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Nota di contenuto	Front Cover; Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, FDA and ICH Guidelines; Copyright Page; Contents; Acknowledgments; Preface; The Study Schema and Study Design; Intent to Treat Analysis; How to Choose the Endpoints; Diagnostic Tests; Mechanism of Action; Standards; Methodology; Clinicaltrials.Gov and other Registries for Clinical Trials; Introduction; Abbreviations and Definitions; Biography; 1 The Origins of Drugs; I. Introduction; II. Structures of Drugs; a. Origins of warfarin; b. Origins of methotrexate and 5-fluorouracil; c. Origins of ribavirin d. Origins of paclitaxele. Origins of cladribine; f. Origins of drugs in high-throughput screening; g. Origins of therapeutic antibodies; III. The 20 Classical Amino Acids; IV. Animal Models; a. Introduction; b. Estimating human dose from animal studies; 1. NOAEL approach; 2. MABEL approach; c. Scaling up the drug dose, acquired from animal studies, for use in humans; 2 Introduction to Regulated Clinical Trials; I. Introduction; II. Study Design; III. The Study Schema; a. Examples of schema from clinical trials; b. Sequential treatment versus concurrent treatment - the Perez schema

c. Neoadjuvant chemotherapy versus adjuvant chemotherapy - the Gianni schemad. Neoadjuvant chemotherapy plus adjuvant chemotherapy - the Untch schema; e. Forwards sequence and reverse sequence - the Puhalla schema; f. Both arms received three drugs, each arm at a different schedule - the Sekine schema; g. Staging - the Blumenschein schema; h. Staging and restaging - the Czito schema; i. Methodology tip - staging; j. Decision tree - the Baselga schema; k. Decision tree - the Katsumata schema; l. Methodology tip - what is "tumor progression"?
m. Methodology tip - unit of drug dose expressed in terms of body surface arean. Run-in period - the schema of Dy; o. Methodology tip - c-kit and imatinib; p. Run-in period - the Hanna schema; q. How to maintain blinding of the treatment, when the study drug and the control treatment are provided by different-sized pills (or by different volumes of solutions)...; r. Methodology tip - bevacizumab and VEGF; s. Dose escalation - the Moore schema; t. Pharmacokinetics - the Marshall schema; IV. Further Concepts In Study Design; a. Active control; b. Add-on design active control
c. Three-arm study - clinical trial with two different active control armsV. Summary; VI. Amendments to the Clinical Study Protocol; 3 Run-In Period; I. Introduction; a. Washout period; b. Detecting baseline adverse events; c. Excluding potential study subjects who have safety issues correlating with the study drug; d. To include only study subjects with controllable pain; e. To determine the maximal tolerable dose; f. To achieve and ensure steady state in vivo concentrations of study drug
g. To allow a period of adjustment of lifestyle of the study subjects, for example changes in dietary patterns

Sommario/riassunto

Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines is a practical guidebook for those engaged in clinical trial design. This book details the organizations and content of clinical trials, including trial design, safety, endpoints, subgroups, HRQoL, consent forms and package inserts. It provides extensive information on both US and international regulatory guidelines and features concrete examples of study design from the medical literature. This book is intended to orient those new to clinical trial design and provide them with a better u