

File no: VAC-16011(11)/13/2026-eoffice (E. No.:33504)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division- Vaccine)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

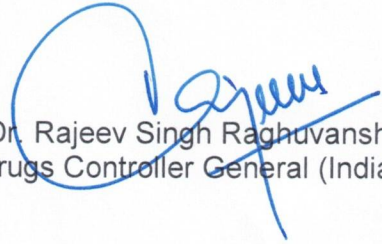
27 FEB 2026

Office Memorandum

Subject: Central Inspection Plan for Clinical Trial Site Inspection of Vaccines for year 2026-Regarding.

This is with reference to this office OM dated 08.01.2025 for conduct of clinical trial site inspections for vaccines in the year 2025. Subsequently it has been decided to conduct inspection of the clinical trial sites for the year 2026.

In this context, you are requested to carry out inspection of the clinical trial sites (under your jurisdiction as per enclosed list) using a risk based approach in accordance with GCP guidelines, NDCT Rules-2019 and SOPs and submit the inspection report along with specific recommendation to this Directorate for further action.


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To: All Zonal, Sub Zonal offices of CDSCO.

Encl: As stated above.



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Tentative Central Inspection Plan for Clinical Trial Inspections (Vaccines) for Year 2026

Sr. No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Principal Investigator & Clinical Trial Sites
Q1 (Jan 2026 To Mar 2026)							
1.	M/s Biological E. Limited, Sy. No: 549,550,552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana - 500078, India.	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Liquid Hexavalent Vaccine)	Phase III	A prospective, single randomised, active controlled Phase-III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule with Protocol No: BECT094/LHV	CT - 04/2025	22-04-2025	Dr. Mohit Poddar Maharaja Agrasen Superspecialty Hospital Central Spine, Agrasen Aspatal Marg, Sector -7, Vidyadhar Nagar, Jaipur Rajasthan – 302039



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2.	M/s Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034	Live Attenuated Varicella Vaccine	Phase III	A Phase III, Multicentre, Randomized, Observer-blind, Active-controlled, Parallel group, Non-inferiority Study to Evaluate Immunogenicity and Safety of Varicella vaccine (Barycela-) in Healthy Pediatric Population 12 months to 12 years of age" vide protocol number DRL-VAR-008 Version 3.0 dated 04 Sep 2024.	CT - 01/2025	17-01-2025	Dr Anand Kawade KEM Hospital Research Centre, Vadu Rural Health Program At post Vadu Budruk, Taluka Shirur, District Pune-412216
3.	M/s Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034	Live Attenuated Varicella Vaccine	Phase III	A Phase III, Multicentre, Randomized, Observer-blind, Active-controlled, Parallel group, Non-inferiority Study to Evaluate Immunogenicity and Safety of Varicella vaccine (Barycela-) in Healthy Pediatric Population 12 months to 12 years of age" vide protocol number DRL-VAR-008 Version 3.0 dated 04 Sep 2024.	CT - 01/2025	17-01-2025	Dr G Bala Kishor St. Theresas Hospital, Sanathnagar, Hyderabad, Telangana - 500018



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4.	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Taluka - Sanand, Dist. -Ahmedabad, Gujarat (India) - 382213.	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine	Phase II	"A prospective, randomized, parallel, single-blind, two-arm, active- controlled, multicentre, age de-escalation, phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s Zydus Lifesciences Ltd. in healthy participants" vide protocol no. BTPT.24.001; Version No.01; Dated: 21 Jan 2025.	CT - 17/2025	12-09-2025	Dr. Lisa Sarangi Hi-Tech Medical College &Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar -751025, Odisha
Q2 (Apr 2026 To June 2026)							
5.	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India-500078	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, randomized, active-controlled, phase-III study of evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule". [Protocol No. BECT089/IPV-Phase-III/CT-01 Version No. 1.0 Dated 02.12.2024].	CT- 03/2025	07-04-2025	Dr. Rohith H R* BGS Global Institute of Medical Sciences, Department of Paediatrics, No. 67, BGS Health and Education city Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India.



