

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, October 23, 2026
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Northwest Medical Specialties, PLLC, Tacoma, WA
Principal Investigator: Sibel Blau, MD
Protocol: AstraZeneca, D8311C00001
NCT Number: NCT07391657
Meeting Type: Initial Review of Protocol and Site
Title: A Phase III, Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4)

1. Call to order:

The Meeting was called to order at 8:04 am Pacific 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 four Institutional Representatives 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:

An 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for AZD0120 since it consists of autologous T cells modified by a self-inactivating lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of AZD0120 locally**, provided all other criteria for study closure are met.

8. 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: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed the qualifications of the Principal Investigator and had no concerns.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 there is no photo of the storage room or internal transport container since Bloodworks NW oversees the storage, transportation, and on-site preparation of the study agent.
2. An Institutional Representative confirmed that the study agent is transported from Bloodworks NW to Northwest Medical Specialties, PLLC in the sponsor-provided liquid nitrogen shipper.
3. The Committee recommended that the door to the biohazardous waste storage room at the Puyallup location be labeled with a biohazard symbol and that an updated photo be provided to IBC Services.
4. An Institutional Representative confirmed that the red bags shown in the biohazardous waste storage room at the Tacoma location are not used for disposal of biohazardous waste and that biohazardous waste is stored in hard-sided, red biohazardous waste containers. The Committee recommended that a photo of the biohazardous waste containers in this room be provided to IBC Services.
5. An Institutional Representative confirmed that the computer equipment in Exam Room 7 at the Tacoma location will be moved and the study agent will be prepared on that countertop.
6. An Institutional Representative confirmed that Slide 9 in the Tacoma Photos document represents the hallway outside the private preparation and dosing room.

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 8:20 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 10-14-2025

Investigator's Brochure, Edition 2.0, dated 05-11-2026

Investigational Medicinal Product Handling, Version 1.0, dated 08-31-2026

Biological Risk Assessment and Summary, updated 09-15-2026

Site Map, NWMS Puyallup, dated 10-07-2026

Site Map, NWMS Tacoma, dated 10-07-2026

Site Inspection Checklist, expires 09-11-2028

Photos, Puyallup, dated 10-07-2026

Photos, Tacoma Exam Room 7, dated 10-07-2026

Biohazard Sign, dated 09-16-2026

SOP, Biosafety for AZD0120, dated 10-07-2026

Training, Shipping Certification, dated 08-06-2025

CV, Blau, S., signed 01-04-2026