"HOW TO REPORT"

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Reference texts

- Directive 2001/20/EC, art.15 (2)

'Following inspection, an inspection report shall be prepared..'

- Directive 2005/28/EC, art.30 (2)

- Procedure for reporting of GCP Inspections requested by the EMEA (INS /GCP/4)- CAP inspections

Volume 10 of the publications "The rules governing medicinal products in EU" contains guidance documents applying to CTs

- Guidance for the preparation of GCP Inspection Reports (June 2008)
- Guidance for the communication of GCP Inspections and Findings (June 2008)
- Guidance for exchange of GCP Inspection Reports according to Directive 2001/20/EC art.15 (2) (May 2009)

Inspection report requirements

- Must be clear and understandable
- Must reflect the conduction of the inspection
- Must evaluate the compliance with (EU and) national regulations, GCP, ethical and scientific standards
- Must evaluate the validity and reliability of the data recorded/submitted according to the scope of the inspection, answering all the questions asked in the inspection request, e.g. CHMP, National Authority (MA Unit, etc.)

Inspection report

-**Investigator site (Pharmacy, laboratory, EC)**

-**Laboratory**

-**Sponsor /CRO site**

Different formats
(national procedures, EMEA procedures)

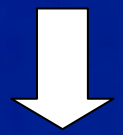
IR Investigator site
Basic Items

- Administrative information
- Reference texts and documents for the inspections
- Conduct of the trial
- Documents reviewed during the inspection, including a summary of the SDV conducted
- Accountability of medicinal products
- Laboratories, technical departments
- Monitoring and auditing
- GCP compliance, summary and conclusion
- Dates and signatures

IR Sponsor site
Basic items

- Administrative information
- Reference texts and documents for the inspections
- Sponsor system inspection
  - -organisation and personnel
  - -facilities and equipment
  - -SOPs
  - -QA
  - -monitoring
  - -IMP management
  - -data management
  - -CTs pharmacovigilance
- GCP compliance, summary and conclusion
- Dates and signatures

NON-COMPLIANCE



FINDINGS

Critical, Major, Minor

Each deviation or at least for critical and major findings should refer to the requirements for which it is non-compliant (legislation, guidelines, trial protocol)

(for CAP Inspections for each deviation)

Conclusion of the Inspection Report

Conduction, recording and reporting of the trial acceptable/non-acceptable according to the principles of GCP

If the inspection is related to MA, a recommendation should be given on whether the quality of the reported data allows its use in a MAA

An IR is defined as complete when the inspectors have assessed the responses from the inspectees on the findings described in the original IR

HOW MANY REPORTS?

-For National Inspections: according to national procedure, one IR for each inspected site or an overall report encompassing all sites within a common inspection.

-For CAP Inspections: one IR for each inspected site + one IIR (Integrated Inspection Report)

Forwarding the IR

Directive 2001/20/EC

Art.15 (2)

Following inspection, an inspection report shall be prepared. It must be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the Agency, at their reasoned request.

Directive 2005/28/EC

Art.30 (2)

Inspection reports shall be made available by the Member States only to the recipients referred to in Article 15(2) of Directive 2001/20/EC, in accordance with national regulations of the Member States and subject to any arrangements concluded between the Community and third countries.

Inspection report-For whom?

Within a Members State
according to national regulations and procedures

-Inspectees

and/or

-Sponsor/CRO

-Courts/other authorities (if required)

-MA applicant

Reporting in EUDRACT

Essential information about the inspection and its findings

EUDRACT database
(according to the Directive 2001/20)

Communication on GCP inspections and findings

(guidance document, national procedures/regulations)

If relevant findings (quality of the study, subject safety and/integrity):

