Handbook of Statistics in Clinical Oncology, Third Edition

From Chapman and Hall/CRC

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Many new challenges have arisen in the area of oncology clinical trials. New cancer therapies are often based on cytostatic or targeted agents, which pose new challenges in the design and analysis of all phases of trials. The literature on adaptive trial designs and early stopping has been exploding. Inclusion of high-dimensional data and imaging techniques have become common practice, and statistical methods on how to analyse such data have been refined in this area. A compilation of statistical topics relevant to these new advances in cancer research, this third edition of **Handbook of Statistics in Clinical Oncology** focuses on the design and analysis of oncology clinical trials and translational research.

Addressing the many challenges that have arisen since the publication of its predecessor, this third edition covers the newest developments involved in the design and analysis of cancer clinical trials, incorporating updates to all four parts:

- *Phase I trials:* Updated recommendations regarding the standard 3 + 3 and continual reassessment approaches, along with new chapters on phase 0 trials and phase I trial design for targeted agents.
- *Phase II trials*: Updates to current experience in single-arm and randomized phase II trial designs. New chapters include phase II designs with multiple strata and phase II/III designs.
- *Phase III trials*: Many new chapters include interim analyses and early stopping considerations, phase III trial designs for targeted agents and for testing the ability of markers, adaptive trial designs, cure rate survival models, statistical methods of imaging, as well as a thorough review of software for the design and analysis of clinical trials.
- *Exploratory and high-dimensional data analyses*: All chapters in this part have been thoroughly updated since the last edition. New chapters address methods for analyzing SNP data and for developing a score based on gene expression data. In addition, chapters on risk calculators and forensic bioinformatics have been added.

Accessible to statisticians and oncologists interested in clinical trial methodology, the book is a single-source collection of up-to-date statistical approaches to research in clinical oncology.

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Editorial Review

Review

"A strength of the handbook is the large number of examples that are included in most chapters that expand on the theoretical basis underpinning the relevant methodology. Each chapter provides details of new developments in the specific methodology and provides a comprehensive list of references for the reader to seek further information when required. … The book contains a wealth of information about a wide range of statistical methodologies, some of which are not limited to clinical trials. … a valuable update to a resource that covers a comprehensive range of topics related to the design, analysis and interpretation of clinical trials in cancer research."
?Peter Baade, *Australian & New Zealand Journal of Statistics*, 2013

Praise for the Second Edition:
"The new topics and contributions in this edition include the recently developed tools for high-dimensional data and bioinformatics in clinical oncology research. A new section has been added emphasizing the importance and rapid developments of these topics over the 5 years since the publication of the first edition. Some of the original sections have been updated to include the state-of-the-art knowledge and tools in all topics. The end result is a comprehensive edited volume covering statistical and bioinformatics methods that provide the foundation for important research and clinical trials in cancer. … Like the last edition, this current edition will be an important addition to the libraries of all health research centers. The book will be prized as a reference book for biostatisticians, biomedical researchers, and oncologists for planning, conducting, analyzing, and interpreting cancer research."
?*Journal of the American Statistical Association*, Vol. 104, No. 487, September 2009

"This is a expanded and revised second edition of a text that was initially well received by the community. The book comprised of 33 chapters, grouped into 6 sections. … The text is extremely well referenced. The authorship represents the leaders in the field. A significant strength of this book is its example-driven approach to the ‘out-of-the-box’ but practical issues faced by those conducting cancer clinical trials. The book provides a critical assessment of the state of science through a thorough review of the methods, applications, and available resources. … a detailed and mostly comprehensive text on the topics of cancer clinical trial design, conduct, analysis, and interpretation."
?Daniel Sargent, Sumithra Mandrekar, and Ann Oberg, Mayo Clinic, *Biometrics*, December 2006

About the Author

John J. Crowley is president and CEO of Cancer Research and Biostatistics (CRAB), Seattle, Washington, director of the SWOG Statistical Center, and a faculty member at the Fred Hutchinson Cancer Research Center. The author or coauthor of more than 350 refereed articles, book chapters, and other publications, Dr. Crowley is a fellow of the American Statistical Association and the American Association for the Advancement of Science and a member of the International Biometrics Society, the American Society for Clinical Oncology, and the International Association for the Study of Lung Cancer. He received his BA (1968) from Pomona College, Claremont, California, and his MS (1970) and PhD (1973) in biomathematics from the University of Washington, Seattle.

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Antonio Haynie:

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