



**Annexure:****Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid	
Composition:	Each dose of 0.5 mL of vaccine contains:	
	<b>Active ingredient</b>	<b>Quantity</b>
	Adeno virus particles (Expressing COVID-19 spike protein)	5 x 10 <sup>10</sup> virus particles
	<b>Inactive ingredients</b>	
	L-Histidine	10 mM
	Sodium Chloride	35 mM
	Magnesium Chloride	1 mM
	Polysorbate 80	0.1% (w/v)
	Sucrose	7.5% (w/v)
	Ethanol	0.5% (w/v)
	EDTA Disodium Salt	0.1 mM
Water for Injection	q.s.	
Indications:	Prevention of COVID 19 infection	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Andhra Medical College Maharani Peta, Visakhapatnam, Andhra Pradesh, 530002, India	IEC King George hospital, Maharani Peta Collector Office Junction, Visakhapatnam, Andhra Pradesh, 530002, India ECR/197/Inst/KGH/2013/RR-20	Dr. B. Devi Madhavi
2	JSS Academy of Higher Education and Research Bannimantap Road, Sri Shivarathreeshwara Nagara, Bannimantap A Layout, Bannimantap, Mysore,	Institutional Ethics Committee, 2 <sup>nd</sup> Floor, JSS Medical College, SS Nagar, Mysore – 570015, Karnataka, India ECR/387/Inst/KA/2013/RR-19	Dr Praveen Kulkarni
3	Seth G. S. Medical College and KEM Hospital Acharya Donde Marg, Parel East, Parel, Mumbai	Institutional Ethics Committee Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai 400 012, Maharashtra, India ECR/229/Inst/MH/2013/RR-19	Dr Nithya Gogtay
4	KEM Hospital Research Centre Vadu Rural Health	KEM Hospital Research Centre Ethics Committee , TDH building,	Dr. Ashish Bavdekar

	Program, Vadu Budruk, Taluka Shirur, Pune - 412216	3 <sup>rd</sup> Floor, Sardar Moodliar Road, Rasta Peth, 303 Pune-411011, Maharashtra ECR/272/Inst/MH/2013/RR-19	
5	B J Medical College and Sassoon General Hospital Jai Prakash Narayan Road, Pune Railway Station, Pune, 411001	Institutional Ethics Committee of B. J. Government Medical College and Sassoon General Hospital Jai Prakash Narayan Road, Pune Railway Station, Pune, 411001 ECR/280/Inst/Maha/2013/RR-19	Dr. Muralidhar Tambe
6	All India Institute Of Medical Sciences (AIIMS), Jodhpur Department of Community Medicine and Family Medicine, Basni Industrial Area, MIA 2 <sup>nd</sup> Phase, Basni, Jodhpur - 342005	Institutional Ethics Committee 1 <sup>st</sup> floor, Research Block, AIIMS Jodhpur, Basni, Jodhpur - 342005, Rajasthan, India ECR/866/INST/RJ/2016	Dr.Pankaja Raghav
7	Rajendra Memorial Research Institute of Medical Sciences (Indian Council of Medical Research) Department of Health Research, Ministry of Health & Family Welfare, Govt of India, Agamkuan, Patna-800007	Rajendra Memorial Research Institute of medical Sciences RMRIMS Indian Council of medical Research Agamkuan Patna-800007, Bihar, India ECR/480/Inst/BH/2014/RR-17	Dr. Krishna Pandey
8	Institute of Community Medicine, Madras Medical College, Old Central Jail Campus, Park Town, Chennai 600 003	The Institutional Ethics Committee - The Madras Medical Mission, 4-A, Dr. J.J Nagar, Mogappair, Chennai - 600037 ECR/140/Inst/TN/2013/RR-16	Dr. T. S. Selvavinayagam
9	Department of Community Medicine and School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER), Sector -12, Chandigarh-160012	Institutional Ethics Committee Room No - 6006, sixth floor, Research Block B, Postgraduate Institute of Medical Education and Research, Sector 12 Chandigarh - 160012, India ECR/25/Inst/CH/2013/RR-16	Dr. Madhu Gupta
10	Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Dhankawadi, Pune- Satara Road, Pune Maharashtra - 411043 India	Institutional Ethics Committee BVDU, Bharati Hospital and Research Centre, Bharati Hospital, Pune - Satara Road Dhankawadi, Pune Maharashtra - 411043 India ECR/313/Inst/MH/2013/RR-19	Dr. Sanjay Lalwani
11	Jehangir Clinical Development Center Pvt.Ltd, Jehangir hospital premises 32, Sasoon, Road	Jehangir Clinical Development Center Pvt.Ltd, Jehangir hospital premises 32, Sasoon, Road Pune, Maharashtra - 411001 India	Dr Kiranjit Singh

