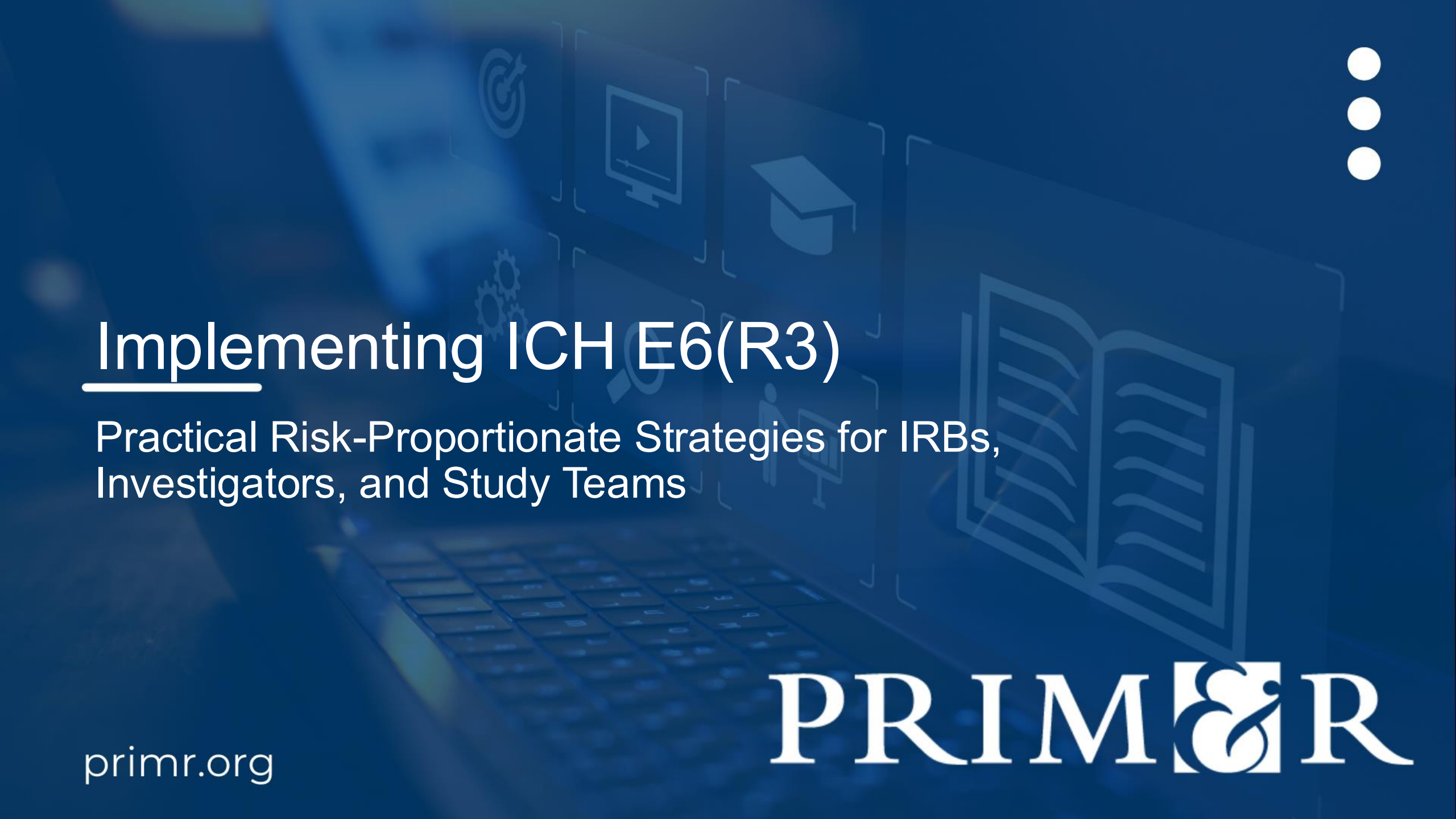


Implementing ICH E6(R3)

Practical Risk-Proportionate Strategies for IRBs, Investigators, and Study Teams

primr.org

PRIM&R

Implementing ICH E6(R3):

