

## GCP Routine Inspection Process

### PLANNING

A “preliminary notification to organisation of statutory inspection” is sent to the organisation which requests the pre-inspection dossier

Organisation supplies the pre-inspection dossier

The inspection dates are confirmed with the Organisation.

The inspection plan is developed with the organisation and finalised

### INSPECTION

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

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

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

### REPORTING

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

Once CAPA acceptable, an inspection closing letter and GCP statement are issued