Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2022

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/22/000007	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	Phase III	A Phase III randomized open label multi-center study to compare immunogenicity and safety of BBV154 with COVAXIN®, and to assess Lot to Lot Consistency of BBV154 in Healthy Volunteers" vide Protocol No: BBIL/BBV154-III/2022 Version No: 1.0; Date: 05-01-2022.	CT- 01/2022	27-01-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.01.2022 CT permission was granted.
2	BIO/CT/21/000163	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	Phase III	"Phase 3, Randomized, Multi-Centric, Open-labeled Study to Evaluate Immunogenicity and Safety of BBV154 Booster Dose in Participants Previously Vaccinated with the COVID-19 Vaccines approved under New Drugs & Clinical Trials Rules, 2019" vide Protocol No: BBIL/Booster/2021 Version No: 2.0; Dated 05-01-2022.	CT- 02/2022	27-01-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.01.2022 CT permission was granted.
3	BIO/CT/22/000003	M/s National Institute Of Epidemiology, Indian Council Of Medical Research, R127, 2nd Main Road, Tamil Nadu Housing Board(TNHB) Ayapakkam, Chennai-600077, Chennai (India) – 600077	Whole Virion Inactivated Corona Virus Vaccine	Phase IV	Safety and immunogenicity of the third dose of COVISHIELD/COVAXIN vaccine using homologous and heterologous regimen in immunocompromised patients: Single-blind, Randomized, non□inferiority" vide Protocol No: NIE/IHEC/202112-0	CT- 03/2022	08-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.01.2022 CT permission was granted.
4	BIO/CT/21/000156	M/s Dr Reddy's Laboratories Limited, IPDO, Survey no 54, Bachupally Vilage Qutubullapur Mandal (India)- 500090	A vector vaccine for the prevention of the coronavirus infection	Phase III	A Phase III, Randomized, Open Label, Multicentre Clinical Study in Parallel Assignment to Evaluate Immunogenicity and Safety of a Booster Dose of Sputnik Light Vector Vaccine against COVID-19 in Adult Indian Subjects" [Protocol No: DRL-SLB-007].	CT- 04/2022	22-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.03.2022 CT permission was granted.
5	BIO/CT/22/000018	M/s Serum Institute Of India Pvt. Ltd., S. No. 105-110, Manjari Bk. Manjari Bk. Pune (India) - 412307	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine [COVOVAX]	Phase III	A phase 3, observer blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of COVOVAX in Indian adults who have received primary vaccination against COVID□19"[Protocol no.: COVOVAX-Booster	CT- 05/2022	22-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.03.2022 CT permission was granted.

6	BIO/CT/21/000048	M/s Joint Force Pharamchem Pvt. Ltd.,, 504, Part B,Samarth Commercial Premisesco.So.Ltd 5th Floor,Survey No.27/E,Hissa No.1(PT),CTS No.337/1,Mumbai city Govandi (India) - 400088	Hepatitis A (Live) Vaccine, Freeze-Dried	Phase III	Prospective, Multicentre, Randomized, Double-Blind, Parallel-Group, Phase III Study Comparing Immunogenicity, Safety, and Tolerability of Single Dose of Hepatitis A (Live) Vaccine, Freeze-dried versus BiovacTM-A (Freeze-dried Live Attenuated Hepatitis A Vaccine) in Healthy Indian Children" [Protocol Number: JFP/HAV/CT-01/21, Version no. 1.1, Dated 25.08.2021]	CT- 06/2022	25-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 02.07.2021 CT permission was granted.
7	BIO/CT/21/000135	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) (24 Valent)	Phase I	A prospective open label non-comparative Phase-I clinical study to evaluate safety, tolerability, reactogenicity and immunogenicity of single intramuscular dose of Biological E's 24valent pneumococcal polysaccharide conjugate vaccine in 18-45 years-old healthy adults" [Protocol no. BECT075/PCV-Phase-I/CTP-01, Version no.:1.0 Final dated 01.09.2021].	CT- 07/2022	25-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.09.2021 CT permission was granted.
