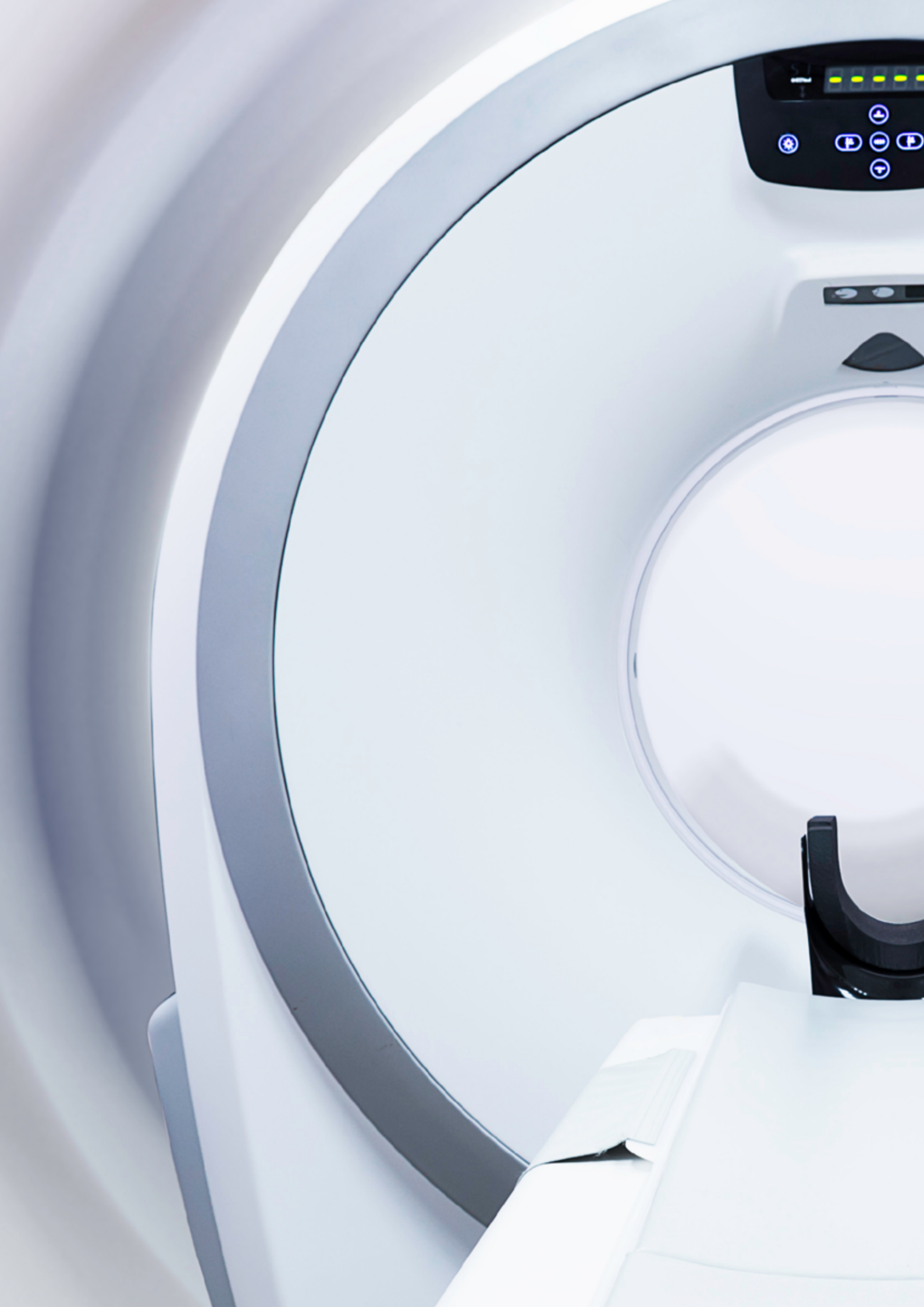
Accenture Life Sciences

Patient Inspired. Outcomes Driven.

SMART MEDICAL DEVICES

THE NEW SOURCE FOR INNOVATION

Human-centered R&D



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Smart medical devices: The new source for innovation

By 2040, 9.5 billion people will live on Earth[1]. All of them will need to receive healthcare, but the financial collapse of the healthcare system is predicted to strike much sooner than 2040. The well-being of aging populations in developed countries will be significantly threatened by the healthcare savings programs initiated to avoid the collapse. Already today, 60 percent of people living in developed markets are older than 60[2]. Also, in emerging markets, the picture is especially bleak, with large numbers of people, no matter what their age, having no access to healthcare at all.

To address these challenges, healthcare industry players, together with clinicians, will have to get much better at innovation. Makers of next-generation medical devices will play a central role in this push for innovation. Such devices will be smart and context-sensitive, tailored to unique characteristics and needs of markets, patients, caregivers and payers. According to Accenture research[3], context-sensitive products have the best chances of winning in the marketplaces of the future.

