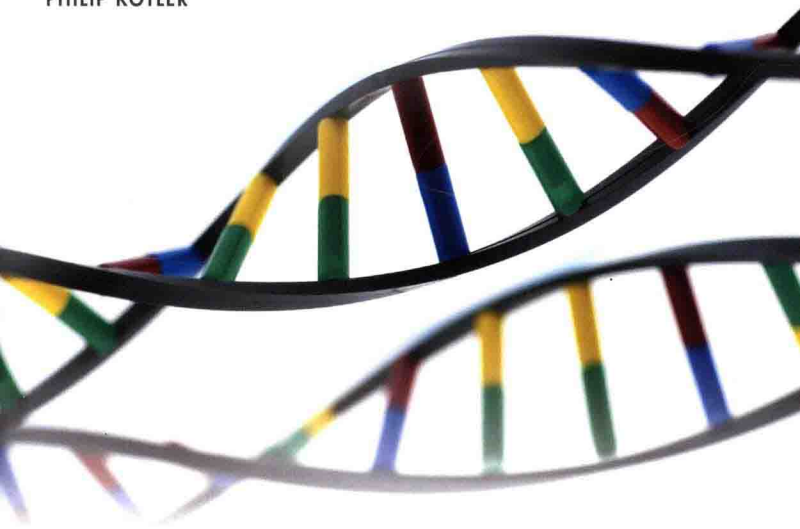
# MANAGING BIOTECHNOLOGY

## FROM SCIENCE TO MARKET IN THE DIGITAL AGE

FRANÇOISE SIMON
GLEN GIOVANNETTI

FOREWORD BY
PHILIP KOTLER



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"Biotech companies have long been innovators, using the latest technologies to enable cutting edge science to help patients with serious diseases. This book is essential to help biotech firms understand how they can–and must–apply the newest technologies including disruptive ones, alongside science, to innovate and bring new value to the healthcare system."

**JACQUALYN FOUSE, PhD,** *Executive Chair, Dermavant Sciences and Retired President and Chief Operating Officer, Celgene*

"Simon and Giovannetti have written an essential user's manual explaining the complicated interplay of the patients who deserve cutting-edge medical care, the biotechnology companies (big and small) creating the breakthroughs, and the healthcare organizations and clinicians who bridge those worlds."

**BRUCE DARROW, MD, PhD,** *Chief Medical Information Officer, Mount Sinai Health System*

"Since the mapping of the human genome was completed nearly 15 years ago, the biotechnology industry has led the rapid translation of raw science to today's innovative medicines. However, the work does not stop in the lab. Delivering these novel medicines to patients is a complex and multifaceted process, which is elegantly described in this new book."

**JOHN MARAGANORE,** *President and Chief Executive Officer, Alnylam Pharmaceuticals*

"A comprehensive and captivating review of the many and sometimes unexpected impacts of digitalization on the Bio Industry. A 'must read' for anyone involved in the race for efficiencies and the quest for patient-centric solutions."

**BERNARD POUSSOT,** *former Chairman and CEO, Wyeth*

**A comprehensive overview of the new business context for biopharma companies, featuring numerous case studies and state-of-the-art marketing models**

Biotechnology has developed into a key innovation driver, especially in the field of human healthcare. But, as the biopharma industry continues to grow and expand its reach, development costs are colliding with aging demographics and cost-containment policies of private and public payers. Concurrently, the development and increased affordability of sophisticated digital technologies has fundamentally altered many industries including healthcare. The arrival of new information technology (infotech) companies on the healthcare scene presents both opportunities and challenges for the biopharma business model. To capitalize on new digital technologies from R&D through commercialization requires industry leaders to adopt new business models, develop new digital and data capabilities, and partner with innovators and payers worldwide.

Written by two experts, both of whom have had decades of experience in the field, this book provides a comprehensive overview of the new business context and marketing models for biotech companies. Informed by extensive input by senior biotech executives and industry experts, it analyzes the strategies and key success factors for the financing, development, and commercialization of novel therapeutic products, including strategies for engagement with patients, physicians, and healthcare payers. Throughout the book, case studies provide researchers, academics and students, corporate marketers, senior managers, consultants, financial analysts, and other professionals involved in the biotech sector with insights, ideas, and models.

