

Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2025

S.No.	File No.	Firm Name	Name of Product	Phase	Title of study	Permission No.	Date Issued	Summary
14.	BIO/CT/25/000043	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) – 411028	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (21- Valent)	Phase I	A Phase 1, Prospective, Randomized, Two-Arm, Active-Controlled, and Double-Blind Study to Evaluate the Safety, Tolerability and Immunogenicity of Serum Institute of India's 21-valent Pneumococcal Conjugate Vaccine (SIIPCV21) in Healthy Indian Adults". [Protocol No. PCV-21-001, Version 1.0, dated: 06th March 2025].	CT - 14/2025	08-09-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 22.05.2025 CT permission was granted.
15.	BIO/CT/25/000012	M/s Biological E. Limited, Plot no.1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India – 500078.	Yellow Fever Vaccine, Live, Attenuated (Freeze-dried)	Phase I	A prospective open-label, randomized, controlled Phase-I clinical study to evaluate the safety, tolerability and reactogenicity of single dose of Biological E's Yellow Fever Vaccine administered to 18-45 years-old healthy adults"(Protocol BECT093/YFV-Phase-I/CTP-02, Version: v2.0 dated 07.05.2025).	CT - 15/2025	08-09-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.04.2025 CT permission was granted.
16.	BIO/CT/25/000083	M/s. Biological	SARS-CoV-2 (Covid-19)	Phase III	A prospective single blind randomized Phase-III	CT - 16/2025	08-09-2025	Based on review of documents submitted

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		E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet , Medchal-Malkajgiri (District), Telangana-500078	Vaccine (Variant JN.1)		comparative study to evaluate immunogenicity and safety of Biological E's JN.1-RBD subunit Covid-19 vaccine in 18-80 years old individuals. (Protocol no. BECT092/JN.1-Covid-19-Phase-III/CTP-02, Version no. 2.0 dated 11.06.25).			and the recommendations of Subject Expert Committee (SEC) meeting dated 04.06.2025 CT permission was granted.
17.	BIO/CT/25/000010	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Taluka - Sanand, Dist. - Ahmedabad , Gujarat	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine	Phase II	"A prospective, randomized, parallel, single-blind, two-arm, active-controlled, multicentre, age de-escalation, phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s Zydus Lifesciences Ltd. in healthy participants" vide protocol no. BTPT.24.001; Version No.01; Dated: 21 Jan 2025.	CT - 17/2025	12-09-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.03.2025 CT permission was granted.

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		(India) - 382213.						
18.	BIO/CT/25/000066	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) – 411028	Trivalent Nanoparticle Influenza (tNIV) Vaccine & Covid Trivalent Influenza Combination (CIC) Vaccine.	Phase II/III	A Phase II/III, multicentre, observer-blind, randomized, active controlled study to evaluate immunogenicity and safety of a trivalent nanoparticle influenza vaccine and Covid Influenza Combination Vaccine compared with licensed influenza and Covid -19 vaccines in adults. (Protocol no: CIC-tNIV-01, Version no. 4.0 dated 09 July 2025).	CT - 18/2025	15-09-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.06.2025 CT permission was granted.