practice, but not a requirement. The Committee and Site had no concerns holding the review.

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: Previous meeting minutes from 12-18-24 were reviewed and approved with no changes requested.

New Business:

PI:	Shah, Rohan MD
Sponsor:	AbbVie Inc.
Protocol:	RGX-314-3101 A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: RGX-314-3101 (also known as M23-409) is a Phase 3, multicenter, partially masked, randomized, active-controlled, parallel-arm study sponsored by AbbVie Inc and designed to investigate the efficacy and safety of the study agent ABBV-RGX-314 administered as a single subretinal injection in participants with neovascular age-related macular degeneration (nAMD). ABBV-RGX-314 (also known as RGX-314 and surabgene lomparvovec [sura-vec]) is a recombinant adeno-associated viral vector (rAAV) serotype 8, containing a transgene that encodes for soluble anti-vascular endothelial growth factor (VEGF) antigenbinding fragment (Fab) protein. The investigational product (IP) is administered by subretinal injection.

Biosafety Containment Level (BSL): The study agent ABBV-RXG-314 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

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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 Annual Review Report 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.
 - In response to a question from the Committee, the Site confirmed they believe a piece of sterile gauze is placed into the cup during the drip test. The Committee stipulated the Site to confirm that the drip test will be performed in a manner approved by the institution to mitigate any potential spill or splatter of the study agent during the drip test.
 - The Committee noted that one of the two disinfectants listed does not have a label claim against non-enveloped viruses. The Chair noted this disinfectant would be removed from the approved list. The Committee also noted the other disinfectant lists variable contact times for different non-enveloped viruses and that the norovirus contact time is likely the most applicable to this study agent. The Chair noted that the contact time would be updated in the approved documents. The Site had no concerns limiting use of disinfectants for use on this study agent to the appropriate disinfectant at the appropriate contact time
 - The Committee noted a photo of an eyewash at the dosing area shows a plastic bottle partially placed in front of the eyewash line. The Committee recommended the Site confirm whether this bottle is still present, and if so to arrange the sink countertop in a manner to ensure immediate unobstructed access to the eyewash.
 - In response to a question from the Committee, The Site confirmed that the Surgical Center does keep the biohazard waste boxes closed when not in use. The Site Map & Photos will be annotated to reflect. The Committee had no concerns.

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

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- Stipulations stated by the Committee:
 - The Site to confirm that the drip test will be performed in a manner approved by the institution to mitigate any potential spill or splatter of the study agent during the drip test by 02/03/2025. 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 1:38 PM

Post-Meeting Pre-Approval Note: None