GCP Inspection Process



PLANNING

An 'advance notice of statutory inspection' is sent to the Organisation supplies The inspection dates The inspection plan is organisation requesting for a **GCP** inspection developed with the are confirmed with **GCP** inspection dossier to be dossier organisation and finalised the Organisation. submitted After organisation inspection, the inspection of Main inspection takes any other sites takes place as applicable [e.g. place of the organisation Investigator(s) sponsored by commercial (Commercial Sponsor, Where critical organisation, Laboratories etc 1 Host Organisation) issues are found. these may be referred to the **Clinical Trial** Inspection The organisation **Action Group** After the last site responds, and the inspection, a Once CAPA acceptable, (CTIAG) Corrective Action report of the a closing email and GCP Preventative Action findings is issued inspection statement are (CAPA) plan is to organisation issued

reviewed for acceptability