PHARMACY, MEDICINES & POISONS BOARD

GCP INSPECTION CHECKLIST

ABBREVIATIONS / ACRONYMS

ADR	Adverse Drug Reaction
ALSS	Advanced Life Support Systems
CRF	Case Report Form
CoA	Certificate of Analysis
CPR	Cardio-pulmonary resuscitation
CRO	Clinical Research Organisation
CV	Curriculum Vitae
DSMB	Data Safety Monitoring Board
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IP	Investigational Product
NA	not checked or not applicable
PI	Principal Investigator
RA	Regulatory Authority
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

GCP INSPECTION CHECKLIST

Names of Inspectors	
Date of Inspection	
Name and address of the site	
Protocol number	
Stage of study:	
Before trial commencement	
During clinical conduct	
After completion of trial	
Name of principal Investigator	
Name of Sub (Co) Investigator	
Study Title	
Regulatory Authority Protocol approval No.	

Version & date:	
Amendment History approval	
Version & date:	
Ethics Protocol approval **Version & date:**	
Informed consent (ICON) Version approved & date:	
Amendment History approval	
Version & date:	
Screening date of 1st participant	
How many participants enrolled?	
How many participants withdrew from the study?	
How many participants completed the study?	

Observations are classified into the categories "Critical", "Major", "Other (Minor)". The recommendations are listed at the end of the report. To be classified at a later stage

A.	**FACILITY INSPECTION**	**YES**	**NO**	**NA**
1	**Consulting Area**			
1.1	Is the consulting area where the PI/designated Physician evaluates the participants during visits adequate in size?			
1.2	Are there lock-up cupboards for confidential documents?			
1.3	Is the trial specific equipment available in the consulting room?			
1.4	If not, is the area where procedures are performed adequate and easily accessible?			
1.5	Does the PI manage and maintain the trial visits? To add to inspection training that this could be not applicable in the case of field sites			
2	**Procedure Room**			
2.1	Is all equipment e.g. Baumanometer, scale, lung function machine (asthma, COPD) as per protocol calibrated and validated?			
2.2	Are SOPs on how to use equipment available?			
2.3	Is the blood sampling area kept according to infection control			

A.	FACILITY INSPECTION	YES	NO	NA
	procedures?			
2.4	Waste handling according to applicable guidelines, e.g. from the RA or site or government?			

A.	FACILITY INSPECTION	YES	NO	NA
2.5	Is the emergency trolley available in the procedure area? As per the requirements for vaccines and medical devices ➢ Is the trolley locked and are the keys available and controlled? ➢ Is the emergency trolley frequently checked and documentation as proof available? ➢ Are expiry dates clearly checked and controlled? ➢ Oxygen and accessories available, checked and signed? ➢ Are PI and sub-investigators ALSS trained? ➢ Are clinical staff CPR trained?			
3	**Pharmacy (Investigational Product storage area)**			
3.1	Is the pharmacy access controlled, temperature and humidity controlled?			
3.2	Are vaccines stored as per required temperature and humidity?			
3.3	Is the preparation of investigational product management done according to the approved protocol by suitable qualified staff?			
3.4	In case of vaccines, are a spillage SOP available and the study team trained to handle such an incidence?			
3.5	Are electronic or hand-written temperature logs available?			
3.6	Is an SOP on how to handle electricity or temperature failure in the pharmacy available?			
3.7	Are the different studies Investigational Products in separate lock-up cupboards and clearly identified'?			
3.8	Are vaccines transported and handled as per cold chain requirements?			
4	**Archive**			
4.1	Is there an agreement between Sponsor and Trial Site/CRO on the archiving of documentation?			
4.2	Is this clause documented in the protocol or contract			
5	**Clinical Laboratory**			
5.1	Is the clinical laboratory at the same site?			
5.2	If not, are procedures in handling biological samples clearly documented? (If clinical laboratory is nearby arrange for a GLP inspection)			
5.3	Are all equipment and testing procedures used in the laboratory validated?			

A. FACILITY INSPECTION	YES	NO	NA
5.4 Is the laboratory accredited for the tests to be performed?			
6 Waste disposal			
6.1 Is the disposal of biological specimens and sharps appropriate?			

B. DOCUMENTATION

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of GCP and all applicable regulatory requirements. (ICH GCP section 8.1) WHO reference?

Check the *availability* of the following documents:

(During the planning stage, the following documents should be generated ***before*** the conduct of the trial) **General**	YES	NO	NA
1.1 Approved, signed and final version of the Protocol (including amendments)			
1.2 Final version of the Investigator's Brochure			
1.3 Information Leaflet, information regarding the trial in lay terms			
1.4 Informed Consent Form (translation) and applicable procedure			
1.5 Sample of the case report forms (CRF) as per protocol requirements			
1.6 Any other written information (e.g. advertisements)			
1.7 IEC approval of advertisement for participant recruitment			
1.8 Financial aspects of the trial as predefined in an agreement between the Investigator and the sponsor			
1.9 Guaranteed indemnity / insurance document / statement			
1.10 Signed agreements between involved parties e.g. Investigator/CRO, Investigator/Sponsor			
1.11 Source documents and CRF verification procedure (SOP) available?			
1.12 Clear documentation of transfer of responsibilities			
1.13 All approval documentation: • Independent Ethics Committee approval (Clearly stated which dated version of protocol and informed consent is approved.) • Regulatory approval. (Clearly stated which dated version of protocol and informed consent is approved.)			

