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"" Ultrasound Techniques""""Grayscale Ultrasound""; "" Doppler Ultrasound""; "" Echocardiography""; "" Bone Ultrasonometry""; "" Radiation Dosages Among Imaging Modalities""; "" Conclusion""; ""References""; ""Chapter 2: The Metrics and New Imaging Marker Qualification in Medical Imaging Modalities""; ""Introduction""; "" Discrimination or Sensitivity and Specificity""; "" Precision and Accuracy""; "" Reliability""; "" Relevant""; "" Accepted by Regulatory Agencies""; "" Acceptable Cost""; "" Acceptable to the Subject""; "" Safe for the Subject and Operator""

"" Development of New Biomarkers"""" Identification of Systematic and Random Errors""; "" Conclusion""; ""References""; ""Chapter 3: Radiation Risks and Dosimetry Assessment""; ""Introduction""; "" How Do We Assess the Radiation Dose?""; "" What Are the Risks?""; "" What Do I Tell Participants?""; "" What Will the IRB/REC Want to Know?""; "" Training and Quality Assurance""; "" Appendix 3.1: Units of Radiation Dose, Risk Estimates and Measurement of Radiation Dose""; ""References""; ""Chapter 4: Imaging Review Charters and Operational Considerations""; ""Background""

""Historical Development and Use of Imaging Review Charters"""" Current Use of Imaging Charters""; "" State-of-the-Art Imaging Review Charters""; ""Standard Content""; "" Defining the Response Criteria""; "" Designing the Read""; ""Reader Allocation for Oncology Trials""; ""Purpose of the Global Session""; "" The Eligibility Read""; "" Reading for Confirmation of PD in Oncology""; "" Selecting and Screening Readers""; "" Reader Training/Mock Read""; "" Reader Monitoring""; ""Adjudication in Oncology""; "" Use of the Imaging Charter in Adaptive Design Clinical Trials""

"" Efficacy and Safety Reads""

Sommario/riassunto

Medical Imaging in Clinical Trials is a key text in understanding the methodology and the metrics that are required in the field of medical imaging. As the pharmaceutical, biotech and medical device industries continue to identify ways to improve and speed up product development, medical imaging plays a more significant role. Medical Imaging in Clinical Trials aims to educate and provide a hands-on text for those involved in clinical trials and either new to medical imaging and having to assimilate it into clinical trials or requiring to understand the key differences between clinical trial imaging and "routine" clinical imaging. It is targeted to those professionals involved in clinical trials at the clinical research site, pharmaceutical and medical device industries, and regulators. This is not the "how to image" book written for the radiologist or Radiological Technologist, but covers the critical aspects of clinical trial methodology that are important for these individuals to understand. This book addresses the ethics and radiation dosages of the different modalities, the end points commonly used for the different trial phases, the acquisition and analysis techniques, as well as the logistics management of medical imaging and the role of the central imaging lab or imaging core lab (ICL) which is now the standard requirement for clinical trials. Furthermore this text delves into the details of the major therapeutic areas where medical imaging plays a primary or secondary efficacy or safety end point.