**FRANÇOISE SIMON, PhD,** is Professor Emerita, Columbia University and Senior Faculty, Icahn School of Medicine at Mount Sinai. Dr. Simon has over thirty years of experience in working with Fortune 500 companies, new ventures, European and Asian firms, and the United Nations.

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Cover Design: Wiley
Cover Image: © LAWRENCE LAWRY/Gettyimages

www.wiley.com

ISBN 978-1-119-21617-9

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Also available as an e-book

SIMON
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This edition first published 2017


*Registered Office*
John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, USA

*Editorial Office*
111 River Street, Hoboken, NJ 07030, USA

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ISBN: 978-1-119-21617-9

Cover image: © LAWRENCE LAWRY/Gettyimages
Cover design by Wiley

Set in 10/12 pt TimesLTStd-Roman by Thomson Digital, Noida, India

10 9 8 7 6 5 4 3 2 1

*MANAGING BIOTECHNOLOGY*

*In memory of my parents, Yvonne David and Louis Simon*
—Françoise Simon

*To my wife Lisa, who has been a companion on the Life Sciences journey for over 30 years in multiple cities, with tremendous flexibility, support and patience, including with this project*
—Glen Giovannetti

# *FOREWORD*

The healthcare sector is undergoing unprecedented change. Aging populations and the rising incidence of chronic diseases have strained budgets, resulting in policy reforms that are changing the way healthcare is provided, consumed and paid for around the globe. The traditional contrast between the European universal payer system and the US freer market model is starting to fade, as more than half of US reimbursement now comes from public entities such as Medicare and Medicaid. In emerging markets, despite the rise of middle-class populations, challenges remain, from intellectual property to manufacturing quality, drug pricing. and patient access to health services.

Major players in the health ecosystem—patients, providers, manufacturers, and payers—are changing their behaviors in response by assuming more financial responsibility for improving health outcomes, adopting new technologies, and leveraging data to drive innovation and care delivery. In parallel, the confluence of radical advances in biotechnology and information technology is leading to a new model of precision medicine. It gives unprecedented power to individuals, and it allows the deep integration of the customer voice into innovation, from product co-creation to continuous monitoring.

As it has happened in many other industries, the entrance of nontraditional players is poised to disrupt the health industry and its incumbents, creating a cadre of new potential leaders. Some of these include consumer, telecom, and tech powerhouses; Apple, IBM, Google, Intel, and QualComm have all made major investments in health. A plethora of start-ups, particularly in the data analytics space, is also upending business as usual. Today, health data is fragmented and in silos.

While consumer data collected on smartphones and biosensors are still not connected to medical offices and electronic health records, there is great promise in eventually providing seamless care to patients, from research to the clinic, and moving from treatment of illness to prevention and prediction. Consumers have become accustomed to the convenience of personal technologies and will increasingly demand the same from their health providers, including more remote care and data sharing. With health budgets already under strain, the value generated by these insights may come at the expense of healthcare industry incumbents.

The global biopharmaceutical industry finds itself in the middle of this storm. In a world where payment will be based on demonstrating real value, the industry's traditional development and commercial strategies are no longer fit for purpose. Commercial-stage biopharma companies are beginning to adapt their strategies, reducing their dependence on large sales forces that promote undifferentiated

products. They now seek to unlock value across their operations—from how they approach R & D (leveraging data and focusing on precision medicine and orphan diseases), to the evidence they collect to support value arguments, to providing "beyond-the-pill" solutions that may require partnerships with nontraditional entrants.

Emerging biotech companies working on exciting new science must also adapt their financing strategies to this new reality. No longer is it enough to sell investors on the promise of new scientific approaches. Biotechs must also articulate why their scientific advances will result in differentiation in a competitive global market. In *Managing Biotechnology: From Science to Market in the Digital Age*, Françoise Simon and Glen Giovannetti provide a comprehensive overview of the new business context and global strategies for biotechnology companies. The book is an important source of insight into critical topics such as networked innovation, alliances, commercialization, and digital communications. It serves as a roadmap to take concepts and products from science to market, and it captures the range of knowledge that students and managers need to leverage emerging technologies. It can also help interested policymakers aiming to grow and support biotech clusters worldwide to understand the risks, opportunities and challenges of the biotech industry.

This in-depth examination, based on the authors' broad experience, will be useful in teaching and inspiring current and future leaders across sectors driven by biotechnology. It will contribute high-value guidance for all stakeholders, from providers and payers to manufacturers. Most importantly, it may play a part in helping to bring new medicines to market and improving patients' lives and outcomes.