(During the planning stage, the following documents should be generated ***before*** the conduct of the trial) **General**	**YES**	**NO**	**NA**
1.14 List of Ethics Committee members			
1.15 Latest signed and dated CV's of investigators			
1.16 Proof of GCP training of all study team members			
1.17 Pre-trial GCP site assessment report (only at the Sponsor site)			
1.18 List of DSMB members			
1.19 Verify the availability of the Local Safety Monitor's CV			
1.20 Trial initiation visit , agenda and study team attendance list			
1.21 Verify the availability of the Serious Adverse Event reporting forms and reporting procedures/timelines (including supporting SOP's)			
Laboratory			
1.22 Normal values / ranges for medical / laboratory / technical procedures as supplied by the laboratory / contract laboratory			
1.23 Laboratory Certification			
1.24 Laboratory Accreditation			
1.25 Quality Control or quality assessment of laboratory by the sponsor			
1.26 Validation methods where applicable			
Investigational Product			
1.27 Sample labels of IP (only at Sponsor)			
1.28 All shipping records of IPs (dates, batch numbers)			
1.29 Proof that conditions as stated in the protocol have been maintained during shipment and storage of products			
1.30 CoA of IPs (Check stability, expiry dates)			
1.31 Vaccine accountability records e.g. quantities ordered and received			
1.32 Decoding procedures for blinded trials			
1.33 Master randomization list (only at Sponsor site)			
1.34 Instruction for handling of investigational product and trial related materials			
1.35 Proof that the correct diluent has been packed according to the correct storage condition and shipped with the vaccine?			

2 ICH GCP section 8.3 (In addition to having on file the aforementioned documents the following documentation should be added to the files ***during*** the conduct of the trial) **Documentation**		**YES**	**NO**	**NA**
2.1	Updates of Investigator's Brochure e.g. ADRs			
2.2	Any approved amendments to o protocol o informed consent			
2.3	IEC and regulatory approval of any new investigators, and their CVs			
2.4	Proof of GCP training			
2.5	Updates of normal values / ranges for medical / laboratory / technical procedures as supplied by the laboratory / contract laboratory			
2.6	Vaccine accountability documentation and correct use of the product according to the protocol and IP management			
2.7	Shipment documentation of any new batches of IPs including CoA, batch release and temperature control.			
2.8	Communications other than monitoring visits o Letters o Meeting minutes and agendas o Notes of telephone calls			
2.9	Signed Informed Consents			
2.10	Source documents, e.g. X-rays, serology printout, diary cards			
2.11	Signed and dated CRFs			
2.12	SAE reporting to sponsor			
2.13	Reporting of any serious unexpected ADR and relevant safety information to NRA and IEC where required			
2.14	Progress reports to IEC			
2.15	Participant screening log			
2.16	Participant identification code list			
2.17	Participant enrolment log			
2.18	Study team signature sheet with delegated functions by PI			
2.19	Retained biological samples (records, storage conditions)			
2.20	All deviations e.g. inclusive/exclusive criteria (waiver) recorded			

3	**ICH GCP section 8.4** (Documentation ***after*** completion or termination of the trial)			
3.1	IP accountability at site (final reconciliation)			
3.2	Documentation on disposal of IPs			
3.3	Completed participant identification code list			
3.4	Audit Certificate (if applicable), i.e. if carried out			
3.5	Final trial close-out monitoring report			
3.6	Final report by investigator to IEC and regulatory authority (refer to ICH GCP section 4.13)			
3.7	Clinical study report (refer to ICH GCP section 5.22)			
3.8	Treatment allocation and decoding documentation that have occurred available.			
3.9	Is a follow up plan available (post trial period) for participants with adverse events related to the IP as per protocol?			

C.	**INFORMED CONSENT PROCESS**	**YES**	**NO**	**NA**
1	Was the informed consent form version used the same as the one approved by the IEC/IRB?			
2	Was a written SOP used to solicit informed consent?			
3	Were all the participants given a copy of a signed informed consent form?			
4	Did all the participants sign the consent form prior to any study related procedure?			

D. GENERAL INFORMATION

1 Ask for an organogram of the Trial Site/CRO and note the following points:

1.1 number and categories of people employed

1.2 description of the qualifications, training and experience of the personnel

1.3 work load of study team

1.4 number of concurrent clinical studies performed on site and identification of participants to avoid confusion and mix-ups of IP's administration

2 Ask for a description of the quality assurance system set up at the trial site.

3 Check the existence, availability, accessibility and validity of the operating procedures; ask for a list of the Standard Operating Procedures used for the trial.

4 Verify the availability of 100 % of all documentation particularly the ICF, CRF and source documents.

5 Perform verification of Informed Consent forms as per NRA requirements.

6 Perform at least 25 % Source documentation versus CRFs verification

7 Perform a100 % accountability of IP

E. REFERENCES

1 ICH Guideline for good clinical practice, recommended for adoption at step 4 of the ICH process on 1 May 1996

2 Guidance on General Considerations for Clinical Trials (ICH-E8)

3 Guidelines for good clinical Practice (GCP) for trials on pharmaceutical products. WHO Technical Report Series, No. 850, Annex 3, 1995