1. Record Nr. UNINA9910965710703321

Titolo	Assuring data quality and validity in clinical trials for regulatory decision making : workshop report : Roundtable on Research and Development of Drugs, Biologics, and Medical Devices / / Jonathan R. Davis ... [et al.] editors
Pubbl/distr/stampa	Washington, DC, : National Academy Press, c1999
ISBN	0-309-17280-2 0-309-52024-X 0-585-14261-0
Edizione	[1st ed.]
Descrizione fisica	1 online resource (88 p.)
Collana	The compass series
Altri autori (Persone)	DavisJonathan R
Disciplina	615/.1
Soggetti	Clinical trials - Quality control
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references (p. 75-76).
Nota di contenuto	Front Matter; Preface; Acknowledgments; Contents; Executive Summary; Introduction; Presubmission and Submission; FDA Regulatory Review; Summary of Issues; Directions for the Future; Final Comments; APPENDIX A Workshop Agenda; APPENDIX B Speakers and Panelists; APPENDIX C Workshop Registrants; APPENDIX D Glossary and Acronyms
Sommario/riassunto	In an effort to increase knowledge and understanding of the process of assuring data quality and validity in clinical trials, the IOM hosted a workshop to open a dialogue on the process to identify and discuss issues of mutual concern among industry, regulators, payers, and consumers. The presenters and panelists together developed strategies that could be used to address the issues that were identified. This IOM report of the workshop summarizes the present status and highlights possible strategies for making improvements to the education of interested and affected parties as well as facilitating future planning.