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European Medicines Agency

Annex II to the guidance document of protection of personal data and commercially confidential information while using CTIS

The template applies to Good Clinical Practice (GCP) inspections carried out to category 1 trials where the publication of clinical trial information is delayed by a deferral.

On date xx to xx an inspection(s) of clinical trial 202X-000000-00-00 has/have been carried out at the clinical trial facility(ies) *(list the inspection site if sponsor, clinical investigator site, CRO site, etc.. according to the information made publicly available in CTIS structured data)*

<site name X – function>

<site name Y – function>

The inspection at site name <TBC> has revealed:

- No major findings;

- Major findings and adequate corrective and preventive actions have been proposed/implemented by the inspected parties;

- Critical findings and adequate corrective and preventive actions have been proposed/implemented by the inspected parties.