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6.	M/s Biological E. Limited, Sy. No: 549,550,552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana - 500078, India. Telephone No.: 91-40-67588301, FAX: 91-40-30128159,	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Liquid Hexavalent Vaccine)	Phase III	A prospective, single randomised, active controlled Phase-III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule with Protocol No: BECT094/LHV-Phase-III/CTP-01, 1.0 Final dated 16.12.24.	CT-04/2025	22-04-2025	Dr. N. S. Mahantshetti M.B.B.S & M.D (Paediatrics) KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.
7.	M/s Techinvention Lifecare Limited ,1004, The Summit Business Bay, Off Weh Metro Strn, Andheri Kurla Rd, Andheri (E), Mumbai (India) - 400093	Varicella Vaccine, Live Attenuated, Freeze-dried	Phase III	A prospective, randomized, single blind, parallel, active controlled, multicentre, Non-inferiority Phase III study to evaluate the immunogenicity and safety of live attenuated Varicella vaccine of Sinovac Biotech Ltd, China compared To VARIPED® Vaccine (Varicella Vaccine live I.P by MSD Pharmaceuticals Pvt Ltd, India) in Healthy paediatric	CT-05/2023	28-06-2023	Dr. Dinesh Kumar Uttar Pradesh Institute of Medical Sciences, Etawah, Uttar Pradesh.



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				subjects In India.			
8.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) – 411028	Trivalent Nanoparticle Influenza (tNIV) Vaccine & Covid Trivalent Influenza Combination (CIC) Vaccine.	Phase II/III	A Phase II/III, multicentre, observer-blind, randomized, active controlled study to evaluate immunogenicity and safety of a trivalent nanoparticle influenza vaccine and Covid Influenza Combination Vaccine compared with licensed influenza and Covid -19 vaccines in adults. (Protocol no: CIC-tNIV-01, Version no. 4.0 dated 09 July 2025).	CT-18/2025	15-09-2025	Dr. Vineet Jain Hakeem Abdul Hameed centenary Hospital and Centre for Health Research and Development, Hamdard Institute of Medical Sciences and Research, Guru Ravidas Marg, Hamdard Nagar and Society for Applied Studies, 680, Gali No. 5, Nai Basti, Devli Gaon, New Delhi, Delhi- 110062.
9.	M/s Dr Reddys Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) - 500034	Live Attenuated Varicella Vaccine	Phase III	A Phase III, Multicentre, Randomized, Observer-blind, Active-controlled, Parallel group, Non-inferiority Study to Evaluate Immunogenicity and Safety of Varicella vaccine (Barycela-) in Healthy Pediatric Population 12 months to 12 years of age" vide protocol number DRL-VAR-008 Version 3.0 dated 04 Sep 2024.	CT - 01/2025	17-01-2025	Dr Jai Prakash Narayan Jawahar Lal Nehru Medical College, Kala Bagh Ajmer Rajasthan - 305001
10.	M/s Techinvention Lifecare Limited ,1004, The Summit Business Bay, Off	Combined Tetanus Toxoid, Reduced	Phase III	A multicenter, randomized, observer-blind, non-inferiority, Phase III study to evaluate the immunogenicity and Safety of	CT-11/2023	11-03-2023	Dr. Srikanth Tripathy Dr. D.Y. Patil Medical College, Hospital &



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	Web Metro Stn, Andheri Kurla Rd, Andheri (E), Mumbai (India) - 400093	Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine (Tdapgen)		Boostagen ^{RED} TM (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNet-Asia compared to ADACEL® vaccine by Sanofi Pasteur Limited in healthy subjects aged 4-65 years.			Research Centre, Pune, Maharashtra-411018
11.	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Taluka - Sanand, Dist. -Ahmedabad, Gujarat (India) - 382213.	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine	Phase II	"A prospective, randomized, parallel, single-blind, two-arm, active- controlled, multicentre, age de-escalation, phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s Zydus Lifesciences Ltd. in healthy participants" vide protocol no. BTPT.24.001; Version No.01; Dated: 21 Jan 2025.	CT - 17/2025	12-09-2025	Dr. Javdekar Bakul Balchandra Dhiraj Hospital, SBKS MI & RC, At& Post: Piparia, Taluka: Waghodia, Vadodara-391760,



