

Meeting Minutes



Institution:	Nova Scotia Health Authority		
Meeting Date:	October 20, 2025		
Meeting Time	11:00 AM Atlantic 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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Pressman, Cynthia	Yes	Core Member: Biosafety Expert/HGT Expert
	Thompson, Rachel	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	Member	Voting	Member Type
	Hilchie, Ashley	No	Site Contact
	Hanna, Mina	Yes	Local Unaffiliated Member
Guests:	MacDonald, Kelly (Site Representative); Trajkovic, Aleksandra; Kearsey, Joy		
Staff:	Smith, Jennifer		

Call to Order: The IBC Chair called the meeting to order at 11:02 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 4/14/25 were approved by the IBC with no changes.

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New Business:

PI:	Rendon, Ricardo
Sponsor:	CG Oncology, Inc.
Protocol:	CORE-008 A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: CORE-008 is a multi-arm, open-label Phase II trial sponsored by CG Oncology, Inc. and designed to assess the safety and efficacy of cretostimogene grenadenorepvec in participants with high-risk non-muscle invasive bladder cancer. The study agent cretostimogene grenadenorepvec consists of a recombinant, conditionally replicating oncolytic adenovirus. The investigational product (IP) is administered by Intra-vesicular Instillation.

Biosafety Containment Level (BSL): The study agent cretostimogene is based on a recombinant Risk Group 2 virus containing more than two-thirds of the native genome, requiring the use of BSL-2/CL-2 containment under the NIH Guidelines.

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, aerosols 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.
 - 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.

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- Occupational Health Recommendations: The Sponsor notes that individuals who are at a potentially higher risk from working with or handling the study agent, such as pregnant or breastfeeding women and immunosuppressed or immunocompromised individuals, should not prepare, administer, or otherwise handle the study agent or materials contaminated with the study agent or provide direct care for treated participants presenting with any symptoms of illness attributed to cretostimogene for at least 1 week after treatment or until complete resolution of symptoms.
- 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 PI's credentials, 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.
 - In response to a question from the Committee, the Site confirmed that the participant will remain in the administration room for the duration of the study agent retention period. The Chair reminded the Site that if the participant needs to be moved to a waiting room or other area during the retention period, the IBC will need to review and approve any new arrangements prior to their initiation. The Site had no concerns.
 - The Site confirmed that the emergency contact numbers on the Biohazard Sign are not monitored 24 hours. The Site noted that personnel are adequately trained to call security if an emergency occurs. The Committee had no concerns.
 - In response to a question from the Committee, the Site confirmed that the cork boards in the procedure rooms are disposed of if they are contaminated.
 - The Committee requested that the Site send Sabai a photo of the IP freezer with a biohazard sticker affixed when the freezer has been received from the Sponsor. The Site had no concerns.

Motion: A motion of Full Approval for the study at CL-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: None

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 11:36 AM

Post-Meeting Pre-Approval Note: None