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Practical Experience in GCP inspections, non EU/EEA countries

Flávia Regina Souza Sobral –
Specialist on Regulation and Health Surveillance
GCP inspector and evaluator of clinical trials protocols at Anvisa/BRAZIL

Inspections in non- EU/EEA countries

- **Authority/agency that performs inspections:** Anvisa – National Health Surveillance Agency

- **Sites most commonly inspected:** *Nowadays, we only do GCP inspection in research sites. In this place, we check: facilities and competences of: clinical investigator, sponsor and/or CRO in compliance with GCP. We intend to start GCP inspection in the Sponsor and CRO.*

Three Most Common Findings

Inspection Finding 1

LACK OF TRAINING RECORDS:
In many GCP inspections, we have verified that people have done activities, but, in some cases, we could not find evidences or records about training.

Inspection Finding 1

- *In Brazil, we follow "GOOD CLINICAL PRACTICES: Document of the Americas" – Pan American Health Organization and IN 4/2009:* Treats of the Guide to Good Clinical Practice Inspection (Check-List) – *Anvisa. This Finding* violates the following items*:*

Document of the Americas - *5.2.5 Training of the study participants should be documented including: the name of the staff persons trained, procedures and dates.*

IN 4/2009 – *B8 Are there training records available?*

- **IMPACT:** *When we can`t find training records, we don`t have sure if the people are able to do the activities that they was delegate. So, this can compromise GCP aspects.*

Inspection Finding 2

LACK OF CRITICAL SOP`s:
We have verified, that, in some cases, we couldn`t find SOP`s to critical activities. In our regulation (IN 4/2009), we describe what activities are considered critical.

Inspection Finding 2

This Finding violates the following items*:*

- **Document of the Americas** *6.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems* ***with written SOPs*** *to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).*

  - ***IN 4/2009*** B.5 Are there critical SOP`s written?

- **IMPACT:** *When there are not SOP`s: the same procedure can be done in different ways (no standard), there aren`t periodic updates, there is no guarantee to* perform the procedure correctly. *This can increase mistakes.*

Inspection Finding 3

ARCHIVE ROOM WITHOUT MANAGEMENT, ORGANIZATION, CONTROL AND SAFETY OF DOCUMENTS:

In many GCP inspections, we have checked that the archive room has not guaranteed safety of documents. In many cases, we could not find control of fire, flood, plague, for instance. We could realize that, in some cases, they have not controlled whom could enter in this place.

Inspection Finding 3

This Finding violates the following items*:*

- **Document of the Americas:** 5.9.4 *The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.*

- **IN 4/2009:** A.7 – Archive

- **IMPACT:** When documents are not stored appropriately, this fact can violate principles of GCP like: *All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification*. This can generate distrust in results generated by research.

Discussion

- **Societal/cultural/traditional constraints specific to your country that you believe inspectors from other countries should be aware of when performing GCP inspections in your country:**
- Brazilians have a very warm way to communicate that may be confused with very friendly behaviour.

- ***Proposals on how, despite these issues, international legislation can still be adhered to.***
- *Our legislation is very similar with international standards in GCP like ICH, WHO. So, we believe that there is not problem in adherence.*