Meeting Minutes

Institution:	M.A.G.I.C. Clinic LTD
Meeting Date:	March 23, 2026
Meeting Time	9:00 AM Mountain 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
Renyk, Deanna	Yes	Local Unaffiliated Member
Maynard, Deanna	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Kornaga, Elizabeth	Yes	Local Unaffiliated Member

Guests:	Shaheen, Ahmad (joined at 9:09 AM MT)
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 9:00 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 4/10/25 were approved by the IBC with no changes.

New Business:

Meeting Minutes

PI:	Khan, Aneal
Sponsor:	Spur Therapeutics Limited
Protocol:	FLT201-03 A Phase 3 Safety and Efficacy Trial of FLT201 Gene Therapy in Patients with Gaucher Disease Type 1
Review Type:	Annual Review, Change in Research (move to a new location)
NIH Guidelines Section:	III-C-1

Trial Summary: FLT201-03 (GALILEO-3) is a non-randomized Phase III study sponsored by Spur Therapeutics Limited and designed to assess the efficacy and safety of FLT201 in adult participants with Gaucher disease Type 1 on stable treatment with enzyme replacement therapy (ERT) or substrate reduction therapy (SRT) for at least 2 years. The study agent FLT201 is a recombinant, replication-defective adeno-associated viral (AAV) vector expressing the human lysosomal enzyme β-glucocerebrosidase (GCase). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent FLT201 is a recombinant Risk Group 1 AAV vector that does not encode hazardous transgenes and is used in the absence of a helper virus, therefore BSL-1/CL-1 is the recommended containment level under the NIH Guidelines. 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, splashes, and needlestick exposures 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: 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 noted that the storage freezer is located in the Laboratory. The Facility Details Form and Site Map will be administratively updated to reflect this information.
    - The Site confirmed that biohazard signs will be posted on the doors of the rooms where study agent is stored, prepared, and administered. The Committee stipulated that the Site send Sabai updated photos showing the posted biohazard sign on the doors where study agent will be used by 4/23/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Site confirmed that biosafety training is completed annually.
    - The Committee noted that the Site's shipping certificates do not meet Transport Canada's standard and provided the Site with a link for guidance. The Committee stipulated that the Site provide Sabai with updated shipping certificates that meet Transport Canada standards by 4/23/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Site confirmed that Stericycle picks up the biohazardous waste directly from the waste storage location and will confirm specific details of the pick-up process.
    - The Site confirmed they do not have a plumbed eyewash station on site, but do have disposable eyewash bottles wherever the study agent is used.
    - The Committee discussed the biosafety containment level for this study and agreed that CL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at CL-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 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:
    - The Committee stipulated that the Site send Sabai updated photos showing the posted biohazard sign on the doors where study agent will be used by 4/23/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

- The Committee stipulated that the Site provide Sabai with updated shipping certificates that meet Transport Canada standards by 4/23/26. 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 9:34 AM.

Post-Meeting Pre-Approval Note: None