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ICH E6 : Good Clinical Practices (GCP)

General Questions

- What is ICH? What does it do?
- What is GCP? What is it for?
- Why should we implement GCP?

ICH

International Conference on Harmonization

Changed to International Council for Harmonization, October, 2015

GCP

Good Clinical Practices

ICH History

- **Background**

  Drug development global,

  Regulation national

- **History**

  To harmonize very detailed technical requirements

  To reduce or eliminate the need to duplicate the testing carried out during the research and development of new medicines

- **Participants**

  Regulatory agencies/ industry from EU, Japan, US

- **Concerns**

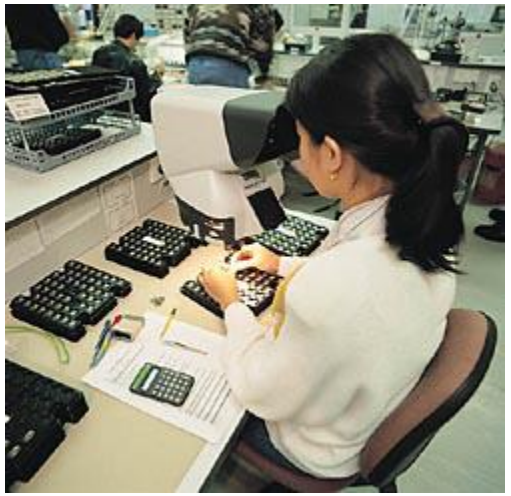
  Rising costs of health care

  Increasing costs of R+D

  Public expectation of little delay for new, safe, efficacious tx

ICH Goal

- Remove redundancy / duplication in development and review process
- For new medicinal products, single set of data should demonstrate:
  - Safety
  - Quality
  - Efficacy



ICH Processes

- ICH members develop guidelines through step-wise process
- Applicable to:
  - Drugs
  - Biologics
  - Medical devices (test articles)
- Approved by ICH members, then adopted by National Regulatory Authorities

ICH Topics

- **Safety [S] - *in vitro* & *in vivo* preclinical testing**
- **Quality [Q] - chemical & pharmaceutical QA**

- **Efficacy [E] - clinical studies in humans**

Multidisciplinary [M] - terminology
- electronic standards
- common documents

ICH Efficacy Guidelines

- **E1: Exposure (to assess clinical safety)**
- **E2: Clinical Safety (includes data management)**
- **E3: Study Reports**
- **E4: Dose Response Studies**
- **E5: Ethnic Factors (acceptability of foreign data)**
- **E6: Good Clinical Practices (GCP)**
- **E7/11: Special Populations**
- **E8/9/10: Clinical Trials Design (includes biostatistics)**
- **E12: Therapeutic Categories**

ICH Good Clinical Practices (GCP)

- **Accepted for generating clinical trial data intended for submission to regulatory agencies**
- **Consist of:**
  - Guiding Principles
  - Standards
  - Requirements
- **Principles can apply to other clinical research:**
  - NIH Guidance on conduct of clinical research
  - NIAID Clinical Terms of Award
- Governs all clinical research supported by extramural funds

ICH GCP Standrads

- **International ethical and scientific quality standard for:**
  - Designing
  - Conducting
  - Recording
  - Reporting

GCP Design Standards

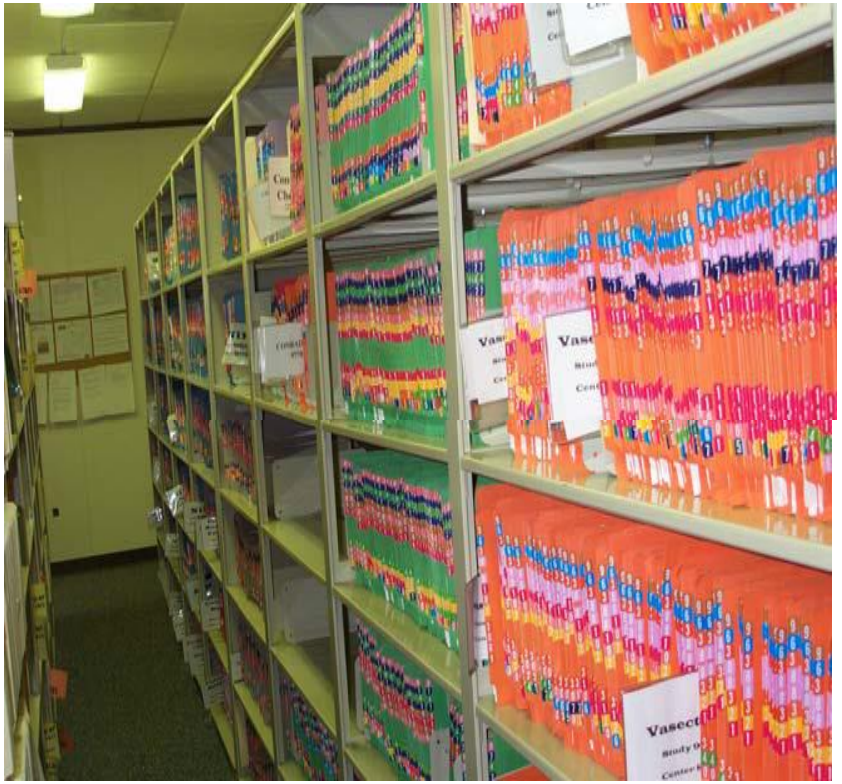
- **Protocol, Investigator Brochure content**
- **Scientifically sound, feasible**
- **Adequate resources**
- **Randomization / blinding procedures**

