

Meeting Minutes

Institution:	VA Cancer Specialists HGT		
Meeting Date:	September 22, 2025		
Meeting Time	11:00 AM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
	Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Singh, Christopher	Yes	Local Unaffiliated Member
	Cochrane, Monica	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Browne, Angella	Yes	Local Unaffiliated Member
Guests:	Sullivan, Marcy (joined at 11:08) Hooley, Morgan Han, Sarah		
Staff:	Hemmelgarn, Marian		

Call to Order: The IBC Chair called the meeting to order at 11:01 AM. 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 6/20/25 were approved with no changes.

New Business:

PI:	Spira, Alexander MD
Sponsor:	BioNTech SE
Protocol:	BNT122-01 A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BNT122-01 is a Phase II clinical trial sponsored by BioNTech SE designed to assess the safety and potential efficacy of a recombinant personalized cancer vaccine for the treatment of participants with advanced colorectal cancer following surgical resection. The study agent RO7198457 (autogene cevumeran) consists of messenger RNA (mRNA) expressing personalized tumor antigens formulated as a liposome complex for delivery by intravenous injections. The investigational product (IP) is administered by intravenous injections.

Biosafety Containment Level (BSL): Because the study agent RO7198457 consists of synthetic mRNA incapable of replication and does not encode for known hazardous transgenes (e.g., toxins or oncogenes), BSL1 containment is considered the minimum biocontainment level. The administration of this agent by intravenous infusion in a clinical setting requires compliance with the OSHA Bloodborne Pathogen Standard.

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, splashes and needlesticks of the IP during preparation and/or administration procedures. 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.

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- 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 information provided by the Chair was accurate.
 - The Site confirmed the accuracy of the Annual Review Report.
 - The Committee noted that the Biological Safety Cabinet (BSC) certification report was not available with other Site documents. The Site has confirmed that the BSC was recertified on 9/12/25 but the Site is waiting for the report to be provided by the vendor. The Committee stipulated that the Site provide the BSC certification report by 10/21/25.
 - In response to a question from the Committee regarding the biohazard waste storage process, the Site clarified that the plastic biohazard waste containers (with tied plastic bag inside) are placed inside the cardboard biohazard waste boxes and brought down at the time of vendor pickup. The Site photos file will be administratively updated to note this practice.
 - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site provide the BSC certification report by 10/21/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Spira, Alexander MD
Sponsor:	Genprex, Inc.
Protocol:	ONC-003 A Phase 1/2 Open-Label, Dose-Escalation and Clinical Response Study of Quaratusugene Ozeplasmid in Combination with Osimertinib in Patients with Advanced, EGFR-Mutant, Metastatic Non-Small Cell Lung Cancer who have Progressed after Treatment with Osimertinib
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ONC-003 (Acclaim-1 Trial) is a Phase 1/2 open-label trial sponsored by Genprex Inc. designed to identify the maximum tolerated dose (MTD) and progression-free survival of quaratusugene ozeplasmid (Reqorsa® ; formerly known as GPX-001), in combination with osimertinib (Tagrisso®) for treatment of participants with advanced metastatic non-small cell lung cancer (NSCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the TUSC2 tumor suppressor gene and complexed in a cholesterol nanoparticle. The investigational product (IP) is administered by intravenous infusions (IV).

Biosafety Containment Level (BSL): Because the study agent quaratusugene ozeplasmid consists of a recombinant DNA plasmid incapable of replication and which encodes for a protein with no known toxic or carcinogenic properties, BSL1 containment can be considered as the minimum biocontainment level. The administration of this agent by intravenous injection in a clinical setting requires compliance with the Bloodborne Pathogens Standard.

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 aerosols, spills, and splashes of the IP during preparation and/or administration procedures. 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.

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- 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 information provided by the Chair was accurate.
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 - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site provide the BSC certification report by 10/21/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

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Adjournment: The IBC Chair adjourned the meeting at 11:49 AM

Post-Meeting Pre-Approval Note: None