The Fundamentals of International Clinical Research

ICH and GOOD CLINICAL PRACTICES

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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

GCP

Good Clinical Practices
ICH History

Background:
Drug development global, Regulation national

Purpose:
to harmonize very detailed technical requirements

Participants:
Regulatory agencies/ industry from EU, Japan, US
ICH History

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
ICH GCP

- 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 STANDARDS

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
Compliance with GCP provides public assurance of:

- Protection of subject’s rights, safety, well-being
- Consistence with Helsinki Declaration
- Credible Data
ICH = International Conference on Harmonization

- ICH sets international standards for technical requirements to license new drugs
- Issues guidelines
- DMID follows ICH guidelines for clinical research conduct and oversight
SUMMARY

- **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