Clinical Trials Online Library
List of Contents and Appendices

1. Clinical Trials: Ensuring Patient Safety

List of Contents

Section 1: Clinical Trials: Ensuring Patient Safety & Data Integrity

Section 2: Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees.
Draft FDA guidance on the roles, responsibilities and operating procedures for data monitoring committees in overseeing clinical trials.

Section 3: Statistical Principles for Clinical Trials
ICH guidance, adopted by the FDA, on the statistical principles that should be applied to trials, an area that is key to data monitoring committees.

Section 4: Structure and Content of Clinical Study Reports
ICH guidance, adopted by the FDA, on the reports that compile the clinical and statistical descriptions, presentations and analysis of the data DMCs review.

Section 5: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.
FDA guideline on the terminology and procedures for gathering and reporting adverse events during clinical development, an area that DMCs watch.

Section 6: Guideline for the Monitoring of Clinical Investigations.
FDA guidance explaining the acceptable approaches to monitoring clinical investigations for data integrity and human subject protection.

Section 7: Information Program on Clinical Trials for Serious or Life-Threatening Diseases.
FDA guidance giving recommendations for sponsors on submitting information about clinical trials for serious or life-threatening diseases to a data bank.

Section 8: Good Clinical Practice: Consolidated Guide.
ICH guideline, adopted by the FDA, toward a unified standard in the European Union, Japan and the U.S. for the mutual acceptance of clinical data.

Section 9: OHRP Compliance Activities: Common Findings and Guidance
OHRP Compliance Activities: Common Findings and Guidance.
OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance.

Section 10: NCI Data Monitoring Policy and Plan Recommendations.
National Cancer Institute papers: one explaining the agency's policies on data monitoring, and the other giving advice for a data monitoring plan.

Section 11: NIH Data Monitoring Policies.
National Institutes of Health policies concerning data monitoring: the first giving general guidance, the second addressing Phase I and II trials and the third on reporting adverse events to an IRB.
2. Confidentiality in Clinical Trials: Understanding Your Liability

List of Contents

Introduction
Defining the Issue
The Law of Insider Trading
Identifying Areas of Risk
Best Practices
FAQs
Conclusion

Appendices

Appendix A: Securities Exchange Act of 1934
Appendix B: Final Rule: Selective Disclosure and Insider Trading
Appendix C: 17 CFR Part 243 —Regulation FD
Appendix D: Congressional Research Service’s “Legal Analysis of Whether Trading Stock Based on Secret Information Obtained from Medical Researchers Could Be Considered Insider Trading Prohibited by the Federal Securities Laws”
Appendix E: Sen. Chuck Grassley’s August 2005 letter to the SEC
Appendix F: Sen. Chuck Grassley’s May 2006 letter to the SEC
Appendix G: Online links to news articles

3. Managing Cardiovascular Risk with the Thorough QT Study

List of Contents

Introduction
Cardiovascular Safety
Safety Regulations
Development Strategy
Study Design
Surveillance During Later Phases
Frequently Asked Questions (FAQs)
Conclusion

Appendices

Appendix A: Guidance for Industry S7A Safety Pharmacology Studies for Human Pharmaceuticals
Appendix B: ICH S7B Guideline Step 2 Revision The Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals
Appendix C: Guidance for Industry E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
4. Planning for Clinical Trials Disasters

List of Contents

Introduction
Why Planning Matters
Plan Elements and Tips
External Resources
Preparing for an Uncertain Future
One Company’s Process—A Case Study
International Experiences
Lessons Learned
FAQs
Conclusion

Appendices

Appendix B: FDA Offers Tips About Medical Devices and Hurricane Disasters
Appendix D: California OES Clinic Disaster Plan Guidance

5. Step-by-Step Guide to Safe and Effective Clinical Trials

List of Contents

Introduction
Team Organization
The Protocol
Selecting and Working With Investigators
Tracking Progress
Data Quality
FAQs

Appendices

Appendix A: ICH E6 Good Clinical Practice: Consolidated Guidance
Appendix B: FDA’s A Guide to Informed Consent
Appendix C: FDA’s Guideline for the Monitoring of Clinical Investigations
Appendix D: Structure and Content of Clinical Study Reports
Appendix E: 21 CFR Parts 31223 and 31253
Appendix F: FDA Forms 1571 Investigational New Drug Application
Appendix G: FDA Form 1572 Statement of Investigator