

GOOD CLINICAL PRACTICE



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International Conference on Harmonisation of Technical
Requirements for Registration of Pharmaceuticals for Human Use
ICH Harmonised Tripartite Guideline

GUIDELINE FOR GOOD CLINICAL PRACTICE

www.ifpma.org/ich1.html

Recommended for Adoption
at Step 4 of the ICH Process
on 1 May 1996
by the ICH Steering Committee

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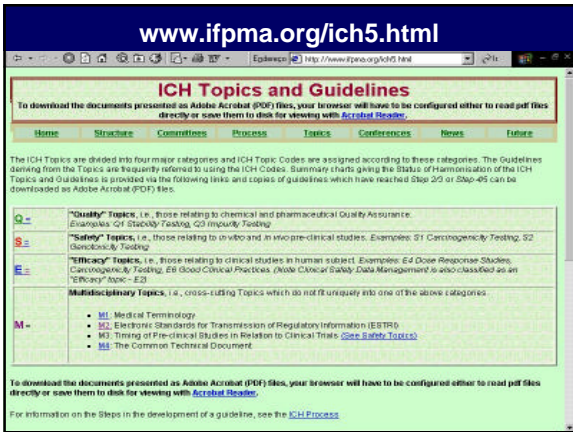
ICH
International Conference on Harmonisation
of Technical Requirements for Registration of Pharmaceuticals
for Human Use

Welcome to the Official Web Site for ICH

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health. This Mission is embodied in the Terms of Reference of ICH.

- > Structure of ICH
- > ICH Steering Committee and Expert Working Groups
- > ICH Process for Harmonisation of Guidelines
- > ICH Topics and Guidelines: E12A and S7 have been released from the last ICH Steering Committee Meeting, March 2000, Tokyo



www.ifpma.org/ich5.html

ICH Topics and Guidelines

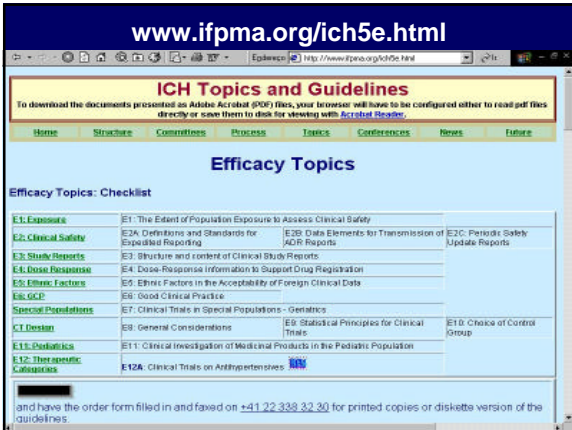
To download the documents presented as Adobe Acrobat (PDF) files, your browser will have to be configured either to read pdf files directly or save them to disk for viewing with Acrobat Reader.

The ICH Topics are divided into four major categories and ICH Topic Codes are assigned according to these categories. The Guidelines deriving from the Topics are frequently referred to using the ICH Codes. Summary charts giving the status of harmonization of the ICH Topics and Guidelines is provided via the following links and copies of guidelines which have reached Step 2/3 or Step 4/5 can be downloaded as Adobe Acrobat (PDF) files.

| | |
|------------|--|
| Q = | "Quality" Topics , i.e., those relating to chemical and pharmaceutical Quality Assurance. Examples: Q1 Stability Testing, Q2 Impurity Testing. |
| S = | "Safety" Topics , i.e., those relating to in-vivo and in-vitro pre-clinical studies. Examples: S1 Genotoxicity Testing, S2 Genotoxicity Testing. |
| E = | "Efficacy" Topics , i.e., those relating to clinical studies in human subject. Examples: E4 Dose Response Studies, Genotoxicity Testing, E6 Good Clinical Practices (Now: Clinical Safety Data Management) is also classified as an "Efficacy" topic. E2B |
| M = | Multidisciplinary Topics , i.e., cross-cutting Topics which do not fit uniquely into one of the above categories. <ul style="list-style-type: none"> • M1: Medical Terminology • M2: Electronic Standards for Transmission of Regulatory Information (ESTRI) • M3: Timing of Pre-clinical Studies in Relation to Clinical Trials (See: Safety Topics) • M4: The Common Technical Document |

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For information on the Steps in the development of a guideline, see the [ICH Process](#).