8	BIO/CT/21/000057	M/s Serum Institute Of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road Hadapsar Pune (India) - 411028	Inactivated Salk Polio Vaccine (Adsorbed)	Phase II/III	" A Phase II/III, Multicenter, Double Blind, Randomized, Active Controlled Study to evaluate Safety and Immunogenicity of SII Inactivated Salk Polio Vaccine (Adsorbed) in comparison with Sii Licensed Inactivated Poliovirus Vaccine(IPV)" [Protocol no.: IPV:01, Version no.: 2.0, Final dated 03-Sept-2021].	CT-08/2022	28-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 02.07.2021 CT permission was granted.
9	BIO/CT/22/000004	M/s Gennova Biopharmaceuticals Limited ,T-184 Emcure House Bhosari MIDC Pune Maharashtra (India) - 411026	HGCO19 Lyophilized mRNA Vaccine for Injection (COVID-19)	Phase II/III	"A Prospective, Multicentre, Randomized, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of the candidate GEMCOVAC-19 (COVID-19 vaccine) in healthy pediatric subjects of 5 to less than 18 years" vide protocol no. GBL/GEMCOVAC-19/2022/01 Version 3.0 Dated 10 Feb 2022.	CT- 09/2022	29-03-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.01.2022 CT permission was granted.
10	BIO/CT/21/000159	M/s Pfizer Limited, The Capital 1802/1901, Plot No. C-70 G Block Bandra-Kurla Complex Bandra (E) Mumbai City (India) - 400051	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (13-valent)	Phase IV	A Phase 4, open-label, single-arm, multicenter study to describe the safety of 13-valent Pneumococcal Conjugate vaccine in adults 18 to 49 years of age in India [Protocol no: B1851214 Version No. Final Date 15-OCT-2021].	CT- 10/2022	07-04-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.03.2022 CT permission was granted.

11	BIO/CT/21/000169	M/s Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213	Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent)	Phase III	"A prospective, randomized, two arm, parallel, active controlled, multicentre, phase III clinical study to compare the immunogenicity and safety of Inactivated Influenza vaccine (split virion) I.P. (Tetravalent) 0.5 ml of M/s Cadila Healthcare Limited with Fluarix -Tetra of M/s GlaxoSmithKline Pharmaceuticals Limited in healthy children aged 6 to 35 months" [Protocol No. 21-13, Version no. 00, Dated 07-DEC-2021]	CT-11 /2022	21-04-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.03.2022 CT permission was granted.
12	BIO/CT/21/000147	M/s VHB Life Sciences Limited, 50-AB,Government (Erstwhile Kandivali Co-operative) Industrial Estate, Charkop, Kandivali West, Mumbai-400 067, Maharashtra, India	Varicella Vaccine Live Attenuated IP	Phase III	"A Phase-III, Randomized, Open Label, Parallel Group, Active Controlled, Multicentre, Non Inferiority Clinical Study to Evaluate the Immunogenicity and Safety Of Varivax® [Varicella vaccine (Live Attenuated, Lyophilized I.P.) of VHB Life Sciences Limited] Compared to a Marketed Varicella Vaccine in Healthy Paediatric Subjects aged between 1 to 12 years" vide Protocol No: BCR-VHB-001 Version No. 2.0 dated 28.02.2022.	CT- 12/2022	05-05-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.02.2022 CT permission was granted.
13	BIO/CT/21/000150	M/s Post Graduate Institute Of Medical Education And Research, Chandigarh, Room Number 4043, Research Block B, PGIMER, Chandigarh-160012 Chandigarh (India) - 160012	Whole Virion Inactivated Corona Virus Vaccine	Phase IV	"Safety, tolerability and immunogenicity after administration of Covid-19 vaccine in homologous prime/boost schedule [Covishield: Covishield; Covaxin: Covaxin] as compared with heterologous prime/boost [Covishield: Covaxin; Covaxin: Covishield] schedule among adults in North India: An observer blind non inferiority randomized Control Trial" [Protocol no.: ICMR/PGIMER Covishield/Covaxin, Version 3.0]	CT- 13/2022	24-05-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 11.04.2022 CT permission was granted.
14	BIO/CT/22/000056	M/s Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Limited), Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat (India) - 382481	Novel Corona virus-2019-nCoV Vaccine (recombinant)	Phase III	"A prospective, randomized, open label, active controlled, multicenter, phase III clinical study to evaluate the immunogenicity and safety of single booster dose of ZyCoV-D of M/s Zydus Lifesciences Limited in adult subjects already vaccinated with 2 doses of Covaxin or Covishield" vide Protocol No. Project No.: 22-04, Version 01 dated 30.05.2022	CT- 14/2022	03-06-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 25.05.2022 CT permission was granted.
