Meeting Minutes

Institution:	SCRI Oncology Partners		
Meeting Date:	May 19, 2026		
Meeting Time	11:00 AM Central Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Dash, Chandravanu	Yes	Local Unaffiliated Member
	Liu, Bindong	Yes	Local Unaffiliated Member
	Ladd, Sarah	No	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Lay Petcu, Emily	No	Site Contact
Guests:	Ward, Sandy		
Staff:	Smith, Jennifer		

Call to Order: The IBC Chair called the meeting to order at 11:00 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 4/28/26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Premji, Sarah
Sponsor:	BriaCell Therapeutics
Protocol:	BC-IMT-04 Randomized, Open-label Study of the Bria-IMT Regimen and Check Point Inhibitor vs Physician's Choice in Metastatic Breast Cancer (BRIA-ABC)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: BC-IMT-04 is a randomized, Phase III trial sponsored by BriaCell Therapeutics and designed to assess the efficacy and safety of SV-BR-1-GM (Bria-IMT) in adult participants with metastatic breast cancer. SV-BR-1-GM consists of an allogeneic, irradiated breast tumor cell line transfected with a plasmid containing the CSF2 gene to augment the immune response against cancer cells. The investigational product (IP) is administered by intradermal injection.

Biosafety Containment Level (BSL): The study agent SV-BR-1-GM consists of an irradiated, replication-defective recombinant human cell line stably transfected with plasmid. To allow for consistency with handling human blood products or cell lines, BSL2 containment is the recommended biocontainment level.

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: 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 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 Committee noted that the 4th Floor Pharmacy BSC certification report expired last week and the Site confirmed that the BSC had been recertified. The Committee stipulated that the Site send Sabai an updated BSC certification report for the 4th Floor Pharmacy by 6/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Site confirmed that the priming and shaking off excess fluid steps during study agent preparation will occur in the BSC. The Site will follow up with the Sponsor to see if there is an alternative to shaking the needle and syringe.
  - The Site confirmed that the study agent will be stored in the shipper in the 4th floor pharmacy and could provide a photo of this arrangement.
  - The Site confirmed that the study team will use the hand thawing method, not a dry bath, for thawing the study agent vials. In the event that a dry bath would be used, the Site would submit a photo of this arrangement. The Committee had no concerns.

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 BSC certification report for the 4th Floor Pharmacy by 6/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Lee, Hans MD
Sponsor:	AstraZeneca Pharmaceuticals LP
Protocol:	D831EC00001 A Modular, Phase I, Open-label, Multicenter Study to Evaluate the Safety, Tolerability, Cellular Kinetics, Immunogenicity, Pharmacodynamics, and Preliminary Efficacy of AZD0120, a Dual-targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19 in Participants with Multiple Myeloma (DURGA-2)

Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: D831EC00001 is a modular, open-label, Phase I trial sponsored by AstraZeneca Pharmaceuticals LP and designed to assess the safety, tolerability, and efficacy of AZD0120 in adult participants with multiple myeloma. AZD0120 is an autologous T cell product engineered to express a dual Chimeric Antigen Receptor (CAR) targeting both CD19 and BCMA. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent AZD0120 consists of primary human cells transduced with a recombinant Risk Group 3 lentiviral vector; therefore, BSL2 containment is the recommended biocontainment level under the NIH Guidelines. Since this agent consists of primary human cells with the potential for transmission of bloodborne pathogens, compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) is also required.

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: 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 confirmed biohazardous waste containers are brought into the administration rooms during study agent handling.

Motion: A motion of Full Approval 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: None

PI:	McKean, Meredith MD
Sponsor:	BioNTech SE
Protocol:	BNT152-01C Phase I, first-in-human, open-label, dose escalation trial to evaluate safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of BNT152+153 in patients with solid tumors.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BNT152-01C is an open-label, first-in-human Phase I clinical trial sponsored by BioNTech SE and designed to assess the safety and efficacy of two study agents BNT152 and BNT153 alone, or in combination (BNT152+153), in participants with advanced solid tumors. The investigational study agents BNT152 and BNT153 consist of messenger RNAs (mRNAs) coding for interleukin-7 (IL-7) and interleukin-2 (IL-2), respectively, fused to human serum albumin. The mRNAs are formulated as liposome complexes. The investigational product (IP) is administered by intravenous bolus injections or intravenous infusions.

Biosafety Containment Level (BSL): Because the study agent BNT152 and BNT153 consists of recombinant RNA incapable of replication, BSL1 containment is considered the default biocontainment level. The administration of this agent by intravenous infusion in a clinical setting requires at a minimum OSHA Bloodborne Pathogen (BBP) Standard Precautions.

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: 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 4th Floor Pharmacy BSC certification report expired last week and the Site confirmed that the BSC had been recertified. The Committee stipulated that the Site send Sabai an updated BSC certification report for the 4th Floor Pharmacy by 6/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-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 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 BSC certification report for the 4th Floor Pharmacy by 6/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Pelster, Meredith MD
Sponsor:	Chimeric Therapeutics Ltd
Protocol:	CHM-2101-001 A Phase 1/2 Study to Evaluate CHM-2101, an Autologous Cadherin 17 (CDH17) Chimeric Antigen Receptor (CAR) T Cell Therapy for the Treatment of Relapsed or Refractory Gastrointestinal Cancers.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CHM-2101-001 is a Phase I/II open-label study sponsored by Chimeric Therapeutics Ltd. designed to assess the safety, tolerability, and efficacy of CHM-2101 in participants with advanced relapsed or refractory gastrointestinal cancers. CHM-2101 is an autologous chimeric antigen receptor (CAR) T-cell product that specifically targets human cadherin 17 (CDH17), a glycoprotein that is highly expressed in numerous gastrointestinal cancers. The investigational product (IP) is administered by single intravenous (IV) infusion.

Biosafety Containment Level (BSL): The study agent CHM-2101 consists of primary human cells engineered with a recombinant, replication-defective form of a Risk-Group 3 lentivirus. BSL2 containment is recommended under the NIH Guidelines. This study also requires compliance with the OSHA Bloodborne Pathogens Standard.

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: 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.

Motion: A motion of Full Approval 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: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:54 AM.

Post-Meeting Pre-Approval Note: None