www.ifpma.org/ich5e.html

ICH Topics and Guidelines

Efficacy Topics

Efficacy Topics: Checklist

| | | | |
|-------------------------------------|---|--|-------------------------------------|
| E.1: Exposure: | E1: The Extent of Population Exposure to Assess Clinical Safety | | |
| E.2: Clinical Safety: | E2A: Definitions and Standards for Equivalence Reporting | E2B: Data Elements for Transmission of ADR Reports | E2C: Periodic Safety Update Reports |
| E.3: Study Reports: | E3: Structure and content of Clinical Study Reports | | |
| E.4: Dose Response: | E4: Dose-Response Information to Support Drug Registration | | |
| E.5: Ethical Factors: | E5: Ethical Factors in the Acceptability of Foreign Clinical Data | | |
| E.6: GCP: | E6: Good Clinical Practice | | |
| Special Populations: | E7: Clinical Trials in Special Populations - Geriatrics | | |
| E.7: Design: | E7: General Considerations | E8: Statistical Principles for Clinical Trials | E10: Choice of Control Group |
| E.8: Paediatrics: | E8: Clinical Investigation of Medicinal Products in the Paediatric Population | | |
| E.9: Therapeutic Categories: | E12A: Clinical Trials on Antihypertensives | | |

and have the order form filled in and faxed on +41 22 338 32 30 for printed copies or diskette version of the guidelines.

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Guideline for Good Clinical Practice Introduction

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

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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.

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Guideline for Good Clinical Practice Introduction

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

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Guideline for Good Clinical Practice Introduction

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

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Guideline for Good Clinical Practice Introduction

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

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Guideline for Good Clinical Practice 1. Glossary

1.1 Adverse Drug Reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

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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).

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**3. Institutional Review Board /
Independent Ethics Committee (IRB/IEC)**

- 3.1 Responsibilities
- 3.2 Composition, Functions and Operations
- 3.3 Procedures
- 3.4 Records

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4. Investigator

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- 4.2 Adequate Resources
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- 4.4 Communication with IRB/IEC
- 4.5 Compliance with Protocol, 4.6 Investigational Product(s)
- 4.7 Randomization Procedures and Unblinding
- 4.8 Informed Consent of Trial Subjects
- 4.9 Records and Reports
- 4.10 Progress Reports, 4.11 Safety Reporting
- 4.12 Premature Termination or Suspension of a Trial
- 4.13 Final Report(s) by Investigator

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5. Sponsor

- 5.1 Quality Assurance and Quality Control
- 5.2 Contract Research Organization (CRO)
- 5.3 Medical Expertise
- 5.4 Trial Design
- 5.5 Trial Management, Data Handling, and Record Keeping
- 5.6 Investigator Selection
- 5.7 Allocation of Responsibilities
- 5.8 Compensation to Subjects and Investigators
- 5.9 Financing
- 5.10 Notification/Submission to Regulatory Authority(ies)
- 5.11 Confirmation of Review by IRB/IEC
- 5.12 Information on Investigational Product(s)

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5. Sponsor

- 5.13 Manufacturing, Packaging, Labelling, and Coding Investigational Product(s)
- 5.14 Supplying and Handling Investigational Product(s)
- 5.15 Record Access
- 5.16 Safety Information
- 5.17 Adverse Drug Reaction Reporting
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**6. CLINICAL TRIAL PROTOCOL AND
PROTOCOL AMENDMENT(S)**

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- 6.3 Trial Objectives and Purpose
- 6.4 Trial Design
- 6.5 Selection and Withdrawal of Subjects
- 6.6 Treatment of Subjects
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6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

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- 6.9 Statistics
- 6.10 Direct Access to Source Data/Documents
- 6.11 Quality Control and Quality Assurance Procedures
- 6.12 Ethics
- 6.13 Data Handling and Record Keeping
- 6.14 Financing and Insurance
- 6.15 Publication Policy
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7. INVESTIGATOR'S BROCHURE

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 - 7.2.1 Title Page
 - 7.2.2 Confidentiality Statement
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7. INVESTIGATOR'S BROCHURE

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 - 7.3.1 Table of Contents
 - 7.3.2 Summary
 - 7.3.3 Introduction
 - 7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation
 - 7.3.5 Nonclinical Studies
 - 7.3.6 Effects in Humans
 - 7.3.7 Summary of Data and Guidance for the Investigator

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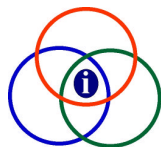
8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL

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- 8.2 Before the Clinical Phase of the Trial Commences
- 8.3 During the Clinical Conduct of the Trial
- 8.4 After Completion or Termination of the Trial

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