

Meeting Minutes

Institution:	Digestive Health Research of North Texas		
Meeting Date:	October 08, 2025		
Meeting Time	12:00 PM Central Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Wang, Anthony	Yes	Core Member: Biosafety Expert/HGT Expert
	Liang, Fu-Cheng	Yes	Local Unaffiliated Member
	Milligan, Rebekah	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Masouka, James	Yes	Local Unaffiliated Member
Guests:	None		
Staff:	Payne, Kaylie		

Call to Order: The IBC Chair called the meeting to order at 12:02 PM. 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: None

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New Business:

PI:	Dowd, Katherine MD
Sponsor:	CG Oncology, Inc
Protocol:	CRETO-EAP An Expanded Access Program of Cretostimogene Grenadenorepvec in Participants with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: CRETO-EAP is an open-label, expanded access trial (EAP) sponsored by CG Oncology, Inc. and designed to provide access to cretostimogene grenadenorepvec, a recombinant, conditionally replicating oncolytic adenovirus, in patients with non-muscle invasive bladder cancer (NMIBC) unresponsive to BCG. The investigational product (IP) is administered by intravesical instillation into the bladder.

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 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, 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.
 - 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,

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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.
 - The Site confirmed that the catheter will be removed, and the participant will void in the restroom after the dwell period.
 - In response to a question from the Chair, the Site confirmed they have a procedure in place for restroom disinfection after use of participant
 - The Committee recommended the Site post eyewash signage for the plumped eyewash stations. The Site had no concerns.
 - The Committee stipulated the Site post a biohazard symbol on the door of the Biowaste Waste Storage location. The Site had no concerns and will provide an updated photo once completed.
 - In response to a question from the Chair, the Site confirmed the ordered biowaste containers have been received. The containers do have a lid with a biohazard symbol. The Committee stipulated the Site provide a photo of the non-sharps biowaste container and the wall-mounted sharps container.
 - In response to a question from the Chair, the Site confirmed the participant will not be brought into the dosing room until after preparation is completed. The Facility Details Form will be administratively updated to reflect this best practice.
 - The Site confirmed the participant will remain in the dosing room during the dwell period. The Chair reminded the Site that if there are any changes to this practice, it will require IBC approval prior to implementing that change. The Site had no questions.

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:
 - Site to post a biohazard symbol on the door of the Biowaste Waste Storage location and provide a photo to Sabai by 11/7/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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- Site to provide a photo of the non-sharps biowaste container and the wall-mounted sharps container to Sabai by 11/7/2025. 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.

Adjournment: The IBC Chair adjourned the meeting at 12:55 PM

Post-Meeting Pre-Approval Note: None