

File No: BIO/CT/25/000013  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

FDA Bhawan Kotla Road,  
New Delhi-110002  
Dated:

**From:**

The Drugs Controller General, India  
Directorate General of Health Services,

**To**

M/s. Biological E. Limited,  
Sy. No. 549, 550, 552 to 556,  
Kolthur Village, Shameerpet,  
Medchal-Malkajgiri (District),  
Telangana, INDIA – 500078

**Subject:** Permission for conducting a clinical trial titled “A Phase II/III randomised, single blind, comparative, multicentre study to evaluate the safety and immunogenicity of Biological E’s live, attenuated Measles-Rubella vaccine (MR) in 9-12 months old healthy infants” [Protocol no. BECT076/MRV-Phase-II/III/CTP-02, Version: v2.0 dated 07.05.2025]- regarding.

**Reference:** Your Application No. BIO/CT04/FF/2024/47080 dated 31.01.2025 on the subject mentioned above.

**Sir,**

Please refer to your application no. BIO/CT04/FF/2024/47080 dated 31.01.2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase II/III Clinical Trial of “Measles-Rubella (MR) Vaccine, Live, Attenuated (Freeze-dried) I.P.” in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

**Yours faithfully,**

**RAJEEV SINGH  
RAGHUVANSHI**

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SINGH RAGHUVANSHI  
Date: 2025.10.30 17:56:06  
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**(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)**

File No: BIO/CT/25/000013  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

**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 permits M/s. Biological E. Limited (SEZ), Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana, INDIA - 500078, Tel: 91-40-67588301; Fax:91-40-30128159 to conduct clinical trial of the new drug or investigational new drug as per protocol number: BECT076/MRV-Phase-II/III/CTP-02, Version: v2.0 dated 07.05.2025 in the below mentioned clinical trial sites.

**CT No.: CT- 20/2025**

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.
4. It may kindly be noted that merely granting permission to conduct clinical trial with the vaccine does not convey or imply that based on the clinical trial data generated with the vaccine, permission to market this vaccine in the country with automatically be granted to you.

**Place: New Delhi**

**Date:**

**RAJEEV SINGH** Digitally signed by RAJEEV  
**RAGHUVANSHI** SINGH RAGHUVANSHI  
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**(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:	Measles-Rubella (MR) Vaccine, Live, Attenuated (Freeze-dried) I.P.	
Therapeutic class:	Vaccine (Viral vaccine)	
Dosage form:	Lyophilized powder for Subcutaneous injection upon reconstitution.	
Composition:	<b>Composition:</b>	
	Each single dose of 0.5 mL reconstituted vaccine contains:	
	<b>Active Ingredients</b>	<b>Quantity</b>
	Measles virus (Edmonston-Zagreb) propagated in MRC 5 cells	≥ 1000 CCID <sub>50</sub>
Rubella virus (Wistar RA 27/3 strain) propagated in MRC 5 cells	≥ 1000 CCID <sub>50</sub>	
	Reconstituted the vaccine vial with 2.5 mL diluent (0.9% w/v sodium chloride injection I.P).	
Indication(s):	For active immunization against Measles and Rubella viral diseases in children from 9 months of age.	

### Details of clinical trial sites-

S. No.	Name and Address of clinical trial sites	Ethics committee details	Name of principal investigators
1.	Aditya Multispecialty Hospital, 13-3-52, 3rd Line, Gunturuvari Thota, Kothapet, Beside Peoples Trauma, Guntur-522001, Andhra Pradesh, India.	IEC Aditya Multispeciality Hospital, 13-3-52, 3rd Line, Gunturivari Thota, Kothapet Beside Peoples Trauma, Guntur, Andhra Pradesh – 522001, India. [ECR/1347/Inst/AP/2020/RR-25]	Dr. Nagarjuna Chadalavada M.B.B.S & MD (Paediatrics)
2.	Chittaranjan Seva Sadan College of Obstetrics, Gynaecology & Child Health, Professor of Pediatrics & HOD, 37, S.P. Mukherjee Road, Kolkata-700026, India.	Chittaranjan Seva Sadan I.E.C Chittaranjan Seva Sadan 37, Shyama Prasad Mukherjee Road, Bhowanipore, Kolkata, West Bengal-700026, India. [ECR/1542/Inst/WB/2021]	Dr. Subhasish Bhattacharyya M.B.B.S, M.D & DNB (Paediatrics)
3.	All India Institute of Medical Sciences (AIIMS), Gate No, 1, Great Eastern Rd, opposite Gurudwara, AIIMS Campus, Tatibandh, Raipur-492099, Chhattisgarh, India.	Institute Ethics Committee, AIIMS Raipur, Room No. 2103, 2nd Floor, South Wing, Medical College Complex, Gate No.5, All India Institute of Medical Sciences, G.E Road, Tatibandh, Raipur, Pin-492099, Chhattisgarh, India. [ECR/714/Inst/CT/2015/RR-21]	Dr. Atul Jindal M.B.B.S, DCH & MD (Paediatrics)