These products have higher emotional and intelligence scores than other products do. A high emotional score indicates that the product fits a need (for example, a chronically ill patient at home), and therefore healthcare consumers are more willing or able to use the product (enhancing treatment adherence, for instance). Intelligence score refers to how well the product reflects understanding of the healthcare consumer's context (such as treatment history) to guide him or her through the next best step (including decisions about medical options or lifestyle changes). Tomorrow's successful R&D departments will be staffed with engineers who know how to build context-sensitiveness and intelligence into the next generation of their medical devices.

Context-sensitive products will win in the marketplaces of the future.

The new era of smart medical devices

Smart medical devices that support a safe increase in self-care, personalization of treatments, predictability of outcomes or proactiveness of interventions will truly reinvent care quality. They will enhance, the way in which patients engage with treatments and reduce underlying health costs. As a result, they can help finance a high-quality healthcare system into the future.

Design Thinking and Design Doing approaches have enabled consumer-oriented industries to uncover and build smart products and business models that weren't previously imaginable. We examine these approaches and their benefits closely later in this paper. Many of these highly connected and user-centered devices take advantage of cutting-edge digital technology and real-time data to generate instantaneous insights personalized to human needs.

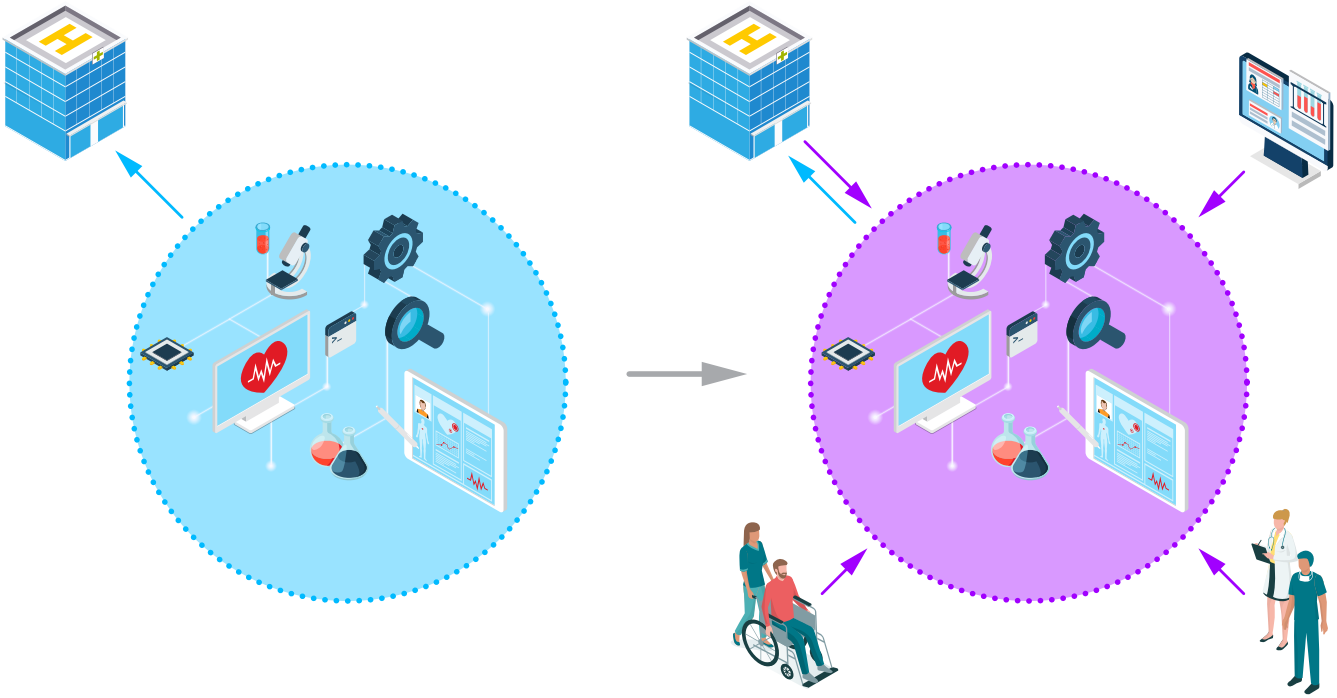
Accordingly, the innovation focus in the medical technology industry should evolve from solely product driven toward healthcare-context driven. Table 1 provides an overview of five smart medical device archetypes and their disruptive impact on the healthcare system.

