



## Translational Research Methods in Diabetes, Obesity, and Nonalcoholic Fatty Liver Disease

A Focus on Early Phase Clinical Drug Development

2nd Edition 2019

Following the success of the first edition, this widely sourced textbook provides a detailed overview of current and emerging translational research methods and regulatory considerations for diabetes, obesity, and nonalcoholic steatohepatitis (NASH), representing leading-edge knowledge in drug development for metabolic diseases.

The textbook has expanded its coverage of metabolism-related translational research topics with special consideration given to the drug discovery process and cardiovascular research methods. Most notably, translational methods for NAFLD/NASH, a rapidly expanding area of research, are discussed extensively in this edition.

Editors » Andrew J. Krentz MD, Christian Weyer MD, Marcus Hompesch MD

Content includes » Quantification of insulin action in human subjects » Assessment of islet  $\alpha$ -and  $\beta$ -cell function » Pharmacokinetic and pharmacodynamic assessment of novel and biosimilar insulins » Non-invasive quantitative magnetic resonance imaging and spectroscopic biomarkers in NAFLD » Structural and functional imaging of muscle, heart, endocrine pancreas and kidneys in cardiometabolic drug development » PET and CT measurement of brown fat thermal activation » Isotopic tracers for the measurement of metabolic flux rates » Role of tissue biopsy in drug development for NAFLD » Utility of invasive and non-invasive cardiovascular research methodologies » Omics: potential role in early phase drug development » Peptide drug design for diabetes and related metabolic diseases » Emerging circulating biomarkers for the diagnosis and assessment of treatment responses » Regulatory considerations for early study and clinical development.

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The chapters in this book provide important contributions to our knowledge on the scientific and regulatory issues related to metabolic drug development, focusing on early clinical proof of mechanism, early stage indicators of drug efficacy, biomarkers and safety and providing a critical analysis of cutting-edge translational research methodologies.

Jerrold M. Olefsky, MD, University of California, San Diego, Professor of Medicine, Associate Dean for Scientific Affairs