4.	Belagavi Institute of Medical Sciences, Dr. B. R. Ambedkar Road, Sadashiv Nagar, Belgaum-590001, Karnataka, India.	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Belagavi, Dr. B R Ambedkar Road, Belagavi (Belgaum), Karnataka – 590001, India. [ECR/801/Inst/KA/2016/RR-20]	Dr. Shailesh Patil M.B.B.S, MD (Paediatrics)
5.	BGS Global Institute of Medical Sciences, Department of Paediatrics, No. 67, BGS Health and Education city Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India.	Institutional Ethics Committee, Department of Community Medicine, Room No.01, Second Floor, College Building, BGS Global Institute of Medical Sciences, No. 67, BGS Health and Education City, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India [ECR/1307/Inst/KA/2019/RR-24]	Dr. Rohit H R M.B.B.S, MD, DNB & DCH (Paediatrics)
6.	Bharati Vidyapeeth (Deemed to be University) Medical College Hospital and Research Centre, Department of Paediatrics, Ground floor, Pune-Satara Road, Dhankawadi, Pune-411043, Maharashtra, India.	Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Institutional Ethics Committee Office 4th floor, Bharati Hospital & Research Centre, Pune - Satara Road, Dhankawadi Pune - 411043, Maharashtra, India. [ECR/313/Inst/MH/2013/RR-24]	Dr. Sonali Hemant Palkar MBBS, DCH & MD (Community Medicine) Fellowship in Paediatrics infectious diseases.
7.	Cheluvamba Hospital, Mysore Medical College & Research Institute, Irwin Rd, Mysore-570001, Karnataka, India.	IEC-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute Irwin Road Mysuru, Karnataka - 570001 India [ECR/134/Inst/KA/2013/RR-19]	Dr. Prashanth M.B.B.S, MD (Paediatrics)
8.	Chirayu Hospital, Kalwar Rd, Hathoj, Jaipur-302012, Rajasthan, India.	IEC Chirayu Hospital (A Unit of KSCH Pvt. Ltd), Kalwar Road, Hathoj, Jaipur 302012 [ECR/1582/Inst/RJ/2021]	Dr. Kishori Sharan Agarwal M.B.B.S & DNB (Paediatrics)
9.	Christian Medical College & Hospital, Brown Road, CMC Campus, Ludhiana-141008, Punjab, India.	Institutional Ethics Committee, Christian Medical College & Hospital, Brown Road Ludhiana, Punjab- 141008, India. [ECR/120/Inst/PB/2013/RR-24]	Dr. Monika Sharma, MBBS, MD (Paediatrics)

10.	ESIC Medical College & Hospital, Clinical Trial Unit (MRU) Multidisciplinary Research Unit, Basement, NH-3, NIT, Faridabad- 121001, Haryana, India.	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana, India-121001. [ECR/1539/Inst/HR/2021]	Dr. Onkar Singh Bhinder M.B.B.S & MD (Paediatrics)
11.	Kurnool Medical College/ Government General Hospital, Budhawara Peta, Kurnool-518002, Andhra Pradesh, India.	Institutional Ethics Committee Kurnool Medical College & Government General Hospital, Budhawarpeta, Kurnool, Andhra Pradesh - 518002, India. [ECR/2105/Inst/AP/2025]	Dr. B. Vijai Anand Babu M.B.B.S, MD (Paediatrics)
12.	GMERS Medical College and Civil Hospital, Department of Paediatrics, Near Gujarat High Court, S.G. Highway, Sola, Ahmadabad-380061, Gujarat, India.	Institutional Ethics Committee GMERS medical college, Sola Highway Near Gujarat High court, Ahmedabad, Gujarat – 380061, India. [ECR/404/Inst/GJ/2013/RR-20]	Dr. Nehal Suryakant Patel M.B.B.S & MD (Paediatrics)
13.	UCMS & GTB Hospital, Dilshad Garden, Delhi-110095, India.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, Delhi, East Delhi - 110095, India. [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang M.B.B.S & MD (Paediatrics)
14.	Medstar Speciality Hospital, #641/17/1/3,, Kodigehalli Main Road, Sahakar Nagar-560092, Bangalore, Karnataka, India.	Medstar Speciality Hospital Ethics Committee, Medstar Speciality Hospital, No 641/17/1/3 Kodigehalli Main Road, Sahakarnagar Post, Bangalore, Urban Karnataka-560092, India. [ECR/1324/Inst/KA/2019/RR-24]	Dr. Prashanth, M.V M.B.B.S, M.D (Paediatrics) & FIPM (Neonatology)
15.	Institute of Child Health (ICH) 11, Dr. Biresh Guha Street, Kolkata, West Bengal-700017, India.	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guba Street, Kolkata-700017. [ECR/359/Inst/WB/2013/RR-24]	Dr. Monjori Mitra M.B.B.S, DCH & DNB (Paediatrics)
16.	JLN Medical College, Kala Bagh, Ajmer 305001, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Jai Prakash Narayan M.B.B.S & M.D (Paediatrics)