Practical Risk-Proportionate Strategies for IRBs, Investigators, and Study Teams

MRCT CENTER
THE MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

The MRCT Center

The MRCT Center is focused on addressing the conduct, oversight, ethics, and regulatory environment of clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

www.mrctcenter.org

MRCT Center Disclaimer

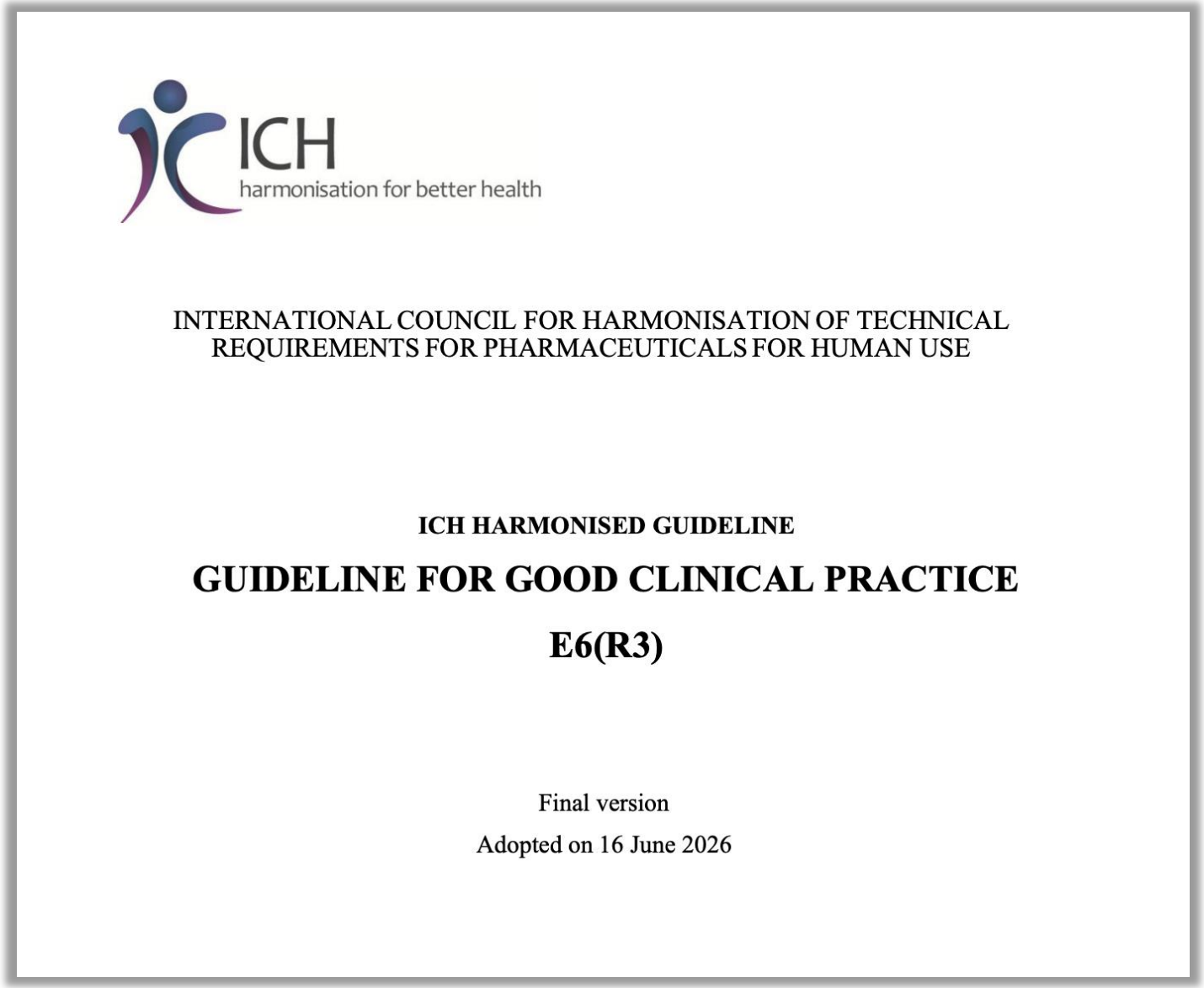
- The opinions contained are those of the authors and presenters and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions, and government entities (see www.MRCTCenter.org), as well as by grants.
- We are committed to autonomy in our research and to transparency in our relationships.

Today's Webinar:

Practical Risk-Proportionate Strategies for IRBs, Investigators, and Study Teams

- What is actually changing?
- Focus on: IRB, Investigator, Essential Records
- Case Study
- Q & A

What is actually changing?



ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

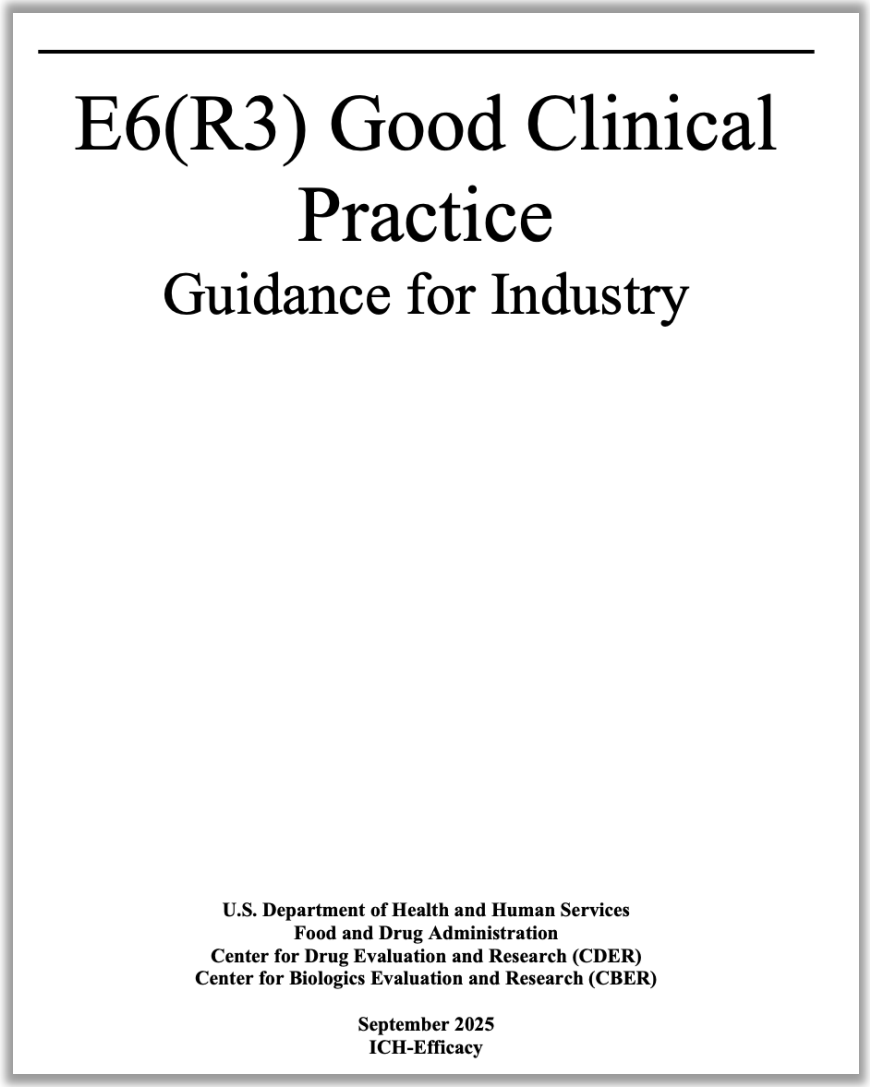
ICH HARMONISED GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R3)

