SECOND EDITION

BIODESIGN

The Process of Innovating Medical Technologies

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BRINTON, KUMAR, WATKINS, DENEND

BIODESIGN

The Process of Innovating Medical Technologies

A practical guide to the new era of global opportunity and value-based innovation in medical technology

This step-by-step guide to medical technology innovation, now in full color, has been rewritten to reflect recent trends of industry globalization and value-conscious healthcare. Written by a team of medical, engineering, and business experts, the authors provide a comprehensive resource that leads students, researchers, and entrepreneurs through a proven process for the identification, invention, and implementation of new solutions.

- Nearly 70 case studies on innovative products from around the world explore successes and failures, provide practical advice, and enable readers to learn from real projects.
- "Getting Started" sections for each chapter encourage readers to take action and apply what they've learned to their own work.
- A collection of nearly 300 videos, created for the second edition of the book, expand upon critical concepts, demonstrate essential activities within the process, and bring the innovation experience to life.
- A wealth of additional material supports the book, including active links to external websites and resources, supplementary appendices, and timely updates.
- New to this edition, two opening sections highlight the importance of globalization and cost-effective healthcare in the medtech industry, themes which are carried throughout the book.

Readers can access videos and additional materials quickly, easily, and at the most relevant point in the text within the ebook, or on the companion website at ebiodesign.org, alongside instructor resources.

"Biodesign is on the forward edge of one of the most exciting new frontiers of healthcare. This impressive and engaging work provides a thorough look at the innovation process. But this is certainly not just for the scientific innovators: it is a must-read for anyone in any aspect of healthcare today."

Alex Gorsky, *Chairman and CEO, Johnson & Johnson*

"I can't think of a more important place to turn creativity loose than in designing the future of healthcare. But it's a complicated scene – and it's easy to get lost in the maze of stakeholders, regulation, and financing. Biodesign lays out a clear and logical map to find and pursue opportunities for real innovation. One of the core messages in this new edition is that, by placing the need for affordability up front in design process, innovators can more explicitly create technologies that bring value to the healthcare system. This is design thinking at its best!"

David Kelley, *Founder, Hasso Plattner Institute of Design at Stanford University*, *Founder, IDEO*

"A must-to-read textbook for anyone in academia or industry, in any country, who wants to innovate and deliver value to patients and health systems around the world."

Koji Nakao, *Chairman of Terumo and the Japanese Federation of Medical Device Associations*

"If you want to know how to come up with a both innovative and transformative technology in medicine, there isn't a better resource than this book by Paul Yock and his colleagues at Biodesign. Over 13 years ago, the program at Stanford brought together trans-disciplinary innovators – engineers, physicians and business experts – to not only design their formidable program, but to teach all the rest of us how to do it."

Eric J. Topol, *Director, Scripps Translational Science Institute*

"this book on biodesign will be invaluable for any inventor or entrepreneur. It contains very useful information on such critical areas as design principles, regulatory issues, clinical trial strategies, intellectual property, reimbursement strategies, and funding- and it backs them up with interesting real-life experiences and case studies".

Robert Langer, *David H. Koch Institute Professor, MIT*

"This practical but comprehensive resource is keeping up with the rapid developments affecting medical device innovation. The authors draw on their own extensive experiences and insights, as well as diverse case studies, to present the full range of strategic and operational considerations to bring valuable new therapies to patients in the US and around the world."

Mark McClellan, *Director, Health Care Innovation and Value Initiative, Brookings Institution*

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Additional resources for this publication at ebiodesign.org

To innovators – past, present, and future – and the patients who inspire them . . .

. . . and in tribute to Wallace H. Coulter, a pioneer in developing affordable healthcare technologies with a global impact.

Contents

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

Preface

There is no greater satisfaction than seeing a patient being helped by a technology that you've had a hand in creating. And thanks to continuing advances in science and technology, healthcare is more open for innovation than at any time in history.

Despite this promise, however, medical technology innovators face significant hurdles – especially in the new era of cost containment. If not managed skillfully, patents, regulatory approval, reimbursement, market dynamics, business models, competition, financing, clinical trials, technical feasibility, and team dynamics (just to name a few of many potential challenges) can all prevent even the best idea from reaching patient care.

So, where should you begin as an innovator? What process can you use to improve your chances of success? What lessons can you learn from the inventors, engineers, physicians, and entrepreneurs who have succeeded and failed in this endeavor before? This book delivers practical answers to these important questions.

Who should read it and why?

Biodesign: The Process of Innovating Medical Technologies provides a comprehensive roadmap for identifying, inventing, and implementing new medical devices, diagnostics, and other technologies intended to create value for healthcare stakeholders. It has been written to be approachable for engineering, medical, and business students at both the undergraduate and graduate level, yet comprehensive and sophisticated enough to satisfy the needs of experienced entrepreneurs and medtech executives. For instructors, it provides a proven approach for teaching medical technology innovation that begins pre-idea and extends through preparing for commercialization. It is ideally suited to support team-oriented, project-based learning experiences in academic and industry settings.

The text describes the biodesign innovation process, which we initially developed to support the biodesign innovation and fellowship programs at Stanford University. Over 13+ years, the process has been built and refined based on:

- Presentations and mentoring by more than 200 industry leaders who have participated in our training programs
- Our experience advising more than 150 project teams that have applied the process to their work
- Feedback from those who have learned the process through our executive education courses, as well as input and suggestions from students, fellows, instructors at other universities, and industry representatives using the first edition of the book
- Extensive field-based research

Our confidence that the process is effective is based on the results of the students and fellows trained at Stanford and through our university-based partnerships in India and Singapore. Already over 30 of these projects have been converted to externally funded companies that have raised an aggregate of over $250 million. More importantly, even though these are young companies, over 250,000 patients have already been treated by the technologies invented by our trainees. We have also been encouraged by the positive feedback we received on the process following the release of the first edition of the text.

What's new and important in the second edition of the biodesign book?

We initially wrote the *Biodesign* book because there was no comprehensive text that described the complete innovation process with a focus on the medical technology sector. Many excellent books address entrepreneurship generally or pieces of the device development

process, but our goal was (and is) to provide a definitive, comprehensive resource for the medtech community.

Since the first edition of *Biodesign* was published in 2010, however, the medical technology industry and, more broadly, the healthcare ecosystem has experienced tumultuous change. As healthcare costs escalate on an unsustainable trajectory, a high priority is being placed on medical technologies that deliver *value* – that is, good outcomes at an affordable cost. In parallel with these forces, the global medical technology landscape is evolving rapidly, with large-scale demand for improved healthcare and a new focus on frugal innovation for developing economies. In this changing environment, veteran medtech innovators may feel as though they are treading unfamiliar new ground, and aspiring inventors and entrepreneurs are faced with navigating an even more complex and challenging landscape.

Besides the need to update the text in response to these major environmental changes, we felt a personal imperative to create the second edition. Over the past several years we have learned more about how to teach the biodesign innovation process. We've had the chance to use the text with students, fellows, entrepreneurs, and executives, and gather feedback from instructors at other universities around the world who are using it in their courses. Through these interactions, we realized that there were messages that we could clarify and some that we should emphasize more strongly. As a result, we have revised the text substantially for the second edition to address three critical factors:

1. **Value orientation** – The healthcare industry has become increasingly competitive, with the primary customers of medical technologies – governments, private payers, provider groups, and patients – focusing intensely on the cost of medical technologies and related services. In this environment, it is more essential than ever for products and related services to demonstrate measurable value to their intended users. The second edition of *Biodesign* more explicitly recognizes the importance of value generation in healthcare and includes guidance to better address this imperative in all phases of our process. Be sure to read the section "Focus on Value" in the pages that follow the preface for more context on value and how it is treated within the text.
2. **Going global** – The first edition of the text was largely US-centric, but in the second edition we devote significantly more attention to describing the changes in the process of medtech innovation resulting from the growing importance of markets, clinical opportunities, and sources of innovation outside of the United States. We focus on key strategic considerations for operating in a more global healthcare environment and share substantially more examples from medtech innovators working around the world. To dig more deeply into some key issues, we have added a section on "Global Perspectives," in which we spotlight six regions that present interesting medtech opportunities.
3. **Better ways to teach and learn** – While the fundamental biodesign innovation process remains the same in the new version of the text, we have rewritten a number of sections to provide more focus and clarity; and we offer more examples and case material in areas that are best understood experientially. One important take-away is that our approach appeared too linear in the first edition, and we have made concerted effort to explain within the chapters when and why a more iterative method is necessary. We have also captured a number of important lessons in the "Process Insights" section that follows the preface. Readers will significantly increase their effectiveness if they take these key themes to heart and keep them in mind as they work through the chapters within each major section of the text.

Our core belief remains that innovation is both a process and a skill that can be learned. We hope that the new edition of *Biodesign* will help to better equip aspiring and experienced innovators alike to be successful in the dynamic medtech industry. Tumultuous changes notwithstanding, the dynamics of the emerging healthcare burden around the world demand continued innovation, and technology innovators will continue to be central to this mission.

How to maximize the benefit of this book: a user's guide

The steps in the biodesign innovation process build on each other and, in this respect, it makes sense for readers to work their way through the text in chapter order. Taking this approach provides innovators with the most complete understanding of the biodesign innovation process and the most valuable overall learning experience. We have heard of many medtech innovators using the text as a roadmap for their projects, starting at the beginning and following the process to help drive their progress.

That said, each chapter is sufficiently robust to support alternate approaches to the content. For instance, instructors can pick and choose the chapters most relevant to their specific courses (e.g., some of the chapters in the Implement section may be a bit advanced for undergraduates, but they are ideally suited to graduate-level innovation or business planning classes). And experienced device executive and entrepreneurs can use the book as a reference as they encounter specific challenges on their way to market with a new technology.

In terms of organization, we present the biodesign innovation process in:

- three distinct **phases**, Identify, Invent, and Implement;
- that are divided into two **stages** each (six in total);
- which are supported by 29 core **activities**, with a chapter on each one.

Figure P1 summarizes the overall process. Keep in mind that it's not nearly as linear in practice as it appears in this depiction. The iterative and cyclical nature of the process is further explained throughout the text.

As you navigate *Biodesign*, we encourage you to pay attention to a series of different features that

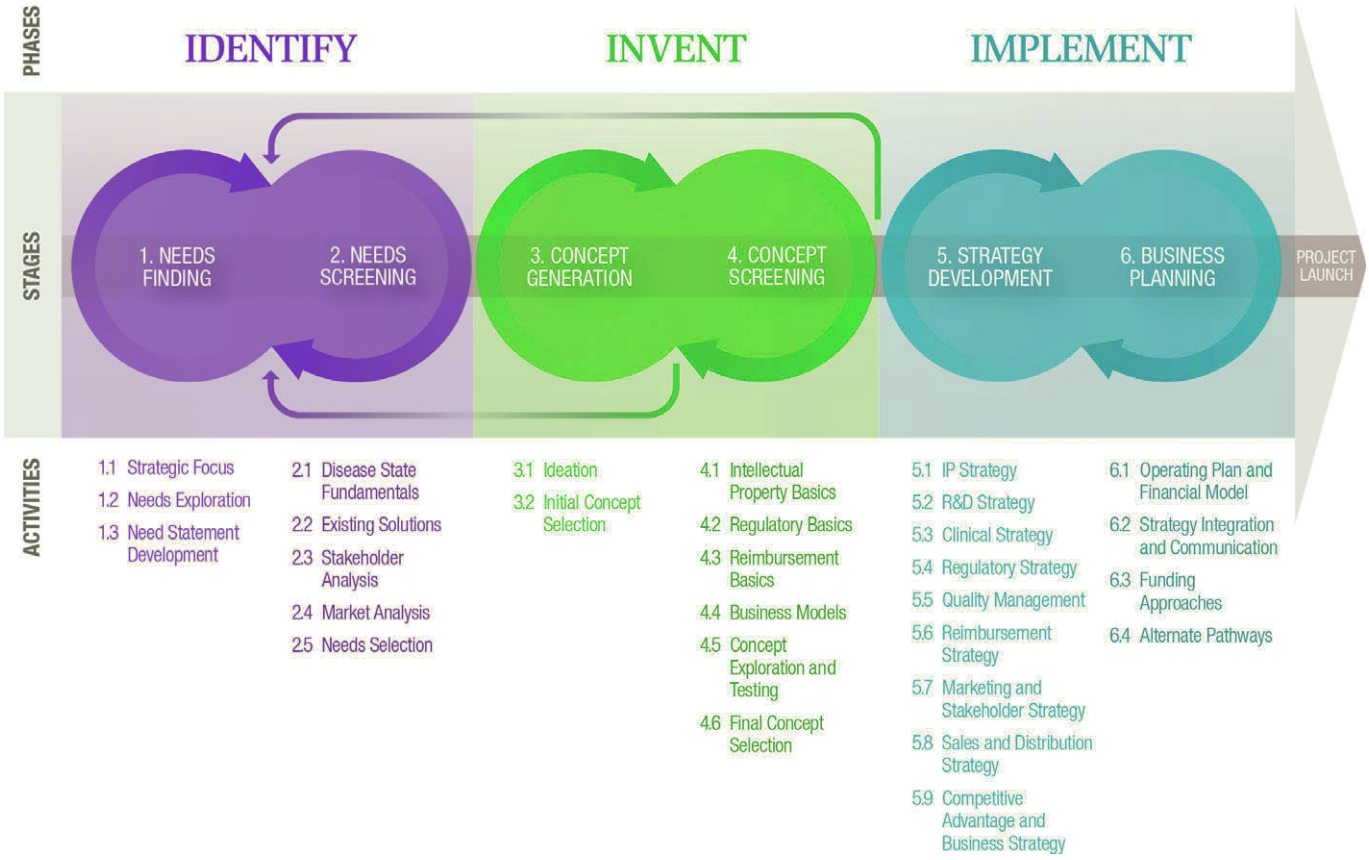

FIGURE P1
The biodesign innovation process.

have been designed to help you optimize the value you receive from the text.

As you begin – Immediately following the preface, you'll find relevant information that expands upon the three primary reasons we created the second edition of the book. These materials set a context for understanding and applying the content of the chapters.

- **Focus on value** – The medtech industry is in the midst of a transition to a stronger value orientation, in which the improvement a technology offers relative to its price is an essential ingredient of success. This section explores the forces behind this shift and their implications to innovators as they design, develop, and prepare to commercialize new products and services.
- **Global perspectives** – An introduction to factors driving the globalization of the medtech industry and changes in how innovators source, develop, and sell their technologies. We also profile six regions, Africa, China, Europe, India, Japan, and Latin America, providing background on these geographies, highlighting potential barriers to medtech innovation, and outlining tactics that can help innovators work more successfully in these areas.
- **Process insights** – Through feedback and our teaching experience, we have identified a series of key themes that you should keep top-of-mind while reading the chapters within each major section of the book. These are core strategies that cut across the stages and activities within each phase and will help you to keep on track as you proceed with the process. Instructors that emphasize these points in their teaching and readers who embrace this information will be able to navigate the biodesign innovation process more effectively.

Throughout the book – You should also be on the look-out for a few categories of information that have been added or broadened in the second edition.

New

- **Videos** – The second edition of *Biodesign* is supported by a brand new collection of nearly 300 videos on topics spanning the complete biodesign innovation process. These clips, which include expert presentations and advice, interviews with innovators, demonstrations, and other exercises, are available to all readers in the video library at ebiodesign.org. Those reading the electronic version will find select videos embedded in the book directly where they are most relevant.

Expanded

- **"From the Field" case studies** – These short stories, which provide real-world examples of how innovators, teams, and companies have tackled important challenges in the biodesign innovation process, were one of the most popular features of the first edition. Accordingly, we increased the number of case studies by more than 50 percent. Look for 36 new and/or rewritten stories in the second edition of the text, many of which spotlight groups developing innovative medtech solutions outside of the US. At the end of each stage, we present a case study on Acclarent, maker of a device to treat chronic sinusitis. This running example spotlights how one real company executed the entire biodesign innovation process, from need finding to commercialization.

Updated

- **"Getting Started" sections** – For each chapter, readers will find a practical, action-oriented guide that they can follow to execute every step in the biodesign innovation process when working on an actual project. To make these sections more useful in the electronic version of the text, they have been populated with active web links to take readers directly to essential references and resources. In the print version, the key steps for getting started are listed, with the complete, interactive guides accessible at ebiodesign.org.

Enhanced

- **ebiodesign.org** – To better support the second edition of *Biodesign*, we have completely redesigned

ebiodesign.org to be more user friendly and content rich. In addition to the video library and interactive getting started sections, ebiodesign.org includes additional content in the form of online appendices for many chapters. This is also where we'll post important updates, new videos, and other learning materials as they become available. Instructors can access our course syllabus, select presentation slides, and exam questions/answers via the Instructor Resources section of the site.

