

FINDING VALUE IN INTELLIGENT MEDICAL PRODUCTS



INTRODUCTION

We all know how quickly the healthcare landscape has been changing over the past few years, spurred on by the shift to value-based care, the dizzying speed of technological advancement, and the focus on patient-centric solutions. These factors are forcing a convergence among all aspects of care - pharma with drug delivery and medication adherence programs, medtech with evermore complex software and data management, and everyone with artificial intelligence (AI) are just a few examples. As if these disruptive changes aren't enough - consumerization, augmented and virtual reality, regulatory and cybersecurity compliance, and the connectedness of everything are having a huge impact on how we all expect to interact and engage with all aspects of healthcare.

All this has given rise to a new ecosystem model for medtech companies – **intelligent medical products**. There is real opportunity for those medtech companies who embrace the business model changes required to thrive in this ecosystem - and real danger of being relegated to commoditized niche players for those that don't.

What is an intelligent medical product? It's hard to pin down a consistent, widely accepted definition but an intelligent medical product, in addition to performing its intended diagnostic or therapeutic device functions, certainly involves a significant use of software to capture and use data. This data, drawn from multiple sources (device, user, clinical information system, and others), is used to drive information and insights to achieve these goals:

- Increase patient engagement in their healthcare
- Provide a better context within which to make informed, patient-centric care decisions
- Increase caregiver efficiency and productivity
- Improve the quality of care provided
- Improve care coordination throughout the healthcare ecosystem
- Drive efficiencies in medical device manufacturing and post-launch operations
- Provide a foundation for emergent and value-added services

Intelligent medical products include devices and solutions like Bluetooth-connected autoinjectors, insulin pumps connected to continuous glucose monitors, image assisted surgery, robotic surgery systems, and analytic initiatives that drive personalized medicine, among others.

While intelligent medical products provide obvious benefits for healthcare providers and patients, finding the value in intelligent medical products for medical device companies can be elusive and challenging. As these companies seek to add intelligent medical products to their product portfolios, many are struggling to capture the right balance of business strategy, innovation, core organizational capabilities, and the right partnerships to drive lasting value.



1

CHALLENGES TO FINDING VALUE

Companies are often constrained by factors hard to overcome without significant changes to strategy, structure, and approach.

Clinging to traditional views

Many companies have rigid internal organizational structures with clear - and wide - separation between engineering disciplines or product teams which makes it difficult, if not impossible, to build a team to pursue the multi-discipline needs of an intelligent medical product. This often results in an unwieldy arrangement where percentages of time from key contributors are allocated to an effort - but it is not the singular priority for anyone. It may look good on paper, but such efforts are doomed from the outset. All too often, key contributors are pulled from such efforts to support the current product portfolio, and then are expected to bounce back, pick up where they left off, and carry on. Still, many try this approach and plod along, thinking they're doing the right thing.

One approach that some companies try is to treat an intelligent medical product as a "special initiative" side project. This may sound good and may appease a board of directors and key customers who are wondering what you're doing about this intelligent medical product phenomenon, but ultimately this is a dodge around embracing the inevitability of intelligent medical products as part of your core strategy. Intelligent medical products are a reality - the challenge is finding your place - and the value - in it.

Another challenge for some companies is the inability to shift away from their traditional marketing view of their own value. They cling to the device. After all, it has served them well up to this point and provided good market share and lots of revenue. Over time - and in a shorter time span than you might think - the market share and revenue margin begin to erode, often usurped by good-enough competitors with better intelligent medical product solutions. It's important to understand that it's not just the

device, and it's not just the data either, but rather how you drive value through the ecosystem. This view fundamentally challenges your traditional core business model - you still need to pay attention to what got you here but recognize the need to adapt to the changing ecosystem around you.

