

IBC Administrative Approval Letter – Sponsor



May 20, 2026
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Your IBC Administrators recently received updates to the following sponsor documents for this study:

AbbVie Inc. M23-415

- IB, ABBV-RGX-314
- Risk Assessment, M23-415, 5-20-26.pdf

Review by your IBC Regulatory Team determined that the changes identified in these documents do not significantly alter the biosafety risk profile for the study or the exposure risk for the clinical staff preparing or administering this study agent.

Review Decision: Administrative Approval Granted.

Approval Date: May 20, 2026

IBC Expiration Date: May 18, 2027

Protocol: Protocol, M23-415 (Version 1.0, dated February 11, 2026)

Investigator's Brochure: IB, ABBV-RGX-314 (Version 15, dated April 24, 2026)

Pharmacy Manual: Admin Manual, Sura-vec, ABBV-RGX-314 (Version 3.0, dated April 28, 2026), PM, M23-415 (Version 1.0, dated March 26, 2026)

Supplementary Sponsor Documents:

Please note that your existing IBC authorization expiration date for this study will remain unchanged.

If you have any questions, please do not hesitate to contact us at IBCteam@sabaiqlobal.com.