

## Meeting Minutes



<b>Meeting Date:</b>	June 05, 2025, at 10:00 AM Central Time	
<b>Meeting Place:</b>	Teleconference (Remote) Meeting open to the public	
<b>Present:</b>	Hauke, Caitlyn	
	Hoffman, Dusty (joined at 10:08 AM CT)	
	Helm, Allen	
	Rastein, Daniel	
	Rehard, David	
<b>Absent:</b>	Popa, Kyle	
<b>Guests:</b>	Heather McHatton	
<b>Staff:</b>	Jennifer Smith	
<b>Institution:</b>	University of Missouri	

**Call to Order:** The meeting was called to order at 10:03 AM. A quorum was present.

**Conflicts of Interest:** None declared by voting members of the IBC.

**Meeting Minutes:** Previous meeting minutes were reviewed and approved with no requested changes.

### New Business:

<b>PI:</b>	Elkeeb, Ahmed Mohamed, M.D., M.B.A.
<b>Sponsor:</b>	AbbVie Inc.
<b>Protocol:</b>	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)
<b>Review Type:</b>	Annual Review
<b>NIH Guidelines:</b>	III-C

**Trial Summary:** RGX-314-3101 (also known as M23-409) is a Phase 3, multi-center, partially masked, randomized, active-controlled, parallel arm study sponsored by AbbVie Inc (with REGENXBIO acting as an agent) 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) is a recombinant adeno-associated viral vector (rAAV) serotype 8, containing a transgene that encodes for soluble anti-vascular endothelial growth factor (VEGF) antigen-binding fragment (Fab) protein.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

### Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
  - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.
- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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.
  - The Committee stipulated that the Site verify that a biohazard sign is located on the Biohazard Waste Storage Room door and send Sabai IBC an updated photo within 30 days.
  - The Committee stipulated that the Site verify that a biohazard symbol is present on the non-sharps biohazard waste container in the administration location and send Sabai IBC an updated photo within 30 days.
  - The Site confirmed that the PI does both preparation and administration and they exchange gloves between the processes. A note was administratively added to the Facility Details form to reflect this procedure.

**Motion:** A motion of Approval with Stipulations for the study at BSL-1 plus Standard Precautions was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
  - The Committee stipulated that the Site verify that a biohazard sign is located on the Biohazard Waste Storage Room door and send Sabai IBC an updated photo by 7/5/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site verify that a biohazard symbol is present on the non-sharps biohazard waste container in the administration location and send Sabai IBC an updated photo by 7/5/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

### Reminder of IBC Approval Requirements.

**Adjournment:** 10:33 AM

## Meeting Minutes



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