Some companies have managed to navigate the internal organizational and business model challenges, only to stumble when it comes to the operational aspects of intelligent medical products. One such temptation is to rely on your internal IT infrastructure and staff, when that organization and technology stack are probably not set up to handle external customer support or the system service expectations for performance, availability, and security essential to support intelligent medical products that may now include an app, a web portal, data governance, advanced analytics, and cloud deployment in multiple target markets.





Underestimating disruptive factors

Disruptive innovation in the healthcare industry in the intelligent medical product space is moving at the same frenetic pace as in other industries - you just may not be aware of it yet, especially if you are only looking at your traditional competition. This disruption can come from various sources: a good-enough competitor to your core product who offers better connectivity and value-added services around information and analytics; the ever-increasing play in this space from Google, Apple, Amazon, and others;

or an “invading” third-party who simply wraps new services and connectivity channels on top of your existing product and turns you into a commodity provider overnight (think of what Trivago has done to other online hotel and travel businesses). This kind of disruption may even come from your own current design, research, or manufacturing partner who has gained enough knowledge and experience to expand into being a competitor instead of just being a supplier.

Lack of true systems thinking

Consider the diagram below. If your focus is drawn only to the endpoints and not to the connections, then you may not be seeing that it is the web of connections that hold the greater lasting value, whereas the endpoints have value but are always subject to commoditization and being replaced by the next best solution in that space.

Systems thinking is the ability to see beyond an endpoint and envision the value in the set of connections emanating from your current position. Where traditional systems analysis focuses on system decomposition, systems thinking is more holistic in its approach and looks at how systems interrelate and work overtime within the context of an ecosystem. This ability to manage the complexity of a “system of systems” approach is likely difficult to find within your company, because the natural tendency is to focus on your product portfolio – the devices - and what it takes to manage those core assets, and you may be new to viewing connected solutions as an essential part of your core strategy.

