

CLINICAL EVALUATION OF MEDICAL DEVICES

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Principles and Case Studies

Second Edition

Edited by

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PREFACE

The original edition of this text, *Clinical Evaluation of Medical Devices: Principles and Case Studies*, provided the first overview of key principles and approaches to medical device clinical trials, illustrated with a series of detailed, real-world case studies. The book is designed as a resource for clinical professionals and regulatory specialists working in the field of new medical device development and marketing. Since the first edition of this text was published in 1997, the rapid pace of innovation in health care technologies continues to yield exciting and important new products. The regulatory landscape has also evolved, reflecting some of the changes and needs within the medical device industry.

The purpose of *Clinical Evaluation of Medical Devices: Principles and Case Studies, Second Edition* is to provide an updated and expanded presentation of the scientific methods and regulatory requirements applied to the study of new significant risk medical devices. The text now includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this purpose as well as health care technology assessment methods; (2) information on new statistical methodologies applied to medical device trials; and (3) all new case studies, including examples of combination products, three-phase development models (i.e., feasibility, FDA approval, Medicare reimbursement), and novel study designs. This second edition builds on the strength and foundation of the first, and would not have been possible without those colleagues who graciously contributed their expertise in the form of chapters and ideas to the final product.

Karen M. Becker, PhD
John J. Whyte, MD, MPH

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