Meeting Minutes

Institution:	Maryland Oncology Hematology - Rockville		
Meeting Date:	April 02, 2026		
Meeting Time	1:00 PM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
	Hawley, Robert	Yes	Local Unaffiliated Member
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Hughes, Corilyn	No	Site Contact
	Singh, Christopher	Yes	Local Unaffiliated Member
Guests:	Truslow, Starlene; Lalagari, Sujana		
Staff:	McFarland, Christine		

Call to Order: The IBC Chair called the meeting to order at 1:00 PM EST. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 4/7/2025 were reviewed and approved with no changes

requested.

New Business:

PI:	Merck Sharp & Dohme LLC
Sponsor:	Full Sponsor Name
Protocol:	V940-009: A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab with or Without V940 in Participants with Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab with Platinum-based Doublet Chemotherapy (INTerpath-009).
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: V940-009 is a Phase III randomized, placebo-controlled study sponsored by Merck Sharp & Dohme LLC designed to evaluate the safety and efficacy of V940 in combination with pembrolizumab in adult participants with non-small cell lung cancer (NSCLC). V940 (also known as mRNA-4157) is a novel mRNA-based individualized neoantigen therapy (INT) consisting of a lipid encapsulated mRNA that encodes up to 34 participant-specific neoantigens. The investigational product (IP) is administered by intramuscular injection.

Biosafety Containment Level (BSL): The study agent V940 (mRNA-4157) is a non-infectious synthetic mRNA that is not associated with disease in healthy adults. The mRNA is incapable of replication and does not express known hazardous transgenes. Therefore, BSL-1 containment may be considered as the minimum biocontainment level when handling the study agent under NIH Guidelines II-A-3. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the summary of the Site's arrangements and activities with the study agent, as provided by the Chair, was accurate.
  - The Site confirmed the Annual Review Report information provided to the Committee remains accurate.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were 0 votes against and 0 abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 1:22 PM EST

Post-Meeting Pre-Approval Note: None