Focus on Value

What do we mean by "value" and why is it so important?

The escalation of healthcare costs is one of the major economic and political issues of our time. The problem is most apparent in the United States, where healthcare as a share of the economy has more than doubled over the past 35 years. Spending on health accounted for 7.2 percent of the nation's gross domestic product (GDP) in 1970, expanded to 16 percent in 2005, and is projected to be as high as 20 percent of GDP by 2015.[1]

Simply put, the US economy cannot sustain this spending trajectory, which has outpaced GDP growth for years (see Figure V1).[2] The problem is not just straining the federal budget: state and local governments have been forced to reduce support for education, infrastructure, and other critical expenditures as they struggle to fund Medicaid and other health programs. In the private sector, the cost of employment-based health insurance is one of the main reasons workers have seen their wages stagnate.[3]

Despite the fact that the US spends two-and-a-half times more per capita on health than most developed countries,[4] it does not necessarily provide the best care to its citizens. In 2000, when the World Health Organization ranked the health systems of its 191 member states for the first time ever, the US found itself in 37th position.[5] In a more recent study that compared the US to Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom on measures of quality, efficiency, access to care, equity, and the ability of citizens to lead long, healthy lives, America occupied last place. As the report pointed out, "While there is room for improvement in every country, the US stands out for not getting good value for its healthcare dollars."[6]

Against this backdrop, economists, researchers, and policy makers alike have pointed to medical technology as a dominant factor driving increased health expenditures in the US. Their estimates of the impact of technical innovation on accelerating costs vary considerably, but some argue that new technologies and the procedures that accompany them account for one-third to one-half of real long-term spending growth in healthcare.[7] To be sure, many of these technologies have provided major advancements in health and longevity, ranging from

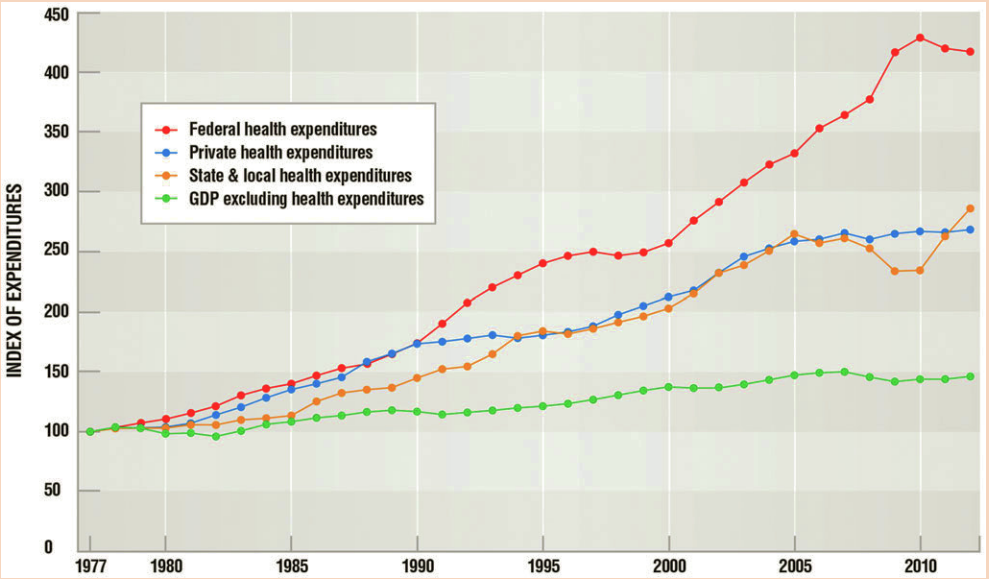

FIGURE V1
Indexes of US health expenditures and GDP (excluding health expenditures), per capita, adjusted for inflation, 1977–2007 (compiled based on National Health Expenditure data, CMS.gov).

diagnostic breakthroughs such as CT and MRI scanning to life-saving surgical and interventional therapies for the heart and brain. Increasingly, however, even revolutionary developments such as these are being weighed against the unsustainable rise in healthcare costs.

