

File No: BIO/CT/25/000052
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division-Vaccine)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permit M/s Pfizer Limited, The Capital, 1802/1901, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra (India) - 400051 Telephone No.:022-66932176, FAX:022-26540274 to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: C3671040 Version No. Protocol Amendment 2, Date 26-JAN-2026 in the below mentioned clinical trial sites.

CT No.: CT- 05/2026

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Respiratory Syncytial Virus Vaccine -PF-06928316																																			
Therapeutic class:	Vaccine																																			
Dosage form:	Lyophilized Powder for solution for injection																																			
Composition:	Composition of Lyophilized Drug Product (DP)																																			
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	Each dose of 0.5 ml after reconstitution contains:																																			
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	Ph.Eur, JP)		
	Sodium Chloride (USP-NF, Ph.Eur, JP	2.19	1.10
	Water for Injection (USP-NF, Ph.Eur, JP)	q.s to 1 mL	q.s to 0.5 mL
Presentation:	2 mL glass vial		
Indication(s):	Active immunisation of individuals 18 years of age and older for the prevention of lower respiratory tract disease caused by RSV		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Suyog Hospital, 2nd Floor, B-Wing, Krushi Utapanna Bazar Samiti Sankul, Dindori Road, Panchavati, Nashik Maharashtra – 422003	Suyog Hospital Institutional Ethics Committee, Suyog Hospital, 2nd Floor, B-Wing Krushi Utapanna Bazar Samiti, Sankul, Dindori Road, Panchavati, Nashik-422003, Maharashtra, India ECR/965/Inst/MH/2017/RR-25	Dr. Kailash Jagdish Rathi
2.	Bharati Vidyapeeth (DU) Medical College Hospital and Research Centre, Pune-Satara Road, Dhankawadi, Pune-411043, Maharashtra, India	Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Institutional Ethics Committee Office-4th floor, Bharati Hospital and Research Centre Pune - Satara Road, Dhankawadi Pune – 411043, Maharashtra, India ECR/313/Inst/MH/2013/RR-24	Dr. Sonali Hemant Palkar
3.	Chettinad Hospital and Research Institute, Rajiv Gandhi Salai, Kelambakkam - 603103, Tamil Nadu, India	CARE-IHEC for Faculty Research Chettinad Academy of Research And Education Chettinad Healthy City, Rajiv Gandhi Salai (OMR) Kelambakkam Kanchipuram Tamil Nadu -603103 India ECR/1589/Inst/TN/2021	Dr. Durga Krishnan
4.	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer 305001, Rajasthan, India	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan – 305001 India ECR/1156/Inst/RJ/2018/RR-22	Dr. Sanjiv Maheshwari
5.	BGS Global Institute of Medical Sciences (BGSGIMS) No.67, BGS Health and Education City, Uttarahalli Road, Kengeri,	Institutional Ethics Committee, Department on Community Medicine BGS Global Institute of Medical Sciences 67 BGS Health	Dr. Mohan M

	Ground Floor, Bangalore, Karnataka, India, 560060	and Education City, Uttarahalli Road, Kengeri, Ground Floor, Bangalore, Karnataka, India, 560060 ECR/1307/Inst/KA/2019/RR-24	
6.	Aakash Healthcare Private Limited, Hospital Plot, Road No. 201 Sector-3 Dwarka, New Delhi – 110075, Delhi, India	Aakash Healthcare Institutional Ethics Committee Aakash Healthcare Super Specialty Hospital Plot, Road No. 201 Sector-3, Dwarka, New Delhi Dwarka North West Delhi Delhi - 110075 India ECR/1265/Inst/DL/2019/RR-24	Dr. Akshay Budhraj
7.	Maharaja Agrasen Super speciality Hospital Agrasen Aspatal Marg, Central Spine, Sec. 7 Jaipur, Rajasthan – 302039, India	IEC, Maharaja Agrasen Hospital Maharaja Agrasen Superspeciality Hospital Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Jaipur Rajasthan - 302039 India ECR/1222/Inst/RJ/2019/RR-22	Dr. Manish Jain
8.	Belagavi Institute of Medical Sciences Dr B R Ambedkar road, Belagavi (Belgaum) 590001, Karnataka, India	Institutional Ethics Committee BIMS Belagavi Institute of Medical Sciences, Belagavi, Dr B R Ambedkar Road, Belagavi (Belgaum) Karnataka - 590001 India ECR/801/Inst/KA/2016/RR-25	Dr. Viveki Rachgonda
9.	King George Hospital, Maharanipecta, Vishakhapatnam-530002, Andhra Pradesh, India	IEC King George hospital, King George Hospital, Maharanipecta collector office junction Visakhapatnam Andhra Pradesh - 530002 India ECR/197/Inst/KGH/2013/RR-20	Dr. Konatham Rambabu
10.	All India Institute of Medical Sciences, Ansari Nagar, New Delhi Delhi - 110029	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi Delhi - 110029 India ECR/538/Inst/DL/2014/RR-25	Dr. Vijay Hadda
11.	Institute of Post Graduate Medical Education & Research and SSKM Hospital 244, AJC	IPGME and R Research Oversight Committee IPGME&R SSKM hospital 244 Acharya J. C.	Dr. Gaurisankar Kamilya

	Bose Road, Kolkata 700020, West Bengal, India	Bose Road – Kolkata Kolkata West Bengal - 700020 India ECR/35/Inst/WB/2013/RR-24	
12.	Sri Ramaswamy Memorial Medical College Hospital & Research Centre, Centre for Clinical Trials and Research, SRM Nagar, Kattankulathur, Chengalpattu, Tamil Nadu - 603203, India.	SRM Medical College Hospital and Research Centre Sri Ramaswamy Memorial Medical College Hospital & Research Centre, SRM Nagar, Kattankulathur, Chengalpattu, Tamil Nadu - 603203, India ECR/431/Inst/TN/2013/RR-24	Dr. Satyajit Mohapatra
13.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi, Delhi -110060, India	Sir Ganga Ram Hospital Ethics Committee Room no: 1643, 6 th floor, Casualty Building, Old Rajinder Nagar, New Delhi-110060 ECR/20/Inst/DL/2013/RR-24	Dr. Atul Gogia
14.	Radhakrishna Multi speciality Hospital and IVF Center, 3-4 Sunrise Tower, J P Road, Opp. Canara Bank, Girinagar, Bangalore, Karnataka- 560085	Institutional Ethics Committee, Department of Community Medicine, Room No. 01, Second Floor, College Building, BGS Global Institute of Medical Sciences, 67, BGS Health and Education City, Uttarahalli Road, Kengeri, Bangalore 560060, Karnataka, India. ECR/1307/Inst/KA/2019/RR-24	Dr. Vivek G

In addition to point 3, the permission is subject to following conditions:

1. The Phase-III clinical trial should be conducted as per approved protocol titled "A Phase 3 Study in India to Describe the Safety and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in adults." [Protocol No. C3671040, Version: Protocol Amendment 2 Dated 26.01.2026]"
2. A data safety monitoring board (DSMB) will be constituted to review the safety data for all the enrolled subjects in the study.
3. Firm shall submit Ethics Committee approval for proposed Phase-III clinical trial.
4. Only CDL, Kasauli certified batches shall be used in the clinical trial.
5. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and should be validated.
6. Firm shall submit Ethics Committee registration for King George Hospital, Maharanipecta, Vishakhapatnam.

Place: New Delhi

Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority