MINUTES OF 56th MEETING OF THE TECHNICAL COMMITTEE HELD ON 30.06.2026 FROM 02:00 PM ONWARDS UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINCAL TRIALS ON NEW CHEMICAL ENTITIES IN LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013

Present:

1.	**Dr. Loveneesh G. Krishna,** Director General of Health Services, Ministry of Health and Family Welfare, New Delhi.	**Chairman**
2.	**Dr. Parmod Kumar,** Associate professor, Dept. of Medical Oncology, AIIMS Jodhpur, Rajasthan.	**Member**
3.	**Dr. Abhishek Kumar,** Senior Medical Officer, Northern Railway Central hospital, New Delhi.	**Member**
4.	**Dr. Vinod Kumar,** Associate Professor, Dept. of Forensic Medicine & Toxicology, LHMC, New Delhi.	**Member**
5.	**Dr. Maneesha Inamdar,** Director, Dept. of Stem Cell, BRIC Institute for Stem Cell Science and Regenerative Medicine, (BRIC-inStem), Bangalore, Karnataka.	**Member**
6.	**Dr. Alok Srivastava**, Former Head, Dept. of Centre for Stem Cell Research (CSCR), CMC Vellore, Tamil Nadu.	**Member**
7.	**Dr. Arkasubhra Ghosh,** Director, Dept. of Cell & Gene Therapy, Grow Research Laboratory, Narayana Nethralaya, Foundation, Bommasandra, Karnataka.	**Member**
8.	**Dr. Vikram Mathews,** Director & Professor, Dept. of Clinical Hematology, Christian Medical College, Vellore, Tamil Nadu.	**Member**
9.	**Dr. Indranil Banerjee,** Professor, Dept. of Pharmacology, LHMC, New Delhi.	**Member**
10.	**Dr. Jerin Jose Cherian,** Scientist-E, Dept. of Health Research, Representative from ICMR, New Delhi.	**Member**
11.	**Dr. Heena Tabassum,** Scientist D, Non Communicable Diseases ICMR, New Delhi.	**Member**
12.	**Dr. Manikrao Ghadlinge,** Professor & HOD, Dept. of Pharmacology, RML Hospital, New Delhi.	**Member**
13.	**Dr. Thejaswi,** Professor & HOD, Forensic Medicine & Toxicology, RML Hospital, New Delhi.	**Member**
14.	**Dr. Rajeev Singh Raghuvanshi**, Drugs Controller General (India), New Delhi.	**CDSCO**
15.	**Dr. Annam Visala,** Joint Drugs Controllers (India)	**CDSCO**

The chairman welcomed the members of the Committee for 56th Technical Committee meeting. Thereafter, 01 proposal was placed before the Committee for deliberation. The Committee discussed the proposals and gave its recommendation.

Minutes of 56th meeting of the Technical Committee held on 30.06.2026 from 02:00 pm onwards under the chairmanship of DGHS for supervising clinical trials on new chemical entities in light of directions of the Hon'ble Supreme Court of India on 03.01.2013

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
CGTP Division			
1.	File no. ELL-14011(11)/4/2026-eoffice, Comp. No.:35632 A Prospective, Single-Arm, Open-Label, Multi-Center, Phase I/II Study to Evaluate the Safety and Efficacy of LOMACART in Patients with Relapsed or Refractory Multiple Myeloma (AURORA)" (Protocol Versions: 3.0.0 dated 15 December 2025)	M/s. Micro Crispr Pvt. Ltd., Vapi, Gujarat	Earlier, firm's proposal for conducting Phase I/II clinical trial of LOMACART was discussed in SEC meetings dated 04.02.2026 and 05.03.2026, wherein after detailed deliberation, the SEC experts recommended as following: 1. Firm proposed to conduct first in human dose in three subjects at AIIMS, New Delhi which is acceptable. 2. Patient should have been exposed to at least three lines of therapy (including immunomodulator, proteasome inhibitor and anti-CD38 therapy), and known sub groups with the very poor prognosis and lack of good available options. 3. Firm shall amend the phase of the trial as "Phase-I" and title of the trial should include "First in human" and delete the clause of marketing authorization from their protocol. 4. Comprehensive Risk Management strategy for the protocol implementation along with the patient specific management shall be provided in detail. 5. 21-day Safety assessment should to be changed to 28-Day. 6. Phase II trial plan for inclusion of patients with at least one or more prior line of therapy will be evaluated based on the outcomes of the Phase I trial. The firm did not agree with the recommendations of SEC w.r.t. Point no. 2 and 3, however, the firm accepted other recommendations of SEC. Accordingly, the firm requested to place the proposal for evaluation by the Technical Committee. In this regard; the firm presented the detailed justifications w.r.t point no. 2 and 3 before the Technical Committee (TC) experts. The TC experts observed that the proposed CAR-T product construct is different than the CAR-T products approved for clinical trial and currently, globally approved CAR-T for Relapsed or Refractory Multiple Myeloma.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Further, there are currently no active or ongoing clinical trials globally for LOMACART. After detailed deliberation, The TC experts recommended that: • The clinical trial design may be considered as "Phase I/II trial" instead of "Phase I trial". • Before proceeding to Phase II part of the clinical trial, the safety and dose has to be established by the firm in Phase I trial considering that LOMACART is third generation CAR-T product. • Adequate safety PK and biomarkers assessment data from Phase I trial shall be submitted to CDSCO for its evaluation, before proceeding to Phase II trial. • Phase I clinical trial shall be conducted with at least three prior lines of therapy including immunomodulator, proteasome inhibitor and anti-CD38 therapy. • Based on the outcome of interim Phase I trial data, Phase II clinical trial may be conducted with at least two prior lines of therapy, including exposure to an immunomodulatory agent, and a proteasome inhibitor, with or without prior exposure to an anti-CD38 monoclonal antibody. • The clause of marketing authorization shall be deleted from the phase I/II clinical trial protocol. Accordingly, firm shall submit the revised clinical trial protocol to CDSCO for further review by Subject Expert Committee.