Since the birth of the modern medtech industry in the mid-twentieth century, the majority of medical technology companies pursued a philosophy that has been described as "progress at any price."[8] Innovators and companies were focused on developing new products that resulted in improved clinical outcomes, almost regardless of their associated cost. In some cases, this meant simply making marginal enhancements in order to sell a next-generation technology at a higher price. These strategies were successful for many years because the fee-for-service payment system in the US largely uncoupled the providers, who make the treatment decisions, from the payers, who bear the costs of their choices. In this way, the market forces that operate in other sectors of the economy have not been effective in maximizing the value of health technologies and services. By spending trillions of dollars on new innovations, the US fueled the growth of the medical technology industry and helped to foster a view that complex and expensive technology was the hallmark of superior healthcare.

While the US has been hardest hit by uncontrolled health spending, it certainly is not alone. The countries in the European Union and Japan, which together with the US account for 75 percent of all medtech sales today,[9] have also been wrestling with how to manage mounting healthcare costs. Moreover, as the middle class expands in developing countries such as India, China, and Brazil, these patients are demanding increased access to more advanced healthcare, potentially initiating the same spiral of escalating health expenditures. In fact, these issues are already emerging, with medical device sales growing two- to five-times faster in these markets than in developed countries.[10]

Together these forces have launched a fundamental shift in the healthcare sector. The affordability of care relative to its quality is now a primary focus in both developed and developing markets. "Progress at any price" is no longer a tenable strategy as health systems universally place increasing emphasis on ensuring a good value for the healthcare dollars they spend. In developed countries such as the US, providers, hospitals, clinics, and (in some cases) payers are consolidating to achieve economies of scale and organization. Value-based payment models are emerging. And purchasing managers and executives are playing a more central role in deciding which medical technologies to adopt, with physicians influencing, rather than dictating, those choices. In developing countries, health systems recognize they are facing increased demand for medical technologies but are actively pursuing more affordable, cost-effective products and services designed specifically to address the needs of patients and providers in settings with fewer resources. In other words, around the world, the need for medical technologies that deliver clear *value* to their intended users has never been more imperative.

The concept of value is widely understood in general terms, but is more difficult to articulate as a concept to be considered throughout the biodesign innovation process. Here are a few key points that resonate with us about value and value creation:

- Value is an expression of the improvement(s) a new technology and its associated services offer relative to the incremental cost. Just because a new technology provides an improvement doesn't mean it will create value.
- Importantly, value is not realized unless the cost/improvement equation is compelling enough – that is, has enough marginal benefit over other available solutions – to cause decision makers to change their behavior and adopt the new technology.
- We are in a period of transition with respect to who the key decision makers are in the healthcare field. In particular, purchasing power is shifting from individual physicians to integrated health systems and patients are becoming more knowledgeable and active healthcare consumers. In the process, both of these audiences are demanding greater cost transparency.
- In parallel, the assessment of value is evolving from being product specific to outcomes oriented. Stated another way, decision makers are increasingly evaluating total solution offerings across an episode of care rather than focusing on an individual technology or service. Within this context, new types

of value-based offerings and innovative business models are emerging.

Understanding what we mean by value is important because it has a major impact on how you approach the biodesign innovation process. In short, while medtech companies used to strive to produce products that delivered optimal improvement (without undue attention to cost), we are now seeing purchasers demand offerings that drive cost as low as possible. In certain situations there will be willingness to sacrifice some degree of performance for a better price (see Figure V2). Amidst the uncertainty of today's value-oriented environment, technologies that significantly – not incrementally – generate measurable savings while providing acceptable (or better) quality will be the ones with the clearest path forward.

So how can innovators practically address value in the design, development, and commercialization of their medtech offerings? There are multiple steps in the biodesign innovation process where opportunity exists to create and deliver value (as you navigate the book, you will see substantial attention to value in almost every chapter). But there are three critical points at which value should be a primary focus:

- **Value exploration** – Early in the biodesign innovation process (see chapters 1.1 and 1.2), innovators should begin scanning for problems and opportunities that are ripe for value realization. This means actively seeking *need areas* where improved economic outcomes can potentially be generated. As they perform research, observations, and interviews, innovators have traditionally watched for what we call *practice-based value signposts*; for example, opportunities to address problems such as keeping patients out of the hospital, shortening the length of hospital stays, and reducing procedure time. But in the new environment, they should take a more explicit plunge into investigating *budget-based value signposts*, such as big line items on facility budgets, negative outliers in the cost-effectiveness of existing treatments, and extreme variations in treatment costs across geographies. These and other economic signals will guide the next generation of medtech innovators to promising areas to begin needs finding.

