1. Record Nr. UNINA9910983345103321

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| Titolo | Introduction to surgical trials / / edited by Stephen Lyman, Olufemi R. Ayeni, Jason L. Koh, Norimasa Nakamura, Jón Karlsson |
| Pubbl/distr/stampa | Cham : , : Springer Nature Switzerland : , : Imprint : Springer, , [2024] |
| ISBN | 9783031775635<br>3031775635 |
| Edizione | [First edition.] |
| Descrizione fisica | 1 online resource (x, 215 pages) : illustrations |
| Collana | Medicine Series |
| Disciplina | 616.7 |
| Soggetti | Surgery - Research<br>Surgery - Research - Moral and ethical aspects<br>Orthopedics<br>Epidemiology<br>Surgery<br>Biometry<br>Bioinformatics<br>General Surgery - methods<br>Clinical Trials as Topic<br>Research Design<br>Biostatistics<br>Computational Biology<br>Epidemiologic Research Design<br>Orthopedic Procedures - methods |
| Lingua di pubblicazione | Inglese |
| Formato | Materiale a stampa |
| Livello bibliografico | Monografia |
| Nota di bibliografia | Includes bibliographical references. |
| Nota di contenuto | SECTION A: Trial Design -- Why Do We Need Surgical Trials? -- Addressing the Challenges to Surgical Randomization -- Randomization Strategies -- Surgical Trial Design: Interventions & Blinding -- Sample Size and Power Considerations for Surgical Trials -- Optimizing Recruitment in Randomized Controlled Trials -- Treatment Allocation -- Crossover and early failure in surgical trials -- Strategies to Optimize Follow-up in Surgical Trials -- Considerations in Choosing Outcomes Measures -- Length of Follow-Up -- SECTION B: Conducting |

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| | a Trial -- Ethics considerations and approval in human research and in orthopaedics -- Trial Start Up Considerations: Budget, Staffing, Logistics -- Adverse Events Reporting & Data and Safety MonitoringTrial Closeout -- SECTION C: Trial Completion -- Missing Data & Imputation -- Statistical Analysis for Surgical Trials -- CONSORT Reporting Standards -- SECTION D: Regulatory Standards -- The Regulatory Pathway to Market Class III Surgical Medical Devices in the United States -- European Standards -- Regulatory Standards for Surgical Trials in Asia: the Japanese Experience -- SECTION E: Alternatives to the Classic RCT -- Pragmatic TrialsPlatform Trials -- Prospecitve Cohort StudiesSurgical Registries -- The Future of Trials. |
| Sommario/riassunto | Filling a gap in literature, this book examines surgical trials with a special focus on the underlying principles, challenges, and best practices to successfully conduct rigorous surgical research. While randomized controlled trials (RCTs) remain the gold standard for evaluation of the safety and efficacy of most medical interventions, they are particularly difficult to implement successfully in the context of surgery. As a result, recruitment rates are often extremely low, crossover from non-operative to operative is common, and patients randomly allocated to surgery often simply decline to have the procedure. All of these challenges call into question the recent generalizability and fundamental quality of traditional surgical RCTs. As such, this book explores advanced alternative trial design methods and describes the current regulatory environment around the world. Designed as a practical guide, it is a valuable tool for surgeons, epidemiologist and biostatisticians involved in this challenging field. |