Final version

Adopted on 16 June 2026



E6(R3) Good Clinical Practice

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2025
ICH-Efficacy

https://www.ich.org/page/efficacy-guidelines

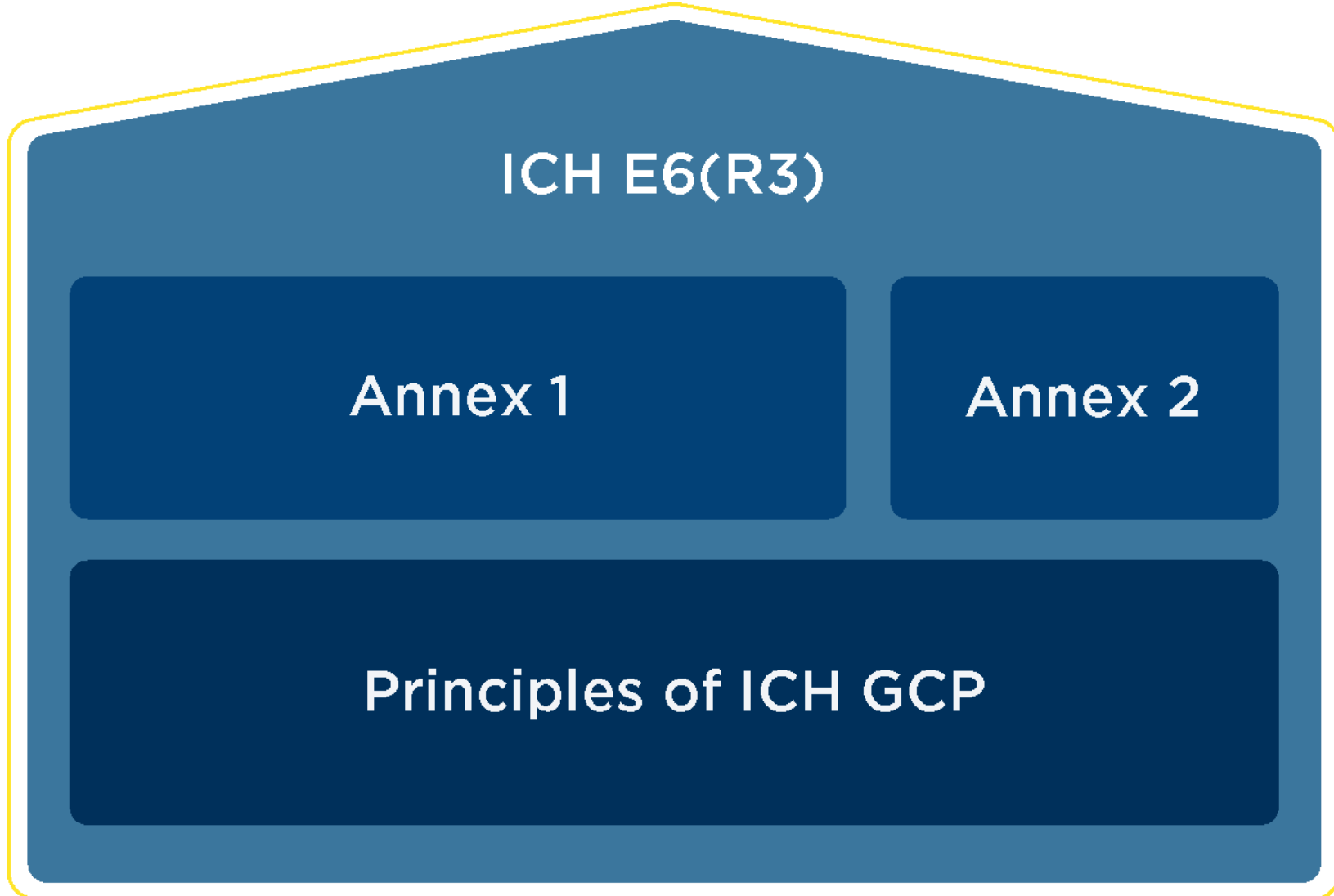
ICH E6(R3)

