Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2023

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/22/000051	M/s Pfizer Limited, The Capital 1802/1901 Plot No. C-70 G Block Bandra-Kurla Complex Bandra (E) Mumbai City (India) - 400051	20-valent Pneumococcal Conjugate (20vPnC) Vaccine	Phase III	A phase 3, single-arm, multicenter trial to describe the safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine in pneumococcal vaccine–naïve adults ≥18 years of age in India" vide Protocol no.: B7471010, Final protocol Amendment -1, 22-DEC-2022.	CT- 01/2023	12-01-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.11.2022 CT permission was granted.
2	BIO/CT/22/000088	M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road Dholka Dholka (India) – 387810	Recombinant Rabies G Protein Vaccine	Phase III	A randomized, open label, assessor blind, parallel, Active controlled, multicentric, bridging clinical trial to evaluate the immunogenicity and safety of three dose THRABIS vaccine (Recombinant Rabies G Protein Vaccine), administered as a simulated post exposure immunization in healthy children " [Protocol No. CRSC22001, Version 04, Dated - 20/12/2022].	CT-02 /2023	03-02-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.01.2023 CT permission was granted.
3	BIO/CT/22/000107	M/s Biological E - Shameerpet, Plot No 1, S.P.Biotechnology Park, Phase II Kolthur Village Shameerpet Mandal (India) - 500078	DTwP-HepB-IPV-Hib Vaccine (Liquid Hexavalent Vaccine)	Phase I	"A Prospective Randomised Phase-I study to evaluate the Safety, Reactogenicity & Immunogenicity of single booster dose of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 16-24 months old healthy toddlers" [Protocol no. BECT078/LHV-PI/CTP-02, Version no.:2.0 dated 28.12.2022]	CT- 03/2023	27-04-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.01.2023 CT permission was granted.
4	BIO/CT/22/000092	M/s Biological E - Shameerpet, Plot No 1, S.P.Biotechnology Park, Phase II Kolthur Village Shameerpet Mandal (India) - 500078	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human)	Phase III	A Phase III, open label, prospective, multicenter, label expansion study to evaluate safety and immunogenicity of Inactivated Japanese Encephalitis Vaccine (JEEV™) in 49-70 years old adults and in the healthy 9-12 months old infants either alone or when co-administered with a licensed MMR vaccine at 9 months of age" [Protocol no. BECT071/JEV-PIII_LE/CTP-01, Version no.:2.0 dated 27.12.2022].	CT- 04/2023	23-05-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.04.2022 CT permission was granted.

5	BIO/CT/22/000084	M/s TechInvention Lifecare Pvt. Ltd., # 1004, The Summit Business Bay, Off. WEH Metro Station, Andheri Kurla Road, Andheri E, Mumbai – 400093	Varicella Vaccine, Live Attenuated	Phase III	A prospective, randomized, single blind, parallel, active controlled, multicentre, non Inferiority Phase III study to evaluate the immunogenicity and safety of Live Attenuated Varicella Vaccine of Sinovac Biotech Ltd, China compared to VARIPED® Vaccine (Varicella Vaccine Live I.P by MSD Pharmaceuticals Pvt., Ltd., India) in healthy paediatric subjects in India" [Protocol No. CRN_3110/2021, Version 1.0, dated 27-10-2021].	CT-05/2023	28-06-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.09.2022 CT permission was granted.
6	BIO/CT/22/000101	M/s Biological E - Shameerpet, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village Shameerpet Mandal (India) - 500078	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase II	A prospective multicentre open label randomized active controlled Phase-II study to evaluate safety, tolerability and immunogenicity of inactivated poliomyelitis vaccine (Adsorbed) of Biological E Limited in 6-8 weeks old infants"[Protocol no. BECT077/IPV-S19-Phase-II/CTP-01, Version no.:1.1 Final, dated 26-Dec-2022].	CT- 06/2023	19-07-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.12.2022 CT permission was granted.
7	BIO/CT/23/000008	M/s Reliance Life Sciences, Center, R-282, TTC Area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai (India) – 400 701	RLS Protein Subunit Vaccine against SARS CoV 2 Virus	Phase II	"Prospective, multi-center, randomized, open label, active control, phase 2 clinical study to evaluate immunogenicity, safety and tolerability of single heterologous booster dose of RelCoVax® (Protein Subunit Vaccine of Reliance Life Sciences against SARS-CoV-2 Virus) with Corbevax® (Protein Subunit Vaccine of Biological E Ltd. against SARS-CoV-2 Virus) vide Protocol no.: RLS/VAC/2023/01, Version 3.0, Dated: 30-Jun-2023	CT- 07/2023	27-07-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 28.06.2023 CT permission was granted.
8	BIO/CT/23/000065	M/s Biological E - Shameerpet, Plot No 1, S.P.Biotechnology Park, Phase II Kolthur Village Shameerpet Mandal (India) - 500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	Phase IV	A prospective multicentre Phase-IV study to evaluate the safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine when administered in6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants vide protocol no: BECT081/PCV-Phase-IV/CTP-01, Version no: 1 dated 14.03.2023.	CT- 08/2023	21-08-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.06.2023 CT permission was granted.