Smart Medical Devices	Archetypes				
	Automation	**Self-care**	**Personalization**	**Outcome**	**Intervention**
Innovation Driver	• Simplify or increase productivity of caregiver	• Reduce dependency on clinical expertise or care infrastructure	• Enable individualized, targeted treatments (e.g. based on genetic profile, disease status or comorbidities)	• Provide treatment recommendation based on predicted disease progression • Focus on complete care episode including comorbidities	• Solutions that continually monitor and execute corrective medical/ behavioral actions (Closed-Loop-System)
Business rationale	• Improve device usability to increase product differentiation	• Create new service revenue model • Reduce total cost of treatment	• Create new insight-based revenue model • Reduce total cost of treatment	• Create new shared risk-based revenue models with payer • Pull through business for comorbidities • Reduce total cost of treatment	• Create new shared risk-based revenue models with payer • Pull through business for comorbidities • Reduce total cost of treatment
Example	• Artificial Intelligence-supported imaging diagnostic to improve cancer detection	• Tablo Selfcare Dialysis from Outset Medical	• Digital supported tumor boards like the IntelliSpace Precision Medicine solution	• Intelligent implants like smartfuse that improve post-surgery rehabilitation	• Artificial pancreas device systems
Patient benefits	• Quicker treatment decisions	• Higher treatment engagement • Better quality of life	• Higher treatment engagement • Better quality of life • Less onerous side effects	• Optimized outcomes	• Increased quality of life • Stopping of disease progression through provision of artificial cure or proactive intervention
Clinician Benefits	• Higher throughput • More time for the patient	• Reduction of medical infrastructure • Caregiver productivity gains	• Caregiver productivity gains • Efficient medication	• Reduction of redundant clinical procedures • Complete treatment visibility	• Reduction of medical infrastructure • Reduction of emergencies/ crisis hospitalizations
Paradigm Shift	**Pay for better service**	**Pay for better outcome**	**Pay for better outcome**	**Pay for better outcome**	**Pay for better health**

TABLE 1.

The benefits of such innovations are alluring indeed. These solutions can shift the paradigm of the healthcare system from paying and providing care to ill people to paying not only for outcomes but also for prevention to keep people from ailing in the first place. But to make these new products and services possible, medical technology R&D teams will have to rebalance the focus of their innovation efforts to include contextual factors. While traditional, product-focused approaches to R&D take an "inside-out" perspective, attending to contextual factors enables an "outside-in" view that can lead to more successful innovation. (See Figure 1.)

FIGURE 1. From an inside-out to an outside-in perspective



A perfect example of how a strict outside-in focus can improve quality of life, outcomes and treatment cost is the KidneyX Program Prize Finalist Outset Medical[4]. KidneyX is the Innovation Accelerator Program run by the US Department of Health and Human Services with the American Society of Nephrology. Outset Medical has developed a new dialysis machine, called Tablo, purely with the patient in mind. Tablo is a complete technology upgrade of a treatment that is one of the costliest per patient, owing to its high dependency on clinic personnel and hospital infrastructure.

Outset simplified the device operation to the extent that it can be safely executed by the patient on his or her own in a clinic or at home. The self-care dialysis approach is expected to bring down per-treatment cost by a factor of five. In addition, simplification of the innovation enables patients to conduct dialysis daily at home instead of having to go to a clinic three days each week. Published clinical research suggests that this will result in significantly better treatment outcomes and a higher quality of life for patients.[5]


Heart Attack

The limitation of traditional engineering

Innovation in the medical devices industry still centers on scientific advancements in products and their components. What's more, the industry is extremely complex—operating at the intersection of life sciences, hardware engineering and software craftsmanship. Thus, medical devices often contain a multitude of diverse components, each requiring a unique set of skills to create.

Take in-vitro diagnostic devices. These feature components like plastic consumables; biochemical components for test reactions; robots for sample preparation, assay setup, and detection; and embedded software, user interfaces, databases, bioinformatics software and cloud platforms.

To tackle this complexity, medical device companies traditionally choose to pursue one or more of the following strategies:

MERGERS AND ACQUISITIONS to gain new capabilities, innovative R&D, hardware engineering or bioinformatics

EXTERNAL DEVELOPMENT OF COMPONENTS that lie outside their core competencies, such as software development or clinical workflow integration

ENGAGEMENT WITH CONSULTANCIES to strengthen in-house capabilities, build new departments or bolster engineering prowess

ENGAGEMENT WITH HIRING AGENCIES to improve in-house capabilities or bridge resource gaps

STRATEGIC ALLIANCES with (for example) pharmaceutical leaders to enable personalized healthcare or big-tech companies to gain access to analytical or usability capabilities

Too often, medical device companies adopt a variety of these strategies in a scattered, uncoordinated manner. This regularly leads to a heterogeneous product and project portfolio, which complicates the innovation process in ways that don't add value for device users. In addition, innovation decisions are bound by upfront designs and classic waterfall methods of development, which only worsen the complexity, as too many R&D investment dollars go into enabling incremental improvements instead of breakthrough innovations. Therefore, innovations take more time than they should to be ready for market, and the resulting medical products prove overly complicated for users.

These problems leave traditional med-tech companies vulnerable to attacks from digital- or consumer-native giants like Google, Amazon, CVS Health or Apple. Such giants enter the health-technology market first with lifestyle fitness apps but have their eye on health tech that leverages big data.

Take CVS Health, which plans to develop and launch its own dialysis device to provide better care. CVS intends to use its more consumer-oriented patient access and care infrastructure to provide more treatment options with a better lifestyle fit for patients and provide more education to slow down the progression of renal disease.[6]

Such rivals excel at meeting healthcare consumers' and providers' rising expectations of easy, seamless experiences as they use medical products and services. Indeed, Accenture research indicates that expectations regarding healthcare offerings have shifted. For instance, many younger consumers expect healthcare products and services to be just as easy to use as their smartphones and other electronics[7].

80% of IT executives in a recent Accenture clinic survey suggested that greater use of artificial intelligence and machine learning would add more value to their work.[8]

What's more, clinicians demand smarter support. In fact, 80 percent of IT executives in a recent Accenture clinic survey suggested that greater use of artificial intelligence and machine learning would add more value to their work.[8]

More and more medical device R&D executives are realizing that classic waterfall approaches aren't helping them tackle their most pressing innovation challenges. And they know they need a new blueprint for innovation–one that takes into account the entire journey that healthcare stakeholders travel as well as the ultimate purpose of the devices they're developing.

For instance, with our example of in-vitro diagnostics, true innovation and new revenue models will come not from increasing the diagnostics' throughput, but from accelerating the time in which patients or clinicians get the insights they need. Companies that can seamlessly orchestrate multiple disciplines into a unified, high-value experience that delivers superior outcomes for stakeholders will stand the best chance of pulling ahead of rivals–and staying ahead.

With these realities in mind, let's now take a closer look at Design Thinking and Design Doing and consider how they can help medical device players supercharge their innovation engine.

Design Thinking injects new forces of innovation into med-tech R&D

Design Thinking is a human-centered approach to solving complex, ill-defined problems. It's a creative process that brings together multidisciplinary teams and individuals to experiment, build prototypes, gather feedback and continuously improve.

Through quick iteration, Design Thinking seeks to understand people, challenge assumptions and redefine problems—all with an eye toward identifying fresh solutions that lie beyond current understanding.

The self-referential nature of most markets, characterized by well-established interpretations of user requirements that go unchallenged, tends to stifle innovation or lead to just incremental improvements in products and services. Very often, these interpretations are backed up by market research conducted by the same preferred agencies that have been asking the same questions of users for many years. To break free from these constraints, companies must expand their view beyond known user needs, and focus on creating offerings that address the right problem—that is, products or services that improve quality of life, keep populations healthy and lower treatment costs.

Companies that master Design Thinking can uncover breakthrough ideas that are hidden today, but that will seem obvious tomorrow.

Why? At its core, Design Thinking provides a fresh view of the world. It's a highly deliberate way of gaining insights into people's behaviors, needs and values—and then using those insights to challenge the status quo and, even better, to create something entirely new.

Design Thinking differs from other kinds of thinking—most notably, Analytical Thinking—in a few key respects, as the table 2 shows.

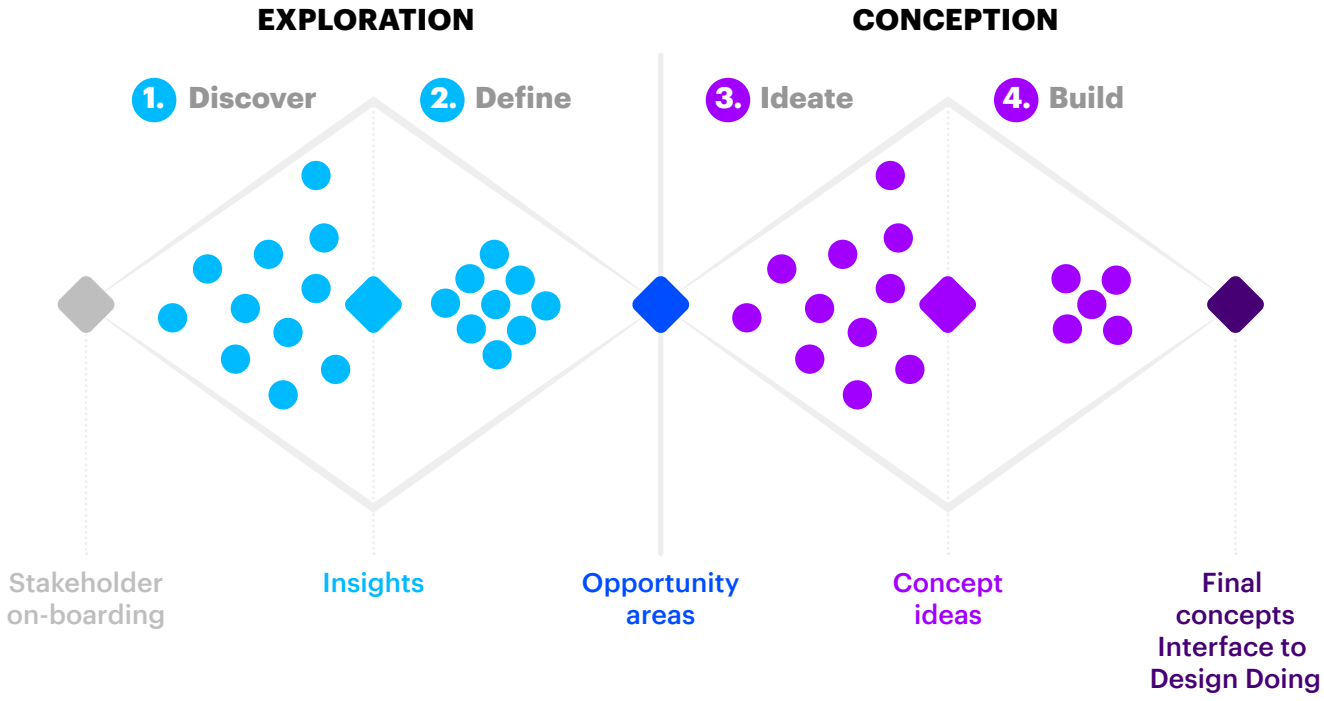
ANALYTICAL THINKING	DESIGN THINKING
"What's the right answer?"	"What's the right question?"
"What should we make?"	"Why should we make it?"
"How should we make it?"	"What should it feel like?"
Requires quantitative evidence of what good looks like	Requires qualitative confidence what good looks like
Is a repeatable, proven process	Is an intuitive, responsive practice
Is driven by business value	Is driven by human value

TABLE 2.

Analytical Thinking is great for driving business efficiency, profitability and growth—but not so good for identifying the next new idea. For imagining what's next, companies need Design Thinking. Indeed, in today's business climate, especially for the med-tech industry, Design Thinking can provide a framework for putting patients and other healthcare stakeholders at the center of R&D efforts, which is essential for maximizing innovation.

But as with any unfamiliar framework that an organization decides to adopt, Design Thinking cannot be introduced as a "one and done" workshop, session or Post-It note event. To deliver on its promise, it must become a pillar of a company's organizational culture and a fundamentally new way of approaching problems. (See Figure 2.) Even more important, it must be followed by action—which we call Design Doing.

FIGURE 2. Design Thinking process



Design Doing increases speed to value

Design Thinking can't create true value unless it inspires change. That means quickly transforming insights gained from this new way of thinking into tangible solutions that solve users' actual problems while also delivering measurable business value for the company.

For instance, through Design Thinking, multidisciplinary teams conceive of new products, solutions and processes. Then, through Design Doing, a diverse group of designers, software developers, data scientists and hardware engineers quickly develop functional prototypes. The group tests these prototypes with real users and proves or disproves the value of the resulting solution.

For many organizations—particularly in high-tech domains like software development—the concepts of Design Thinking and Doing executed in an agile mode are not new, and they have boosted innovation rates. Yet in many companies, these fall short when applied to the entire product development lifecycle. In the med-tech industry, halfhearted application of these concepts has led to misfires in usability, technical interoperability and business viability of products that get developed. Perhaps not surprisingly, many medical device companies have shied away from adopting the agile approach often used in software development.

That's because they are mistakenly concerned that this approach would be incompatible with regulatory processes required by federal agencies such as the US Food and Drug Administration (FDA). Additionally, many med-tech companies are overwhelmed by their own product and technology complexity when trying to manage innovation in an agile mode.

To address the complexity of the product development lifecycle, medical device companies need to combine Design Thinking and Doing with an emphasis on multidisciplinary collaboration. The goal? To enable diverse teams to quickly ideate, prototype and deliver solutions that create real value for the business and for different user groups. (See Figure 3.)

