Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2025 (From 01.01.2025 to 31.12.2025)

S. No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/24/000037	M/s Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034	Live Attenuated Varicella Vaccine	Phase III	A Phase III, Multicentre, Randomized, Observer-blind, Active-controlled, Parallel group, Non-inferiority Study to Evaluate Immunogenicity and Safety of Varicella vaccine (Barycela-) in Healthy Pediatric Population 12 months to 12 years of age" vide protocol number DRL-VAR-008 Version 3.0 dated 04 Sep 2024.	CT - 01/2025	17-01-2025	Based on review of documents submitted and the recommend ations of Subject Expert Committee (SEC) meeting dated 22.08.2024 CT permission was granted
2	BIO/CT/24/000082	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India-500078	Pneumoco ccal Polysacch aride conjugate vaccine (Adsorbed) (14-Valent)	Phase IV	A single blind, randomized, active-controlled, phase-IV study of evaluate immunogenicity and safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine (PNEUBEVAX-14), administered to	CT - 02/2025	20-03-2025	Based on review of documents submitted and the recommend ations of Subject Expert Committee

					healthy children aged 5 years to <18 years and healthy adults aged 18 years and above" [Protocol no. BECT090/PCV14-Phase-IV/CTP-01 Version No.: 1.0 dated17.06.24]			(SEC) meeting dated 03.10.2024 CT permission was granted.
3	BIO/CT/24/000158	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India-500078	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, randomized, 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-	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated	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-	CT - 04/2025	22-04-2025	Based on review of documents submitted and the recommendations of Subject

		Malkajgiri District, Telangana - 500078, India. Telephone No.: 91-40-67588301, FAX: 91-40-30128159,	Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Liquid Hexavalent Vaccine)		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.			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, Dist.: Ahmedabad, Gujarat (India) - 382213.	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,	Rabies Vaccine, Human I.P. (Purified Chick	Phase IV	An Open-label, multicentre, phase IV clinical study to assess the safety and immunogenicity of	CT - 06/2025	15-05-2025	Based on review of documents submitted and the

		42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Taluka - Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213.	Embryo Cell Culture Rabies Vaccine) [PCECVPM]		VaxiRab N administer for prophylaxis against rabies, Protocol No. VAXI.24.002, Version 1 dated 27.09.2024			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 evalutate 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,	Quadrivalent Human Papillomav	Phase I	A Phase-I, open label clinical trial to assess the safety and	CT - 08/2025	20-05-2025	Based on review of documents

		Trasad Road, Dholka – 382 225, Dist: Ahmedabad Gujarat State, India	irus (HPV) Vaccine		immunogenicity of Quadrivalent Human Papillomavirus (HPV) Vaccine in healthy subjects [Protocol No.: CRSC24001, Version no.: 01 dated 08.07.2024]			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.	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.

					ZMMR.24.001, Version No.: 01 dated 07.10.2024.			
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 recommend ations 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-Bavla N.H. No. 8A, Village - Changodar,	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.:	CT - 11/2025	27-05-2025	Based on review of documents submitted and the recommend ations of Subject Expert Committee (SEC) meeting dated

		Taluka - Sanand, Dist. - Ahmedabad, Gujarat(India) – 382213,			01 Dated: 25/09/2024.			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 recommend ations 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	CT - 13/2025	20-06-2025	Based on review of documents submitted and the recommend ations of Subject Expert Committee (SEC)

					January 2025			meeting dated 22.05.2025 CT permission was granted.
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,	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	CT - 15/2025	08-09-2025	Based on review of documents submitted and the recommendations of Subject Expert

		Telangana, India – 500078.			18-45 years-old healthy adults"(Protocol BECT093/YFV-Phase I/CTP-02, Version: v2.0 dated 07.05.2025).			Committee (SEC) meeting dated 29.04.2025 CT permission was granted.
16	BIO/CT/25/000083	M/s. Biological E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana-500078	SARS-CoV-2 (Covid-19) Vaccine (Variant JN.1)	Phase III	A prospective single blind randomized Phase-III 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).	CT - 16/2025	08-09-2025	Based on review of documents submitted and the recommend ations 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-	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	CT - 17/2025	12-09-2025	Based on review of documents submitted and the recommend ations of

