F.No: QA/01/Central Inspection Plan/CT/2018
Director General of Health Services
Central Drugs Standard Control Organisation
Office of Drugs Controller General (India)
FDA Bhawan, Kotla Road,
New Delhi-110002
(QA Division)

Dated: 01 JAN 2018

Office Memorandum

As a process of Clinical trial oversight, CDSCO-HQ has prepared tentative Central Inspection Plan for the Year 2018 for inspections of the clinical trials permitted with respect to vaccines in accordance with the elements of SOP QA-INS-004. You are requested to conduct clinical trial inspections as per plan with the team comprising of inspectors trained in GCP, along with subject expert. Drugs inspectors from respective states may also join the inspection team.

The clinical trial inspection report shall be submitted after completion of inspection to this office along with your recommendations for further action by this office.

(Dr. G. N. Singh)
Drugs Controller General (India)

Encl: 1. Central Inspection Plan for clinical trial inspections for year 2018

To:
All DDC(I)s of North Zone, West Zone, South Zone, Ahmedabad Zone, Hyderabad Zone, Varanasi Sub Zone, Jammu Sub Zone and Baddi Sub Zone.

Copy to:
Guard file (QA Division & Biological division)
PS to DCGI

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

List of Clinical Trials (Vaccines) to be inspected in the year 2018

S. No	Name of Investigational Product	Study Title
1.	Recombinant Quadrivalent Human Papilloma Virus	A Phase-I, open label clinical trial to assess the safety and tolerability of recombinant Quadrivalent Human Papilloma Virus (qHPV) (type 6,11, 16,18) vaccine manufactured by Serum Institute of India Pvt. Ltd. in healthy adult volunteers.
2.	Tetanus Vaccine	A Phase I open label study to evaluate the safety of Tetanus Vaccine (Adsorbed) in Healthy Indian Adults.
3.	HPV Vaccine	An open label, single treatment, single period, single dose, clinical phase I study to assess the safety and tolerability of Bivalent Papillomavirus (Types 16L1 & 18L1) vaccine of M/s Cadila Healthcare Ltd., India adult female human subjects.
4.	Zika Virus Vaccine	A Phase I, multicenter, double-blind, placebo controlled, randomized (Intra group) Clinical trial to evaluate two dose of three sequentially escalating cohort of Zika Virus vaccine, inactivated (Adsorbed) (BBV121) in healthy adult Dengue Sero- negative and dengue Seroposiive Volunteers.
5.	r-BCG Vaccine	A multicenter Phase II/III double-blind, randomized, Placebo controlled study to evaluate the efficacy And safety of VPM1002 in the prevention of tuberculosis (TB) recurrence in pulmonary TB patients after successful TB treatment in India
6.	Hapititis A Vaccine	A Prospective, Multicentre, Randomized, Double Blind, Parallel Group, Phase III Study Comparing Immunogenicity, Safety, and Tolerability of Single Dose of Hepatitis A (Live) Vaccine, Freeze-dried from Sinopharm versus Biovac^{TM}-A (Freeze-dried Live Attenuated Hepatitis A Vaccine) from Wockhardt in Healthy Indian Children.
7.	MR Vaccine	A prospective, randomized, two arm, single blind, parallel, active controlled, multicentre,phase III clinical study to evaluate the immunogenicity and safety of Inactivated Influenza vaccine (split virion) I.P.(Tetravalent) of M/s Cadila HealthcareLimited in healthy children aged 6 months to 17 years.

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List of Clinical Trials (Vaccines) to be inspected in the year 2018

S. No	Name of Investigational Product	Study Title
8.	Inactivated Influenza vaccine (splitvirion) I.P. (Tetravalent)	A prospective, randomized, two arm, single blind, parallel, active controlled, multicentre,phase III clinical study to evaluate the immunogenicity and safety of Inactivated Influenza vaccine (split virion) I.P.(Tetravalent) of M/s Cadila HealthcareLimited in healthy children aged 6 months to
9.	Inactivated Influenza vaccine (splitvirion) I.P. (Trivalent)	A prospective, randomized, two arm, single blind, parallel, active controlled, multicentre, phase III clinical study to evaluate the immunogenicity and safety of Inactivated Influenza vaccine (split virion) I.P.(Trivalent) of M/s Cadila Healthcare Limitedin healthy children aged 6 months to 17years
10.	Tetanus Vaccine	An open- label, single treatment, single-period, single dose, clinical phase I study to assess the safety and tolerability of tetanus vaccine of M/S Bio Vaccine (India) Private Limited in healthy, adult, male, human subjects.
11.	Diptheria, Tetanus, Pertussis (whole cell), Hepatitis B(rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed)	A Prospective, randomized, two arm, single blind, parallel active-controlled, multicenter, non-inferiority clinical study to evaluate the immunogenicity and safety of Diptheria, Tetanus, Pertussis (whole cell), Hepatitis B(rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) of M/S Cadila Healthcare Limited compared to Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B(rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) of M/S Panacea Biotech Limited in Healthy infants.
12.	Tetanus Vaccine	A Prospective, age decending, randomized, two arm, single blind, parallel, active controlled, multicentre, non-inferiority, Phase II/III clinical study to evaluate the immuniginity and safety of Tetanus Vaccine (Adsorbed) of M/s bio Vaccines (India) Private Limited compared to Tetanus Vaccine (Adsorbes) of M/s Serum Insitute of India Limited in healthy subjects aged 10-60 years of age.
13.	Inactivate Hapititis-A Vaccine	An Open Label Phase I Study to evaluate the Safety and Immuniginicity of Inactivated Hepatitis-A Vaccine when administered as a Single Dose in two groups of Healthy Subjects of 19 to 49 years and 12 to 18 years of age.

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S. No	Name of Investigational Product	Study Title
14.	Rotavirus Vaccine (Liquid)	A Phase II/III, multicenter, open-label, randomized study of liquid Bovine rotavirus Pentavalent vaccine (LBRV-PV) to evaluate lot-to-Lot consistency and to compare non-inferiority with ROTASIIL (lyophilized BRV-PV) in healthy infants in India
15.	Diphtheria-Tetanus-Acellular Pertusis-Inactivated Polivirus Type I, II & III and Haemophilus Influenza Type b Titanus Toxiod Conjugate Vaccine (Infanrix-IPV/Hib) (SB213503)	A Phase III, open-label, multicentre study to evaluate the immuniginicity and safety of GSK Biologicals' Combined Diphtheria-Tetanus-Acellular Pertusis-Inactivated Polivirus Type I, II & III and Haemophilus Influenza Type b Titanus Toxiod Conjugate Vaccine (Infanrix-IPV/Hib) (SB213503) administered at 6, 10 and 14 weeks in 112 healthy Indian infants.
16.	14-Valent Pneumococcal Vaccine	Phase II clinical trial titled "An open label parallel randomized Phase II comparative study to evaluate safety tolerability and immunogenicity of two intramuscular doses of 14 valent pneumococcal polysaccharide conjugate vaccine administered 2 months apart to 12 to 23 month old healthy Indian PCV naive toddlers