GCP Conduct Standards

- **Regulatory + IRB approvals**
- **Comply with protocol**
- **Informed consent, Confidentiality**
- **Medical management, adverse events**
- **Product accountability**
- **Qualifications + Training**

GCP Recording Standards

- **CRF completion**
- **Data handling**
- **Security, audit trails**
- **Product**
- **Accountability**
- **Study Files/ Essential Documents**



GCP Reporting Standards

- **Adverse Events, interim reviews, progress reports, final reports, monitoring/audit reports to:**
  - Sponsors
  - IRB/IEC
  - Regulatory authorities
  - Other investigators

ICH GCP Requirements

- **Requirements & responsibilities delineated for:**
  - IRB/IEC
  - Investigators
  - Sponsors

IRB/IEC Requirements & Responsibilities

- **Responsibilities**
  - **– Composition, function, operations**
  - **– Procedures**
  - **– Records**

Investigators Requirements (1)

– **Professional qualifications and agreements**

– **Adequate resources**

–**Medical care of trial subjects**

– **IRB communication**

– **Protocol compliance**

– **Investigational product**

Investigators Requirements (2)

– **Randomization + unblinding**

– **Informed consent of trial subjects**

– **Records + reports**

– **Study conduct**

- **Safety reporting**
- **Premature trial termination or suspension**

GCP Essential Documents

- Permit evaluation of trial conduct and data quality

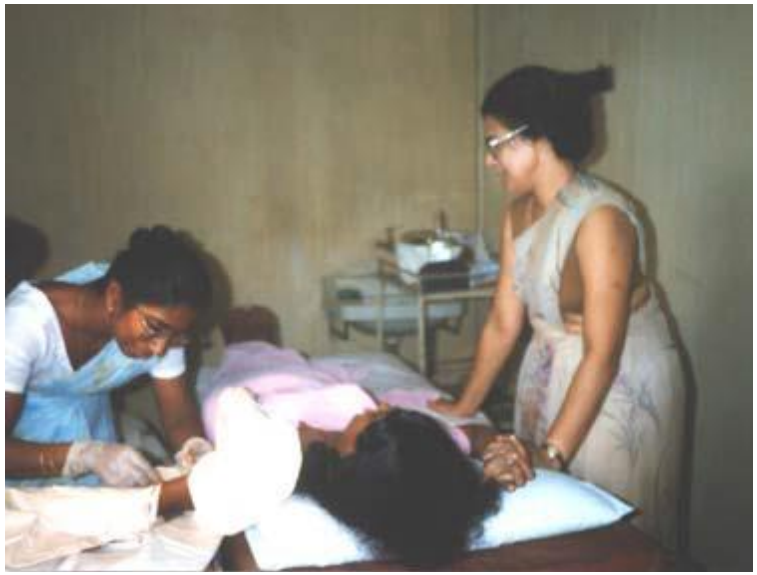
- **Files of**
  - **– Investigator**
  - **– Sponsor**

Phase of trial:

- **– Before start**
- **– During conduct**
- **– After completion**

Assurance

- **Compliance with GCP provides public assurance of:**
  - **Protection of subject's rights, safety, well-being**
  - **Consistence with Helsinki Declaration**
  - **Credible Data**



SUMMARY

- **ICH = International Council for Harmonization**
  - ICH sets international standards for technical requirements to license new drugs
  - Issues guidelines
  - DMID follows ICH guidelines for clinical research conduct and oversight
- **GCP = Good Clinical Practices (ICH E6)**
  - Covers design, conduct, recording and reporting of clinical research
  - Designed to ensure:
    - **Ethical research,**
    - **High quality, credible data**

Web resources for ICH/GCP

- US FDA:

http://www.fda.gov/oc/oha

- ICH Website:

http://www.ifpma.org/ich1.html

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