thsti ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान BRIC a DBT Organization
BRIC-Translational Health Science and Technology Institute
(An Institute of the Biotechnology Research and Innovation Council, Govt. of India)
NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway,
P.O. Box No. 04, Faridabad – 121001

No. THSTI/S&P/REOI/02/25-26 **Dated:08.09.25**

3rd CORRIGENDUM

Ref.: REOI No. THSTI/S&P/REOI/02/25-26 dt. 20th August 25.

Name of Work/Services: Development of a novel monoclonal antibody: Process development and GMP manufacturing of drug substance and drug product for Investigational New Drug.

Consequent to the Pre-EOI meeting held with prospective bidders on 27.08.2025, and in continuation of the above-cited REOI, the following amendments, clarifications, and changes are hereby issued for the information of all concerned. These shall be deemed to form an integral part of the REOI document.

1. **Amendment in Estimated Value of Works and Earnest Money Deposit (EMD):**

S. No.	Particulars	Existing Value	Revised Value
1	Estimated Value of Works	₹ 1000 lakh	₹ 1500 lakh
2	Earnest Money Deposit (EMD)	₹ 20 lakh	₹ 30 lakh

2. **Amendment in Scope of Work (Para 2 of REOI):**

Existing Clause: "Note" at the bottom of para 2:

Some variation in scales or quantities is possible, based on requirements of preclinical and clinical studies, or available scales at the bidder's facility. Further details will be provided in the RFP document.

Revised Clause: "Note" at the bottom of para 2:

Some variation in scales or quantities of is possible, based on requirements of preclinical and clinical studies, or available scales at the bidder's facility. Drug Product fill volume, concentration and batch size may vary depending on the requirement and may not necessarily correspond to the entire output of a Drug Substance batch. Further details will be provided in the RFP document.

3. **Amendment in Project Duration (Para 4 of REOI):**

In addition to the existing conditions under this clause following condition has been added:

iv. The time required for getting regulatory approvals such as test or manufacturing license, or delays from BRIC-THSTI in supplying the necessary information or approvals required for progress of any of the activities in the project will be considered as excused delays.

4. Amendment in Role of BRIC-THSTI & Bidder (Para 5 of REOI):

Existing Clause:

i. **Role of BRIC-THSTI: -**BRIC-THSTI shall provide the RCB expressing the mAb of interest. BRIC-THSTI will also provide critical reagents required for binding assay as part of batch release.

Revised Clause:

i. **Role of BRIC-THSTI:** BRIC-THSTI shall be responsible for the following:

A. Provide the RCB expressing the mAb of interest.
B. Provide critical reagents required for binding assay as part of batch release or carry out potency tests for batch release (depending on the type of assay).
C. Obtain permission for preclinical studies and conduct preclinical studies.
D. Provide preclinical and clinical protocols, preclinical report or other information needed for the bidder to obtain requisite approvals or licenses to carry out the work falling in their scope.

Existing Clause:

ii. **Role of Bidder:**

B.6 Analytical and stability studies, and product characterization.

Revised Clause:

B.6 Analytical and stability studies, and product characterization (only specialized tests may be outsourced with BRIC-THSTI approval).

The other terms and conditions of the RFP document shall remain unchanged.

Sd/-
Administrative Officer (S&P)