Good Clinical Practices (GCP)

The 8 chapters of GCP

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Part 2/7

2. Principles of ICH GCP

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2	Principles of ICH GCP
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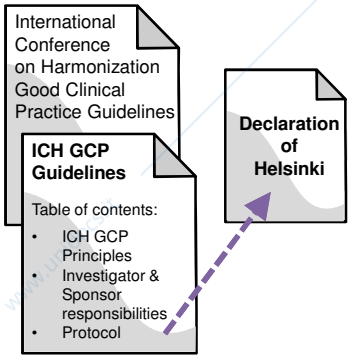
8	Essential documents for the conduct of a clinical trial

2. Principles of ICH GCP

Contains the 13 principles having their origin in the Declaration of Helsinki.

With the revision 2, some principles were better described



2. Principles of ICH GCP

2.1 Clinical trials (CT) shall be conducted in accordance with the ethical principles (Declaration of Helsinki), GCP and regulatory requirements

2.2 Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks

2. Principles of ICH GCP

2.3 Rights, safety, and well-being of the trial subjects = the most important considerations and shall prevail over interests of science and society

2.4 The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the clinical trial

2. Principles of ICH GCP

2.5 Clinical trials shall be scientifically sound, and described in a clear, detailed protocol

2.6 A trial shall be conducted in compliance with the protocol that has a favourable opinion from an ethics committee

2.7 Responsibility of an appropriately qualified physician for medical care and medical decisions on subjects

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2.8 Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s)

2.9 Freely given informed consent shall be obtained from every subject prior to clinical trial participation

2. Principles of ICH GCP

2.10 All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

Addendum "This principle applies to all records referenced in this guideline, irrespective of the type of media used."

2.11 The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules

2. Principles of ICH GCP

2.12 Respect of GMP (Good Manufacturing Practice) for the manufacturing, handling and storage of IMP and use of IMP in accordance with the approved study protocol

2.13 Implementation of systems with procedures to assure quality of the clinical trial

Addendum *"Aspects of the trial that are essential to ensure human subject protection and reliability of trial results should be the focus of such systems."*

i.e. Risk based

THANK YOU FOR YOUR ATTENTION !