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Q3 (July 2026 To Sep 2026)

12.	M/s Urihk Pharmaceutical Private Limited, 602-603, Sai Samarth Business Park, Near Wasan Motors, Deonar Village Road, Deonar, Govandi (East) Mumbai (India) - 400088	Recombinant Hepatitis E Vaccine (E. Coli)	Phase IV	A Prospective, Multicentre, Single Arm, Phase-IV Study to evaluate the Safety and Immunogenicity of Recombinant Hepatitis E Vaccine (E. Coli) in Healthy Adults. [Protocol Number: CRNI/CTP/24/07, Version Number: 02; dated 15/Oct/2024]	CT-15/2024	30-12-2024	Dr. Hari Shankar Joshi, ICMR- Regional Medical Research Centre, Gorakhpur, Baba Raghav Das (BRD) Medical College Campus, Gorakhpur, Uttar Pradesh PIN-273013
13.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) -411028	Typhoid Conjugate Vaccine (Bivalent)	Phase-II/III	A Phase 2/3, double-blind, randomized, active-controlled, multi centric study to evaluate the safety, immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024".	CT-10/2025	26-05-2025	Dr Kheya Uttam Ghosh Institute of Child Health, 11 Dr Biesh Guha Street, Kolkata -700017, West Bengal, India
14.	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, randomized, active-controlled, phase-III study of evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine,	CT-03/2025	07-04-2025	Dr. N. S. Mahantshetti M.B.B.S & M.D (Paediatrics) KLEs Dr. Prabhakar Kore Hospital & Medical Research



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	District, Telangana, India-500078			administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule". [Protocol No. BECT089/IPV-Phase-III/CT-01 Version No. 1.0 Dated 02.12.2024].			Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.
15.	M/s Novo Medi Sciences Private Limited ,Shop No. 2, Suyash Heights, Plot No. 36 Sector-18, Khargar Panvel (India) - 410210	13-valent Pneumococcal Polysaccharide Conjugate Vaccine (TT/DT)	Phase III	A prospective, randomized, double-blind, multi-center, phase III study to assess and compare the immunogenicity and safety of the 13-valent Pneumococcal Polysaccharide Conjugate Vaccine in healthy Indian subjects.	CT-09/2024	11-09-2024	Dr. Sanjay Pandey All India Institute of Medical Sciences, Patna Bihar-801507.
16.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) –411028	Typhoid Conjugate Vaccine (Bivalent)	Phase-II/III	A Phase 2/3, double-blind, randomized, active-controlled, multi centric study to evaluate the safety, immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024".	CT-10/2025	26-05-2025	Dr Uma Muralidharan Meenakshi Mission Hospital & Research Centre, Lake area, Melur Road, Madurai, Tamil Nadu, India



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17.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) –411028	Typhoid Conjugate Vaccine (Bivalent)	Phase-II/III	A Phase 2/3, double-blind, randomized, active-controlled, multi centric study to evaluate the safety, immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years", Protocol No. TCV-02, Version: 1.0, dated 21st Oct 2024".	CT-10/2025	26-05-2025	Dr Ritesh Jain Marwari Hospital, Guwahati, Assam, Room No.: 520, Clinical Research Unit, 5th Floor, Marwari Hospitals, Sati Joymati Road, Athgaon, Guwahati, Assam, India.
18.	M/s. Biological E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana-500078	SARS-CoV-2 (Covid-19) Vaccine (Variant JN.1)	Phase III	A prospective single blind randomized Phase-III comparative study to evaluate immunogenicity and safety of Biological E's JN.1-RBD subunit Covid-19 vaccine in 18-80 years old individuals. (Protocol no. BECT092/JN.1-Covid-19-Phase-III/CTP-02, Version no. 2.0 dated 11.06.25).	CT-16/2025	08-09-2025	Dr. Keyur Brahme SSG General Hospital, Anandpura, Vadodara - 390001, Gujarat, India.
19.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Sy. No. 281-284 & 321, Biotech Park Phase	Inactivated Kyasanur Forest Disease (KFD) Vaccine	Phase I	A First-in-Human Randomized, Double Blind, Placebo-Controlled Phase I Study in Healthy Indian Adults to Evaluate the Safety, Reactogenicity and Immunogenicity of inactivated KFD vaccine developed by the	CT - 22/2025	12-11-2025	Dr. Muralidhar Varma, Manipal Academy of Higher Education, Kasturba Medical College, Manipal, Udupi, Karnataka -576104, India.



