Annexure-I of QMS-INS-007

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002

Tentative Central Inspection Plan for Clinical Trial Inspections (Vaccines) for Year 2025

S.No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Principal Investigator & Clinical Trial Sites
				Q1 (Jan 2025 To Mar 2025)			
1.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Anil Jacob Purty Pondicherry Institute of Medical Sciences (A unit of the Madras Medical Mission), Ganapathichettikulam, Kalapet, Puducherry – 605014
2.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A PhaseIII, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Teena Mary Joy Amrita Institute of Medical Sciences, Kochi, Ponekkara, P.O. – 682041 Kerala
3.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Suman Kanungo ICMR-National Institute Of Cholera and Enteric Diseases(ICMR-NICED)P-33,C.I.T, Road, Scheme - XM, Beliaghata, Kolkata – 700010 West Bengal
4.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001, Version no. 4.0 dated 24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Krishna Pandey ICMR- Rajendra Memorial Research Institute of Medical Sciences, Agamkuan, Patna 800007, Bihar, India

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5.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Savita Verma Pt. B.D. Sharma, Postgraduate Institute of Medical Sciences, University of Health Sciences, Rohtak Haryana, 124001
6.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Mohammad Shameem Jawaharlal Nehru Medical College, Aligarh Muslim University Aligarh UP 202002
7.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Versionno.4.0dated24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Shubhangi Kanitkar Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri Pune.
8.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults."[Protocol no. PAN-ICMR-DengiAll-001,Version no.4.0dated 24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Melvin George SRM Medical College Hospital & Research Centre Kattankulathur, Chengalpet 603203

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9.	M/s Panacea Biotec Ltd., A-27, B-1 Extension, Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized)	Phase III	"A Phase III, Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." [Protocol no. PAN-ICMR-DengiAll-001,Version no.4.0dated 24 Nov.2022]	CT-03/2024	28-02-2024	Dr. Shantala G.B Bangalore Medical College & Research Institute, KR. Road, Fort, Bengaluru - 560002.
Q2 (Apr 2025 To June 2025)							
10	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 Telephone No.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocolno.:221265 protocol amendment 01 Dated 19-Apr- 2024	CT-08/2024	19-08-2024	Dr. Shantanu Munshi Calcutta School of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata West Bengal-700073.
11	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 TelephoneNo.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.:221265 protocol amendment 01 Dated 19-Apr- 2024	CT-08/2024	19-08-2024	Dr. Vinay Bhomia Sanjivani Super Speciality Hospital Pvt Ltd, 1, Uday Park Society, Near Sunrise Park, Vastrapur Ahmedabad Gujarat -380015
12	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 Telephone No.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated19-Apr- 2024	CT-08/2024	19-08-2024	Dr.Manoj Lahoti Suyash Institute of Medical Sciences, Gudhiyari Road Kota Raipur Chhattisgarh - 492001.

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13	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 Telephone No.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated 19-Apr- 2024	CT-08/2024	19-08-2024	Dr. Durga Krishnan Chettinad Hospital and Research Institute, Rajiv Gandhi Salai, Kelambakkam 603103 Tamil Nadu.
14	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 TelephoneNo.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated 19-Apr-2024	CT-08/2024	19-08-2024	Dr. R.G. Vivek 1st Floor Beside Dialysis Ward, Belagavi Institute of Medical Sciences, Dr. B. R. Ambedkar Road, Belagavi-590001, Karnataka
15	M/s GSK Pharma India Private Limited, 01, Battery House Bhula bhai Desai Road Mumbai (India) - 400026 Telephone No.:02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)	Phase III	A Phase 3, randomized, placebo- controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated19-Apr-2024	CT-08/2024	19-08-2024	Dr. Dipanjan Bandopadhyay North Bengal Medical College and Hospital, Sushruta Nagar Siliguri West Bengal – 734012 .
Q3 (July 2025 To Sep 2025)							
16	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24Valent)	Phase II	An open label randomized Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14weeks dosing schedule"[Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.:2.0 dated 02.04.24, Amendment No.:1.0 dated 02.04.24]	CT-11/2024	30-10-2024	Dr. B.S. Chakravarthy King George Hospital Collectorate Junction, Maharani peta, Visakhapatnam – 530002, Andhra Pradesh.

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17	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24Valent)	Phase II	An open label randomized Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14weeks dosing schedule" [Protocol no. BECT085/PCV-Phase-II/CTP-02,Version No.:2.0 dated 02.04.24, Amendment No.:1.0 dated 02.04.24]	CT-11/2024	30-10-2024	Dr. N.S. Mahantshetti, KLEs Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka
18	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24Valent)	Phase II	An open label randomized Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14weeks dosing schedule" [Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.:2.0 dated 02.04.24, Amendment No.:1.0 dated 02.04.24]	CT-11/2024	30-10-2024	Dr. Jai Prakash Narayan Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer -305001, Rajasthan.
19	M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24Valent)	Phase II	An open label randomized Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14weeks dosing schedule" [Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.:2.0 dated 02.04.24, Amendment No.:1.0 dated 02.04.24]	CT-11/2024	30-10-2024	Dr. Anil Kumar Pandey ESIC Medical College & Hospital, New Industrial Town, Faridabad -121001, Haryana
Q4 (Oct 2025 To Dec 2025)							
20	M/s Serum Institute of India Pvt.Ltd.,212/2Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India) – 411028	Meningococcal(A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	Phase III	A Phase 3, Randomized, Double-blind, Controlled, Multi-Center Study to Compare Immunogenicity and Safety of SIIPL Meningococcal ACYWX Conjugate Vaccine(NmCV-5) with that ofLicensed Meningococcal ACWY Vaccine Menactra® in Healthy Indian Children of9monthsto17 Years of Age" vide Protocol no. ACYWX-05,VersionNo1.0Dated16-MAY-2024.	CT-12/2024	05-11-2024	Dr. Anand Kawade KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka-Shirur, District- Pune-412216 -

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21	M/s Serum Institute of India Pvt.Ltd.,212/2Off Soli Poonawalla Road, Hadapsar ,Pune, Maharashtra (India) – 411028	Meningococcal(A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	Phase III	A Phase 3, Randomized, Double-blind, Controlled, Multi-Center Study to Compare Immunogenicity and Safety of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Indian Children of 9months to 17 Years of Age" vide Protocol no. ACYWX-05,Version No1.0 Dated16- MAY-2024.	CT-12/2024	05-11-2024	Dr. Deepti Thandaveshwara JSS Hospital,Mysuru-570004,Karnataka
22	M/s Serum Institute of India Pvt.Ltd.,212/2Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India) – 411028	Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)	Phase III	A Phase 3, Randomized, Double-blind, Controlled, Multi-Center Study to Compare Immunogenicity and Safety of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Indian Children of 9 months to 17 Years of Age" vide Protocol no. ACYWX-05,Version No1.0 Dated16- MAY-2024.	CT-12/2024	05-11-2024	Dr. Kheya Ghosh Uttam Institute of Child Health 11, Dr.Biresh Guha Street, Kolkata, West Bengal - 700001
23	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 no. 3.0 dated 04 Sep 2024.	CT- 01/2025	17.01.2025	Dr. G Bala Kishor St. Theresas Hospital, Sanathnagar, Hyderabad, Telangana - 500018

Note:

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