		Bavla N. H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Taluka - Sanand, Dist. - Ahmedabad, Gujarat (India) - 382213.			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. N BTPT.24.001; Version No.01; Dated: 21 Jan 2025.			Subject Expert Committee (SEC) meeting dated 26.03.2025 CT permission was granted.
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.
19	BIO/CT/24/000140	M/s. Biological E. Limited, Plot No. 1, Biotech	Meningococcal Group A, C, W-	Phase I	A Prospective, Open label, randomized, controlled Phase-I clinical	CT - 19/2025	14-10-2025	Based on review of documents

		Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India -500 078 India	135, Y, X Conjugate Vaccine (Adsorbed & Unadsorbed)		study to evaluate the safety and immunogenicity of single intramuscular dose of Biological E's Meningococcal Conjugate Vaccine, administered to 18-45 years-old healthy adults (Protocol number: BECT091/MCV Phase-I/CTP-01 Version No. 1.0, Dated: 13.09.24)".			submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 15.01.2025 CT permission was granted.
20	BIO/CT/25/000013	M/s. Biological E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana, INDIA – 500078	Measles-Rubella (MR) Vaccine, Live, Attenuated (Freeze-dried) I.P.	Phase II/III	A Phase II/III randomised, single blind, comparative, multicentre study to evaluate the safety and immunogenicity of Biological E's live, attenuated Measles-Rubella vaccine (MR) in 9-12 months old healthy infants" [Protocol no. BECT076/MRV-Phase-II/III/CTP-02, Version: v2.0 dated 07.05.2025].	CT - 20/2025	30-10-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.04.2025 CT permission was granted.
21.	BIO/CT/25/000046	M/s Human Biologicals Institute (A	Typhoid Bivalent Conjugate	Phase I	An open label Phase I study to evaluate the safety and	CT - 21/2025	31-10-2025	Based on review of documents

		division of ndian Immunologicals Limited), Rakshapuram, Gachibowli, Telangana (India) – 500032	Vaccine		immunogenicity of Typhoid bivalent conjugate vaccine of HBI when administered to healthy male subjects of 18 to 50 years of age" [Protocol Number: HBI/Typ1/25/01.1.1, Version: 01; Amendment: 01; Dated: 23 July 2025].			submitted and the recommend ations of Subject Expert Committee (SEC) meeting dated 24.06.2025 CT permission was granted.
22	BIO/CT/25/000138	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Sy. No. 281-284 & 321, Biotech Park Phase III, Karkapatla (V), Markook Mandal, Siddipet District, Telangana (India) – 502281	Inactivated Kyasanur Forest Disease (KFD) Vaccine	Phase I	A First-in-Human Randomized, Double Blind, Placebo-Controlled Phase I Study in Healthy Indian Adults to Evaluate the Safety, Reactogenicity and Immunogenicity of inactivated KFD vaccine developed by the Human Biologicals Institute" [Protocol no: KFD-001, Version: 5.5, dated 07.08.2025].	CT - 22/2025	12-11-2025	Based on review of documents submitted and the recommend ations of Subject Expert Committee (SEC) meeting dated 05.02.2024 CT permission was granted.
23	BIO/CT/25/000063	M/s Panacea Biotec Ltd., B-1 Extn. -/A-27,	Diphtheria, Tetanus, Pertussis	Phase I	"An open label, non-comparative, Phase I study to evaluate the	CT - 23/2025	12-11-2025	Based on review of documents

		Mohan Co-Op, Industrial Estate, Mathura Road, Delhi (India) – 110044	(Whole Cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) I.P.		safety, tolerability and preliminary immunogenicity of a fully liquid pentavalent DTwp-HepB-Hib Vaccine (MyFiveTM, Panacea Biotec Ltd.) in healthy subjects 15-18 months of age" (Protocol number: PBL/24/07/MyFive, Version Number: 01 Dated: 14-04-2025).			submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 28.08.2025 CT permission was granted.
24	BIO/CT/24/000157	M/s. Translational Health Science and Technology Institute, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurgaon Expressway Faridabad, Haryana (India) – 121001.	Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) [VaxiFluTM-4] + LiteVax Adjuvant (LVA)	Phase I	"A randomized, phase I, single-centre, observer-blind, active-controlled, 3-arm study to evaluate the safety, tolerability and immunogenicity of a single administration of TETRALITE, a novel adjuvanted influenza vaccine, in healthy participants aged 18 to 50 years" (Protocol number: DBT/BRIC-THSTI/001/2024 Version 1.1 dated 03.04.2025).	CT - 24/2025	09-12-2025	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 15.01.2025 CT permission was granted