

Principles of ICH GOOD CLINICAL PRACTICE

www.ich1.html



1/16

Evidências.com

Guideline for Good Clinical Practice 2. The principles of ICH GCP

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2/16

Evidências.com

Guideline for Good Clinical Practice 2. The principles of ICH GCP

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3/16

Evidências.com

Guideline for Good Clinical Practice 2. The principles of ICH GCP

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4/16

Evidências.com

Guideline for Good Clinical Practice 2. The principles of ICH GCP

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5/16

Evidências.com

Guideline for Good Clinical Practice 2. The principles of ICH GCP

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

6/16

Evidências.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

7/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

8/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

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

9/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

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

10/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

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

11/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

12/16

Evidencias.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable Good Manufacturing Practice (GMP). They should be used in accordance with the approved protocol.

13/16

Evidências.com

**Guideline for Good Clinical Practice
2. The principles of ICH GCP**

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

14/16

Evidências.com

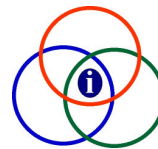
**Guideline for Good Clinical Practice
Introduction**

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

15/16

Evidências.com

Evidências.com



www.evidencias.com

E-mail: email@evidencias.com
Fone: (+19) 9773 3430
Fax: (+11) 3059 0250 ramal 8952

16/16

Evidências.com