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Edizione	[2nd ed.]
Descrizione fisica	1 online resource (432 p.)
Disciplina	615.5072/4
Soggetti	Clinical trials Drugs - Testing
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Rev. ed. of: Lessons from a horse named Jim / by Margaret B. Liu and Kate Davis. c2001.
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Lessons from a horse named Jim and other events in history affecting the regulation of clinical research -- The process : developing new drugs, biologics, and devices -- Good clinical practice and the regulations -- Informed consent and the regulations -- Institutional review boards -- Adverse events and unanticipated problems involving risks to subjects and others -- Monitoring, audits, and inspections -- The principal investigator, the clinical research coordinator, and the study site -- The protocol -- Study feasibility : reviewing a specific protocol -- Study activities -- Study documents/essential documents -- Management of study drugs, biologics, and devices -- Managing clinical trial data -- Global health and international trials.