Clinical Trials in the European Union

Legislation, Guidelines and the Declaration of Helsinki

2023

Book 6

Clinical Trials in the European Union: Selected Legislation, Guidelines, and the Declaration of Helsinki

Legislation

- Directive 2001/20/EC ... relating to the implementation of good clinical practice in the conduct of clinical trials
- Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice
- Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Guidances for the EU Directives

- Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (CT-3) June 2011
- Detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion on a clinical trial on medicinal products for human use
  February 2006, Revision 1
- Questions and Answers on Clinical Trials in the EU
  August, 2011

Guidances for Regulation 536/2014

- Questions and Answers on Clinical Trials Regulation (EU) No 536/2014
  May, 2022

ICH Guidelines (Step 5, EU)

E6 (R2): Good Clinical Practice (Integrated Addendum)

E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

E8 (R1): General Considerations for Clinical Trials

E2F: Development Safety Update Reports

Declaration of Helsinki

World Medical Association, 2013

CLINICAL RESEARCH RESOURCES