For biopharmaceutical firms, the future may hold an enabling scenario of optimized research, but it could also be a disruptive one, of disintermediation by infotechs of patient/provider communications. As the authors point out, success will depend on a melding of new cross-industry business models and of leading edge science, to improve the standard of patient care on a global scale.

*By Philip Kotler*
*S.C. Johnson & Son Distinguished*
*Professor of International Marketing*
*Kellogg School of Management*
*Northwestern University*

# *PREFACE*

Since its founding four decades ago, the modern biotechnology industry has been a source of significant innovation across many parts of the economy, especially in the area of human health. Once-fatal diseases—ranging from HIV and hepatitis C to many cancers—are now chronic conditions or have been effectively cured, due to the introduction of innovative biotech medicines. Many of these medicines were discovered and developed by nimble entrepreneurial companies. New techniques and technology platforms under development by companies both large and small (and in academic, government, and private research labs) continue to create optimism that many more poorly treated, or untreated, conditions will soon be addressed, including many diseases prevalent in aging populations.

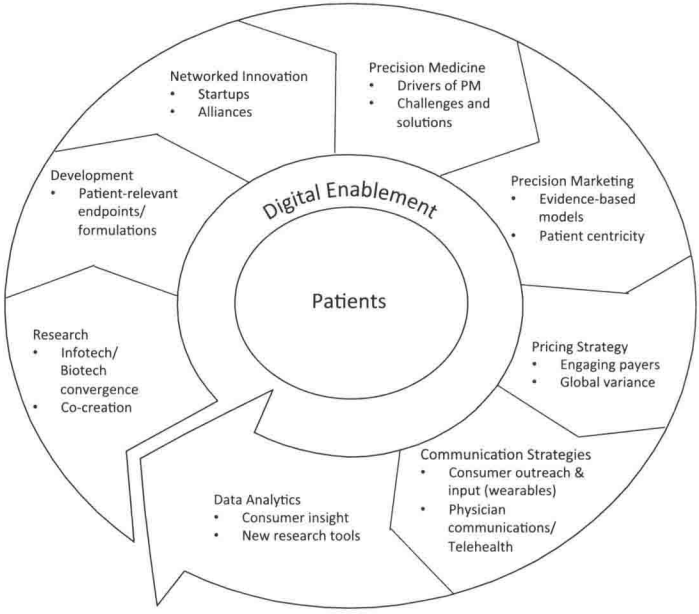
Over the same four decades, the rise of digital technologies has restructured the order of many industries, giving a majority of the global population access to enormous computing power and information, while simultaneously enabling previously unimaginable connectivity through social media platforms. These technologies have had an impact on the delivery and consumption of healthcare, although the pace of change in this industry has lagged many other parts of the global economy.

While scientific innovation remains at the core of the biopharma industry, the long-term trend of constrained health systems budgets and persistent public pressure on drug prices has put the traditional biopharma business model under tremendous strain. Biopharma companies understand that this new reality requires them to objectively demonstrate the real-world value of their products. They also realize that, to address significant unmet medical needs, they must expand their traditional focus on physicians to include engagement with patients and payers; in short, to think "beyond the pill." Adoption of digital technologies and access to, and effective analysis of, data will be key enablers as proof of outcomes becomes the industry benchmark. At the same time, many information technology (infotech) companies view healthcare as an untapped growth area ripe for digital disruption, as was previously seen in the financial and retail sectors. As a result, they are committing significant resources to developing new health offerings. Biopharma companies will have to understand whether these relatively new entrants in healthcare represent collaborators, competitors, or both.

The convergence of these trends is altering the biopharma value chain and ultimately the industry's business model. Traditionally, that value chain was linear, starting with scientific inquiry, product identification, clinical development, and, for those drugs that successfully progressed through regulatory approval, commercialization. As development milestones were achieved, responsibility for the

product was handed off from function to function, with little integration and information sharing (or one-way sharing at best). Strategic decisions, including budgets and capital allocation, often occurred within functional silos. This structure worked in a world in which "me-too" drugs that did not provide much, if any, incremental value could still generate a return on investment through effective sales and marketing.

