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Clinical Trial Transformation under ICH GCP R3

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Life forward

Disclaimer

1. The speaker is an employee in Boehringer Ingelheim China .

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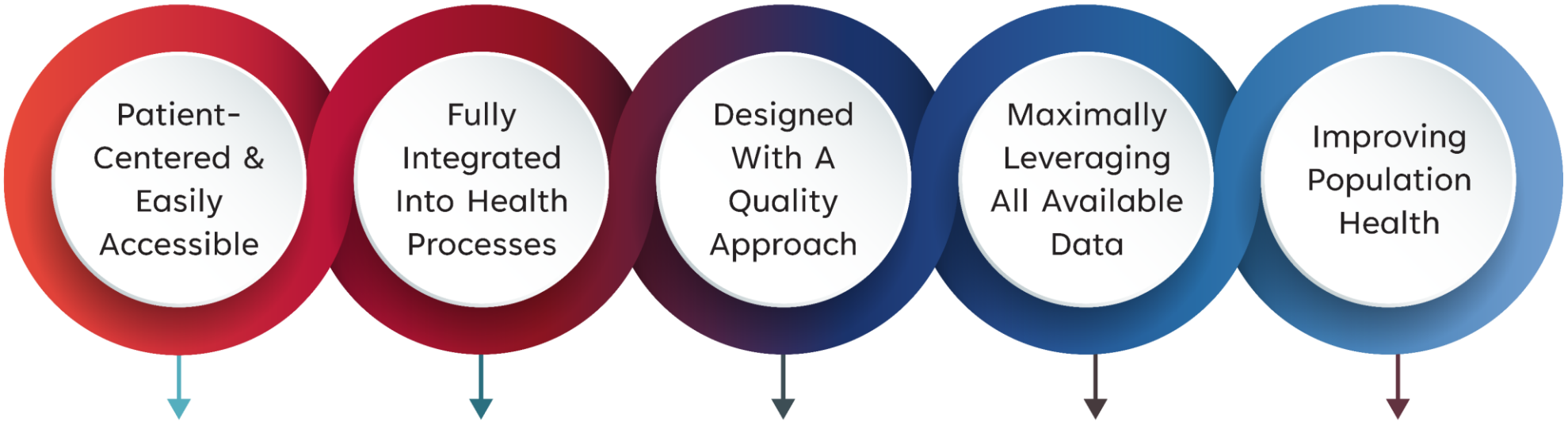
TRANSFORMING TRIALS 2030

CLINICAL TRIALS TRANSFORMATION INITIATIVE

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

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Source: Transforming Trials 2030 - CTTI

GCP Renovation

Interim analysis, external control, observational study, pragmatic elements…

The goal is to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources

CRF, electronic health records, hospital discharge summaries, claims data, patient/disease registries…

<ICH Reflection on ‘’GCP Renovation’’>

- Modernization of ICH E8 (General Considerations for Clinical Trials) and subsequent renovation of ICH E6
- Seek outside stakeholder comment on the revision

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Source: ICH Official web site : ICH

ICH-E6: An Important Global Standard for Clinical Trial Conduct

https://www.ich.org/news/ich-reflection-gcp-renovation-modernization-ich-e8-and-subsequent-renovation-ich-e6

E8 clinical trial design principles

↕

E6 GCP clinical trial conduct principles

- **E6: Good Clinical Practice (GCP) – finalised in 1996**
  - Described the responsibilities and expectations of stakeholders in the conduct of clinical trials;
  - Covered aspects of monitoring, reporting, and archiving of clinical trials; and
  - Included sections for essential documents and investigator brochures
- **E6 (R2) – finalised in 2016**
  - Included integrated addendum to encourage implementation of improved and more efficient approaches to GCP, while continuing to ensure human subject protections; and
  - Updated standards for electronic records.