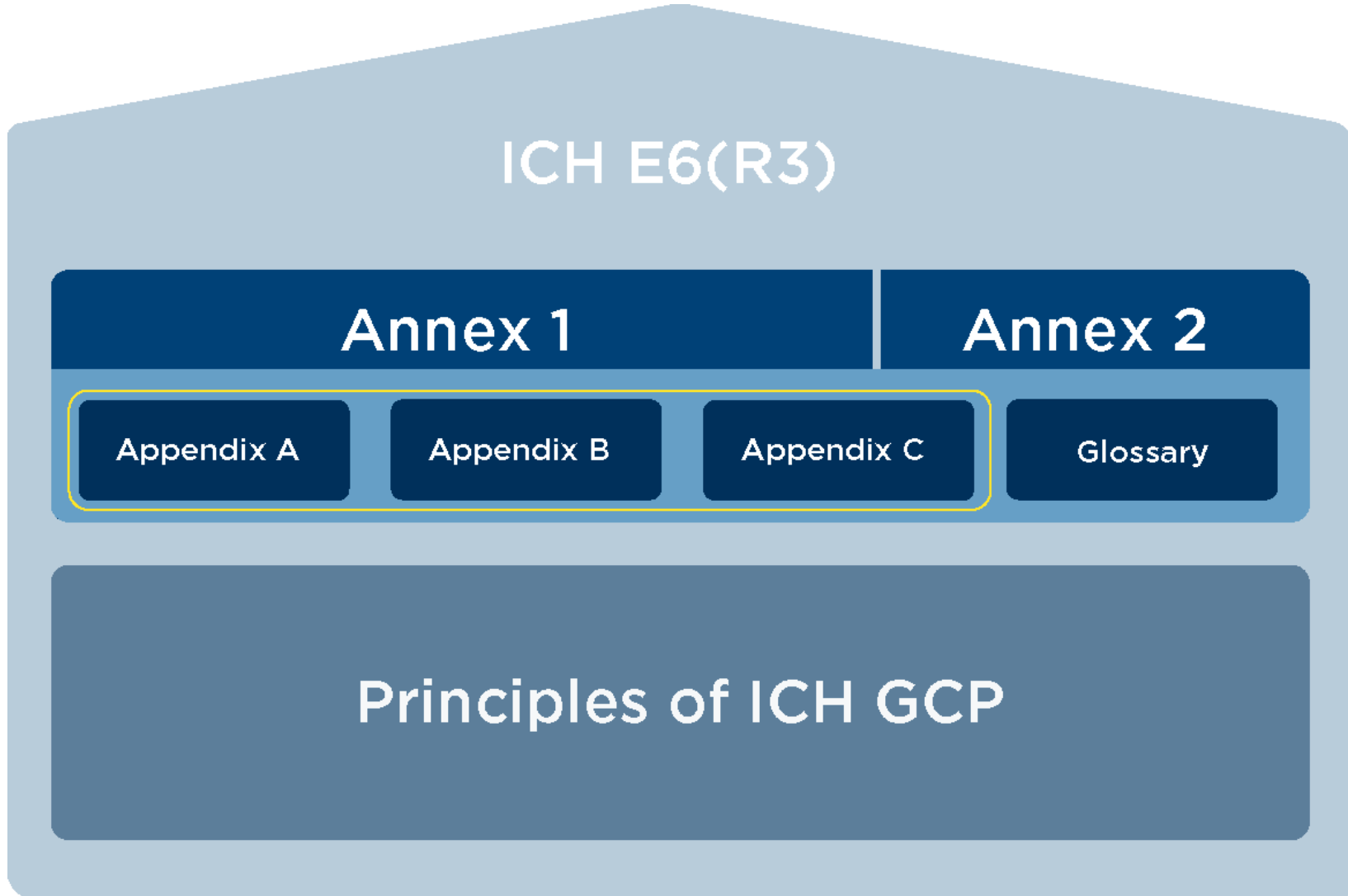
Scope note:

- E6(R3) formally applies to interventional trials of investigational products intended for regulatory submission.
- It's goal is to provide a unified standard to facilitate mutual acceptance by regulatory authorities.

It's Flexible!

- Principles are intended to apply also to interventional trials not intended for submission and even more broadly across clinical trial types and settings.
- It encourages thoughtful consideration and planning of each unique clinical trial or study.


ICH E6(R3)
Annex 1
Annex 2
Principles of ICH GCP


ICH E6(R3)
Annex 1
Annex 2
Appendix A
Appendix B
Appendix C
Glossary
Principles of ICH GCP

Quality by Design

A **prospective** and **multidisciplinary** approach that focuses on:

- Gathering input from interested parties

- Identifying critical trial attributes
  (Critical to Quality Factors)
- Identifying, prioritising, and controlling important risks to trial attributes

Official ICH E6(R3) Training Library

www.ich.org

E6(R3)

> **Step 4 Presentation**

Training Materials

Interpretation and Application of ICH E6(R3): Good Clinical Practice Guideline

Module 1: Introduction and Foundational Concepts, published in October 2025

- Module 1.1 Overview; Transcript
- Module 1.2 Principles of ICH GCP; Transcript
- Module 1.3 Foundational Concepts; Transcript

Module 2: Responsibilities and Oversight, coming soon!

Module 3: Data Governance, coming soon!

Module 4: Informed Consent, published in January 2026

- Module 4.1; Transcript
- Module 4.2; Transcript

Module 5: Essential Records, published in September 2026

- Module 5.1; Transcript
- Module 5.2; Transcript

Case Example:

Practical Risk-Proportionate Strategies

Case Example:
Approved drug for new indication

Study Design & Sponsor

- Open-label, investigator-initiated trial
- Approved drug in a new indication for a rare neuromuscular condition
- PI at the coordinating academic medical center holds the IND

Population & Sites

- 60 participants enrolled
- 3 sites total
- Coordinating center's IRB serves as the reviewing IRB for all 3 sites under a reliance agreement

Endpoint & Study Procedures

- Primary endpoint: functional score at 24 weeks
- Participants self-administer weekly at home, between monthly site visits
- Biomarker samples collected via at-home phlebotomy by a contracted home nursing vendor

Data & Lab Infrastructure

- eCRF: REDCap build from the medical center's own informatics core
- Biomarker samples sent to a central laboratory under a service agreement

THINK + DO