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Titolo	Economisti francesi del primo Settecento : Boisguilbert, Ragguaglio della Francia e altri scritti : Vauban, Progetto d'una decima regia / a cura di Onofrio Nicastro
Pubbl/distr/stampa	Pisa : ETS, 2003
ISBN	88-467-0834-2
Edizione	[Nuova ed.]
Descrizione fisica	371 p. ; 22 cm
Collana	Filosofia ; 65
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Soggetti	Economisti francesi - Sec. 18
Lingua di pubblicazione	Italiano
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Titolo	Principles and practice of clinical research [[electronic resource] /] / [edited by] John I. Gallin, Frederick P. Ognibene
Pubbl/distr/stampa	Amsterdam ; ; Boston, : Elsevier/Academic Press, c2007
ISBN	1-281-05227-2 9786611052270 0-08-048956-7
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (447 p.)
Altri autori (Persone)	GallinJohn I OgnibeneFrederick P
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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front cover; Principles and Practice of Clinical Research; Copyright page; Table of contents; Preface; Acknowledgements; Contributors; Chapter 1: A Historical Perspective on Clinical Research; 1. THE EARLIEST CLINICAL RESEARCH; 2. THE GREEK AND ROMAN INFLUENCE; 3. MIDDLE AGES AND RENAISSANCE; 4. SEVENTEENTH CENTURY; 5. EIGHTEENTH CENTURY; 6. NINETEENTH CENTURY; 7. TWENTIETH CENTURY AND BEYOND; Acknowledgment; References and Notes; PART I: ETHICAL, REGULATORY, AND LEGAL ISSUES; Chapter 2: Ethical Principles in Clinical Research; 1. DISTINGUISHING CLINICAL RESEARCHFROM CLINICAL PRACTICE 2. WHAT DOES ETHICS HAVE TO DOWITH CLINICAL RESEARCH?3. HISTORY OF ETHICAL ATTENTION TOCLINICAL RESEARCH; 4. CODES OF RESEARCH ETHICSAND REGULATIONS; 5. ETHICAL FRAMEWORK FORCLINICAL RESEARCH; 6. ETHICAL CONSIDERATIONS IN RANDOMIZED CLINICAL TRIALS; 7. CONCLUSION; References; Chapter 3: Researching a Bioethical Question; 1. TYPES OF BIOETHICAL ISSUES; 2. TYPES OF BIOETHICAL RESEARCH METHODOLOGIES; 3. EXAMPLES OF IMPORTANT BIOETHICAL RESEARCH; 4. SPECIAL CONSIDERATIONS INBIOETHICAL RESEARCH; References and Notes; Chapter 4: Integrity in Research:

Individual and Institutional Responsibility

1. GUIDELINES FOR THE CONDUCTOF RESEARCH2. SCIENTIFIC INTEGRITY AND MISCONDUCT; 3. MENTOR-TRAINEE RELATIONSHIPS; 4. DATA ACQUISITION, MANAGEMENT, SHARING, AND OWNERSHIP; 5. RESEARCH INVOLVING HUMAN AND ANIMAL SUBJECTS; 6. COLLABORATIVE SCIENCE; 7. CONFLICT OF INTEREST AND COMMITMENT; 8. PEER REVIEW; 9. PUBLICATION PRACTICES AND RESPONSIBLE AUTHORSHIP; Acknowledgment; References; Chapter 5: Institutional Review Boards; 1. HISTORICAL, ETHICAL, ANDREGULATORY FOUNDATIONSOF CURRENT REQUIREMENTSFOR RESEARCH INVOLVINGHUMAN SUBJECTS; 2. INSTITUTIONAL REVIEW BOARDS; 3. CLINICAL RESEARCHERSAND IRBs

4. THE CURRENT IRB SYSTEM UNDER EVALUATION5. CONCLUSION; References and Notes; Chapter 6: Data and Safety Monitoring Boards; 1. DESCRIPTION OF THE DATA ANDSAFETY MONITORING BOARD; 2. DATA AND SAFETY MONITORINGBOARD FUNCTIONS; 3. DATA AND SAFETY MONITORINGBOARD DECISION MAKING; 4. EXAMPLES; 5. CONCLUSIONS; References; Chapter 7: Data Management in Clinical Trials; 1. THE RESEARCH TEAM; 2. PLANNING THE TRIAL; 3. WHERE ARE DATA?; 4. WHO CAN COLLECT DATA?; 5. SITE INITIATION VISIT; 6. INFORMED CONSENT; 7. ELIGIBILITY; 8. REGISTRATION; 9. WHAT DATA DO YOU COLLECT?; 10. TREATMENT PLAN

11. CONCURRENT THERAPY12. ADVERSE EVENT MONITORING; 13. ROUTINE MONITORING VISITS; 14. AUDIT TRAIL; 15. ELECTRONIC DATABASE; 16. SUMMARY; References; Chapter 8: Unanticipated Risk in Clinical Research; 1. THE REASONS; 2. THE DRUG; 3. THE TARGET; 4. THE TRIALS; 5. CASSANDRA REVEALED; 6. EXTENDED STUDIES; 7. FIAU TOXICITY; 8. REASSESSING THEPRECLINICAL STUDIES; 9. RESEARCH OVERSIGHT; 10. THE INVESTIGATIONS BEGIN; 11. SCIENTIFIC MISCONDUCT; 12. THE FDA; 13. THE NATIONAL INSTITUTES OF HEALTH; 14. THE INSTITUTE OF MEDICINE; 15. THE MEDIA; 16. THE CONGRESS; 17. THE LAW; 18. EPILOGUE

Acknowledgments

Sommario/riassunto

The second edition of this innovative work again provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research. Molecular medicine, genomics, and proteomics have opened vast opportunities for translation of basic science observations to the bedside through clinical research. As an introductory reference it gives clinical investigators in all fields an awareness of the tools required to ensure research protocols are well designed and comply with the rigorous regulatory requirements necessary to