Sneak Peek

Biometrics in Clinical Trials

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ONLINE
TRAINING

3 - Day Agenda

Day 1: FOUNDATIONS

- History of clinical trial regulations and ethical standards
- Overview of 1,cH guidelines: E6, E3, E2A-F, Eg
- Data integrity, CSR and CSP structure
- Types of data and TLFs

DAV 2: PRACTICAL IMPLEMENTATION

- eClinical systems and their validation
- CDISC standards: CDASH, SDTM, ADaM
- Clinical data management lifecycle and processes
- Statistical programming and reporting

DAV 3: ADVANCED TOPICS

- Statistical testing aligned with study designs
- Introduction to pharmacokinetics in early-phase trials
- EMA and FDA guidance
- Biometrics role in project teams

Objectives of this Session

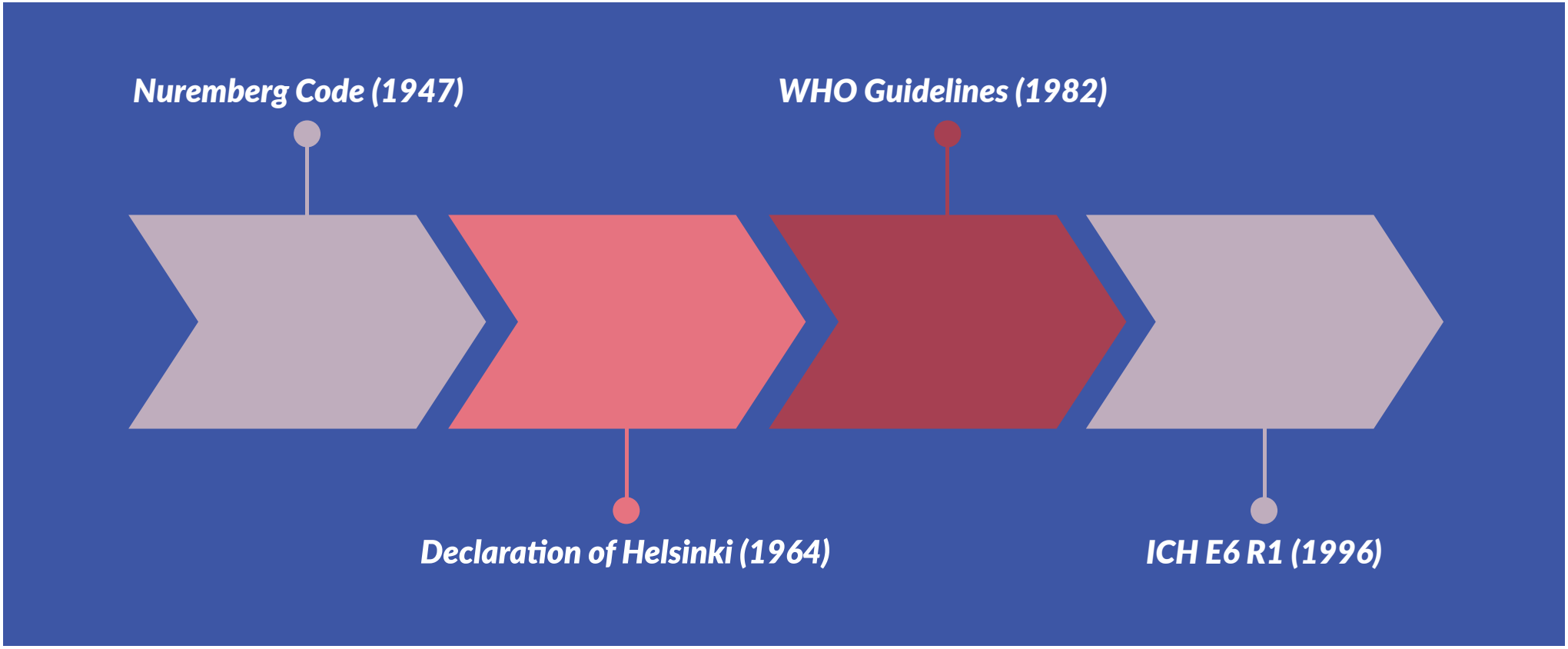
- Understand key principles of ICH E6(R3)
- Explore how data reliability, security, and quality are safeguarded
- Clarify roles and responsibilities in biometrics functions
- Learn how ICH E6(R3) enhances modern clinical research practices

