Record Nr. UNINA9910462065103321 Safe and effective medicines for children [[electronic resource]]: **Titolo** pediatric studies conducted under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act / / Committee on Pediatric Studies Conducted Under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA); Board on Health Sciences Policy; Marilyn J. Field and Thomas F. Boat, editors Washington,: National Academies Press, 2012 Pubbl/distr/stampa **ISBN** 1-283-63634-4 0-309-22550-7 Descrizione fisica 1 online resource (432 p.) Altri autori (Persone) FieldMarilyn J (Marilyn Jane) BoatThomas F 615.1083 Disciplina Soggetti Pediatric pharmacology Drugs - Safety measures Electronic books. 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 and index. Nota di contenuto ""Front Matter""; ""Acknowledgments""; ""Reviewers""; ""Preface""; ""Contents""; ""Boxes, Figures, and Tables""; ""Abbreviations and Acronyms""; ""Summary""; ""1 Introduction""; ""2 Children's Growth and Development and Pediatric Drug Studies""; ""3 Policy Framework for BPCA and PREA""; ""4 Ethical Issues in Pediatric Drug Studies""; ""5 Safety and Efficacy Assessments in Studies Conducted Under BPCA and PREA""; ""6 BPCA, PREA, and Drug Studies with Neonates""; ""7 Outcomes of Written Requests, Requirements, Studies, and Labeling Changes""; ""8 Pediatric Studies of Biologics""; ""References"" ""Appendix A: Study Activities, Methods, and Public Meetings""" Appendix B: Dissemination of Information from Pediatric Studies Conducted Under BPCA and PREA""; ""Appendix C: Biologics in Pediatrics""; ""Appendix D: Biologics Studied and Not Studied in

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