Once CAPA acceptable, a closing email and GCP inspection statement are issued.

An ‘advance notice of statutory inspection’ is sent to the organisation requesting for a GCP inspection dossier to be submitted.

Organisation supplies GCP inspection dossier.

The inspection dates are confirmed with the Organisation.

The inspection plan is developed with the organisation and finalised.

Main inspection takes place of the organisation (Commercial Sponsor, Host Organisation).

Where critical issues are found, these may be referred to the Clinical Trial Inspection Action Group (CTIAG).

After organisation inspection, the inspection of any other sites takes place as applicable [e.g. Investigator(s) sponsored by commercial organisation, Laboratories etc.]

After the last site inspection, a report of the findings is issued to organisation.

The organisation responds and the Corrective Action Preventative Action (CAPA) plan is reviewed for acceptability.

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