History and Principles of Good Clinical Practice

Cristina E. Torres, Ph.D.
Social Science Professor, UPM-NIH
FERCAP Coordinator

ICH:

International Conference on Harmonization

GCP:

Good Clinical Practices

History of GCP

Background

- Need for safe and efficacious products for various health problems
- Drug development is expensive and time consuming
- Need for efficient quality systems
- Global drug market
- Existence of national laws and regulations for drug development

History of GCP

Purpose

- To harmonize the regulations and guidelines for drug development

Participants

- Regulatory agency/industry representatives from Europe, Japan and US

Organization

Health Authorities and Pharmaceutical Companies

- WHO, Canada, Nordic group, Australia

History of GCP

Goal

- Remove redundancy /duplication in development and review process
- For new medical products, data should demonstrate:
  - ***Safety***
  - ***Quality***
  - ***Efficacy***

History of GCP

Process

- Developed guidelines applicable for
  - ***Drugs***
  - ***Biologics***
  - ***Medical devices***
- Approved by ICH members
- Adopted by National Regulatory Authorities

A Brief History of GCP

1948	Nurenbuerg Code	***1991***	France – decree giving Bonnes Pratiques Cliniques legal force
1961	Thalidomide (excl USA)	***1991***	European Community EC GCP guidelines operational
1962	USA - The Drugs Amendment Act – Established the IND procedure	***1991***	Australian GCRP
1964	Worldwide – the Declaration of Helsinki (for the protection of trial subjects)	***1993***	WHO GCP Guidelines
1968	UK – The Medicines Act (for control of clinical trials and product marketing)	***1997***	The ICH Guideline on GCP operational
1976	Germany – The Drug Law	***2000***	Worldwide – The DoH amended
1978	USA – The FDA GCP established	***2005***	EU – "The GCP Directive"
1986	UK – The ABPI Guidelines issued	***2005***	WHO - Handbook for GCP Guidance for implementation
1989	Nordic – GCP Guidelines established		

Declaration of Helsinki * – Principles

- Research must conform to scientific principles
- Protocol and independent ethics committees
- Supervision and conduct of trial by suitably qualified persons
- Objectives and possible benefits balanced against risk to subjects
- Privacy respected and minimal physical and mental impact
  on the subject
- Informed consent

* (1996, 2000, 2002 and 2004)

ICH GCP

- "**I**nternational **C**onference on **H**armonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use"
- Tripartite: USA, EU and Japan
  (***plus*** Australia, Canada, the Nordic countries & WHO)
- The Good Clinical Practice guideline is Topic E6
- Adopted:
  - 17 January, 1997 in the EU (guideline, as CPMP / ICH / 135/95)
  - 1 April, 1997 in Japan (law)
  - 9 May, 1997 in the USA (guideline, in the federal register)

Good Clinical Practice (GCP)

An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects

Public assurance that the rights, safety, and well-being of trial subjects are protected

- Results in credible data
- Consistent with the Declaration of Helsinki

Objectives of ICH GCP

- Provide a unified standard for Europe, Japan, US
- To facilitate the mutual acceptance of clinical data
- Developed in accordance with existing standards in US, Europe, Japan Australia, Canada, Nordic countries and WHO

ICH GCP PRINCIPLES

- Conduct trials according to GCP
- Weigh risks vs benefits
- Protect the subjects
- Have adequate information to justify trial
- Write a sound protocol
- Receive IRB/IEC approval
- Use qualified physicians

ICH GCP PRINCIPLES

- Use qualified support staff
- Obtain informed consent
- Record information appropriately
- Protect confidentiality
- Handle investigational products appropriately
- Implement quality systems

GCP Design Standards

- Written protocol
- Investigator brochure
- Scientific soundness
- Feasibility
- Adequate resources
- Randomization / blinding

GCP Conduct Standards

- IRB & Regulatory approval
- Compliance with protocol
- Informed consent
- Confidentiality of data
- Medical management of adverse events
- Product accountability
- Qualification & training

GCP Recording Standards

- CRF completion
- Data handling
- Security maintenance
- Audit requirements
- Product accountability
- Management of study files/essential documents

GCP Reporting Standards

To

- ***Sponsors***
- ***IRB/IEC***
- ***Regulatory authorities***
- ***Other investigators***

- Adverse events
- Interim reviews
- Progress reports
- Final reports
- Monitoring / audit reports

Responsibilities