

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, June 13, 2025
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Cumberland Valley Retina Consultants, Hagerstown, MD
Principal Investigator: Allen Hu MD
Protocol: AbbVie, Inc., RGX-314-2202
NCT Number: NCT04567550
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 2, Randomized, Controlled, Dose-escalation Study to Evaluate the Efficacy, Safety, and Tolerability of RGX-314 Gene Therapy Delivered via a Single Suprachoroidal Space (SCS) Injection in Participants With Diabetic Retinopathy (DR) With and Without Center Involved-Diabetic Macular Edema (CI-DME) (ALTITUDE)

1. Call to order:

The Meeting was called to order at 12:00 pm Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for RGX-314, since it consists of an AAV vector administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of RGX-314 locally**, provided that all other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee noted that a study staff member is due to renew their IATA shipping training in 2025 and recommended that they submit their newer Shipping Certification to IBC Services upon retraining.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:11 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 10.0, dated 07-02-2024

Investigator's Brochure, Version 14, dated 03-24-2025

Pharmacy Manual, Version 11.0, dated 03-26-2025

Single Suprachoroidal Administration with IP Dilution (5.0x10¹¹ GC), Version 3.0, dated 05-25-2021

Single Suprachoroidal Administration with IP Dilution (1.0 x10¹² GC), Version 1.0. dated 07-19-2021

Single Suprachoroidal Administration Manual, Version 3.0, dated 11-05-2020

Single Suprachoroidal Administration Manual (1.5x10¹² GC), Version 3.0, dated 02-18-2025

Suprachoroidal Administration Manual, Refrigerated IP Dilution (5.0x10¹¹ GC), Version 1.0, dated 10-25-2021

Suprachoroidal Admin Manual, Refrigerated IP Dilution (1.0x10¹² GC), Version 1.0, dated 07-17-2023

Research Modification Evaluation, Protocol, Version 10.0

Research Modification Evaluation, Investigator's Brochure, Version 14

Research Modification Evaluation, Pharmacy Manual, Version 11.0

Research Modification Evaluation, Pharmacy Manual, Version 10.0

Research Modification Evaluation, Single SCS Admin Man (1.5x10¹² GC), Version 2.0

Research Modification Evaluation, Single SCS Admin Man (1.5x10¹² GC), Version 3.0

Biological Risk Assessment and Summary, updated 04-22-2025

Research Modification Evaluation, Site Location Changes, dated 08-06-2024

Site Map, Cumberland, dated 02-19-2025

Site Inspection Checklist, dated 02-24-2025, updated 05-28-2025

Photos, dated 02-19-2025

Biohazard Sign, All studies, dated 02-24-2025

SOP, Biosafety for RGX-314, dated 07-17-2024

Training, Shipping Certifications, expire 2025-2026

CRRF, dated 03-19-2025

Prior Meeting Minutes, Continuing, dated 06-20-2024