Good Clinical Practice (GCP)

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Dichiarazione di trasparenza/interessi*

Le opinioni espresse in questa presentazione sono personali e non impegnano in alcun modo l'AIFA

Interessi nell'industria farmaceutica	NO	Attualmente	Da 0 a 3 anni precedenti	oltre 3 anni precedenti
INTERESSI DIRETTI:				
1.1 Impiego per una società: Ruolo esecutivo in una società farmaceutica	x	☐	☐	☐ obbligatorio
1.2 Impiego per una società: Ruolo guida nello sviluppo di un prodotto farmaceutico	x	☐	☐	☐ obbligatorio
1.3 Impiego per una società: altre attività	x	☐	☐	☐ facoltativo
2. Consulenza per una società	x	☐	☐	☐ facoltativo
3. Consulente strategico per una società	x	☐	☐	☐ facoltativo
4. Interessi finanziari	x	☐	☐	☐ facoltativo
5. Titolarità di un brevetto	x	☐	☐	☐ facoltativo
INTERESSI INDIRETTI:				
6. Sperimentatore principale	x	☐	☐	☐ facoltativo
7. Sperimentatore	x	☐	☐	☐ facoltativo
8. Sovvenzioni o altri fondi finanziari	x	☐	☐	☐ facoltativo
9. Interessi Familiari	x	☐	☐	☐ facoltativo

* Angela Del Vecchio, secondo il regolamento sul Conflitto di Interessi approvato dal CdA AIFA in data 25.03.2015 e pubblicato sulla Gazzetta Ufficiale del 15.05.2015 in accordo con la policy EMA /626261/2014 sulla gestione del conflitto di interessi dei membri dei Comitati Scientifici e degli esperti.

N.B. <Per questo intervento non ricevo alcun compenso>

Agenzia Italiana del Farmaco

AIFA

DEFINITION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the partecipation of human subjects.

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected and that the clinical trial data are credible.

INTERNATIONAL CONFERENCE ON HARMONISATION (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration.

Takes care of all aspects related to the development of a drug, and so the GCP too.

Good Clinical Practice Guidelines

Introduction

1. Glossary
2. The principles of ICH GCP
3. Institutional review board/Indipendent Ethics Committee (IRB/IEC)
4. Investigator
5. Sponsor
6. Clinical trial protocol and protocol amendments
7. Investigator's Brochure
8. Essential documents for the conduct of a Clinical Trial

GCP
AIMS

To guarantee the rights, safety and well-being of study subjects

To ensure that clinical data are credible and reliable

ICH-GCP PRINCIPLES

A) ETHIC GUARANTEE

- 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).
- 2.3 The rights, safety, and well-being of trial subjects are the most important considerations and should prevail over interests of science and society.
- 2.9 Freely given informed consent should be obtained from every subject prior to clinical trial partecipation.

B) TECNICAL-SCIENTIFIC GUARANTEE 1/2

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

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

• 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.

B) TECNICAL-SCIENTIFIC GUARANTEE 2/2

•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).

•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.

C) PROCEDURAL GUARANTEE

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

- 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.

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

QUESTIONS

CONTATTI

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