Meeting Minutes

Institution:	Case Western Reserve University
Meeting Date:	December 02, 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
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
Wilson, LaKetta	Yes	Local Unaffiliated Member
Yun, Yang	Yes	Local Unaffiliated Member
Karlo, Colleen	Yes	Site Contact
Young, Andrew	Yes	Biological Safety Officer

Invited Members Not in Attendance:

Member	Voting	Member Type
Tepfenhart, Benjamin	Yes	Site Contact

Guests:	Jensen, Jordan (left at 11:55 AM EST); Tokach, Nicholas
Staff:	Smith, Jennifer

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 11/4/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Dalal, Jignesh
Sponsor:	Beam Therapeutics, Inc
Protocol:	BTX-AUT-001 A Phase 1/2 Study Evaluating the Safety and Efficacy of a Single Dose of Autologous CD34+ Base Edited Hematopoietic Stem Cells (BEAM-101) in Patients with Sickle Cell Disease and Severe Vaso-Occlusive Crises (BEACON Trial)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BTX-AUT-001 is a Phase 1/2 nonrandomized, open-label, first-in-human (FIH) study sponsored by Beam Therapeutics Inc. to evaluate the safety and efficacy of BEAM-101 in adolescent and adult participants with sickle cell disease (SCD) and severe vascular-occlusive crises (VOCs). BEAM-101 is intended to replace the participant's bone marrow and consists of autologous CD34+ human hematopoietic stem and progenitor cells (HSPCs) genetically modified ex vivo through base editing with specific point mutations in the hemoglobin subunit gamma-1 (HBG1) and hemoglobin subunit gamma-2 (HBG2) promoters to enable the re-expression of gamma globin and production of fetal hemoglobin (HbF) which is both non-sickling and anti-sickling. The investigational product (IP) is administered by intravenous infusion

Biosafety Containment Level (BSL): The genetically modified BEAM-101 investigational cell product poses a potential risk for exposure to bloodborne pathogens requiring compliance with OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). The NIH Guidelines section II-A-3 recommends handling of human tissues including human cells at BSL-2 containment.

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. 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 Committee noted that the Biohazard Signs posted on the pharmacy doors do not denote the specific study agents that may be used. The Committee stipulated that the Site send Sabai an updated photo showing the Biohazard Sign with study agents noted on the pharmacy door by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site affix biohazard stickers to the liquid nitrogen tanks that may store the study agent, the water bath, and the transport container and send Sabai updated photos by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - In response to a question from the Committee, the Site confirmed that the BSCs are not used for this study.
  - The Committee reminded the Site to keep the area around the plumbed eyewash station cleared and recommended the Site send Sabai an updated photo.
  - The Committee noted that the IATA shipping training certificate presented had just expired and stipulated that the Site send Sabai an updated shipping training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee discussed the time allotment indicated on the training documents provided and the content requirements for the BBP training module. The Committee stipulated that the Site send Sabai an outline of the concepts covered in the BBP training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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 Sabai an updated photo showing the Biohazard Sign with study agents noted on the pharmacy door by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site affix biohazard stickers to the liquid nitrogen tanks that may store the study agent, the water bath, and the transport container and send Sabai updated photos by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site send Sabai an updated shipping training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site send Sabai an outline of the concepts covered in the BBP training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Konczal, Laura
Sponsor:	ModernaTX, Inc.
Protocol:	mRNA-3927-P101 A Global, Phase 1/2, Open-label, Dose Optimization Study to Evaluate the Safety, Pharmacodynamics, and Pharmacokinetics of mRNA-3927 in Participants with Propionic Acidemia
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: mRNA-3927-P101 is a first-in-human (FIH) Phase I/II clinical trial sponsored by ModernaTX, Inc. and designed to evaluate the safety, tolerability, pharmacological activity, and efficacy of mRNA-3927 in participants with genetically confirmed propionic acidemia (PA). mRNA-3927 consists of lipid nanoparticle (LNP)-encapsulated messenger RNAs (mRNA) encoding normal human propionyl-CoA carboxylase α and β subunits. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent mRNA-3927 consists of non-infectious synthetic mRNAs incapable of replication and do not express known hazardous transgenes, BSL1 containment is considered the minimum biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne

Pathogens (BBP) 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 or 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.
    - 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 Committee noted that the BSC Certification Report expires at the end of the month and reminded the Site to send Sabai the updated report when it is available.
    - The Committee noted that the IATA shipping training certificate presented had just expired and stipulated that the Site send Sabai an updated shipping training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee discussed the time allotment indicated on the training documents provided and the content requirements for the BBP training module. The Committee stipulated that the Site send Sabai an outline of the concepts covered in the BBP training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

- The Committee noted that the Biohazard Signs and Stickers on the pharmacy doors and equipment denote BSL-2, however this study only requires BSL-1. The Committee stipulated that the Site remove the permanent BSL-2 biohazard sign on the doors and add a removeable Biohazard Sign to the door to reflect the correct, required BSL by 1/2/26. The Committee stipulated that the site replace the biohazard stickers on the equipment that denote BSL-2 with a general biohazard sticker with no BSL distinction. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
- The Committee discussed the administration rooms used for infants and stipulated that the Site send Sabai a photo of the crib/bed/chair where participants will be placed during administration by 1/6/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Motion: A motion of Approval with Stipulations for the study at BSL-1 plus Standard Precautions 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 an updated shipping training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site send Sabi an outline of the concepts covered in the BBP training by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site remove the permanent BSL-2 biohazard sign on the doors and add a removeable Biohazard Sign to the door to reflect the correct, required BSL by 1/2/26. Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the site replace the biohazard stickers on the equipment that denote BSL-2 with a general biohazard sticker with no BSL distinction by 1/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.The Committee stipulated that the Site send Sabai a photo of the crib/bed/chair where participants will be placed during administration by 1/6/26. 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 12:21 PM

Post-Meeting Pre-Approval Note: None