Meeting Minutes

Institution:	University of Toledo
Meeting Date:	October 21, 2025
Meeting Time	3:30 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
Niemi, Christina	Yes	Local Unaffiliated Member
Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
Dudley, Richard	Yes	Local Unaffiliated Member
Wooten, Ronald	Yes	Site Contact
Dissanayake, Ravindika	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Rohrs, Skylar	Yes	Biological Safety Officer

Guests:	Smith, Mary Catherine (Site) Herring, Sarah Elizabeth (Site) Lederer, Nicole E (Site) Pillai, Mahesh (Site)
Staff:	Sreedharan, Aswathy

Call to Order: The IBC Chair called the meeting to order at 3:32 PM Eastern Time. 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 6-18-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Hamouda, Danae, MD
Sponsor:	CG Oncology, Inc
Protocol:	BOND-003: A Phase 3 Study of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus-Calmette-Guerin (BCG)
Review Type:	Annual Review Change in Research
NIH Guidelines Section:	III-C-1

Trial Summary: BOND-003 is a Phase III clinical trial sponsored by CG Oncology Inc. and designed to assess the safety and efficacy of a recombinant, conditionally replicating oncolytic adenovirus designed to express human granulocyte-macrophage colony-stimulating factor (GMCSF) in adults with Non-Muscle Invasive Bladder Cancer (NMIBC) that is unresponsive to standard-of-care therapy with Bacillus Calmette-Guerin (BCG). The investigational product (IP) is administered by intravesical instillation

Biosafety Containment Level (BSL): The study agent cretostimogene is based on a recombinant Risk Group 2 virus 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 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: 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 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 Annual Review Report, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.

    - The Chair noted that this is also a Change in Research to change the Principal Investigator to Dr. Danae Hamouda. The Chair noted that a Change in Principal Investigator will also be administratively approved for another study (PIVOT-006) at the Site. The Committee had no concerns with these changes.
    - The Site verified that the information provided by the Chair was accurate.
    - The Biohazard Sign will be administratively updated to indicate the name of the new PI and the phone number.
    - The Committee noted that the BSC reports provided currently are duplicated, and the report from the Dana Cancer Center is missing. The Committee stipulated that the Site send the current BSC report for the Dana Cancer Center by 11-21-25.
    - In response to a question from the Committee, the Site confirmed that they will not be using the laminar flow hoods for study agent preparation. The Site Photos will be administratively updated to remove any mention of laminar flow hood.
    - In response to a question from the Committee, the Site confirmed that there is a biohazard label on the red biohazardous waste bin located in the Dosing room.

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 send the updated BSC report for the Dana Cancer Center by 11-21-25. 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.

Adjournment: The IBC Chair adjourned the meeting at 4.14 PM Eastern time

Post-Meeting Pre-Approval Note: None