Challenges for CROs and Sponsors

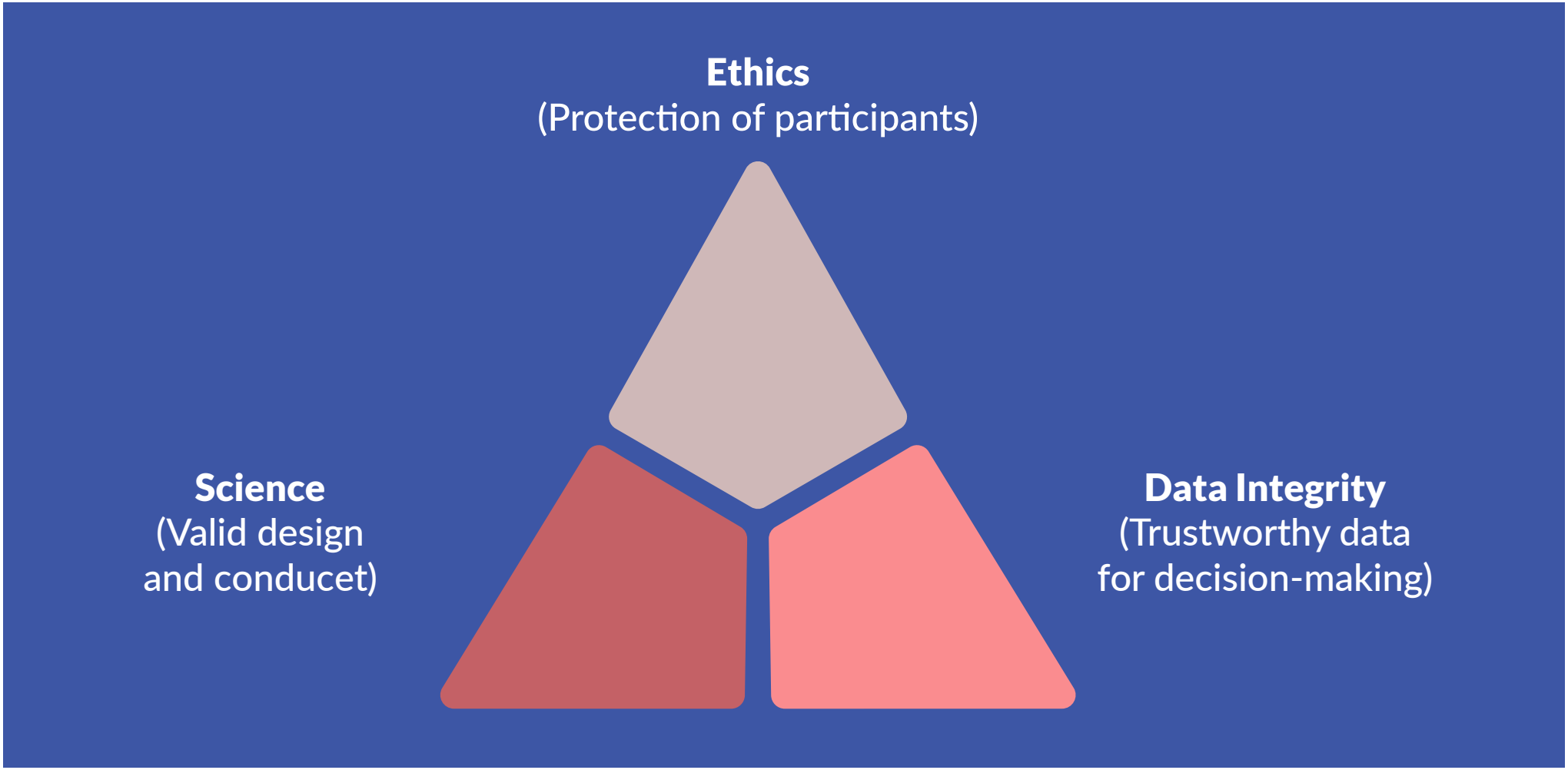
- Regulatory Diversity and Complexity
- Resource Allocation
- Integration and System Administration
- Data Protection and GDPR Compliance
- Change Management and Validation
- Audit Prepardness