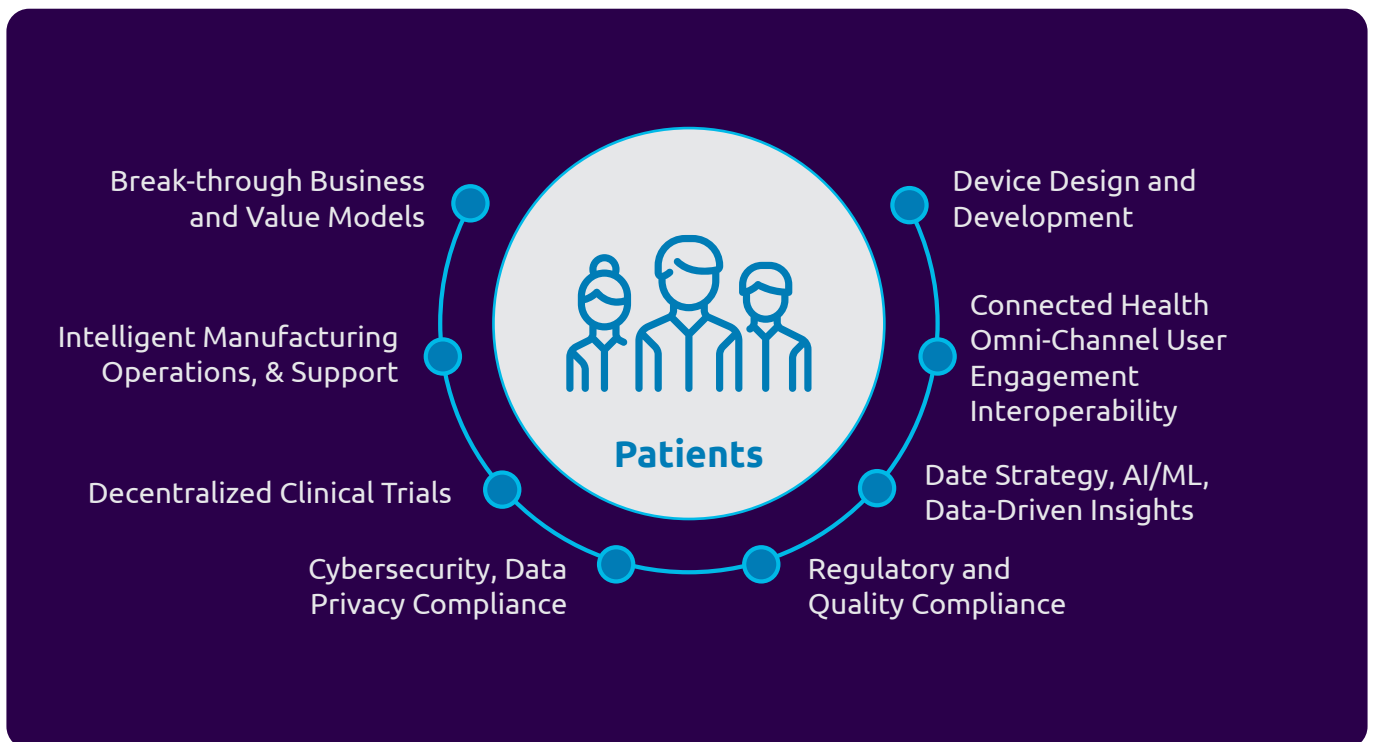
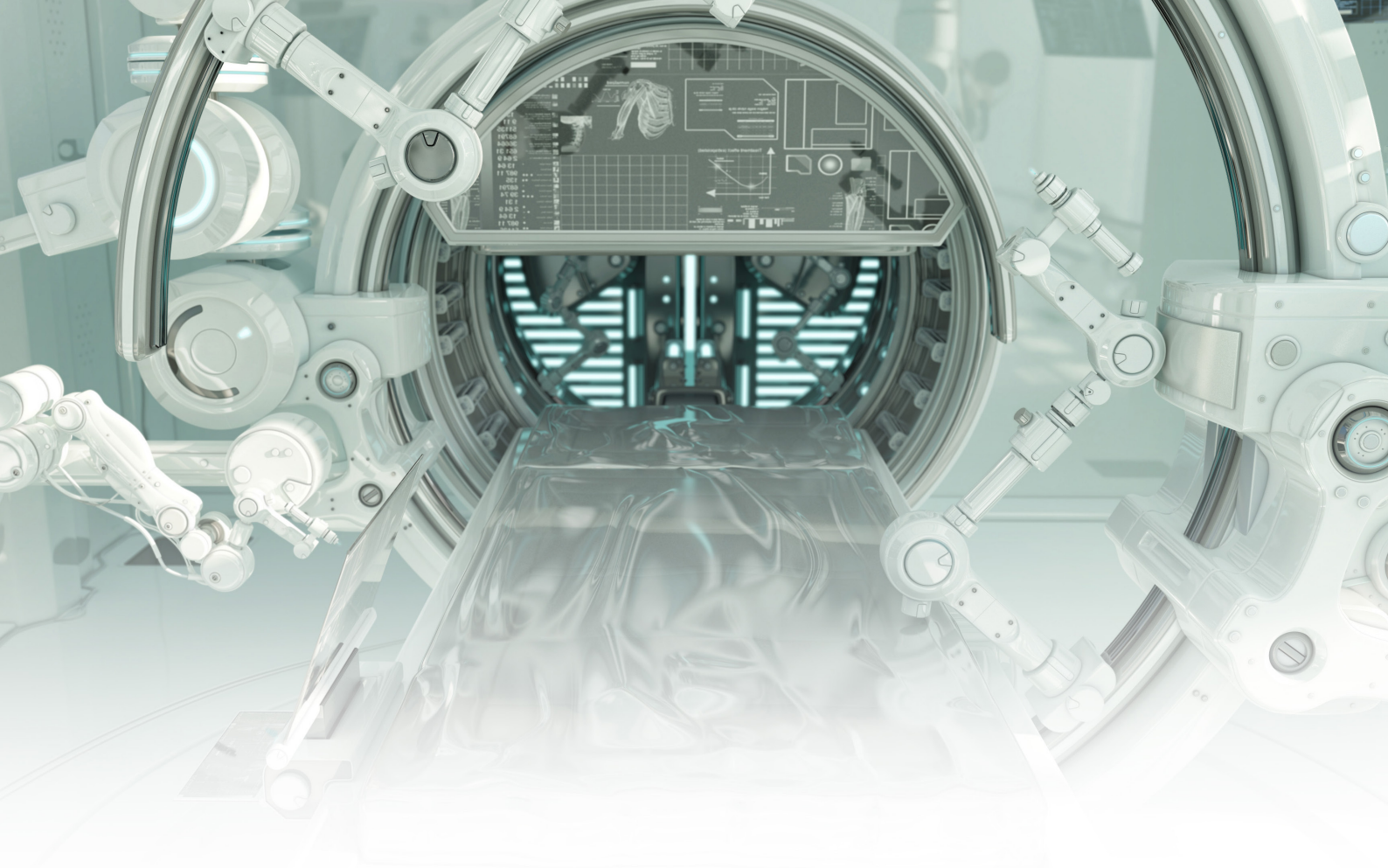


