

# Contents

---

Contributors, ix

Preface, xi

About ISPOR, xiv

Acknowledgments, xv

## **PART 1**

### **Introduction**

- CHAPTER 1 *Therapeutic and Diagnostic Device Outcomes Research: Book Overview and Key Terms* 3  
Marilyn Dix Smith, BSPharm, PhD
- CHAPTER 2 Features of Therapeutic and Diagnostic Devices: Are They Unique? 11  
Gregory de Lissovoy, PhD, MPH; Luis T. Gutierrez, Jr., MBA; and Rita Peeters, PhD, MBA

## **PART 2**

### **Therapeutic and Diagnostic Device Research and Development**

- CHAPTER 3 Therapeutic and Diagnostic Device Research and Development: An Overview 19  
David Parker, PhD; Jenifer Ehreth, MHA, PhD; Randa Eldessouki, MBBCh, MSc, MD; and Eric Faulkner, MPH
- CHAPTER 4 Therapeutic and Diagnostic Device Clinical Development Costs 26  
David Parker, PhD
- CHAPTER 5 Emerging Diagnostic Technologies for Improving Drug Development 29  
John F. Thompson, PhD, and Thomas G. Turi, PhD

## **PART 3**

### **Therapeutic and Diagnostic Device Regulatory Requirements in the United States and Europe**

- CHAPTER 6 Therapeutic and Diagnostic Device Regulations: Efforts toward Harmonization 41  
Randa Eldessouki, MBBCh, MSc, MD

CHAPTER 7	Therapeutic and Diagnostic Device Regulatory Requirements in the United States	44
	Randa Eldessouki, MBBCh, MSc, MD	
CHAPTER 8	Therapeutic and Diagnostic Device Regulatory Requirements in Europe	55
	Randa Eldessouki, MBBCh, MSc, MD, and Rita Peeters, PhD, MBA	
<b>PART 4</b>		
<b>Therapeutic and Diagnostic Device Clinical Outcomes Research</b>		
CHAPTER 9	Therapeutic and Diagnostic Device Clinical Outcomes Research Study Design	65
	Frank J. Papatheofanis, MD, MPH, PhD, and Rita Peeters, PhD, MBA	
CHAPTER 10	Therapeutic and Diagnostic Device Clinical Outcomes Research Issues	75
	David W. Polly, Jr., MD; Randa Eldessouki, MBBCh, MSc, MD; and Rita Peeters, PhD, MBA	
CHAPTER 11	Therapeutic and Diagnostic Device Clinical Outcomes Research Practical Considerations	79
	David W. Polly, Jr., MD	
CHAPTER 12	Therapeutic and Diagnostic Device Clinical Outcomes Measurement	83
	Randa Eldessouki, MBBCh, MSc, MD	
<b>PART 5</b>		
<b>Therapeutic Device Clinical Outcomes Research</b>		
CHAPTER 13	Clinical Endpoints: Ophthalmic and Urologic Therapeutic Devices	91
	Randel Richner, BSN, MPH, and Stephanie Mensh, MPA	
CHAPTER 14	Clinical Outcomes Research Limitations: Cardiovascular Therapeutic Devices	98
	Randa Eldessouki, MBBCh, MSc, MD	
CHAPTER 15	Therapeutic Devices: User Learning Curves	105
	Jonathan Cook, PhD	
CHAPTER 16	Practical Considerations: Orthopedic Therapeutic Device Case Studies	111
	Yvonne Lysakowski, RN, MS	

**PART 6****Diagnostic Device Clinical Outcomes Research**

- CHAPTER 17 Diagnostic Device Performance Measures 133  
Marcel G.W. Dijkgraaf, PhD
- CHAPTER 18 Evaluation of Diagnostic Device Clinical Outcomes 139  
Marcel G.W. Dijkgraaf, PhD

**PART 7****Drug–Device Combination Research**

- CHAPTER 19 Drug–Device Combination: Companion Diagnostics 153  
David Parker, PhD
- CHAPTER 20 Drug–Device Combination: Therapeutic Device Case Studies 160  
Jenifer Ehreth, MHA, PhD

**PART 8****Therapeutic and Diagnostic Device Economic Evaluations**

- CHAPTER 21 Basic Principles of Economic Evaluation 167  
William F. McGhan, PharmD, PhD, and  
Randa Eldessouki, MBBCh, MSc, MD
- CHAPTER 22 Types of Costs and Cost Collection 190  
Kurt Neeser, DVM, MPH, and Christian Weber, MD, MPH
- CHAPTER 23 Therapeutic and Diagnostic Device Economic Analysis Considerations 197  
Frank J. Papatheofanis, MD, MPH, PhD
- CHAPTER 24 Economic Environment for Therapeutic and Diagnostic Devices 222  
Marcel G.W. Dijkgraaf, PhD; David Parker, PhD;  
and Jenifer Ehreth, MHA, PhD

**PART 9****Therapeutic and Diagnostic Device Patient-Reported Outcomes Research**

- CHAPTER 25 Basic Principles of Patient-Reported Outcomes Research 229  
Bruce Crawford, MA, MPH; Susan D. Mathias, MPH;  
and Erin Sullivan, MPH, PhD
- CHAPTER 26 Patient-Reported Outcomes in Therapeutic and Diagnostic Device Research 238  
Erin Sullivan, MPH, PhD, and Susan D. Mathias, MPH

CHAPTER 27	Patient-Reported Outcomes in Decision Making and Communication	253
	Sahar M. Dawisha, MD, FACP, FACR, and Nancy Kline Leidy, PhD	
<b>PART 10</b>		
<b>Evidence Development and Reimbursement</b>		
CHAPTER 28	Developing Evidence: Health Technology Assessment Evaluation and Framework Factors	273
	Eric Faulkner, MPH; Clifford Goodman, PhD; Randel Richner, BSN, MPH; and Randa Eldessouki, MBBCh, MSc, MD	
CHAPTER 29	Developing Evidence: Health Technology Assessment Selection and Synthesis of Evidence	286
	Gregory de Lissovoy, PhD, MPH	
CHAPTER 30	Evidence Development and the Role of Health Technology Assessment in the United States and Europe	292
	Jenifer Ehreth, MHA, PhD, and Rita Peeters, PhD, MBA	
CHAPTER 31	United States Medicare Coverage, Coding, and Payment for Therapeutic and Diagnostic Devices	297
	Stacey J. Ackerman, MSE, PhD; Marilyn Dix Smith, BSPharm, PhD; Jenifer Ehreth, MHA, PhD; Randa Eldessouki, MBBCh, MSc, MD; and Erin Sullivan, MPH, PhD	
CHAPTER 32	Coverage, Coding, and Payment for Therapeutic and Diagnostic Devices in Europe	314
	Jenifer Ehreth, MHA, PhD	
Index		325