17.	JSS Hospital, Mahatma Gandhi Road, Mysuru – 570004, Karnataka, India.	Institutional Ethics Committee JSS Medical College, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar Mysore, Karnataka - 570015 India. [ECR/387/Inst/KAJ2013/RR-22]	Dr. M.D.Ravi M.B.B.S, DCH & M.D (Paediatrics)
18.	Mitra's Multispecialty Hospital, 1, Tilak Road, Ward 12, Hakim Para, Siliguri-734001, West Bengal, India.	Siliguri Sumita Cancer R.W and E. Society, Ramakrishna Vedanta Ashrama Sarani, Pradhan Nagar W/O-2, SLG-3, Siliguri, Darjeeling, West Bengal-73 [ECR/345/Indt/WB/2021]	Dr. Nitish Kumar M.B.B.S & M.D (Paediatrics)
19.	King George Hospital, Collectorate Junction, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India.	Institutional Ethics Committee King George Hospital, Department of Paediatrics, Collectorate junction, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India [ECR/197/Inst/KGH/2013/RR-20]	Dr. B. S. Chakravarthy M.B.B.S, M.D (Paediatrics)
20.	KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.	Institutional Ethics Committee, KAHER (Formerly Known as KLEs University) Nehru Nagar, Belagavi-590010 [ECR/211/Inst/KA/2013/RR-24]	Dr. N.S. Mahantshetti M.B.B.S & M.D (Paediatrics)
21.	North Bengal Medical College and Hospital, Department of General Medicine, Sushruta Nagar, Darjeeling-734012, West Bengal.	Institutional Ethics Committee, North Bengal Medical College and Hospital, North Bengal Medical College, Susrutanagar Siliguri, Darjeeling, West Bengal -734012, India. [ECR/1701/Inst/WB/2022]	Dr. Dipanjan Bandyopadhyay M.B.B.S & M.D (General Medicine)
22.	Maharaja Agrasen Superspeciality Hospital Sec 7, Central Spine, Vidyadhar Nagar, Jaipur-302039, Rajasthan, India.	IEC Maharaja Agrasen Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan [ECR/1222/Inst/RJ/2019/RR-22]	Dr. Mohit Poddar M.B.B.S MD (Paediatrics)
23.	Govt. Medical College & SSG General Hospital, Department of Paediatrics Jail Road, Indira Avenue, Vadodara-390001, Gujarat, India.	Institutional Ethics Committee for Human Research (IECHR), Department of Pediatrics, Ward 17, First Floor, Medical College & SSG Hospital, Vadodara-390001, Gujarat, India. [ECR/85/Inst/GJ/2013/RR-24]	Dr. Omprakash S. Shukla, M.B.B.S, MD & DNB (Paediatrics)