This fundamentally product-centric view of biopharma drug development is outdated. It is no longer tenable for companies to invest in products that, even if proven safe and effective by regulators, do not provide measureable value to patients and health systems. Patient expectations, driven by growing reliance on digital technologies and the connectivity they provide, are also changing. As a consequence, the biopharma value chain has reoriented around a fundamental understanding of patient needs, with data and insights flowing not just in one direction from the lab to the market but also from the market back to the lab, as depicted in the figure.




**Managing biotechnology—framework**

The innovation end of this cycle begins with a deep understanding of disease, including both the biology and the care pathways that patients experience. These insights are informed by a company's own experiences in a disease area

(again, from research and commercial perspectives). The need to develop this depth of expertise is a factor causing many larger companies to fundamentally rethink their portfolios in order to specialize in fewer areas, increasing the likelihood of true differentiation. This is also resulting in broader adoption of precision medicine strategies to target more precisely patient populations that can be segmented by genetic or other characteristics to identify those more likely to respond to a particular drug therapy. In addition, technological convergence will also be a source of insight. For instance, artificial intelligence technologies developed by infotech companies can assimilate and analyze a range of patient and health data to generate new drug development hypotheses.

Understanding the patient care pathway in the actual health setting is important for effective clinical trial designs that support not just a regulatory approval but also negotiations with payers. Patient input is also becoming essential at the clinical development stage where patient relevant endpoints can be considered as part of a strategy to demonstrate effectiveness to a regulator and value to a payer. Connectivity to patients and patient advocacy groups also has the potential to facilitate trial recruitment.

In commercialization, making the case for the value of a product to payers and marketing a drug to providers and patients will be based on a combination of clinical data and "real-world" data that takes into account actual patient experiences, co-morbidities, and care delivery models. In some sense, the innovation phase of the cycle never really ends, as payers put more focus on real-world data over that generated in randomized clinical trials with selective enrollment criteria. Companies entering into risk-based reimbursement models in which payment is based on the achievement of defined outcomes will especially need a deep understanding of the patient journey and what other lifestyle factors might impact those outcomes. In some circumstances, this will drive the need for education, monitoring or other "beyond-the-pill" solutions.

Digitally enabled strategies will result in new ways to connect with patients. They will provide both structured and unstructured data from electronic health records, wearables, monitoring of social media, and other channels for analysis. These data will inform interactions with payers, providers, and regulators and will also feedback into R & D, completing the cycle.

## BOOK STRUCTURE

The structure of this book largely follows the above framework. We have left a detailed discussion of the scientific breakthroughs underpinning the biopharma sector to others. Our book follows the triple transformation of the biopharma sector: networked innovation, including the convergence of infotech and biotech; new digital strategies; and patient centricity through the value chain.

In Chapter 1, we address the impact of technology convergence and the strategies of big infotech players on the biopharma value chain, as well as the barriers to further convergence. As most of the industry's innovation comes from,

or is advanced by, start-up biotechnology companies, in Chapters 2 and 3 we provide information for entrepreneurs around financing and connected innovation through alliances with large companies and other entities. Chapter 4 discusses the impact of an expanding view of precision medicine on drug development and commercialization strategies, including significant market and organizational barriers that must be overcome to promote more widespread adoption.

As a companion to precision medicine, in Chapter 5, we introduce the concept of precision marketing. As payers, physicians, and consumers increasingly expect clinical and economic data to support a medicine's use, biopharma companies can make their product profiles more compelling via evidence-based marketing. This chapter also discusses product launch strategies, multichannel marketing approaches, sales force deployment, and product sustainability. Complementing material in Chapter 5, Chapter 6 explores what patient-centricity means today, discussing in greater detail the concepts described above, as well as the challenges biopharma companies encounter as a result of regulations and a lack of trust by the public.

In Chapters 7 and 8, we discuss approaches to engage with payers on a more strategic (versus transactional) basis, including understanding the needs of various payers and the patient populations they serve. We also develop drug pricing concepts, including novel risk-sharing pricing structures that can be based either on financial or clinical outcomes.

Chapter 9 covers digital health trends among patients and physicians and how digital technologies are impacting the biopharma value chain as well as digital strategies being deployed by biopharma and health systems. Finally, Chapter 10 addresses the data analytic core competencies that companies will need to develop in order to access and extract value from the data that surrounds the product during both development and commercialization.

