

SECOND EDITION

# The CRA's Guide to **Monitoring Clinical Research**

Karen E. Woodin, Ph.D. & John C. Schneider

# The Cras Guide To Monitoring Clinical Research 2nd Edition

**Angela D. Klimaszewski**

## **The Cras Guide To Monitoring Clinical Research 2nd Edition:**

**The CRA's Guide to Monitoring Clinical Research** Karen E. Woodin,Elizabeth Weeks-Rowe,2016-05      *The CRA's Guide to Monitoring Clinical Research* Karen E. Woodin,2008-01-01      **Data and Safety Monitoring Committees in Clinical Trials** Jay Herson,2016-12-19 Praise for the first edition Given the author's years of experience as a statistician and as a founder of the first DMC in pharmaceutical industry trials I highly recommend this book not only for experts because of its cogent and organized presentation but more importantly for young investigators who are seeking information about the logistical and philosophical aspects of a DMC S T Ounpraseuth The American Statistician In the first edition of this well regarded book the author provided a groundbreaking and definitive guide to best practices in pharmaceutical industry data monitoring committees DMCs Maintaining all the material from the first edition and adding substantial new material Data and Safety Monitoring Committees in Clinical Trials Second Edition is ideal for training professionals to serve on their first DMC as well as for experienced clinical and biostatistical DMC members sponsor and regulatory agency staff The second edition guides the reader through newly emerging DMC responsibilities brought about by regulations emphasizing risk vs benefit and the emergence of risk based monitoring It also provides the reader with many new statistical methods clinical trial designs and clinical terminology that have emerged since the first edition The references have been updated and the very popular end of chapter Q A section has been supplemented with many new experiences since the first edition New to the Second Edition Presents statistical methods tables listings and graphs appropriate for safety review efficacy analysis and risk vs benefit analysis SPERT and PRISMA initiatives Newly added interim analysis for efficacy and futility section DMC responsibilities in SUSARs Serious Unexpected Adverse Reactions basket trials umbrella trials dynamic treatment strategies SMART trials pragmatic trials biosimilar trials companion diagnostics etc DMC responsibilities for data quality and fraud detection Fraud Recovery Plan Use of patient reported outcomes of safety Use of meta analysis and data outside the trial New ideas for training and compensation of DMC members Jay Herson is Senior Associate Biostatistics Johns Hopkins Bloomberg School of Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry      EClinical Trials Rebecca Daniels

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