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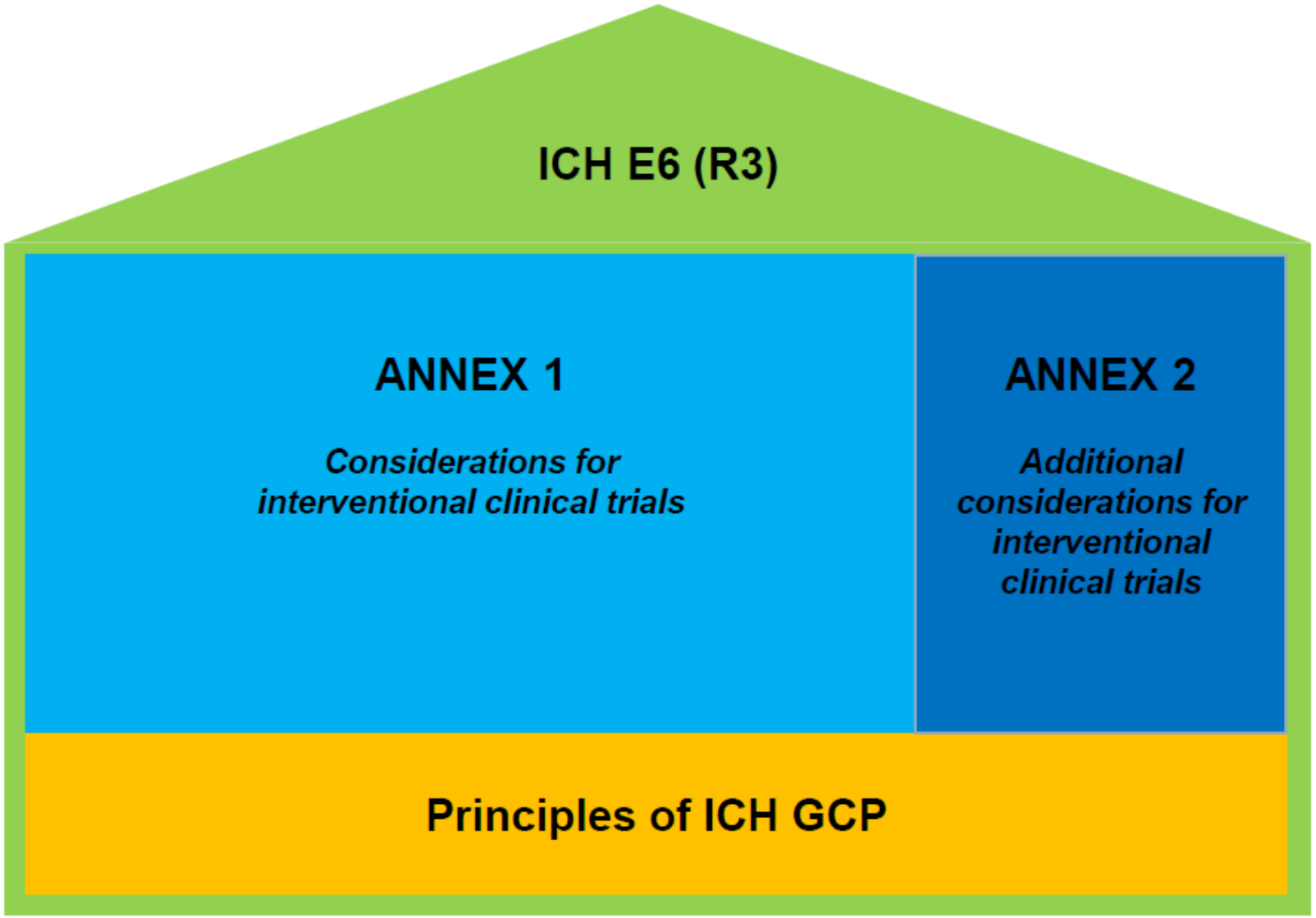
Source: ICH-E6(R3)

OVERVIEW OF ICH E6 (R3)



Source: ICH-E6(R3)

OVERVIEW OF ICH E6 (R3)

Substantial Changes

- **Principles of GCP**
- **Annex 1**
  - Investigator
  - Sponsor
  - Data Governance – Investigator and Sponsor **(New)**
- **Glossary**
- **Appendix C**
  - Essential Records for the Conduct of a Clinical Trial

Other Changes

- **Annex 1**
  - Institutional Review Board (IRB)/ Independent Ethics Committee (IEC)
- **Appendices A & B**
  - Investigator's Brochure
  - Clinical Trial Protocol and Protocol Amendments

Source: ICH-E6(R3)

What is introduced by ICH E6 (R3) Annex 1

❖ Fundamentals remain unchanged:

- The basic principle of GCP is to ensure the safety of trial participants and reliability of trial results

❖ Important updates:

- Clear Scope, Proportionality & Focus on Quality
- Encouraging the exploration of technology, Encouraging engagement and inclusivity:
- Focus on appropriate quality (QbD and proportionate)
  - ✓ **Quality by design** should be implemented to identify the factors (i.e., data and processes) that are critical to ensuring trial quality and the risks that threaten the integrity of those factors and ultimately the reliability of the trial results .
  - ✓ Clinical trial processes and risk mitigation strategies implemented to support the conduct of the trial should be **proportionate to the importance of the data** being collected and the risks to trial participant safety and data reliability. Trial designs should be operationally feasible and avoid unnecessary complexities .

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Source: ICH-E6(R3)

ICH E6(R3) – Annex 2 Structure

Step 2

- Structure

Introduction

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

2. Investigator

- Communication with IRB/IEC
- Informed Consent Considerations
- Investigational Product Management
- Investigator Oversight
- Safety Assessment and Reporting

3. Sponsor

- Engagement and Communication
- Protocol and Trial Design
- Communication with IRB / IEC
- Consent or Permission Considerations for RWD
- Data Considerations
- Investigational Product Management
- Privacy and Confidentiality Considerations
- Sponsor Oversight
- Safety Assessment and Reporting

In keeping with the Annex 1 Format

Microsoft PowerPoint - ICH_E6(R3)_Annex 2_Step 2_Presentation_2024_1122.pptx

- Emphasis on practical considerations for the use of various design elements and data sources.

ICH E6(R3) – Annex 2 Background

- Annex 2 provides considerations that focus on examples of trials that incorporate:

Decentralised Elements

Trial-related activities conducted outside the investigator's location

- *E.g., trial visits conducted at participant's home / local healthcare centre / mobile medical units; or data acquisition performed remotely using digital health technologies (DHTs)*

Pragmatic Elements

Those that integrate aspects of clinical practice into the design and conduct of the trial

- *E.g., simplified protocols with streamlined data collection*

Real World Data (RWD)

Include the use of data relating to patient health status collected from a variety of sources outside of clinical trials

- *E.g., electronic health records (EHRs), registries, claims data*

Current status of ICH E6 (R3)

- Principles & Annex 1
  - May 2023 Step1 sign off, reached Step2a/2b
  - May-Nov 2023 ICH public consultation
  - Close to finalising the document
- Annex 2
  - Nov 2024 Step1 sign off, reached Step2a/2b
  - until Mar 2025 ICH public consultation
- Training Materials
  - Nov 2024- Under development

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THANK YOU!

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