ICH E8(R1)
General Considerations for Clinical Studies

「臨床試験の一般指針」の改訂

伊熊睦博
医薬品医療機器総合機構

Key milestones

Nov. 2017	**Concept Paper** endorsement, **Business Plan** endorsement
May. 2019	**Draft Guideline** Endorsement by the Members of the ICH Assembly under **Step 2** and released for public consultation
Jun. 2019	Step 2 Presentation posted to ICH site
Oct. 2019	End of Public Consultation Period
Oct. 2019	ICH E8(R1) public stakeholder meeting targeted at global stakeholders held
May. 2021	*Step 4: Adoption of an ICH Harmonised Guideline*

"General Considerations for Clinical Studies" is intended to:

1. Describe internationally accepted **principles** and **practices** in the **design and conduct of clinical studies** that will ensure the protection of study participants and **facilitate acceptance** of data and results by regulatory authorities

2. Provide guidance on the consideration of **quality in the design** and **conduct** of clinical studies **across the product lifecycle**, including the identification, during study planning, of **factors that are critical to the quality** of the study, and the management of risks to those factors during study conduct

"General Considerations for Clinical Studies" is intended to:

3. Provide an **overview of the types of clinical studies** performed during the product lifecycle, and describe study design elements that support the identification of quality factors critical to ensuring the protection of study participants, the integrity of the data, the reliability of results, and the ability of the studies to meet their objectives

4. Provide a **guide to the ICH efficacy documents** to facilitate user's access

1 OBJECTIVES OF THIS DOCUMENT

- The ICH Efficacy guidelines are an **integrated set of guidance** covering the **planning, design, conduct, safety, analysis, and reporting** of clinical studies.
- ICH E8 provides an overall introduction to clinical development, **designing quality into clinical studies** and focusing on those factors **critical to the quality** of the studies.
- The guidelines should be considered and used in an **integrated, holistic way rather than focusing on only one guideline or subsection.**

2 GENERAL PRINCIPLES

2.1 **Protection of Clinical Study Participants**

2.2 **Scientific Approach in Clinical Study Design, Planning, Conduct, Analysis, and Reporting**

2.3 **Patient Input into Drug Development**

Consulting with patients and/or patient organisations during drug development can help to ensure that patients' perspectives are captured.

3 DESIGNING QUALITY INTO CLINICAL STUDIES

- The **quality by design** approach to clinical research involves focusing on **critical to quality factors** to ensure the protection of the rights, safety, and wellbeing of study participants, the generation of reliable and meaningful results, and the management of risks to those factors using a **risk-proportionate approach**.

- The approach is supported by the establishment of an **appropriate framework for the identification** and **review of critical to quality factors** at the time of design and planning of the study, and throughout its conduct, analysis, and reporting.

3.1 Quality by Design of Clinical Studies

- the need for **clear pre-defined study objectives** that address the primary scientific question(s);
- selection of **appropriate participants** that have the disease, condition, or molecular/genetic profile that is being studied;
- use of **approaches to minimise bias**, such as randomisation, blinding or masking, and/or control of confounding;
- **endpoints** that are **well-defined**, measurable, **clinically meaningful**, and **relevant to patients**;

4 DRUG DEVELOPMENT PLANNING

4.1 Quality of Investigational Medicinal Product

4.2 Non-Clinical Studies

4.3 Clinical Studies

4.4 Additional Development

5 DESIGN ELEMENTS AND DATA SOURCES FOR CLINICAL STUDIES

5.1 Study Population

5.2 Treatment Description

5.3 Choice of Control Group

5.4 Response Variables

5.5 Methods to Reduce Bias

5.6 Statistical Analysis

5.7 Study Data

6 CONDUCT, SAFETY MONITORING, AND REPORTING

6.1 Study Conduct

6.2 Participant Safety during Study Conduct

6.3 Study Reporting

ICH E8 provides an overall introduction to clinical development, ***designing quality into clinical studies*** *and focusing on those factors* ***critical to the quality*** *of the studies.*

ICH E8(R1)
General Considerations for Clinical Studies

Summer 2021 *Step 4, to be expected*