CAMBRIDGE

Cambridge University Press
978-0-521-51742-3 - Biodesign: The Process of Innovating Medical Technologies
Edited by Stefanos Zenios, Josh Makower and Paul Yock
Table of Contents
More information

Contents

Foreword *page* viii
Preface ix
The Biodesign Community xiv
Biographies xix
Glossary xxi

IDENTIFY

Stage 1 Needs Finding **1**
1.1 Strategic Focus 4
1.2 Observation and Problem Identification 20
1.3 Need Statement Development 37
Case Study: Stage 1 51

Stage 2 Needs Screening **57**
2.1 Disease State Fundamentals 60
2.2 Treatment Options 74
2.3 Stakeholder Analysis 95
2.4 Market Analysis 117
2.5 Needs Filtering 143
Case Study: Stage 2 165

INVENT

Stage 3 Concept Generation **173**
3.1 Ideation and Brainstorming 176
3.2 Concept Screening 193
Case Study: Stage 3 205

Stage 4 Concept Selection **207**
4.1 Intellectual Property Basics 210
4.2 Regulatory Basics 273
4.3 Reimbursement Basics 299
4.4 Business Models 319
4.5 Prototyping 340
4.6 Final Concept Selection 367
Case Study: Stage 4 378

IMPLEMENT

Stage 5 Development Strategy and Planning **385**
5.1 Intellectual Property Strategy 388
5.2 Research and Development Strategy 407
5.3 Clinical Strategy 425
5.4 Regulatory Strategy 458
5.5 Quality and Process Management 473
5.6 Reimbursement Strategy 503
5.7 Marketing and Stakeholder Strategy 536
5.8 Sales and Distribution Strategy 556
5.9 Competitive Advantage and Business Strategy 580
Case Study: Stage 5 596

Stage 6 Integration **609**
6.1 Operating Plan and Financial Model 612
6.2 Business Plan Development 657
6.3 Funding Sources 676
6.4 Licensing and Alternate Pathways 708
Case Study: Stage 6 727

Image Credits 734
Index 735

See **ebiodesign.org** for active web links to the resources listed in each chapter, additional references, content updates, video FAQs, and other relevant information.

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