-Communication to other EU GCP Inspectorates

and to the GCP Inspection Group at EMEA

According to Dir.2001/20/EC, Dir.2005/28/EC, guidance document for exchange of IR reports

exchange of IR restricted and is only allowed under certain circumstances

'Request for exchange of IR' Form

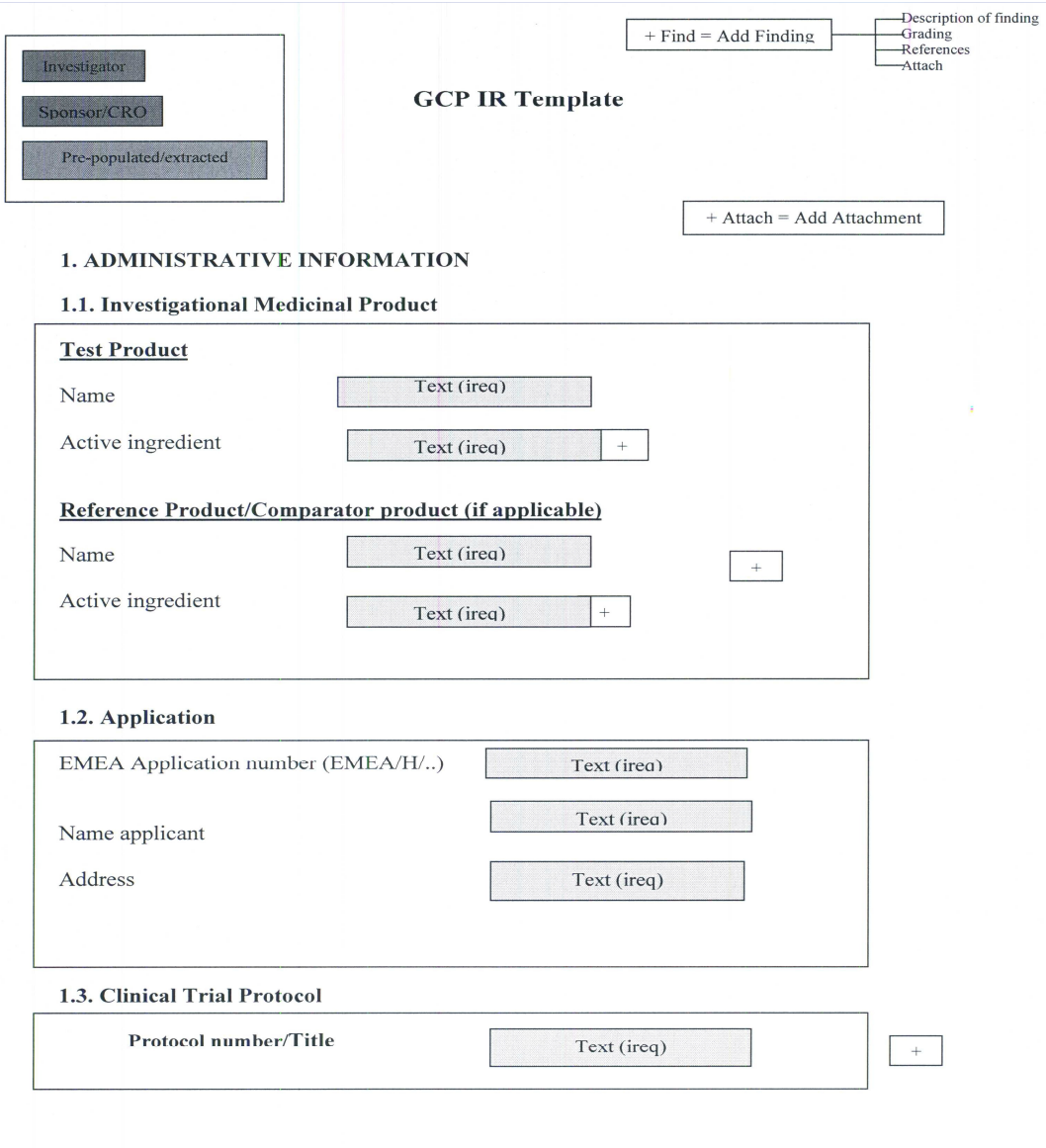
1. requesting CA details
2. CA who is asked to make the IR available
3. Inspection Information
4. Reasons for the request of the IR:
   - -underlying applications for MA
   - -ongoing CTs involved inspected facilities
   - -other significant reasons
5. Signature of the requesting CA representative

Process of a standard inspection report template

Current situation - Problems

- Multiple templates exist based on site roles (clinical investigator/sponsor/CRO/Lab…)
- Repeated sections
- Inconsistent information (different templates provide same information in different ways)
- Confusion between subsections and hints (some subsections are really hints about what information can go under that the parent sections)


As it will be the future……?



Standard GCP IR template in the corporate GXP, which applies to all site roles


Thank you!!