Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2020

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/19/000032	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 Therapeutic Tuberculosis Vaccine. (RUTI® Vaccine)	Phase II	Double-Blind, Randomized, Placebo-Controlled Phase IIb Clinical Trial to Investigate the Efficacy of RUTI® Therapeutic Vaccination as adjuvant of Tuberculosis chemotherapy" Protocol no. RUTIP2-2019-01, version 2.0, dated 4 November, 2019.	CT- 01/2020	20-01-2020	Based on review of documents submitted and the recommendations of IND meeting dated 18.09.2019 (S. No. 10) CT permission was granted.
2	BIO/CT/19/000098	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078	Typhoid Vi Conjugate Vaccine, IP	Phase III	A multicentre follow-up study to assess the immunological persistence of anti-Vi IgG antibodies at 12, 24 and 36 months post primary dose and to evaluate the immune response to a single booster dose of typhoid Vi conjugate vaccine administered at 36 months post primary dose to 6 months to 45-year-old subjects in both treatment arms who participated in the BECT053 study, vide Protocol no. BECT059/TCV-Pha-III, Version No. 1 Dated 09-SEP-2019"	CT- 02/2020	14-02-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 13.12.2019 CT permission was granted.
3	BIO/CT/19/000104	M/s Sanofi Healthcare India Private Limited, Sanofi House, C.T.S-117B, L & T BUSINESS PARK, Saki Vihar Road, Powai Mumbai (India) - 400072	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), Haemophilus influenzaeType b Conjugate and Poliomyelitis (Inactivated) Vaccine (Adsorbed)	Phase III	Phase III, randomized, open-label, multicenter study evaluating the immunogenicity and safety of Shan6 vaccine administered, concomitantly with or without Measles-Mumps Rubella (MMR) vaccine, to healthy toddlers in India vide Protocol no. - Version 1.0 dated 08 November 2019"	CT- 03/2020	24-02-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 09.01.2020 CT permission was granted.
4	BIO/CT/19/000073	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078	Hepatitis B Vaccine (rDNA)	Phase IV	A multicentre single blind, parallel randomized phase-IV non-inferiority study to evaluate the immunogenicity and safety of Biological E's monovalent Hepatitis-B (rDNA) vaccine when administered first dose to neonates within 24 hours of birth followed by a dose at 6 and 14 weeks of age in comparison with a licensed comparator." vide Protocol no. BECT058/rHepB-Birth_Dose-PIV/CTP-02, Version No. 2.0 Final dated 11.11.19.	CT- 04/2020	13-03-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.10.2019 CT permission was granted.
5	BIO/CT/19/000079	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Zika Virus Vaccine (Adsorbed)	Phase IIa	A Phase 2a Double Blind, Placebo-Controlled Randomized Clinical trial to Evaluate Immunogenicity and Safety of A Zika Virus Vaccine (BBV121) in Dengue Sero-Negative and Dengue Sero Positive Healthy Adults" vide Protocol Number: BBIL/ZIKV/IIa/2019 Version and date: 1.0 dated 13 August 2019.	CT- 05/2020	16-03-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 10.10.2019 CT permission was granted.

6	BIO/CT/20/000038	M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India	VPM1002 (rBCG) Vaccine	Phase III	A multicentre, phase III, double-blind, randomized, placebo controlled study to evaluate the efficacy of recombinant BCG VPM1002 in reducing infection incidence and disease severity of SARS-COV-2/COVID 19 among high-risk subjects" vide protocol number: SII-rBCG/COVID-19/IN-01, version 3.0 dated 11.04.2020	CT-06/2020	12-04-2020	Based on review of documents submitted and the recommendations of IND meeting dated 08.04.2020 CT permission was granted.
7	BIO/CT/20/000039	M/s Cadila Pharmaceuticals Limited,1389, Dholka, Ahmedabad-382225 Gujarat, India	Mycobacterium w (Heat Killed)	Phase III	A clinical trial to evaluate the safety and efficacy of Mw in critically ill patients suffering from COVID 19 infection" vide protocol number: CRSC20004 version-02, dated 10th April 2020	CT- 07/2020	15-04-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 08.04.2020 CT permission was granted.
8	BIO/CT/20/000041	M/s Cadila Pharmaceuticals Limited,1389, Dholka, Ahmedabad-382225 Gujarat, India	Mycobacterium w (Heat Killed)	Phase III	A Randomized, Double-blind, Two arm, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of Mycobacterium w in preventing COVID-19 in subjects at risk of getting infected with COVID-19" vide Protocol Number: CRSC20005 Version-02, dated 15th April 2020 with the condition that serology shall be conducted initially and at the end of one of the study period	CT- 08/2020	22-04-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 19.04.2020 CT permission was granted.
9	BIO/CT/20/000042	M/s Cadila Pharmaceuticals Limited,1389, Dholka, Ahmedabad-382225 Gujarat, India	Mycobacterium w (Heat Killed)	Phase III	A Randomized, Double-blind, Two arm, controlled clinical trial to compare the Efficacy and Safety of Mycobacterium w (Mw) administered along with standard of care versus Placebo administered along with standard of care, in adult, COVID 19 positive patients hospitalized but not critically ill" vide Protocol Number: CRSC20006 Version-02, dated 15th April 2020	CT- 09/2020	22-04-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 19.4.2020 CT permission was granted.
10	BIO/CT/20/000049	M/s Haffkine Institute For Training, Research & Testing ,Acharya Donde Marg Parel Mumbai (India) - 400012	Bacillus Calmette-Guerin Vaccine I.P. (Freeze Dried)	Phase II	protocol no. 1.0 titled "Phase 2 Clinical Trial for the Evaluation of BCG as potential therapy for COVID-19" subject to the following conditions: 1. The study should be carried out only in moderate patients. Accordingly the objective criteria for classifying moderate patients should be defined. 2. The primary objective should be the time for resolution of COVID-19 infection only. All other objectives should be secondary objectives. Progression from moderate to severe disease should also be a secondary objective	CT- 10/2020	01-05-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 28.04.2020 CT permission was granted.