24.	Medipoint Hospitals Pvt. Ltd. 241/1 New D.P. Road, Aundh, Pune- 411007, Maharashtra, India.	Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd. 241/1 New D.P. Road, Near Sai Heritage, Aundh, Pune 411007, Maharashtra, India. [ECR/357/Inst/MH/2013/RR-20]	Dr. Jog Pramod Prabhakar M.B.B.S, M.D. & DNB, FIAP (Paediatrics)
25.	NKP Salve Institute of Medical sciences & Research Centre & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road Nagpur-440019, Maharashtra, India.	Institutional Ethics Committee, NKP Salve Institute of Medical Sciences, Digdoh Hills Hingna road Nagpur Nagpur Maharashtra – 440019, India [ECR/88/Inst/MH/2013/RR-24]	Dr. Girish Nanoti M.B.B.S, M.D & DCH (Paediatrics)
26.	Old Government General Hospital (Associated By Govt. Siddhartha Medical College), Two Town, Hanumanpet, Vijayawada-520002, Andhra Pradesh, India.	Institutional Ethics Committee Siddhartha Medical College & Govt. General Hospital, 1st Floor, Central Diagnostic Block, Govt. Siddhartha Medical College, Campus, Ring Road, Gunadala, Vijayawada - 520008, Andhra Pradesh, India. [ECR/633/Inst/AP/2014/RR-24]	Dr. Paruchuri Anil Kumar M.B.B.S, DCH & DNB (Paediatrics)
27.	Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123 Tamil Nadu, India	PMCHRI – IHEC, Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123 [ECR/1399/Inst/TN/2020]	Dr. Ramanath Andy Karayalar M.B.B.S, DCH, MD (Paediatrics)
28.	PT. B D Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Room No:428 Rohtak-124001, Haryana, India	Institutional Ethics Committee Clinical Trial, PGIDS, Pt. B.D. Shanna University of Health Sciences, Rohtak-124001. [ECR/495/Inst/HR/2013/RR-20]	Dr. Savita Verma M.B.B.S & M.D (Pharmacology)
29.	Parul Sevashram Hospital, PO, Limba Waghodia, Vadodara – 391760, Gujarat, India.	PU –IECHR, Parul Institute of Medical Sciences and Research, Parul University, Limba, Vadodara PIMSR, Parul University, Vadodara, Gujarat Waghodia, Vadodara- 391760, India [ECR/702/Inst/GJ/2015/RR-21]	Dr. Prasad Muley M.B.B.S & M.D (Paediatrics)

30.	Sarojini Naidu Medical College & Hospital, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India.	Institutional Ethics Committee S.N Medical, S N Medical College, Raja Mandi Near Agra College, Agra Central Library, Moti Katra Mantola Agra, Uttar Pradesh 282003, India [ECR/1409/Inst/UP/2020]	Dr. Neeraj Kumar M.B.B.S & MD (Paediatrics)
31.	Signus Hospital, 5th Floor, Atlanta Shoppers, Pathardi Phata, Pathardi Road, Nashik-422010, Maharashtra, India	Signus Hospital Ethics Committee, Signus Hospital Ethics Committee, 5th Floor, Atlanta Shoppers, Pathardi Road, Pathardi Phata, Nashik-422010, Maharashtra, India. [ECR/1733/Inst/MH/2022]	Dr. Shyamkant Suresh Patil MBBS, DCH
32.	Shardaben Chimanlal Lalbhai Municipal, General Hospital, Bhagwati nagar, Saraspur, Ahmedabad-380018, Gujarat, India.	Institutional Ethics Committee NHLIC, Smt. NHL Municipal Medical College, V S Campus, Ellisbridge, Ahmedabad, Gujarat -380006, India. [ECR/245/Inst/GJ/2013/RR-24]	Dr. Hetal Vora M.B.B.S & M.D(Paediatrics)
33.	St. Theresa's Hospital (STH), 1 <sup>st</sup> Floor, Room No. 05, Erragadda Main Road, Czech Colony Sanath Nagar, Hyderabad-500018, Telangana, India	Ethics committee St Therasas Hospital, Sanathnagar, Opp Erragadda Raitu Bazar, Hyderabad, Telangana 500018, India [ECR/230/Inst/AP/2013/RR-22]	Dr. G. Balakishor M.B.B.S, DCH & DNB (Paediatrics)
34.	Shubham Sudbhawana Superspeciality Hospital, B31/80- 23B, Bhogabeer, Lanka Varanasi- 221005, Uttar Pradesh, India.	Shubham Sudbhawana Super. Hosp. Ethics Committee, Shubham Sudbhawana Super speciality Hospital, B 31/80, 23B - Bhogabeer, Lanka, Varanasi, 221005, U.P., India. [ECR/667/Inst/UP/2014/RR-20]	Dr. Madhukar Pandey M.B.B.S, MD (Paediatrics)

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

1. The clinical trial should be conducted as per approved protocol titled, "A Phase II/III randomised, single blind, comparative, multicentre study to evaluate the safety and immunogenicity of Biological E's live, attenuated Measles-Rubella vaccine (MR) in 9-12 months old healthy infants" [Protocol no. BECT076/MRV-Phase-II/III/CTP-02, Version: v2.0 dated 07.05.2025].
2. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
3. To submit Ethics Committee approval for Phase-II/III clinical trial.
4. Only CDL, Kasauli tested and certified batches shall be used in the Phase II clinical trial.

5. Only CDL, Kasauli tested and certified consistency batches shall be used in Phase III clinical trial.
6. To submit CRO registration details once obtained from the CDSCO.

**RAJEEV SINGH RAGHUVANSHI** Digitally signed by RAJEEV SINGH RAGHUVANSHI  
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**(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licencing Authority**

**Place: New Delhi**

**Date:**

