EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 June 2017
EMA/359169/2016

Guidance for the preparation of good clinical practice inspection reports and communication of inspection findings

Adopted by GCP Inspectors Working Group (GCP IWG)	4 September 2017

Keywords	***Inspection reports, inspection findings***

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Guidance for the preparation of good clinical practice inspections

Table of contents

1. Introduction 3

2. Preparing inspection reports 3

2.1. Content and format of the IR 3

2.2. Preparing the IR and forwarding to inspectees/ sponsor 4

2.3. Submitting the IR to the EU portal 4

2.4. Communication of GCP inspection findings between Member States 5

3. References 5

1. Introduction

The scope of this document is to provide guidance for the preparation of inspection reports (IRs) and communication of inspection findings identified following GCP (good clinical practice) inspections carried out by national competent authorities of the different Member States, which may take place on any of the following occasions:

- Before, during or after the conduct of clinical trials.
- As part of the verification of applications for marketing authorisation.
- As a follow-up to the granting of authorisation.

The responsibilities set out in this guidance are outlined in the guidance for coordination/ co-operation with other organisations involved in assessing good clinical practice requirements. This guidance for the preparation of the inspection report may be used for any type of inspection (see guidance for the conduct of GCP inspections, including its annexes).

2. Preparing inspection reports

National competent authorities may choose to report on each inspected site separately, or to produce an overall report encompassing all sites within one common inspection. For example, if multiple site inspections occur within one Member State, as part of a single trial or a system inspection, it is acceptable to produce one overall report (e.g. for systems inspection of organisations with related investigator or clinical research organisations sites).

2.1. Content and format of the Inspection Reports

Following an inspection, the Member State under whose responsibility the inspection has been conducted should draw up an inspection report. The IR should reflect the inspection procedures as described in the EudraLex Volume 10 "Guidance for the conduct of GCP inspections" (EMA/839541/2016). There should be an evaluation of the compliance with national and applicable EU regulations, with Good Clinical Practice principles, and applicable ethical and scientific standards. The validity and reliability of the data recorded/ submitted should be evaluated in accordance with the scope of the inspection. Any major or critical deviations should be addressed.

As a minimum, the following items should be recorded in the IR:

1. Administrative information on what was inspected, where, when and also who was present, unless the list of participants is included in the inspection plan.
2. Reference texts and documents for the inspection.
3. Conduct and management of the trial (where applicable).
4. Handling and reporting of data, analyses, inclusion and exclusions of data.
5. Safety related documents and reporting of safety data.
6. Aspects reviewed during the inspection.
7. Compliance/ Non-compliance with national regulations, applicable EU legislation and the principles of GCP.

8. An indication of any opportunity given to the inspectee or other involved party (e.g. investigator, sponsor, applicant) to comment, if and when comments were received, and whether these were accepted or not. This could be included in appendices to the IR, after the responses have been reviewed, according to national procedure.

These items will be described in the IR and the deviations classified as minor (or other), major and critical (see appendix 1 for definitions). Each deviation should quote a reference to the applicable regulatory and legal requirement, for which this non-compliance was identified.

An evaluation of the impact of the deviations should be included, where applicable, and an overall conclusion on whether the conduct, recording and reporting of the trial is acceptable/non-acceptable according to the principles of GCP should be presented. For inspections related to marketing authorisations or completed trials, a recommendation should be given on whether the quality of the reported data allows its use in a marketing authorisation application (MAA).

Some inspections may be entirely focused on patient's safety or rights during the active phase of a trial, and may not lead to an assessment in relation to marketing authorisations.

2.2. Preparing the IR and forwarding to inspectees/ sponsor

If the inspection is conducted by a team of inspectors, the lead inspector is responsible for the preparation of the IR. The IR should be approved/ signed by all the participating inspectors/ experts or just the Lead Inspector, in accordance with national procedures. In the event of a joint inspection, if applicable, the agreement with the content of the inspection report should be documented with the signature of all participants (or otherwise in accordance with national procedures).

The IR will be distributed and circulated within a Member State in accordance with the national regulation and procedures without prejudice of its submission to the EU portal.

For inspections conducted by one inspector, the IR should, if possible, be reviewed by a colleague as a quality check before being submitted to the inspectee(s), according to the MS inspectorate's procedures.

IR should be finalised within a specified time and according to the national timelines, or the agreed timelines for Marketing Authorisation Applications related inspections, and sent to the inspectee(s) and/ or the sponsor in accordance with local regulations and the objectives of the inspection.

The inspectors will consider the responses from the inspectee(s)/ sponsor and will indicate in writing whether or not these are acceptable and what impact, if any, they have on the original inspection findings.

Responses to the inspection report may be included as appendices to the IR.

2.3. Submitting the redacted version of the IR to the EU portal

According to Article 78 (6) of Regulation (EU) No 536/2014, following an inspection the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. The Member State shall make the inspection report available to the inspected entity and the sponsor and once the inspection process has been completed shall submit it through the EU portal.

A redacted version of the inspection report should be submitted. The redaction of the inspection report will be performed by the responsible inspectorate and will be made publicly available as outlined in the

Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited".

The inspection report can also be provided upon request, to other regulatory authorities, to ethics committee, according to national requirements, or to courts, in the case of an enforcement action.

During the registration process for a marketing authorisation, the report could be submitted to the marketing authorisation applicant as well as to the sponsor, where these are different, with the consent of the sponsor and following to the national regulations.

2.4. Communication of GCP inspection findings between Member States

The GCP inspection report can be circulated to other Member States´ national competent authorities, as appropriate, for example in order to ensure that relevant findings are promptly communicated within the European Community.

In these circumstances the inspectorate of a national competent authority conducting the inspection will inform other Member States' inspectorates about these findings. This can be performed as a communication during the GCP Inspectors Working Group meetings at the EMA or any other way considered by the sender, especially if a finding has direct bearing on the quality of the study or patient safety and/ integrity in other participating Member States in the study.

3. References

i. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

ii. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, as amended.

iii. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

iv. EUDRALEX Volume 10 - Clinical trials, of the Rules Governing Medicinal Products in the European Union: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm.

v. Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014", EMA/228383/2015 Endorsed, 2 October 2015.