11	BIO/CT/20/000009	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) - 411028	Yellow Fever Vaccine (Live) I.P.	Phase I	An Open-Label, Randomized, Active Controlled, Phase I Clinical Study to Assess the Safety and Tolerability of SII Yellow Fever Vaccine in healthy adults" vide Protocol Number: YWF:01, Version: 2.0 Final dated 15 May 2020	CT- 11/2020	04-06-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 12.05.2020 CT permission was granted.
12	BIO/CT/20/000001	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	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	Phase II/III	A prospective, randomized, two-arm, parallel, single-blind, active-controlled, multicentre, noninferiority clinical study to evaluate the immunogenicity and safety of Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s Cadila Healthcare Limited compared to Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s Biological E. Limited in healthy subjects" vide protocol no. 19-07, version 1.0 dated 20/05/2020	CT- 12/2020	10-06-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 12.05.2020 CT permission was granted.
13	BIO/CT/20/000004	M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India	Measles and Rubella Vaccine (Live), I.P.	Phase II/III	A Phase II/III, Multicentric, Randomized, Single Blind Study to Compare the Immunogenicity and Safety of Measles and Rubella Vaccine (Live) of HBI with MR-VAC® Vaccine in Healthy Subjects" Protocol no. HBI/MR/II/III/2019/001.02.00, Version-02, Dated: 14 May 2020.	CT- 13/2020	12-06-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.02.2020 CT permission was granted.
14	BIO/CT/20/000077	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Whole Virion Inactivated Corona Virus Vaccine, [BBV152]	Phase I/II	Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers" vide Protocol No: BBIL/BBV152-A/2020 Version No: 2.0 Date: 26-06-2020 after approval of Ethics committee.	CT- 14/2020	29-06-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 25.06.2020 CT permission was granted.
15	BIO/CT/201000085	Mis 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	Novel Corona Virus-2019-nCov vaccine	Phase I/II	A prospective, randomized, adaptive, Phase IIII clinical trial to evaluate the safety and immunogenicity of Novel Corona Virus 2019-nCoV Vaccine Candidate of MIs Cadila Healthcare Limited by intradermal route in healthy subjects"	CT-15/2020	02-07-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 01.07.2020 CT permission was granted.
16	BIO/CT/20/000044	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	Typhoid Vi Conjugate Vaccine I.P.	Phase-IV	A prospective, randomized, parallel, three-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid Vi conjugate vaccine with Measles and Rubella vaccine administered to healthy infants" vide protocol no. 20-03, version 00 dated 17/03/2020.	CT- 16/2020	10-07-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.07.2020 CT permission was granted.

