

**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 the study	Permission No.	Date Issued	Summary
3	BIO/CT/24/000158	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal- Malkajiri District, Telangana, India-500078	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, reandomized, active-controlled, phase-III study of evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule". [Protocol No. BECT089/IPV-Phase-III/CT-01 Version No. 1.0 Dated 02.12.2024].	CT - 03/2025	07-04-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 15.01.2025 CT permission was granted.
4	BIO/CT/25/000002	M/s Biological E. Limited, Sy. No: 549,550,552 to 556, Kolthur Village, Shameerpet, Medchal- Malkajiri District, Telangana -500078, India.	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Liquid Hexavalent Vaccine)	Phase III	A prospective, single randomised, active controlled Phase-III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule with Protocol No: BECT094/LHV-Phase-III/CTP-01, 1.0 Final dated 16.12.24.	CT - 04/2025	22-04-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 25.02.2025 CT permission was granted.
5	BIO/CT/25/000009	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,	Typhoid Vi Conjugate Vaccine I.P	Phase IV	"A prospective, parallel, open-label, two-arm, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Typhoid Vi Conjugate Vaccine I.P. of M/s. Zydus Lifesciences Ltd. in malnourished children as compared to healthy children". Protocol number: ZTCV.24.001 Version: 01 Date: 20 Jan 2025.	CT - 05/2025	22-04-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.03.2025 CT permission was granted.
6	BIO/CT/24/000127	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 (India) -382213.	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECVPM]	Phase IV	An Open-label, multicentre, phase IV clinical study to assess the safety and immunogenicity of VaxiRab N administer for prophylaxis against rabies, Protocol No. VAXI.24.002, Version 1 dated 27.09.2024	CT - 06/2025	15-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.12.2024 CT permission was granted.

7	BIO/CT/24/000036	M/s Biological E. Limited, Plot no. 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana-500078, India.	Typhoid and Paratyphoid A Conjugate Vaccine (Bivalent)	Phase I	A prospective multicentre, open label, Phase-I study to evaluate the safety and immunogenicity of Biological E's Bivalent Typhoid and Paratyphoid A Conjugate vaccine administered to 18-55 years-old healthy adults in India [Protocol no. BECT086/Bi-TCV-Phase-I/CTP-01, Version No.1.0 Final dated 09.12.24].	CT - 07/2025	15-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.03.2025 CT permission was granted.
8	BIO/CT/24/000113	M/s Cadila Pharmaceuticals Limited 1389, Trasad Road, Dholka – 382 225, Dist: Ahmedabad Gujarat State, India	Quadrivalent Human Papillomavirus (HPV) Vaccine	Phase I	A Phase-I, open label clinical trial to assess the safety and immunogenicity of Quadrivalent Human Papillomavirus (HPV) Vaccine in healthy subjects [Protocol No.: CRSC24001, Version no.: 01 dated 08.07.2024]	CT - 08/2025	20-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.11.2024 CT permission was granted.
9	BIO/CT/24/000139	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 (India) -382213	Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried)	Phase IV	"A prospective, randomized, parallel, single-blind, two-arm, active controlled, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. in healthy infants aged 9-12 months". Protocol no. ZMMR.24.001, Version No.: 01 dated 07.10.2024.	CT - 09/2025	26-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.12.2024 CT permission was granted.
10	BIO/CT/24/000153	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) –411028	Typhoid Conjugate Vaccine (Bivalent)	Phase-II/III	A Phase 2/3, double-blind, randomized, active-controlled, multi centric study to evaluate the safety, immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024".	CT - 10/2025	26-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.12.2024 CT permission was granted.

11	BIO/CT/24/000121	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Opp. Ramdev Masala, Sarkhej-Bavlā N.H. No. 8A, Village Changodar, Taluka - Sanand, Dist. - Ahmedabad, Gujarat (India) – 382213	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECVPM]	Phase IV	A prospective, randomized, single-blind, parallel, active-controlled, multicenter, Phase IV clinical study to evaluate the long-term immunogenicity and safety of VaxiRab N compared to a WHO prequalified rabies vaccine in animal bite cases". Protocol No.: VAXI.24.001 Version No.: 01 Dated: 25/09/2024.	CT - 11/2025	27-05-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.11.2024 CT permission was granted.
12	BIO/CT/23/000154	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Telangana (India) – 500032	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults & Adolescents I.P.	Phase III	An open label multicentric clinical trial to evaluate the safety and immunogenicity of Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents I.P. (TeddyVac™ vaccine) in healthy pregnant women." vide Protocol no. HBI/Td3/23/03.2.0, Version No.: 2.0 dated 24.03.2025.	CT - 12/2025	10-06-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 22.05.2025 CT permission was granted.
13	BIO/CT/23/000129	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Telangana (India) – 500032	Tetanus Vaccine (Adsorbed) I. P.	Phase III	An open label multicentric clinical trial to evaluate the safety and immunogenicity of Tetanus vaccine (Adsorbed) I.P. (AbhayTOX® vaccine) in healthy pregnant women with Protocol No: HBI/TOX4/23/02.2.0 Version: 02; Dated: 20 January 2025	CT - 13/2025	20-06-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 22.05.2025 CT permission was granted.
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