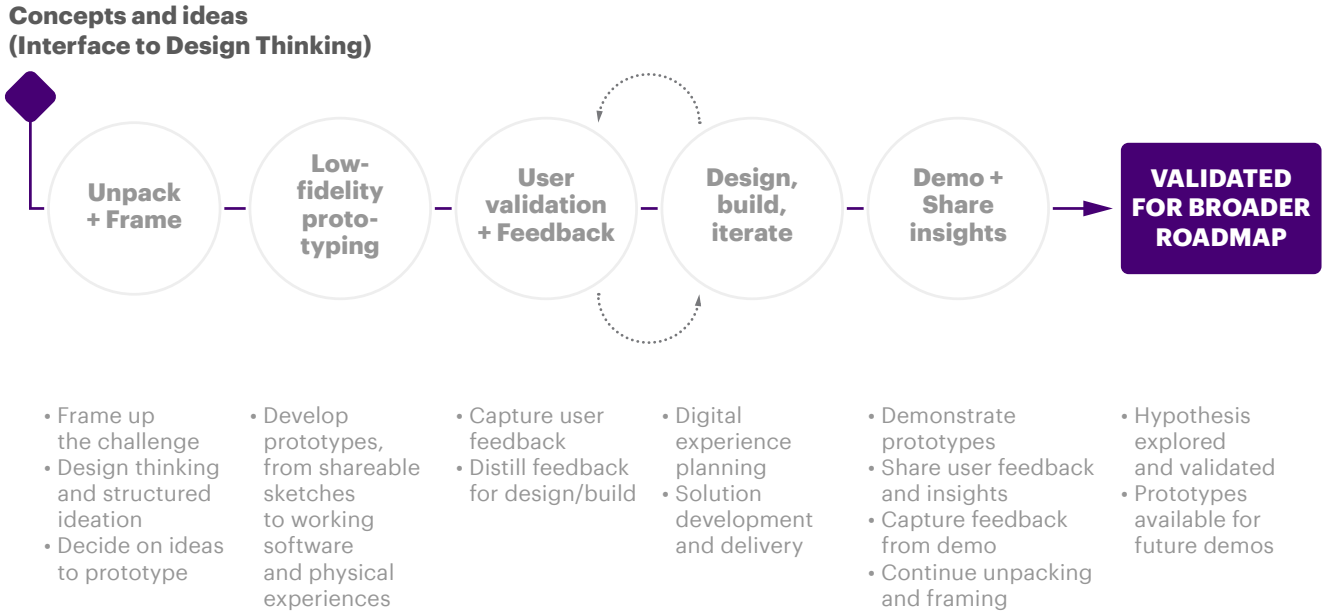
"Thin slicing" is a key Design Doing tool. A thin slice represents the simplest possible, valuable end-to-end slice of a device's functionality that could potentially be released to production. Through thin slicing, teams break complex challenges into small pieces that will create clearly defined value for specific users, enabling them to deliver differentiating elements of a solution first, before engineering a complete solution.

As a result, the organization can collect early external stakeholder feedback for the thin slice to ensure that the new product or service aligns with the company's strategic direction and is truly valued by all stakeholders, including patients, healthcare providers and payers.

To implement Design Thinking and Design Doing successfully in a med-tech company and culture, leaders must define creativity as a top priority and insist that multidisciplinary teams are always used for innovation and development efforts.

To quickly transform innovative ideas into functional, marketplace-ready solutions, teams must adopt an obsessively collaborative way of thinking while also mastering the thin-slice approach to working.

FIGURE 3. From Design Thinking to Design Doing



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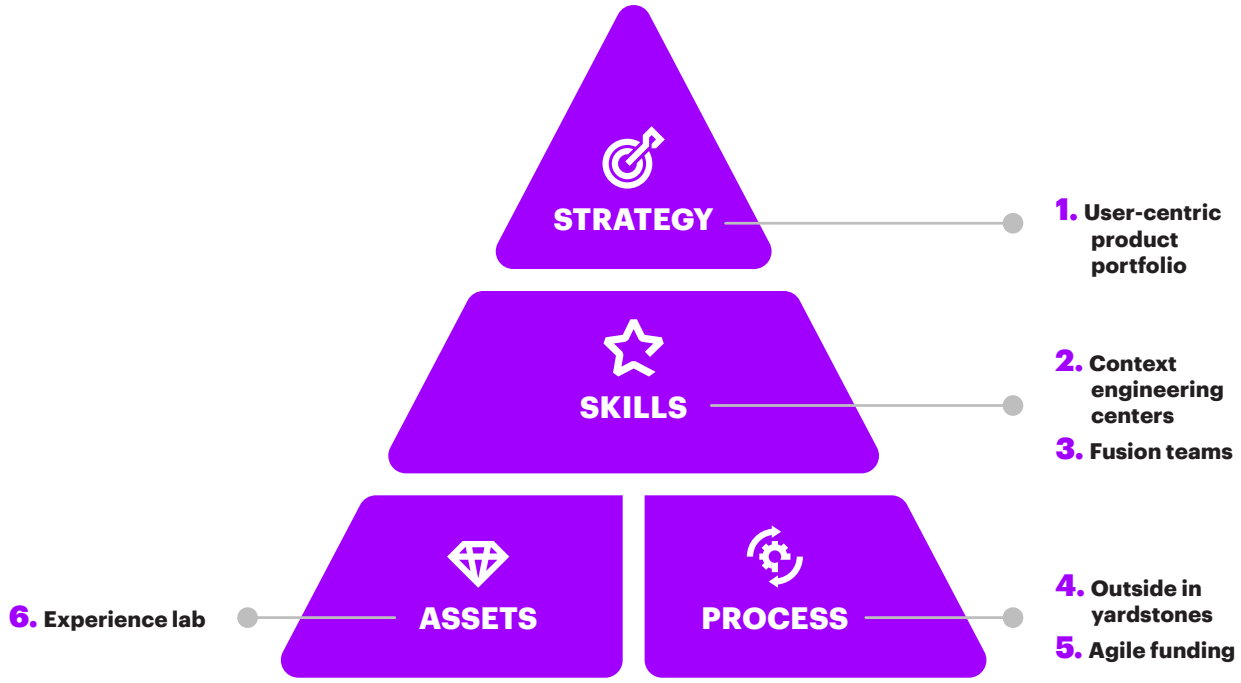
Implementing the new R&D blueprint for innovation