9	BIO/CT/23/000055	M/s. Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar, Pune (India) - 4110288	Quadrivalent Human Papillomavirus (Serotypes 6, 11, 16 & 18) Vaccine	Phase IV	A Phase-IV, single arm, multicentric study to assess the safety of SIIPLs qHPV vaccine(CERVAVAC) when administered in a two-dose schedule to girls and boys aged 9-14 years and in a three dose schedule to women and men aged 15-26 years [Protocol No. SII-qHPV/IN-04 Version 2.0, dated12-Jul-2023]	CT- 09/2023	24-08-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.06.2023 CT permission was granted.
10	BIO/CT/22/000121	M/s IQVIA RDS (India) Private Limited,Omega Embassy Tech Square, Marathahalli- Sarjapur, Outer Ring Road Kadubeesanahalli Bangalore (India)- 560103	Dengue Tetravalent Vaccine (Live, Attenuated)	Phase III	A Randomized, Double Blind, Placebo-Controlled, Phase 3 Trial to Investigate the Safety and Immunogenicity of a Dengue Tetravalent Vaccine (Live, Attenuated) (TDV) Administered Subcutaneously to Healthy Subjects Aged 4 to 60 Years in India" [Protocol no.: DEN-302, Version no. 2.0, Dated 15-JUN-2023].	CT- 10/2023	19-09-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 16.05.2023 CT permission was granted.
11	BIO/CT/22/000154	M/s TechInvention Lifecare Pvt. Ltd., # 1004, The Summit Business Bay, Off. WEH Metro Station, Andheri Kurla Road, Andheri E, Mumbai – 400093	Combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine. (Tdapgen)	Phase III	a Multicentre, Randomized, Observer-blind, Non-inferiority, Phase III Study to Evaluate the Immunogenicity and Safety of BoostagenRED (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNet-Asia compared to ADACEL vaccine by Sanofi Pasteur Limited in Healthy Subjects Aged 4-65 years Protocol Number: CRNI/CTP/009 Version Number: 1.0 dated 17-11-2022.	CT- 11/2023	03-11-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.01.2023 CT permission was granted.
12	BIO/CT/23/000011	M/s Zydus Lifesciences Limited , Zydus Corporate Park, Scheme No. 63 Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway Ahmedabad (India) - 382481	Typhoid Vi Conjugate Vaccine I.P.	Phase IV	A prospective, randomized, parallel, two-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid Vi conjugate vaccine with Yellow fever vaccine administered to healthy subjects". [Study Project No. 23-01, Version No. 02, Dated 14/08/2023]	CT- 12/2023	23-11-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.07.2023 CT permission was granted.

13	BIO/CT/23/000048	M/s NOVO MEDI SCIENCES PRIVATE LIMITED, Royal Status Building, Pandit Wamanrao Sadolikar Marg, Lokmanya Tilak Colony, Dadar, Mumbai, Maharashtra-400014 (India)	Varicella Vaccine (Live, Attenuated)	Phase III	A Prospective, Randomized, Observer Blind, Parallel, Active Controlled, Multicentre, Non-Inferiority Phase III Study to evaluate the Immunogenicity and Safety of Live Attenuated Varicella Vaccine of Novo Medi Sciences Pvt. Ltd. compared to a marketed Varicella Vaccine in Healthy Subjects" [Protocol no. CRNI/CTP/013, Version no.:1.0 dated 20.03.2023].	CT- 13/2023	21-12-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 16.05.2023 CT permission was granted.
14	BIO/CT/23/000007	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road., Hadapsar, Pune, Maharashtra (India) – 411028	Dengue Tetravalent Vaccine (Live, Attenuated)	Phase I/II	A Seamless Phase 1/2, double blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of Dengusiil in Indian adults and children ≥ 2 years of age" [Protocol No. Dengusiil-02 Version No. 2.0 Dated 24.05.2023]	CT- 14/2023	21-12-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 18.07.2023 CT permission was granted.
15	BIO/CT/22/000153	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road., Hadapsar, Pune, Maharashtra (India) – 411028	Yellow Fever Vaccine (Live) I.P.	Phase II/III	A Phase II/III, Multicenter, Double Blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Adults (Protocol No.: YWF: 04, Version: 03 dated 17 Oct. 2023)".	CT- 15/2023	27-12-2023	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 14.12.2023 CT permission was granted.
16	BIO/CT/23/000032	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Mycobacterium Tuberculosis (Live, Attenuated) Vaccine	Phase I	An Open Labelled Phase I Clinical Trial to Assess the Safety, Reactogenicity, Tolerability and Immunogenicity of a Tuberculosis Vaccine BBV169 (MTBVAC), in Healthy Indian Adults"; (Protocol no. BBIL/BBV169-I/2023 Version-4.0; Date: 31-Oct-2023.	CT- 16/2023	01-01-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.10.2023 CT permission was granted.

17	BIO/CT/23/000118	M/s Biological E Limited, Plot No 1, Biotech Park, Phase II Kolthur Village, Shameerpet, Medchal-Malkajgiri District: Telangana -500078	SARS-CoV-2 (Covid-19) Vaccine (Variant XBB.1.5)	Phase III	"A Prospective, single-blind randomized phase - III comparative study to evaluate immunogenicity and safety of Biological E's XBB.1.5 - RBD subunit COVID-19 vaccine in 5-80 years old individuals (Protocol No. BECT083/XBB-COVID-19-PHASE-III/CTP-01, Ver. 1.1, Dated 20.12.2023).	CT- 17/2023	01-01-2024	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 07.12.2023 CT permission was granted.