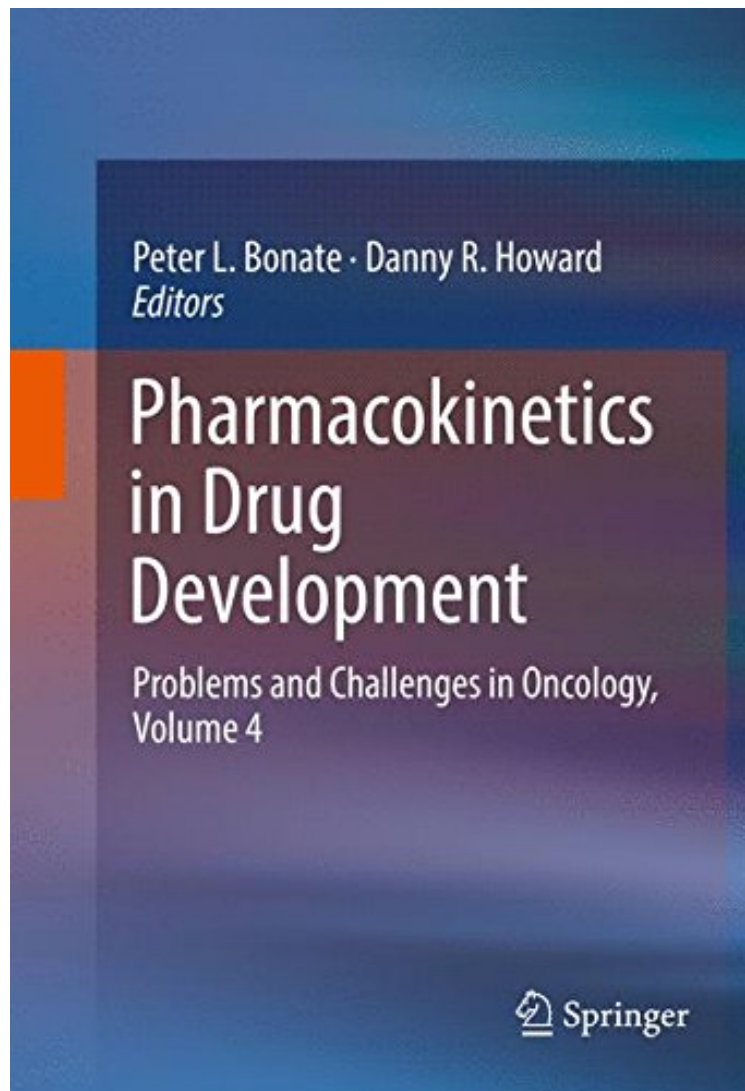


## Pharmacokinetics in Drug Development: Problems and Challenges in Oncology, Volume 4

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In this volume, the specific challenges and problems facing the evaluation of new oncology agents are explored with regards to pharmacokinetic, pharmacodynamic modeling and clinical pharmacology development strategies. This book delivers, with an emphasis on the oncology therapeutic area, the goals set in the first three volumes: namely to provide clinical pharmacologists practical insights for the application of pharmacology, pharmacokinetics and pharmacodynamics for new drug development strategies. Pharmacokinetic-pharmacodynamic concepts for tyrosine kinases, the evaluation of cardiac repolarization prolongation through QTc interval effects, efficacy- and safety-response analyses to support new drug approvals, clinical and preclinical tumor growth modeling, and flat- vs weight-based dose selection are showcased from an oncology clinical pharmacologists point-of-view. Oncology development strategies are surveyed for new FDA-approvals to identify patterns in expectations at time of first approval. The special considerations necessary to address combination drug development, metronomics, biosimilars and breakthrough therapies are also presented.

Part of the series Pharmacokinetics in Drug Development, this book focuses on the unique aspects in the development of oncology drugs. The authors present the material at a level accessible to those already involved in PK/PD and drug development. Overall, this is a good effort to provide insights into the complexities of oncology drug development for preclinical and clinical pharmacologists and clinicians. (Gregory Reed, Doody's Books, February, 2017)

From the Back Cover Back cover copy In this volume, the specific challenges and problems facing the evaluation of new oncology agents are explored with regards to pharmacokinetic, pharmacodynamic modeling and clinical pharmacology development strategies. This book delivers, with an emphasis on the oncology therapeutic area, the goals set in the first three volumes: namely to provide clinical pharmacologists practical insights for the application of pharmacology, pharmacokinetics and pharmacodynamics for new drug development strategies. Pharmacokinetic-pharmacodynamic concepts for tyrosine kinases, the evaluation of cardiac repolarization prolongation through QTc interval effects, efficacy- and safety-response analyses to support new drug approvals, clinical and preclinical tumor growth modeling, and flat- vs weight-based dose selection are showcased from an oncology clinical pharmacologists point-of-view. Oncology development strategies are surveyed for new FDA-approvals to identify patterns in expectations at time of first approval. The special considerations necessary to address combination drug development, metronomics, biosimilars and breakthrough therapies are also presented.

About the Author Peter Bonate has acquired over 22 years of industrial experience: 19 years as a clinical pharmacologist/pharmacokineticist and three years in drug metabolism and bioanalysis. He is currently Executive Director of Pharmacokinetics, Modeling, and Simulation at Astellas. He received his PhD from Indiana University in Medical Neurobiology with an emphasis on the pharmacokinetics of drugs of abuse. He also received an MS in statistics from the University of Idaho and an MS in Pharmacology from Washington State University. He is a Fellow of the American College of Clinical Pharmacology and American Association of Pharmaceutical Scientists (AAPS). Within AAPS he was a founder of the Pharmacometrics focus group, was chair of the Clinical Pharmacology and Translational Research Section, and was AAPS Fellows Committee Chair. Dr. Bonate is a recipient of the AAPS Research Achievement Award in Clinical Pharmacology and Translational Research. He is currently an Associate Editor of the Journal of Pharmacokinetics and Pharmacodynamics. He has served or currently serves on the editorial boards for the Journal of Clinical Pharmacology, Pharmaceutical Research, and the AAPS Journal. He has more than 60 peer-reviewed publications and is author of the books Pharmacokinetic-Pharmacodynamic Modeling and Simulation, 2nd edition and Be a Model Communicator (and sell your models to anyone).