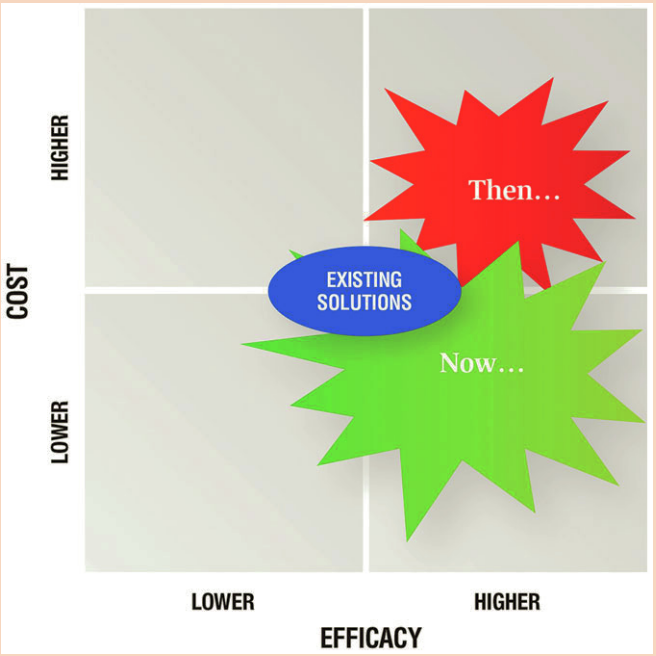

FIGURE V2
The medtech landscape – then and now.

- **Value estimate** – Once promising *needs* have been identified, innovators dive deeper into understanding the potential to create and deliver value through the needs screening stage of the process (especially chapters 2.4 and 2.5). Quantifying value in this stage of the process can be tricky since no specific solutions have yet to be defined. However, innovators can still develop directional estimates of the value associated with their needs in order to ensure it is worth moving forward into concept generation. These estimates are based broadly on understanding who the real decision makers are with respect to adoption/purchasing decisions in each need area, how significant they perceive the need to be, to what degree available solutions are effectively addressing the need, and therefore how much margin there is to offer a new technology with a different improvement/cost equation. The insights gleaned from explicitly considering value at this early stage can save innovators from investing time, resources, and energy in developing solutions that ultimately will not offer a significant enough value proposition (see below) to drive decision makers to adopt them.

- **Value proposition** – As the *solution* to a promising need begins to take shape, innovators can begin thinking about value in more concrete, concept-specific terms. A value proposition describes the net impact of the cost/improvement equation associated with a new offering in terms that are meaningful to decision makers and sufficiently convincing to elicit a change in their behavior. Value propositions form the core of a company's sales and marketing activities and become a source of its competitive advantage and differentiation (see chapters 5.7 and 5.9). Importantly, value propositions must be backed by strong evidence that resonates with decision makers and the influencers that surround them. In the new healthcare environment, value propositions increasingly require the company to share the risk of ensuring that the promised improvements and desired outcomes are realized at the stated cost.

These mechanisms for anchoring the biodesign innovation process on value are broad and directional. We are still in the early stages of what is clearly a profound shift in the way medical technology innovation will address the economics of healthcare. But we hope that these initial ideas, as well as the discussion of value that permeates the text, will serve as a useful starting point for innovators as they embrace this new paradigm in device innovation.

As with any major economic and social transformation, there are tremendous opportunities for those who can position themselves to understand and take advantage of the changes. And the wonderful part about this particular technology sector is that the innovators who are able to make the transition may have the opportunity to benefit millions of patients around the globe.

The biodesign working group on value

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NOTES

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8 Fuchs, op. cit.