No doubt, designing better features for medical devices based on scientific advancements (the inside-out angle) will remain important for R&D departments seeking to create competitive advantage for their organizations.

But the outside-in angle (See Figure 1.) surfaced through Design Thinking and Design Doing will provide even more opportunities for med-tech companies to improve the quality of medical products, services and revenue models.

To get the most from both approaches, med-tech companies will need to embed the new ways of thinking and doing into their existing R&D process. How can they manage this feat? Based on a simple organizational model composed of strategy, skills, processes and assets, we have defined six measures to bring the outside-in perspective into an R&D organization with an eye toward boosting the rate and quality of innovation. (See Figure 4.)

FIGURE 4. Six measures to bring the outside-in perspective into an R&D organization



STRATEGY

1. **User-centric product portfolios:** Many R&D pipelines and product portfolios are clustered and managed by the underlying product technologies. For example, diagnostic companies are traditionally managed and structured along the different technologies, such as computer tomography, mammography and molecular diagnostics. An example of an alternative clinician-centric view for diagnostic would be precision medicine for specific therapies. In addition to managing the product technology, this view would require managing the underlying data and insight generation to enable clinicians to provide precision medicine. By viewing project portfolios through a user- or context-centric lens, R&D can build a fuller picture of the services, data and cloud platforms that are part of doing a good professional job from a user's view. This fuller picture also makes it easier to identify the capitalization strategies required to transform service needs into new business models.

SKILLS

2. **Context engineering center:** Contextual requirements to develop smart medical devices can be broken into two new engineering domains: "emotional engineering" and "intelligent engineering." Emotional engineering is the domain of design thinkers; intelligent engineering, the domain of data scientists. Companies can set up context-engineering centers, which are like a traditional technology engineering center but staffed by the new experts. The center should be well integrated into the innovation process, with experts adding their ideas, requirements and proof of concepts to the process as in any other engineering domain.
3. **Fusion teams:** These teams build on the combined know-how of context engineers and technology engineers. Their mission? Unearth unmet needs for substantial innovations and formulate hypotheses for how a particular idea could solve a problem currently afflicting specific stakeholder groups, such as a patient population, healthcare providers or payers. This approach differs substantially from working side by side or having regular cross-domain review boards, where everyone is still focused on adding his or her area of expertise. Fusion teams think and act as one team, in which members build on each other's expertise. They have a multiplying force and are not just the sum of individual domain expertise.

PROCESSES

4. **Outside-in yardstones:** During project development, med-tech R&D organizations must think in new ways about deliverable sign-offs. Rather than one-size-fits-all milestones that are widely spaced over the development cycle and that cover an entire device, R&D should conduct user-focused reviews of individual thin slices between the traditional milestones. We envision these as more frequent, feature-based "yardstones," where teams present a thin slice to the respective external user group (such as patients, nurses, physicians or technicians). The user group evaluates the thin slice, provides feedback and thus influences whether the yardstone is passed. This process ensures that an increasingly mature and user-centric product is passed from yardstone to yardstone. Companies can thus avoid a costly approval procedure for misfired products, ensuring faster approval and guaranteeing end-user acceptance.

5. **Agile funding:** Design Thinking and Design Doing hinge on agility, which is supported by practices such as thin slicing and early feedback from users. In most large med-tech R&D organizations, waterfall, milestone and activity-driven resource and budget allocation processes hamper agility. These control mechanisms keep R&D projects in scope and on track with the goal of getting them over the finish line as originally promised. But agility is driven by scope change, iterative processes and a focus on meaningful innovation for users. The different nature of agile processes requires a willingness to use different budgeting and resourcing approaches that resemble those used in venture-capital firms. That means funding shorter time periods of a larger portfolio of ideas—with the goal of quickly eliminating low-return ideas and ensuring that the most promising disruptive ideas pay for the failures. This mindset fosters agility, keeps the innovation pipeline fresh and encourages R&D to concentrate on breakthrough projects.