15	BIO/CT/22/000019	M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune - 411028, India.	Typhoid Conjugate Vaccine (Bivalent)	Phase I	"A Double-Blind, Randomized, Active Controlled Phase I Clinical Study to assess the Safety and Tolerability of SII Typhoid Conjugate Vaccine (Bivalent) in Healthy Adults." Protocol Number: TCV: 01 Version and date: 1.0 dated 08 February 2022	CT-15/2022	17-06-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.04.2022 CT permission was granted.

16	BIO/CT/22/000037	M/s Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213	Rabies Vaccine, Human I.P. [Purified Inactivated Vero Cell Rabies vaccine – Lyophilized (PVRV)]	Phase I	An open-label, single-treatment, single-period, single dose, clinical Phase 1 study to assess the safety and tolerability of Rabies Vaccine, Human I.P. Purified Inactivated Vero Cell Rabies Vaccine-Lyophilized (PVRV) of M/s. Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Ltd.), India in Healthy, Adult Human Subjects." [Protocol No. PVRV 1001, Version Number: 01, Dated: 21.03.2022].	CT- 16/2022	27-06-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.04.2022 CT permission was granted.
17	BIO/CT/22/000006	M/s G.C. Chemie Pharmie Ltd., 5C Laxmi Industrial Estate New Link Road Andheri Mumbai (India) – 400053	Pneumococcal Polysaccharide Conjugate Vaccine I.P. (PCV13-TT) (Adsorbed)	Phase III	"A Randomized, Double Blind, Multi-Center, Phase II Study to assess and Compare the Immunogenicity and Safety of the 13-Valent Pneumococcal Polysaccharide Conjugate Vaccine (PCV13-TT) with Prevenar 13® of Pfizer Inc. in healthy infants in India" [Protocol no.: CRN_India/ 0106/2021, Version number: 2.0, Dated 01-03-2022]]	CT- 17/2022	01-07-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.02.2022 and 15.06.2022 CT permission was granted.
18	BIO/CT/20/000072	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	Phase III	A single blind randomised active-controlled Phase-III study to evaluate immunogenicity, safety, tolerability of a candidate 14-valent Pneumococcal Polysaccharide conjugate vaccine administered to 6-8 weeks old Indian Infants at 6 weeks, 14 weeks and 9 months of age (2+1 alternative dosing schedule)" vide Protocol No.: BECT056/PCV-Phase-III/CTP-01 Version No.: 1.0 Final dated 14.05.20	CT- 18/2022	08-09-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.08.2022 CT permission was granted.
19	BIO/CT/20/000180	M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India	Live Attenuated Tetravalent Recombinant Dengue Vaccine	Phase I	"A phase I single blind randomized placebo controlled study to evaluate the safety and immunogenicity of live attenuated tetravalent recombinant Dengue Vaccine of HBI in healthy adults of 18 to 50 years of age." Protocol Number: HBI/Deng/I/2020/003.01.02 Version, 1.0, Amendment 02, Dated: 21 June 2022	CT- 19/2022	12-09-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.08.2022 CT permission was granted.
20	BIO/CT/21/000148	M/s Syngene International Limited, Clinical Development Tower-1 Semicon Park, Electronic City, Phase-II, Hosur Road Bangalore (India)-560100	Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S) (Enteric Coated Tablet)	Phase Ib	A Phase 1b Open Label, Randomized, Dose-Ranging Trial to Determine the Safety and Immunogenicity of an Adenoviral-Vector Based Vaccine (VXA-CoV2-1.1-S) Expressing a SARS-CoV-2 S Protein and dsRNA Adjuvant Administered Orally to Healthy Human Adult Volunteers." [Protocol no.: VXA-COV2-102, Version no. 2.00, Dated 25-FEB-2022]	CT- 20/2022	12-09-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 07.09.2022 CT permission was granted.

