Clinical Operation and Quality Assurance

- From PMDA's Point of View -

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What is GCP?

GCP is an **international ethical and scientific quality standard** for clinical trials .

Compliance with GCP provides･･･

Compliance with GCP provides **public assurance** that

- ✓ The rights, safety and well-being of trial subjects are protected.
- ✓ The clinical data are credible.

What is Quality Assurance?

All those planned and systematic actions that are established **to ensure** that the trial is performed and the data are generated documented (recorded), and reported **in compliance with GCP and the applicable regulatory requirements**.

What is Quality Control?

The operational techniques and activities undertaken within the quality assurance system to verify that **the requirements for quality** of the trial-related activities have been fulfilled.

What is Monitoring？

The act of overseeing the progress of a clinical trial, and of **ensuring** that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).

What to be ensured?

Was the trial conducted adequately ?

- “Adequately” doesn’t mean 100% accuracy
- 100% monitoring / SDV is not always necessary

PMDA

- have to confirm that there are not ‘big’ mistakes
- does not order to type up or write out.
  (ALCOA is important)
- will deal severely with a falsification.

Current Trend

- 24th October 2011
  Revision of the GCP Notification
- 7th March 2012
  Revision of Notification ‘Uniform Forms Regarding Clinical Trial Applications, etc’
- 30th March 2012
  5-Year Clinical Trials Vitalization Plan 2012
- 28th December 2012
  Revision of Ministerial Ordinance on GCP
  Revision of GCP Notification,

Purpose of these Revisions

- To ensure the reliability of the data more
- To promote more harmonization of J-GCP and ICH-GCP
- To streamline clinical trial procedures
- To activate clinical trial by sponsor-investigator

Summary

- Clinical operation is ・・・
- Monitoring is ・・・
- Quality assurance is ・・・
- Inspection by PMDA is ・・・
- Regulatory authority acts ・・・

For trial subjects and every patient!