ASSETS

6. **Experience labs**: Organizations should devise an experience lab for each medical device under development. An experience lab is a low-tech environment that reflects—in emotional and physical respects—the setting in which the medical device will operate, such as an ambulance, intensive-care unit, doctor's office or patient's home. The experience lab is the joint creative space where the whole engineering team comes together to vet a hypothesis or prove a concept by testing the innovation with internal or external user groups early in the R&D process. The lab helps engineers visualize the device in the context of a comprehensive process, including pre- and post-treatment activities, adjacent medical devices and comorbidity healthcare professionals. Thanks to this visualization, engineers can better understand how to improve the device and leverage software and data to make the device smart.

The following examples prove how substantial innovation can be achieved in relatively short time frames when companies put these measures into action.

The **Auris Health** case describes how the team reinvented the controller for the monarch surgical platform. The newly developed controller allows physicians to more precisely diagnose and treat small, hard-to-reach peripheral lung nodules, or lesions. It is a key innovation asset of the monarch platform and a key trigger for J&J's decision to acquire Auris Health, a $ 3.4 billion investment decision.[9] The high quality of the new monarch system is also documented in the 2019 Best of the Best Product Design Award.[10]

The **Siemens Healthineers** case describes how the team reinvented the operating workflow of a CT scanner so that users can run the scan using just a few inputs. Automated patient positioning support makes it even easier to ensure high-quality images. The automation and standardization give radiologists assurance regarding the diagnostic quality of the images and increases operating technicians' productivity.

CASE STUDY: Auris Health Monarch System

USING DESIGN DOING FOR NEW SURGICAL ROBOTICS SOLUTIONS

Recently, Accenture partnered with Auris Health to design and engineer a new surgical robotics controller.

This ambitious goal led to a number of key questions. What controls did the robot need to have? Who would be controlling the robot? How would the design ensure that the robot was both safe and reliable?

Medical device development is expensive and fraught with risk, from financial implications to technical complexity to user adoption. It's therefore vital for Auris Health to identify, verify and ultimately build the right product.

Attempting to answer this vast array of questions sequentially prior to building anything would be a lengthy process. At the same time, it's difficult to converge on a product vision and specific requirements without first addressing key uncertainties.

For this engagement, we alleviated this conundrum through a lightweight requirements document that prioritizes stakeholder goals and reduces the initial number of requirements from thousands to dozens. Auris Health and Accenture teams were able to collaboratively identify key table stakes, such as the form and architecture of the robot's controller.

Traditional instrumentation for the endoscopic procedures consists of handheld catheters that can be articulated using rotating knobs. Therefore, this was also the obvious form factor for a digital robot control, since it would leverage years of surgeon experience with that archetype.

However, a broad series of testable user prototypes assembled in less than four weeks revealed that the majority of the endoscopic surgeons performing the procedure had better control with videogame-style controllers than with the controls they had spent thousands of hours practicing as part of their traditional craft.

Rather than spend hundreds of thousands of dollars attempting to build a fully functional controller to verify this finding, the team built a lightweight mechanical and software simulation to enable surgeons to visualize and feel the controller's performance. These early prototypes could be manipulated to demonstrate core functionality to clinicians, allowing us to quickly and frequently incorporate their feedback.

After 12 weeks of Design Thinking and Design Doing through rapid prototyping and user testing, the joint team had defined and built a concept of the new robot controller. Ultimately, Accenture teams also engineered the production version of the controller as well.

CASE STUDY: Siemens Healthineers

IMPROVING OPERATING PROCEDURES IN RADIOLOGY

In a collaborative effort of our researchers, user experience experts and user interface and product designers, the successful implementation of a new streamlined CT scanner workflow was the result of targeted enhancements to the physical CT scanner design in combination with the introduction of a mobile tablet.

The tablet houses the newly developed Healthineers SOMATOM go. platform to support the operation of the CT scanner. The enhancements are the result of fusion teams working through so called futureNOW exploration workshops. The fusion teams were composed of engineers, user experience experts, user interface and product designers. The futureNOW sessions included techs, doctors and hospital managers to detect the pain-points of the current setup. Based on the solid understanding of the context and user needs, we developed and prototyped possible solutions and tested them in a radiology experience lab.

The new workflow includes a wireless remote, a tablet and a gantry-mounted camera to reduce walking ways for the tech. Providing a mobile but integrated solution for clinicians made the lives of the clinical staff much easier. For example, clinicians can position the console in the same room as the scanner. Thus, they can explain and execute the CT set-up steps side-by-side with the patient. Before, they had to walk back and forth between the patient and technician room. The top-mounted camera provides an easy control to ensure that the patient is never out of frame.

The entire workflow is now centered around improving patient comfort and achieving high-quality image results. The theme of putting the patient into the center of the CT scanner is also considered by a softer and lighter look of the whole design. The innovations can be made easily available to any newly launched Siemens Healthineers CT through the plug-and-play set-up of the SOMATOM go. solution.

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