

1. Record Nr.	UNINA9910140776803321
Titolo	Early drug development [[electronic resource] ] : strategies and routes to first-in-human trials // edited by Mitchell N. Cayen
Pubbl/distr/stampa	Hoboken, N.J., : Wiley, c2010
ISBN	1-118-03520-8 1-283-91645-2 0-470-61319-X 0-470-61317-3
Descrizione fisica	1 online resource (658 p.)
Altri autori (Persone)	CayenM. N
Disciplina	615/.19
Soggetti	Drug development Clinical trials
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.
Nota di contenuto	EARLY DRUG DEVELOPMENT; CONTENTS; Contributors; Foreword; Preface; PART I INTRODUCTION; 1 Drug Discovery and Early Drug Development; References; PART II LEAD OPTIMIZATION STRATEGIES; 2 ADME Strategies in Lead Optimization; 3 Prediction of Pharmacokinetics and Drug Safety in Humans; 4 Bioanalytical Strategies; PART III BRIDGING FROM DISCOVERY TO DEVELOPMENT; 5 Chemistry, Manufacturing, and Controls: The Drug Substance and Formulated Drug Product; 6 Nonclinical Safety Pharmacology Studies Recommended for Support of First-in-Human Clinical Trials; PART IV PRE-IND DRUG DEVELOPMENT 7 Toxicology Program to Support Initiation of a Clinical Phase I Program for a New Medicine 8 Toxicokinetics in Support of Drug Development; 9 Good Laboratory Practice; PART V PLANNING THE FIRST-IN-HUMAN STUDY AND REGULATORY SUBMISSION; 10 Estimation of Human Starting Dose for Phase I Clinical Programs; 11 Exploratory INDs/CTAs; 12 Unique Considerations for Biopharmaceutics; 13 Project Management and International Regulatory Requirements and Strategies for First-in-Human Trials; 14 First-in-Human Regulatory Submissions; Appendix 1: Abbreviations and Acronyms

Appendix 2: Definitions and Glossary of Terms Appendix 3: Some Relevant Government and Regulatory Documents; Appendix 4: Some Relevant Resources with Web Sites; Index

---

Sommario/riassunto

The focus of early drug development has been the submission of an Investigational New Drug application to regulatory agencies. *Early Drug Development: Strategies and Routes to First-in-Human Trials* guides drug development organizations in preparing and submitting an Investigational New Drug (IND) application. By explaining the nuts and bolts of preclinical development activities and their interplay in effectively identifying successful clinical candidates, the book helps pharmaceutical scientists determine what types of discovery and preclinical research studies are needed in order to s

---