Figure 1: The Intelligent Medical Product Ecosystem



2

HOW TO FIND VALUE IN YOUR INTELLIGENT MEDICAL PRODUCT STRATEGY



There are four primary activities you need to undertake to find value in your intelligent medical products, and to avoid being relegated to a commoditized, replaceable position. These bold steps may require you to change your way of thinking, your business model, and your organization - but you'll be in a better position to provide greater value for your customers within this rapidly changing and converging healthcare ecosystem.

1. Rethink your business strategy and model, specifically focusing on:

Your customers' needs - the changing and converging ecosystem is not only affecting you, but your customers as well. Their workflow, collaboration, information needs, reimbursement, and system interaction expectations are all in flux. Your solution to their changing needs may need to be radically different as well. In the diabetes management space, for instance, think how effective CGM and insulin pumps have been - taken separately, they were each reasonable products, but the combination of these two to form a virtual closed loop system redefined an industry. Can your core product be extended, perhaps through a combination approach, to address more of your customers' work needs within the ecosystem?

Your revenue model - the days of relying solely on a device or "box and consumables" are waning. Can you change the game by shifting your pricing and selling structures? Can you move to a metered use and outcomes-based payment structure? Can you add extra cost value-added services? Instead of installing a product, can you offer to take over key aspects of your customers' work using your solutions - for instance, instead of selling lab & test solutions, manage the lab for your customer?

Your sense of market - are there new sectors within your market or new markets that you can now embrace? For instance, if you're managing data within your intelligent medical product solution, do you have the opportunity to sell de-identified data as research data? If your offering provides a mobile point of care testing solution within a hospital, can you extend that to address home health needs?

You may need an objective third-party to assist with this "re-thinking" to get past assumptions that have been built up over time, but the effort to reconsider your approach to innovation - perhaps embracing disruptive innovation considerations in addition to more incremental innovation - can only improve your overall strategy.

2. Embrace a system thinking approach to find value in this converging ecosystem. Systems thinking brings the discipline to capture:

Purposefulness – capturing not only what your product does or intends to do, but also understanding why the users and other stakeholders do what they do with your product within the context of completing their tasks and activities.

Composition – the ability to reach the right compromise among seemingly contradictory needs and interdependencies. Some of these opposing needs are well known: security vs. performance, customization vs. standardization, and others. Some are more subtle – but the point is always to achieve the right balance among the full set of these needs. This requires a holistic view, for this balance cannot be managed by any individual component of a system alone. In addition, the relationship of your product with other products and systems within the ecosystem will change over time, and this evolution needs to be anticipated.

Connectedness – understanding the behavior and value of your product within the context of the ecosystem within which it operates, and understanding the influences and implications of that ecosystem on your product. The concept of “connected” here addresses the inter-connected, inter-operable nature of your product or system in the overall delivery of healthcare.