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	III, Karkapatla (V), Markook Mandal, Siddipet District, Telangana (India) – 502281			Human Biologicals Institute” [Protocol no: KFD-001, Version: 5.5, dated 07.08.2025].			
Q4 (Oct 2026 To Dec 2026)							
20.	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India-500078	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, randomized, active-controlled, phase-III study of evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule". [Protocol No. BECT089/IPV-Phase-III/CT-01 Version No. 1.0 Dated 02.12.2024].	CT-03/2025	07-04-2025	Dr. Jaishree Vasudevan Chettinad Hospital & Research Institute, Chettinad Academy of Research and Education, Chettinad Health City, SH 49A, Kelambakkam Dist., Chennai-603103, Tamil Nadu, India
21.	M/s. Biological E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana, INDIA – 500078	Measles-Rubella (MR) Vaccine, Live, Attenuated (Freeze-dried) I.P.	Phase II/III	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].	CT-20/2025	30-10-2025	Dr. Monika Sharma Christian Medical College & Hospital, Brown Road, CMC Campus, Ludhiana-141008, Punjab, India.



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22.	M/s. Biological E. Limited, Sy. No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri (District), Telangana, INDIA – 500078	Measles-Rubella (MR) Vaccine, Live, Attenuated (Freeze-dried) I.P.	Phase II/III	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].	CT-20/2025	30-10-2025	Dr. Madhukar Pandey Shubham Sudbhawana Superspeciality Hospital, B31/80- 23B, Bhogabeer, Lanka Varanasi- 221005, Uttar Pradesh, India.
23.	M/s Techinvention Lifecare Ltd	Combined Tetanus Toxoid, Reduced Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine (Tdapgen)	Phase III	A multicenter, randomized, observer-blind, non-inferiority, Phase III study to evaluate the immunogenicity and Safety of Boostagen ^{RED} ™ (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNet-Asia compared to ADACEL® vaccine by Sanofi Pasteur Limited in healthy subjects aged 4-65 years.	CT-11/2023	11-03-2023	Dr. Ramesh Chand Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh 206130.
24.	M/s Biological E. Ltd., Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana,	Inactivated Poliomyelitis Vaccine (Adsorbed)	Phase III	A single blind, randomized, active-controlled, phase-III study of evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old	CT-03/2025	07-04-2025	Dr. Nagarjuna Chadavada Aditya Multispecialty Hospital, 13-3- 52, 3rd Line, Gunturuvari Thota, Kothapet, Beside Peoples Trauma,



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	India-500078			healthy infants in 6-10-14 weeks dosing schedule". [Protocol No. BECT089/IPV-Phase-III/CT-01 Version No. 1.0 Dated 02.12.2024].			Guntur-522001, Andhra Pradesh, India.
25.	M/s Cadila Pharmaceuticals Limited 1389, Trasad Road, Dholka – 382 225, Dist: Ahmedabad Gujarat State, India	Quadrivalent Human Papillomaviruses (HPV) Vaccine	Phase I	A Phase-I, open label clinical trial to assess the safety and immunogenicity of Quadrivalent Human Papillomavirus (HPV) Vaccine in healthy subjects [Protocol No.: CRSC24001, Version no.: 01 dated 08.07.2024]	CT-08/2025	20-05-2025	. Dr. Maharshi Desai Apollo Hospital International Ltd., Site Office Building, near ICICI ATM, Plot No. 1A, Bhat, GIDC Estate, Gandhinagar, Ahmedabad-382428, Gujarat, India.

* **Note: Change in Principal investigator.**

Note:

1. This is a dynamic inspection plan published based on the clinical trials approval and maybe updated as and when required.
2. Inspections maybe planned by Zonal/Sub-Zonal offices as per the specific situations which maybe arise from time to time.