Annexure - II(b)
Details of clinical trial Permissions
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S. No	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date Issued	Summary
1.	BIO/CT/24/000069	M/s Bharat Serums and Vaccines Limited	Equine Klebsiella Immunoglobulin Injection 500 mg/5ml (100mg/ml)	Phase I	An open label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of different strengths of Equine Klebsiella Immunoglobulin Injection in adult healthy volunteers" vide Protocol No. BSV_KLEBSIELLA_EQAB_24_03, Version 3.0 dated 11.08.2025.	CT- 01/2026	17.02.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.06.2025 CT permission was granted.
2.	BIO/CT/25/000140	M/s Serum Institute of India Pvt. Ltd.	Quadrivalent Human Papillomavirus (Type 6, 11, 16, 18) Vaccine (Recombinant)	Phase III	A Phase-III, double-blind, randomized, active-controlled, multicentric clinical trial to evaluate the immunogenicity and safety of SIIPL's qHPV vaccine (CERVAVAC®) administered intramuscularly in women aged 27 to 45 years as compared to Merck's HPV 6/11/16/18 vaccine (Gardasil®)" [Protocol	CT-02/2026	26.02.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.10.2025 CT permission was granted.

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					number: SII-qHPV/IN-05, Version 2.0 dated 19.12.2025			
3.	BIO/CT/25/000113	M/s Zydus Lifesciences Limited	Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) in Single dose (0.5 ml)	Phase IV	A prospective, single-arm, multicentre, phase IV clinical trial to evaluate the immunogenicity and safety of Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) of M/s. Zydus Lifesciences Ltd. in healthy pediatric participants aged 6 months to 17 years". Protocol No.: VFLU.25.001 Version No. 02 Protocol Date 22.12.2025	CT-03/2026	13.03.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 25.11.2025 CT permission was granted.

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4.	BIO/CT/25/000034	M/s Reliance Life Sciences Pvt Ltd	Purified Vero Cell Rabies Vaccine (PVRV) (Human) (R-VAC-002)	Phase I	A phase I clinical trial to evaluate safety of single dose of Purified Vero Cell Rabies Vaccine (PVRV) (Human) R-VAC-002 of Reliance Life Sciences Pvt. Ltd. in healthy human adult participants."(Protocol No.: RLS/VAC/2025/05; Version1.0, Dated:02/Jul/2025	CT-04/2026	13.03.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.06.2025 CT permission was granted.
5.	BIO/CT/25/000052	M/s Pfizer Limited	Respiratory Syncytial Virus Vaccine -PF-06928316	Phase III	A Phase 3 Study in India to Describe the Safety and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in adults." [Protocol No. C3671040, Version: Protocol Amendment 2 Dated 26.01.2026	CT-05/2026	18.03.2026	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.06.2025 CT permission was granted.