17	BIO/CT/20/000024	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	Typhoid Vi Conjugate Vaccine I.P.	Phase IV	A prospective, randomized, parallel, multicentre, phase IV clinical trial to evaluate the Lot to Lot consistency of ZyVac TCV of M/s Cadila Healthcare Ltd. Vide protocol No.: 20-02, Version: 01 dated: 26-06-2020	CT- 17/2020	28-07-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 01.06.2020 CT permission was granted.
18	BIO/CT/20/000095	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) - 411028	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)	Phase II/III	A Phase II/III, Observer-blind, randomized, Controlled study to determine the safety and immunogenicity of COVISHIELD (Covid-19 Vaccine) in healthy Indians adults "Vide protocol no. ICMR/SII-COVISHIELD Version No. 2.0, Dated: 29 July 2020	CT- 18/2020	03-08-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.07.2020 CT permission was granted.
19	BIO/CT/20/000019	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	Typhoid Vi Conjugate Vaccine I.P.	Phase IV	A prospective, randomized, two-arm, parallel, single-blind, active-controlled, multicentre, noninferiority, phase IV clinical trial to evaluate the long-term immunogenicity and safety of ZyVac TCV of M/s Cadila Healthcare Limited compared to Typbar TCV of M/s Bharat Biotech International Limited in healthy subjects" vide protocol no. 20-01, version 01 dated 26/06/2020	CT- 19/2020	11-08-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 01.06.2020 CT permission was granted.
20	BIO/CT/20/000078	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Whole Virion Inactivated Corona Virus Vaccine, [BBV152D]	Phase II	An Adaptive, Seamless Phase I, Followed by a Phase II, Randomized, Multicenter Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of the Whole Virion Inactivated SARS-CoV-2 Virus Vaccine, BBV152D Administered Intradermally in Healthy Volunteers" vide Protocol No: BBIL/BBV152D B/2020 Version No: 2.0 Date: 27-07-2020	CT- 20/2020	20-08-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 13.08.2020 CT permission was granted.
21	BIO/CT/20/000150	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078	SARS-CoV-2Equine Antiserum Immunoglobulin (Purified F(ab')2 fragment)	Phase I	A phase I, open label, parallel, randomised trial to assess the safety and efficacy of SARS-CoV-2 Equine Antiserum Immunoglobulin (Purified F(ab')2fragment) in hospitalised COVID-19 patients with moderate disease in addition to standard of care." vide Protocol no. BECT063/Equine.CoV.Ab-Phase I/CTP-01, Version No. 1.1 dated 07.10.2020.	CT- 21/2020	16-10-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 05.10.2020 CT permission was granted.
22	BIO/CT/20/000162	M/s Dr Reddy's Laboratories Limited, IPDO, Survey no 54 Bachupally Vilage Qutubullapur Mandal (India) - 500090	Gam-COVID-Vac Combined Vector Vaccine for SARS-CoV-2 infection (Component I & Component II)	Phase II/III	Randomized, Double-blind, Placebo-Controlled, Parallel-group, multi-Centrephase II/II adaptive clinica trial to assessthe safety and immunogenicity of Gam-Covid-vac combined vector vaccine for SARA-Cov-2 infection india healthy subjects " Protocol No.: RDI-GCV-001 Version no: 3.0, Dated: 19-10-2020	CT- 22/2020	23-10-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 16.10.2020 CT permission was granted.

23	BIO/CT/20/000159	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) - 500078	Whole Virion Inactivated Corona Virus Vaccine, [BBV152D]	Phase III	An Event-Driven, Phase -3, Randomized, double-blind, placebo-controlled, multicentre study to Evaluate the Efficacy, Safety, Immunogenicity and lot-to-lot consistancy of BBV152, Whole Virion Inactivated Corona Virus Vaccine in adult ≥18 years of age " vide protocol no.: BBIL/BBV152-C/2020 Version no.: 3.0, dated: 20-10-2020	CT- 23/2020	23-10-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 20.10.2020 CT permission was granted.
24	BIO/CT/20/000154	M/s Cadila Pharmaceuticals Limited,1389, Dholka, Ahmedabad-382225 Gujarat, India	Mycobacterium w (Heat Killed)	Phase III	A clinical trial to evaluate the safety and efficacy of Mw in critically ill patients suffering from COVID 19 infection." vide Protocol Number: CRSC20004 Version-04, dated 07.10.2020.	CT- 24/2020	27-10-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 05.10.2020 CT permission was granted.
25	BIO/CT/20/000158	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078	Covid-19 Vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS-CoV-2 (Covid-19))	Phase I/II	A prospective open label randome phase-I seamlessly followed by phase-II study to asses the safety, reactogenicity and immunogenicity of Biologica'Es Novel Covid-19 vaccine containig Receptor Binding Domain of SARS-CoV-2 for protection against Covid-19 disease when administered intramuscularly in a two dose schedule (0, 28D) to healthy volunteers.' vide protocol no.: BECT062/Covid-19-Phase-I&II/CTP-01 Version no.: 1.1 dated: 07-10-2020	CT- 25/2020	29-10-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.10.2020 CT permission was granted.
26	BIO/CT/20/000131	s M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India	Chikungunya vaccine (Inactivated)	Phase I	A Phase I Randomized Single Blind Placebo Controlled Study to Evaluate the Safety and Immunogenicity of Chikungunya Vaccine (Inactivated) of HBI when administered by two different dosage schedules to Healthy Subjects of 19 to 49 Years of age." vide Protocol no. HBI/CG/I/2020/001.02.00; Version: 02 dated: 14 October 2020.	CT- 26/2020	04-11-2020	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 30.09.2020 CT permission was granted.
27	BIO/CT/20/000194	M/s Cadila Healthcare Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar,Taluka - Sanand, Dist. Ahmedabad - 382 213	Novel Corona virus-2019-nCoV Vaccine	Phase III	A phase III, randomized, multi-centre, double blind, placebo controlled, study to evaluate efficacy, safety and immunogenicity of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited	CT- 27/2020	04-12-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 02.01.2021 CT permission was granted.