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Descrizione fisica	1 online resource (VI, 258 p. 26 illus., 16 illus. in color.)
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Disciplina	617
Soggetti	Surgery Medical education Medical Education
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	History of Clinical Trials -- Ethics (COI, informed consent) -- Generating a Testable Hypothesis and Underlying Principles of Clinical Trials -- Trial Design: Overview of Study Designs (phase I, II, III, IV, factorial design) -- Defining the Study Cohort: Inclusion and Exclusion criteria (establishing eligibility and exclusion criteria, how should one define a cohort, balance between being inclusive versus selective / efficacy versus effectiveness trials) -- Building your Clinical Trial Research Team (how to assemble the team: database manager, research nurse) -- Clinical Trials: Ensuring Quality and Standardization (GCP, reporting of AE's, establishing SOPs, CRF's) -- Device versus Drug Clinical Trials: Similarities and Important Differences -- Statistics -- Setting the Stage (Sample Size, Power, Randomization, Type II error, Treatment allocation/stratification) -- Statistics -- Handling the Data (Intention to Treat analyses, Subgroups analyses, expressing the data (relative risk), handling missing data) -- Data Safety Monitoring Board: Interim Analyses, Stopping Rules -- Planning for Data Monitoring and Audit -- Clinical Trials: The Budget -- Regulatory Issues (compliance issues, IRB, FDA) -- Publishing your Clinical Trial (authorship, manuscript preparation, journal selection) -- Pragmatic clinical trials -- Cooperative trials -- International trials -- Inclusion of Patient Reported Outcomes -- Participation in clinical trials/as a clinical trialist for the community surgeon. .

Sommario/riassunto

This extensively revised second edition is a unique and portable handbook focusing on clinical trials in surgery. It includes new educational materials addressing the rapid evolution of novel research methodologies in basic science, clinical and educational research. The underlying principles of clinical trials, trial design, the development of a study cohort, statistics, data safety, data monitoring, and trial publication for device and drug trials are also discussed. Clinical Trials provides a comprehensive resource on clinical trials in surgery and describes all the stages of a clinical trial from generating a hypothesis through to trial publication and is a valuable resource for all practicing and trainee academic surgeons.
