History and Principles of Good Clinical Practice

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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
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<th>Event</th>
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<tbody>
<tr>
<td>1948</td>
<td>Nurenburg Code</td>
<td>1991</td>
<td>France – decree giving Bonnes Pratiques Cliniques legal force</td>
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<td>1961</td>
<td>Thalidomide (excl USA)</td>
<td>1991</td>
<td>European Community EC GCP guidelines operational</td>
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<td>1962</td>
<td>USA - The Drugs Amendment Act – Established the IND procedure</td>
<td>1991</td>
<td>Australian GCRP</td>
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<td>1964</td>
<td>Worldwide – the Declaration of Helsinki (for the protection of trial subjects)</td>
<td>1993</td>
<td>WHO GCP Guidelines</td>
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<td>1968</td>
<td>UK – The Medicines Act (for control of clinical trials and product marketing)</td>
<td>1997</td>
<td>The ICH Guideline on GCP operational</td>
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<td>1989</td>
<td>Nordic – GCP Guidelines established</td>
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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

ICH GCP

• “International Conference on Harmonisation 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