## Clinical Trials Inspection

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# Clinical trial inspection

**What is GCP?**

Good Clinical Practice (GCP) is a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**Main goals of GCP:**

- Protecting human rights of clinical trial participants
- Providing standards for the conduct of clinical trials
- Assurance of reliable research process
- Appropriate distribution of responsibilities between parties involved in a clinical trial (investigator’s responsibilities, sponsor’s responsibilities, etc.)

**What is an inspection of a clinical trial of medicinal products?**

**GCP inspection:** official procedures conducted by URPL inspectors authorized by the President of the Office and holding official identity cards. The main goal of their tasks is to verify how a clinical trial is conducted.

**Inspection Process**

Inspection process

A clinical trial inspection is an evaluation of a process conducted simultaneously across many organizations. Generally, it applies to completed research processes and verifies their compliance with GCP and applicable regulatory requirements. Often, the GCP inspection is an integral part of a marketing authorization application. In this case, the aim of the inspection is to validate reliability of the data assessed by clinical experts. Therefore, post-audit recommendations contain preventive and corrective actions.

**Pre-inspection phase**

**Who can be subject to an inspection?**

A regulatory GCP inspection can be conducted at:

- an investigational site,
- a sponsor site,
- a clinical research organization (CRO),
- other places considered as necessary by the competent authority.

**Who can take part in an inspection?**

- Lead and accompanying inspectors,
- Expert/specialist in a particular field,
- Inspected entity: entity conducting a clinical trial, clinical investigator and sponsor.

**Which documents must be prepared before an inspection?**

Information requested by inspectors in the inspection announcement should be submitted by e-mail or send on a CD, DVD or other device to the lead inspector at the following address: *Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warsaw.* Taking into account effective communication between involved parties, the documentation files should be prepared in a transparent manner, allowing for easy navigation between folders. PDF Adobe 5.0 and newer or XLS format (Excel 2003 or 2007) is preferred.

**What is the scope of an inspection?**

Inspectors verify amongst others:

- whether the President of the Office granted approval for conducting the clinical trial and whether all conditions of the approval are met,
- whether the clinical trial is conducted in compliance with the provisions of Good Clinical Practice,
- whether all study participants provided a signed and dated informed consent form,
- whether the clinical trial is conducted according to the protocol and approved protocol amendments,
- the condition of equipment and facilities used during the trial,
- the methods of record-keeping and data storage.

**Inspection**

**Inspection activities at the site**

At the beginning of the clinical trial inspection an opening meeting takes place, during which the lead inspector introduces the inspection team, informs about the purpose and scope of the inspection and confirms the inspection agenda.

During the inspection, inspectees may be asked by the inspection team to prepare and provide additional documents in order to fully explain any arisen unclarities.

Inspectors carry out interviews with persons involved in the clinical trial process. They also investigate storage facilities of the investigational medicinal product, samples collected for laboratory testing and research documentation.

**Termination of the inspection process (Closing meeting)**

Closing meeting is the final step of inspection carried out at the site or organization. The main purpose of this meeting is summarizing observations and discrepancies in conducting the clinical trial with GCP principles. Moreover, the lead inspector informs, when will the sponsor and investigator receive the inspection report.

**Inspection report**

44 days after the final day of inspection, all authorized persons (sponsor, investigator) receive the inspection report in paper format. The report can be also send by email in PDF format, secured by a password. The report describes in detail any findings with references to the corresponding legislative acts, which were breached, and grades the findings accordingly (Critical, Major, Minor or Comment – which is not a non-compliance, but is meant to help in conducting the clinical trial).

Grading of findings

**Types of inspection**

**Routine inspection** – is carried out after an inspection announcement is sent to the entity conducting the clinical trial and to the sponsor 30 days before the planned inspection/control.

**Unannounced inspection** – is carried out when there is suspicion that the life or health of clinical trial participants might be at risk. This type of control is carried out without prior notice given to the entity conducting the clinical trial or the clinical investigator nor the sponsor.

**Types of clinical trials inspections**

According to the above mentioned outline, the Department for Inspection of Medicinal Products carries out the following clinical trials inspections/controls:

- inspection of medicinal products
- inspection of veterinary medicinal products
- control of medical devices