

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, September 8, 2026
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Corewell Health, Grand Rapids, MI
Principal Investigator: David Burdette, MD
Protocol: uniQure France SAS, CT-AMT-260-01
NCT Number: NCT06063850
Meeting Type: Continuing Review of Protocol and Site
Title: A multi-center, phase 1/2a, first-in-human (FIH) study investigating the safety, tolerability, and efficacy of AMT-260 in adults with unilateral refractory Mesial Temporal Lobe Epilepsy (MTLE) administered via Magnetic Resonance Imaging (MRI)-guided Convection-enhanced Delivery (CED)

1. Call to order:

The Meeting was called to order at 11:00 am 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 was 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: 4 NO: 0 ABSTAIN: 1

7. Review of proposed research:

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

The Chair noted 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 AMT-260 since it consists of an adeno-associated viral (AAV) vector being 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 AMT-260 locally**, provided that all 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.

Points of Discussion:

1. The Committee noted that it was previously confirmed that biohazardous waste containers in the dosing room are not lined with a biohazard bag and that the entire container is removed and replaced when full.
2. The Committee recommended that Biosafety SOP Section 4 be revised to read "Full biohazardous waste containers are removed by a licensed biohazardous waste company."
3. The Committee recommended that Site Inspection Checklist, Item #16 be revised to remove the comment stating that biohazardous waste containers are appropriately cleaned and decontaminated prior to being put back into use since they are removed by the licensed biohazardous waste hauler.
4. The Committee recommended that an unobstructed path to the plumbed eyewash station in Room A2906 be maintained.

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 11:12 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 6, Version 7.0, dated 01-09-2026

Investigator's Brochure, Edition 4.0, dated 10-09-2025

Investigational Medicinal Product Handling Manual, Version 9.0, dated 07-02-2026

Neurosurgical Procedures Manual, Version 5.0, dated 08-29-2025

Research Modification Evaluation, Protocol, Amendment 6, Version 7.0

Research Modification Evaluation, Investigator's Brochure, Edition 4.0

Research Modification Evaluation, Investigational Medicinal Product Handling Manual, Version 7.0

Research Modification Evaluation, Investigational Medicinal Product Handling Manual, Version 8.0

Research Modification Evaluation, Investigational Medicinal Product Handling Manual, Version 9.0

Research Modification Evaluation, Neurosurgical Procedures Manual, Version 5.0

Biological Risk Assessment and Summary, updated 07-28-2026

Site Map, Butterworth Hospital, IDS Pharmacy, dated 11-19-2025

Site Map, HDVCH, iMRI OR 8, dated 10-01-2024

Site Inspection Checklist, expires 01-09-2027, updated 06-02-2026

Photos, BW Hospital, IDS Pharmacy, dated 07-31-2026

Photos, HDVCH, iMRI OR 8, dated 08-28-2024

Biohazard Sign, AMT-260, dated 07-30-2026

Biological Safety Cabinet Certification, Butterworth ChemoSuite, expires 01-2027

SOP, Biosafety for AMT-260, dated 03-05-2025

CRRF, dated 06-10-2026

Training Shipping Certifications, expire 2026, 2027

Prior Meeting Minutes, Continuing, dated 09-23-2025