Timeline of Key Historical Events

04



The GCP Triangle



Key ICH Guidelines for Biometrics

06

E6

Good Clinical Practice Principles

E3

Clinical Study Report Structure

E9

Statistical Principles

E2A-F

Safety Data Managment

Registration

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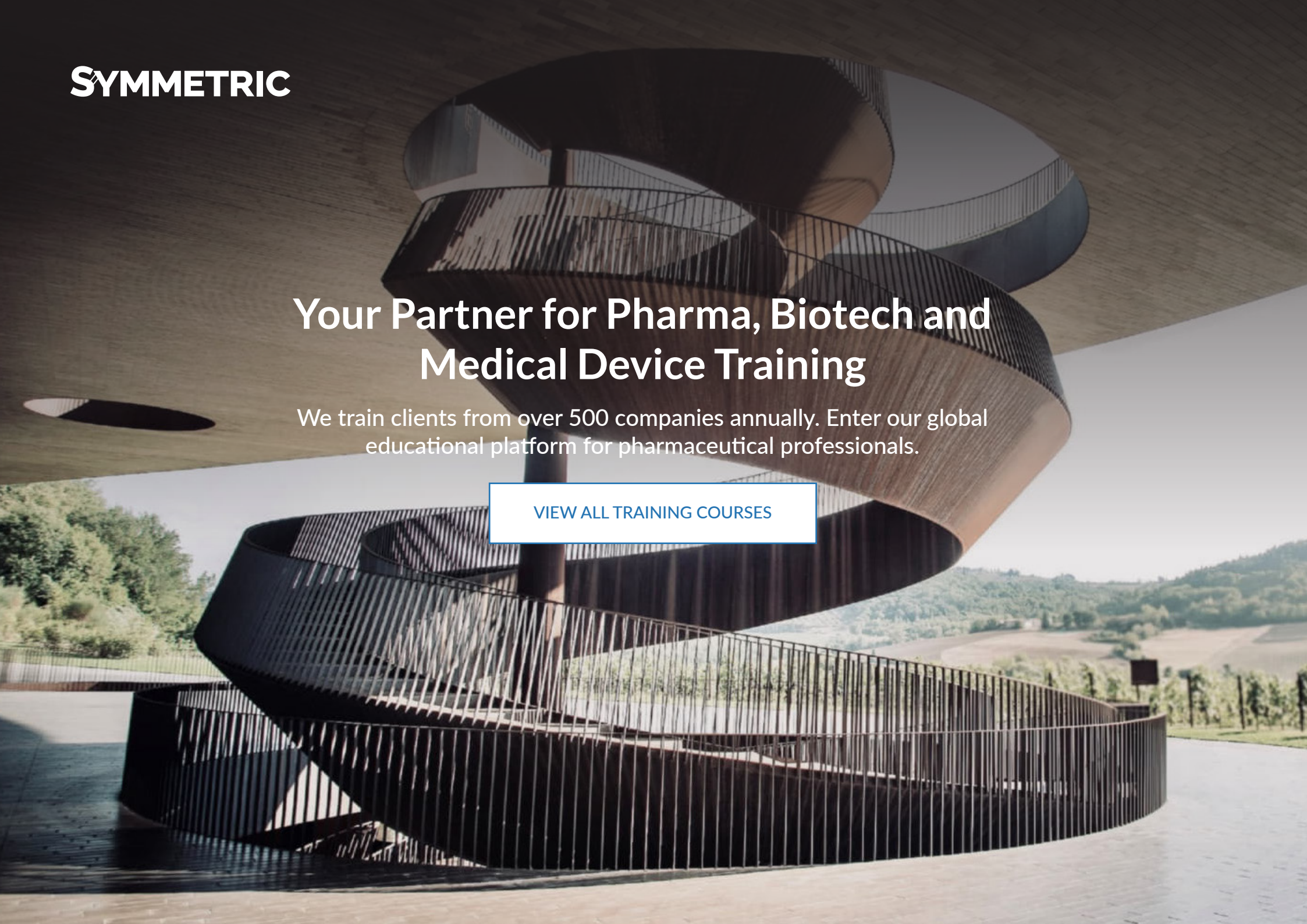
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