21	BIO/CT/22/000034	M/s Tergene Biotech Private Limited ,Suite 121 & 122, Building 450, Genome Valley, Turkapally (V), Shamirpet (M), RR Dist, HYDERABAD (India) - 500078	Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), I.P. (15 valent)	Phase III	A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given in a Reduced Dosing Schedule with Routine Pediatric Vaccinations" vide Protocol no.: CBCC/2021/029, Version no.:2.0, Dated 30.06.2022.	CT- 21/2022	15-09-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 15.06.2022 CT permission was granted.
22	BIO/CT/22/000015	M/s Gennova Biopharmaceuticals Limited,T-184 Emcure House, Bhosari, M.I.D.C,Pune Maharashtra (India) - 411026	Lyophilized mRNA Vaccine for Injection(COVID-19)[Omicron variant - sublineage BA.1]	Phase II	A Prospective, Multi centre, Open-labelled, Randomized, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of GEMCOVAC-OM as a booster in Subjects 18 years of age and older" vide protocol no.GBL/GEMCOVAC-OM/2022/02	CT- 22/2022	03-10-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 07.09.2022 CT permission was granted.
23	BIO/CT/22/000063	M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune - 411028, India.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (10- Valent)	Phase IV	A Phase 4, Cross-Sectional Study to Evaluate the Pneumococcal Nasopharyngeal Carriage in Healthy Toddlers Following Vaccination with 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) as Part of Universal Immunization Program in India As Compared To Non-vaccinated Toddlers" Protocol Number: PCV-10-005 Protocol Version 1.1 Dated: 25 Aug 2022	CT-23/2022	20-10-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 11.10.2022 CT permission was granted.
24	BIO/CT/22/000022	M/s Panacea Biotec Ltd., B-1 Extn/G-3, MCIE Mathura Road New Delhi New Delhi (India) - 110044	Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. (Td Vaccine)	Phase II/ III	A randomized, single blind, multicenter, Phase II/ III study to assess and compare the immunogenicity and safety of Diphtheria and Tetanus (Td) vaccine (adsorbed) of Panacea Biotec Ltd. with BE Td® of M/s. Biological E Ltd in Healthy Adults & Adolescents." Protocol Number: PBL/21/01/Td Version Number: 03 Dated: 04-10-22	CT- 24/2022	26-10-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 15.06.2022 CT permission was granted.
25	BIO/CT/21/000046	M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune - 411028, India.	Typhoid Conjugate Vaccine (Bivalent)	Phase III	An Open label, Randomized, Active-controlled, Multi-centric Phase-III Study in Indian Infants to Assess the Immunogenicity and Safety of SIIPL HEXAVALENT (DTwP-HepB-IPV-Hib) Vaccine Containing Reduced Dose IPV in Comparison with SIIPL Pentavac SD (DTwP-HepB Hib) + Poliovac (IPV) Vaccines, Administered as Separate Injections" Protocol No. SII wHEXA/IN-03, Protocol Version 1.0 Dated 08 Jan 2021.	CT-25/2022	21-11-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 02.07.2021 CT permission was granted.

26	BIO/CT/22/000085	M/s IQVIA RDS (India) Private Limited, Omega Embassy TechSquare, Marathahalli-Sarjapur, Outer Ring Road Kadubeesanahalli Bangalore (India)- 560103	Inactivated Influenza Vaccine (Split Virion) I.P. (Quadrivalent)	Phase IV	A single-arm, open label, multi-centre, Phase IV trial to evaluate the reactogenicity, safety, and immunogenicity of Quadrivalent seasonal influenza vaccine (Fluarix Tetra) in participants aged 65 years and older in India" [Protocol no.: 218702, Version number: 1.0, Dated 22-JUN-2022]	CT- 26/2022	29-11-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.11.2022 CT permission was granted.
27	BIO/CT/22/000070	M/s Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Limited), Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat (India) - 382481	Recombinant Hepatitis E Vaccine (Adsorbed)	Phase II	A prospective, randomized, two-arm, parallel, placebo-controlled, multicentre, superiority, phase II clinical trial to evaluate the immunogenicity and safety of Recombinant Hepatitis E Vaccine (Adsorbed) of M/s. Zydus Lifesciences Limited in healthy subjects" vide Protocol No. Project No.: 22-06, Version 01 dated 07.10.2022	CT- 27/2022	29-11-2022	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.11.2022 CT permission was granted.