Clinical Operation and Quality Assurance

- From PMDA’s Point of View -

Emiko Kondo
Office of Conformity Audit, PMDA
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What is GCP?

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