

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, July 20, 2026
Time: 1:00 pm Central Time
Location: Zoom Teleconference
Institution: Accellacare of Duly, Lisle, IL
Principal Investigator: Amit Patel, MD
Protocol: Ferring Pharmaceuticals A/S, 000423 (ABLE-32)
NCT Number: NCT06510374
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 3b, Randomised, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk (IR) Non-Muscle Invasive Bladder Cancer (NMIBC)

1. Call to order:

The Meeting was called to order at 1:02 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four 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: 4 NO: 0 ABSTAIN: 0

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-2 containment facilities and practices** are required for ADSTILADRIN (nadofaragene firadenovec), since it consists of a recombinant replication-defective adenoviral 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 ADSTILADRIN (nadofaragene firadenovec) locally**, provided that 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: 4

NO:

ABSTAIN:

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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. An Institutional Representative stated that the white canisters next to the plumbed eyewash, as shown in site photos, are not normally there; the plumbed eyewash typically does not have anything in front of it blocking access.
2. An Institutional Representative stated that PDI Sani-Cloth Bleach Wipes are used to decontaminate work surfaces, not 10% bleach solution. The Committee recommended that site documents be revised to reflect this.
3. The Committee noted that the Biological Safety Cabinet (BSC) is due for re-certification in July 2026. The Committee recommended that the BSC certification be provided to IBC Services when available.
4. The Committee noted that "Biohazard" is not checked in the "Equipment Utilization" section of the BSC certification. The Committee recommended that this be checked the next time the BSC is certified.
5. An Institutional Representative confirmed that blue biohazard bags, as shown in site photos, do not contain sharps or liquid waste. The Committee recommended that these bags be placed in a secondary form of containment (e.g. a cardboard box) within the biohazardous waste storage room.
6. The Committee noted that the photos of the biohazardous waste storage room do not show the containers used to hold red bag biohazardous waste and recommended these be obtained from the waste hauler. The Committee also recommended that a leak-proof plastic liner or tray be placed underneath the waste containers if they are made of cardboard, and that a photo of the biohazardous waste container(s) be submitted to IBC Services.
7. The Committee discussed the use of the "Bathroom Out of Order/Biohazard" sign. An Institutional Representative stated that multiple biohazard signs like this are used throughout the facility and that no concerns have been reported by staff or patients regarding the biohazard signage. An Institutional Representative also stated that the bathroom is cleaned within five to ten minutes of use and that the biohazard sign is posted only temporarily while the bathroom is cleaned.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:17 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.0, dated 06-16-2025

Clinical Trial Supply Manual, Version 4.0, dated 03-2026

Prescribing Information, dated 03-2026

Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024

Research Modification Evaluation, Protocol, Version 6.0

Research Modification Evaluation, Clinical Trial Supply Manual, Version 3.0

Research Modification Evaluation, Clinical Trial Supply Manual, Version 4.0

Research Modification Evaluation, Prescribing Information, dated 03-2026

Biological Risk Assessment and Summary, updated 05-21-2026

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Site Map, dated 03-03-2026
Site Inspection Checklist, expires 06-26-2027, updated 07-06-2026
Photos, dated 03-03-2026
Biohazard Sign, dated 07-02-2025
Biohazard Sign for Bathroom, dated 07-02-2025
Biological Safety Cabinet Certification, dated 01-12-2026
SOP, Biosafety for ADSTILADRIN, dated 03-03-2026
Training, Shipping Certification, expires 01-30-2027
CRRF, dated 04-02-2026
Prior Meeting Minutes, Initial, dated 07-21-2025