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Global Perspectives

A world of opportunity …

Although the United States and Europe remain global leaders in medical technology innovation, the story of the medtech sector has become much more diverse in recent years as healthcare has become a global priority. Inventors and companies in countries around the world are playing an increasingly important role in sourcing

FIGURE G1

A snapshot of health and health-related spending in select countries around the world (compiled from The World Bank data, 2011).

ideas, designing and developing them into viable products and services, and introducing them into patient care. In parallel, device sales in developing countries are expanding at a rapid pace. As the US and Europe both sustain growth rates in the low single digits, medtech revenues in countries such as India and China are forecast to increase at a compound annual growth rate of 14 percent and 26 percent, respectively.[1]

The global transformation of the medtech sector has been driven by multiple, interrelated factors. In developed markets, health systems are actively seeking to slow health spending associated with medical technologies as they become more cost conscious and attuned to the value these products deliver. Moreover, as the time, expense, and complexity of developing new solutions in environments like the US continues to increase, innovators are moving offshore and creating new innovation hubs in locations around the world.[2]

In developing markets, disease profiles are shifting from infectious to chronic conditions, which makes diagnostic and device solutions a more important part of efforts to meet the healthcare needs of patients. Governments and private healthcare providers alike are increasing health-related spending (see Figure G1). And innovators and companies in low-resource settings are becoming leaders in inventing more affordable solutions that enable care delivery in any setting and reduce (rather than increase) its cost.[3]

Medtech innovators can certainly find compelling opportunities in both environments. They can also benefit from thinking more globally about how – and where – they source, develop, and sell their new solutions. While many innovators historically used a single market as their base, got established, and then expanded into new markets in a serial manner, they can now take a more global approach from the very beginning of the biodesign innovation process. Various regions in the world are moving into prominence in different parts of the medtech innovation process. To take just a few examples: Israel is home to over 700 medical device companies and leads the world in the medtech patents filed per capita.[4] It has become a hotbed of invention and incubation of medical technologies, with a robust start-up scene. Argentina, Brazil, and Chile have become leaders in conducting high-quality, yet affordable clinical trials for pharmaceutical and medical device companies from around the world.[5] Ireland has developed into a prominent medtech manufacturing center, serving eight of the top 20 medtech multinationals[6] and attracting new enterprises of all sizes.

Of course, each region has its own unique challenges and opportunities. In the pages that follow, we have tried to give innovators a flavor for this range of issues and possibilities by profiling six important medtech markets. Europe and Japan represent geographies outside of the US with well-established device industries; India, China, Latin America, and Africa represent those in which the sector is still emerging. The purpose of these profiles is to provide a context for healthcare innovation in these locations, highlight some of the barriers that innovators may encounter in working there, and share tactics they can utilize to increase their chances of success. We're grateful to the experts who worked with us to develop this valuable content.

Additionally, innovators will find significantly more global content through the remainder of the *Biodesign* text. While the book is still grounded in what's required to identify, invent, and implement a new medical technology in the US, we expanded our treatment of other markets through the inclusion of more global guidance, as well as case studies that feature innovators and companies working across the globe.

Global expansion in the medtech sector can make it possible for patients traditionally underserved by medical devices to benefit from advanced technologies in new and different ways. With the global medtech market on its way to $440 billion by 2018,[7] a world of opportunity truly awaits medtech innovators and the patients they are committed to helping.

NOTES

1 "Global Market for Medical Devices, 4th Edition," *Kalorama Report*, 2013, http://www.kaloramainformation.com/Global-Medical-Devices-7546398/ (March 10, 2014).

2 "Medical Technology Innovation Scorecard: The Race for Global Leadership," PricewaterhouseCoopers, 2011, http://download.pwc.com/ie/pubs/2011_medical_technology_innovation_scorecard_the_race_for_global_leadership_jan.pdf (March 10, 2014).

3 Ibid.

4 "How Did Israel Become a Hotbed for Medical Devices?," Fierce Medical Devices, August 14, 2013, http://www.fiercemedicaldevices.com/story/how-did-israel-become-hotbed-medical-devices/2013-08-14 (January 24, 2014).

5 "Climate Change in Latin America Makes for Successful Clinical Trials," MEDPACE, http://www.medpace.com/pdf/conductingtrialsinlatinamerica.pdf (March 10, 2014).

6 "Business in Ireland," IDA Ireland, http://www.idaireland.com/business-in-ireland/life-sciences-medical-tec/ (January 27, 2014).

7 "Medtech Market to Achieve Global Sales of $440B by 2018," Evaluate press release, October 12, 2012, http://www.evaluategroup.com/public/PressReleases/Medtech-Market-to-Achieve-Global-Sales-of-$440-Billion-by-2018.aspx (January 27, 2014).