Leading the biopharmaceutical enterprise is becoming a more complex proposition because of changing market dynamics, including the growing power of the patient and the emergence of increasingly powerful and accessible digital technologies. This book is intended to highlight these changes and help students, prospective entrepreneurs, and management teams identify both the risks and the opportunities that come from operating in the Digital Age.

## RESEARCH METHODOLOGY

The research material for this book was derived from a variety of public and private sources including peer-reviewed and industry journals, media reports, and financial databases. This research and analysis were supplemented though qualitative interviews conducted over a two-year period with over 150 industry and academic experts, biopharma and infotech executives across research and commercial functions, venture capitalists, and public and private payers.

# *ACKNOWLEDGMENTS*

This book is based on several years of research, and it is also a field study of biopharma strategy through the value chain, including many executive interviews and company case studies. We benefited as well from management seminars and academic executive programs that allowed us to test our models and concepts.

A global network of academic and industry leaders brought great value to our book. At the risk of overlooking several, we first note the experts and executives who contributed thoughtful comments and case studies: Philip Kotler, whose seminal work in healthcare strategy inspired us, and Charlotte Sibley (former SVP, Shire), who generously provided in-depth reviews and expert insights throughout our book; Olivier Brandicourt (Board Member, PhRMA), Roch Doliveux (former CEO, UCB), Wendy Gabel (former VP, Biogen), and Bernard Poussot (Board Member, Roche) also provided valuable comments.

John Maraganore (CEO Alnylam), Michael Pehl (President, Hematology and Oncology, Celgene), and Jacqualyn Fouse (Executive Chair, Dermavant and retired President and COO, Celgene), as well as Emmanuel Blin (former SVP, Bristol-Myers Squibb) contributed company case studies.

In Europe, we benefited from a case study from Maryvonne Hiance, Dominique Costantini, and Emile Loria at OSE Immunotherapeutics, and thoughtful reviews and insights from Philippe Latapie, François Meurgey, and Catherine Parisot.

Françoise Simon would also like to extend her appreciation to her academic colleagues: At the Icahn School of Medicine at Mount Sinai, Dean Dennis Charney; Annetine Gelijns, Professor and System Chair, Population Health Science and Policy; and Senior Associate Dean, Brian Nickerson, for their support, and Dr. Bruce Darrow, Mount Sinai Chief Medical Information Officer, for his technology expertise.

At Columbia, Françoise Simon would like to acknowledge Deans Linda Fried at the Mailman School of Public Health and Glenn Hubbard at the Business School, and she thanks Professors Kamel Jedidi, Don Lehmann, and Michael Sparer for their support, as well as Emerita Professor Marianne Legato for sharing her expertise in gender-based medicine; in Europe, she thanks Professors Nathalie Angelé-Halgand and Frantz Rowe at the Université de Nantes, Martine Bellanger at EHESP, Claire Champenois at Audencia, Pierre Lévy at Université Paris-Dauphine, and Christine Coisne and Loïc Menvielle at EDHEC for providing an academic testing ground for the book.

At INSEAD, Françoise Simon also thanks Professor Stephen Chick and Research Program Manager Ridhima Aggarwal for the use of the PatientsLikeMe case, which she co-wrote with them and excerpted in the book.

Both authors give a special acknowledgement to Ellen Licking, Senior Life Sciences Analyst at EY, for her insights, her network and for her research and editorial contributions. Ellen worked with great dedication to advance the research for the entire book, with particular emphasis on the following areas: precision medicine, data analytics, new pricing models, and strategic payer engagement.

In addition to Ellen, Glen Giovannetti would like to thank many colleagues at EY including Global Life Sciences Sector Leader Pamela Spence, Susan Garfield, Kristin Pothier, and Ryan Juntado for their contributed articles. EY Life Sciences specialists Jeff Greene, Scott Palmer, Mahala Burn, Alan Kalton, Todd Skrinar, Jamie Hintlian, and Adlai Goldberg also provided invaluable insights. Melanie Senior, a life sciences writer and analyst, provided support for the precision medicine and payer engagement sections of the book. Jason Hillenbach and Rajni Sadana ably led a research team who also provided support for many of the figures in the book, and Angela Kyn provided marketing support.

Finally, we would like to thank our publisher, John Wiley & Sons, and our editor, Bob Esposito, and Editorial Director, Justin Jeffryes, for their expert guidance through our book.