	Pune, Maharashtra - 411001 India	ECR/352/Inst/MH/2013/RR-19	
12	Sri Ramachandra Institute for Higher Education and Research (SRIHER) Ramachandra Nagar, Porur Chennai Tiruvallur Tamil Nadu - 600116 India	Institutional Ethics Committee Sri Ramachandra Institute for Higher Education and Research (SRIHER) Ramachandra Nagar, Porur Chennai Tiruvallur Tamil Nadu - 600116 India ECR/203/Inst/TN/2013/RR-19	Dr Ramakrishnan
13	Topiwala National Medical College Nair Hospital, Dr A L Nair Road Mumbai Central, Mumbai, Maharashtra - 400008 India	Institutional Ethics Committee TNMC Nair Hospital, Topiwala National Medical College Nair Hospital, Dr A L Nair Road Mumbai Central, Mumbai, Maharashtra - 400008 India ECR/22/Inst/Maha/2013/RR-19	Dr Renuka Munshi
14	Government Medical College Near Hanuman Nagar Maharashtra - 440003 India	Institutional Ethics Committee, Government Medical College and Hospital, Medical Square Hanuman Nagar, Nagpur, Maharashtra - 440003 India ECR/43/Inst/MH/2013/RR-19	Dr Sushant Meshram
15	Mahatma Gandhi Institute of Medical Sciences Sevagram, Wardha 442102	Institutional Ethics Committee (Department of Pharmacology), Mahatma Gandhi Institute of Medical Sciences, Sevagram Wardha Maharashtra - 442102 India ECR/47/Inst/MH/2013/RR-19	Dr B S Garg
16	All India Institute of Medical Sciences, Director-Department of Pulmonary Medicine & Sleep Disorders, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29, India ECR/538/Inst/DL/2014/RR-20	Dr Randeep Guleria
17	Nehru Hospital, BRD Medical College, Gorakhpur-273013	Institutional Human Ethical Committee, ICMR-RMRC Gorakhpur, BRD Medical College Campus, Gorakhpur- 273013. EC/NEW/INST/2019/191	Dr Kamran Zaman

In addition to point 3, the permission is subject to following condition(s):

1. The Phase II/III clinical trial should be conducted as per protocol titled "A phase II/III, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVISHIELD(COVID-19 vaccine) in healthy Indian adults" vide Protocol No: ICMR/SII-COVISHIELD Version No: 2.0 Date: 29 July 2020.
2. The physical/biological characteristics of the vaccine shall be same as that developed by Oxford vaccine and used in the Phase-I/II Clinical trial. The clinical data generated in this trial shall be considered along with the of the data from the Oxford clinical trial outcome.

3. The indication, specification and dose schedule of the applicant vaccine including storage temperature etc., shall be based on the data generated by the collaborators and also the vaccine manufactured in India.
4. The firm is required to constitute a DSMB to review the safety data and submit to CDSCO for proceeding to the immunogenicity cohort study.
5. This permission is subject to the permission from RCGM for carrying out human studies
6. With respect to proposed clinical trial, firm is required to have: ,
  - a) Permission in Form CT-11 to manufacture batches of COVISHIELD vaccine .
  - b) Permission in CT-17 for import of Oxford vaccine for use in proposed trial .
  - c) Permission in CT-14 for labeling & packaging activity at site of M/s Seveillar Clinical Supplies Services Pvt Ltd. Pune.
7. The formulation intended to be used in the clinical trial shall be manufactured as per GMP using validated procedures and shall have ongoing stability studies programme.
8. Firm shall get its batches for clinical trial tested at CDL, Kasauli in parallel due to COVID-19 pandemic situation.

Place: New Delhi  
Date: 02.08.2020

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(Dr. V. G. Somani)  
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सत्यमेव जयते