Perspective – the ability to see that actions intended to produce one outcome actually cause the opposite results. For example, a hospital information systems (HIS) vendor added capabilities to allow the end user to self-customize and self-configure the product, ostensibly to reduce support and development costs. The result – customers were so confused by the complexity that the vendor ultimately had to add support staff (and cost) to train and help configure the system for each customer.

Emergence – the result of a set of interactions within your product that can yield additional capabilities and values that are not always apparent on first consideration. For example, one radiology information system / picture archiving and communication system (RIS/PACS) vendor added remote diagnostics and monitoring to reduce customer and field support costs. While this achieved its immediate goal, it unexpectedly led to the ability to inform customers of work queue challenges and patterns of use among radiologists and technicians in a way that provided great value to their customers.

Collaboration is the name of the game now given the increasing technical complexity and the multiple disciplines that need to be brought together to create meaningful, value-driven solutions

Based on this analysis, you can determine how to leverage value from your current assets, what additional assets or capabilities are needed to fulfill your business strategy and vision, and the value proposition those bring.

3. Find the right partners because you can't do this all by yourself. Collaboration is the name of the game now given the increasing technical complexity and the multiple disciplines that need to be brought together to create meaningful, value-driven solutions. In order to partner successfully, you need to determine:

Clear objectives - A shared common vision and purpose that builds trust and openness and recognizes the value and contribution of each partner is essential. Additionally, shared and transparent decision-making processes lead to efficient coordination of execution and delivery, and, ultimately, better outcomes.

Allocation of capabilities and responsibilities - You should maintain internal responsibility for those aspects of your collected health strategy that you value as core or for which you have the right competencies and capabilities.

The aspects that are critical or otherwise needed are those responsibilities you should seek the right partner to deliver and maintain. For instance, as a medical device manufacturer you'll want to control device development and manufacturing, but partner with someone for the app and cloud aspects. There are proven methodologies that you can use to help determine what is core for your business, and what aspects provide the best opportunities to partner. The right partner will not only have the right technical skills but will also employ a user-centric approach driven by best-practices experience.

Scalability – building successful and sustainable intelligent medical products without the right partners will ultimately challenge your ability to scale to meet ongoing needs and portfolio growth. Key concerns to consider include:

- Managing ongoing and complex regulatory changes
- Addressing security and privacy concerns
- Turning data into actionable insights through continual refinement of advanced analytics
- Scaling across regions, brands, and third-party devices or apps
- Managing the digital aspects of your intelligent medical product solution (cloud, mobile, etc.)
- Upskilling as necessary to take advantage of continuously evolving and emerging technologies
- Vendor, supplier, and other partner management throughout the product lifecycle

4. Have a clear and purposeful data strategy

that establishes the purpose for and governance of your enterprise and portfolio data to ensure a strategic evolution and roadmap for data as an asset that drives:

- Decentralized clinical trial effectiveness
- Agile and iterative product improvement
- Process efficiency improvement for development, manufacturing, operations, and support
- Foundation for direct value from emergent services, indirect value by reducing opportunity costs, and efficient operations by reducing costs to deliver current and new product solutions Data is not just a byproduct of running your business – it is a critical business asset.

The key to real growth in this changing, converging, intelligent medical product ecosystem – and maybe for survival – is to embrace radical change and innovation. While continuous iterative development based on learning from your customers and the market may have served you well so far, the shift to a patient-centric and intelligent medical product-driven world will disrupt your current business model. Ignore this at your peril; the same forces you are facing now have rocked other industries before - with scores of mature companies unable to hold on, despite their best efforts.

Focus your innovation and investment strategies on how you can find value in this changing ecosystem. Rethinking your business model, embracing systems thinking, and finding the right partners are the essential ingredients to allow you to survive and prosper.



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Contact us at:

engineering@capgemini.com