



FROM GMP TO GBP

FOSTERING GOOD BIOETHICAL PRACTICES AMONG EUROPEAN BIOTECHNOLOGY INDUSTRY

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What is a Clinical Study?

Many Views and Much Confusion

- A clinical study is a research project with human subjects, with human biologic samples or data derived from subjects or samples (art.1 Decl. of Helsinki)
- Clinical studies are necessary to demonstrate safety and effectiveness of a medicine before widespread use
- Research implies that the project is conducted to answer a scientific / medical question
 - Objective is not provision of health care to a patient
 - May imply interventions /diagnostics prescribed by a study protocol or use treatment / diagnostics as prescribed by the treating physician
- Some legislations reserve the term “trial” for an interventional procedure

Human Rights in Clinical Research

Some Basic Principles

- Clinical studies are necessary research experiments on humans
- Participation in such research must be voluntary and based on fully informed and free consent
- Protection of participants takes priority over interest of researchers and society
- Research with humans is only justified when answering relevant medical / scientific questions
- Access to research should only depend on the research protocol and trial objectives
- Privacy of participants and confidentiality of their personal data must be ensured

Regulatory Aspects of Clinical Research

More than National Legislation



- **Laws (binding) e.g.**
 - EU Clinical Trial Directive (2001/20 EC), GCP Directive (2005/28/EC), GMP Directive (2003/94/EC), Pediatric Regulation (1901/2006/EC), Federal Food, Drug and Cosmetics Act US, other EU and non-EU National laws

- **Conventions, Guidelines (not binding) e.g.**
 - Belmont Report 1976
 - Declaration of Helsinki (last edition: 2008)
 - ICH¹ E6: Good Clinical Practice
 - Bioethics Convention Council of Europe 4.4.1997

- **Self Regulation (Policies, Positions), Process-Standards**
 - EFPIA, PhRMA and IFPMA Codes, company policies

¹ *International Conference on the Harmonization of Conditions for market authorization of medicines*

International Conventions and Guidelines

Protecting Research Participants Globally

- Bioethics conventions and guidelines set standards for professionals and legislators
- Guidelines and conventions are specifically relevant when legal and regulatory instruments in a country are lacking or insufficient
- Of particular relevance while Clinical Research expands into developing or inexperienced countries
 - Risk that weaknesses of health and regulatory systems may be exploited
 - Insufficient education / experience of investigators and support staff
 - Specific vulnerable populations e.g. illiterates, uninsured
- Supplemented by professional codes

Good Clinical Practice

(GCP) Protection of Research Subjects and Quality Standard

- GCP describes the ethical and quality standards for conduct of clinical trials
- Objectives of GCP are protection of participants' rights and maintenance of quality of research results
- Compliance with *Good Clinical Practice* is an ethical and scientific requirement
- Studies which are not compliant with GCP
 - Will not be accepted for publication
 - Cannot support registration of a new medicine

Some Issues with EU Clinical Trial Regulations

The European Clinical Trial Directive

- The inconsistent implementation of the Directive 2001/20 in EU member states results in unnecessary complexity of multinational clinical trials e.g.
 - Role, duties and decisions of Ethic Committees
 - Composition of trial dossier and application process
 - Informed consent process and content
 - Conduct of clinical trials by academic researchers and SME's
- Results in decreasing attractiveness of Europe as a clinical trial location
- The de-centralized trial application process raises particular issues regarding transparency in clinical research

Some Recommendations

- Ensure that all participants in research studies enjoy comparable protection and rights independent of sponsor affiliation, country or personal characteristics
 - Regulatory support to SME's and academic sponsors to help them complying with EU clinical trial standards
 - Consistent informed consent process, handling of safety information and data protection standards
- Implement a single trial application dossier and central submission process for all EU member states
- Define comparable roles, responsibilities and training needs of ethics committees for all EU MS
- Revise legislation where appropriate



Thank You