CAMBRIDGE

Cambridge University Press
978-1-107-08735-4 - Biodesign: The Process of Innovating Medical Technologies
Editors Paul G. Yock, Stefanos Zenios, Josh Makower, Todd J. Brinton, Uday N. Kumar and F. T. Jay Watkins
Table of Contents
More information

Contents

Preface ix
Focus on Value 1
Global Perspectives 7
➔ Africa 10
➔ China 14
➔ Europe 18
➔ India 23
➔ Japan 28
➔ Latin America 32
Process Insights 39

PART I: IDENTIFY

Stage 1: Needs Finding 49
1.1 Strategic Focus 50
1.2 Needs Exploration 67
1.3 Need Statement Development 90
Acclarent Case Study: Stage 1 105

Stage 2: Needs Screening 113
2.1 Disease State Fundamentals 114
2.2 Existing Solutions 133
2.3 Stakeholder Analysis 152
2.4 Market Analysis 182
2.5 Needs Selection 215
Acclarent Case Study: Stage 2 239

PART II: INVENT

Stage 3: Concept Generation 249
3.1 Ideation 250
3.2 Initial Concept Selection 268
Acclarent Case Study: Stage 3 280

Stage 4: Concept Screening 285
4.1 Intellectual Property Basics 286
4.2 Regulatory Basics 319
4.3 Reimbursement Basics 350
4.4 Business Models 373
4.5 Concept Exploration and Testing 404
4.6 Final Concept Selection 432
Acclarent Case Study: Stage 4 449

PART III: IMPLEMENT

Stage 5: Strategy Development 457
5.1 IP Strategy 458
5.2 R&D Strategy 478
5.3 Clinical Strategy 503
5.4 Regulatory Strategy 534
5.5 Quality Management 551
5.6 Reimbursement Strategy 573
5.7 Marketing and Stakeholder Strategy 604
5.8 Sales and Distribution Strategy 635
5.9 Competitive Advantage and Business Strategy 663
Acclarent Case Study: Stage 5 686

Stage 6: Business Planning 701
6.1 Operating Plan and Financial Model 702
6.2 Strategy Integration and Communication 725
6.3 Funding Approaches 748
6.4 Alternate Pathways 786
Acclarent Case Study: Stage 6 809

About the Author Team 817
Image Credits 821
Glossary 822
Index 833

See **ebiodesign.org** for videos, online appendices, and active web links to the resources listed in each chapter.

© in this web service Cambridge University Press www.cambridge.org