Selected Guidance Documents on Conducting Clinical Trials

2023
Book 14

Selected Guidance Documents on Conducting Clinical Trials

- Adverse Event Reporting to IRBs — Improving Human Subject Protection
- Electronic Source Data in Clinical Investigations
- Premarketing Risk Assessment
- Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers
- Exception from Informed Consent Requirements for Emergency Research
- Collection of Race and Ethnicity Data in Clinical Trials
- Recommended Approaches to Integration of Genetic Toxicology Study Results
- Exploratory IND Studies
- S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals
- Expedited Programs for Serious Conditions — Drugs and Biologics
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC

CLINICAL RESEARCH RESOURCES