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The Essential Role of Rapid Market Research in Agile Medtech Design and Development

2021 White Paper

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Introduction: Keeping the Customer at the Center of the Work

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Bringing a product to market has always been a risky endeavor. In response, market research techniques have advanced to mitigate that risk. Yet, as the pace of technological advancement accelerates dramatically, the pressure to get products in the hands of patients even faster has resulted in the increasing need for medtech companies to complete their transition from linear processes, like waterfall, in favor of agile methods.

Thrivable's white paper examines the influential role agile now plays in medtech's success. While the emphasis is on relevance to the medtech industry, it's helpful to start with agile's origins. This offers a more complete picture of its benefits to the design and development process while explaining why rapid market research is perhaps the most essential element of an agile approach — one that keeps the customer at the center of the work.

Thrivable Insight: Why Starting Small Can Yield Bigger Success

We recognize that, for some organizations, the transition to agile may come with added challenges due to a company having been organized around waterfall-style planning. In situations like these, it may be beneficial to begin the adoption of agile practices gradually and with a more narrow focus, such as research design.

Leaving Linear Behind: The Road to Agile

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Two decades ago, a group of software developers met to discuss common work challenges and potential solutions. At the root of their challenges was a classic systems engineering design model, known as waterfall, in which sequential predefined steps are taken so that progress flows in a single, downward direction. Each subsequent phase is therefore dependent on the deliverables associated with the prior phase.

Developers using waterfall for software have found that, while the process might be ideal in highly structured environments, it wasn't effective for projects that evolve over time. Waterfall's extensive requirements scoping and micromanaged development process lead to a tremendous amount of waste as changing requirements cause work to be scrapped. Worse, the approach put the customer perspective on the backburner for large periods of time, increasing the chance that the

product did not ultimately meet customer needs.

The outcome of the group's meeting was the Manifesto for Agile Software Development¹, which is framed by the 12 principles these developers believed would lead to more effective project management practices for software. The principles brought back into focus the value of collaboration, cross-functional teams, early delivery, and continual improvement. And, most importantly, the significance of the customer.

Our highest priority is to satisfy the customer through early and continuous delivery of valuable software.

— Manifesto for Agile Software Development, Principle #1

Critical to the Manifesto, as well as the many frameworks and practices associated with agile today, are the four values that emerged from the developers' efforts to uncover "better ways of

developing software by doing it and helping others do it.”

Breaking Complexity Down into Manageable Pieces

In practice, the most striking difference between agile and waterfall is that, unlike waterfall’s reliance on testing as its own isolated phase of development, agile breaks large projects down into smaller pieces so that testing happens simultaneously alongside programming. Agile allows for smaller “chunks” of software to be delivered to the end-user for validation with results used to adapt subsequent development efforts accordingly.

Testing then becomes an iterative process as opposed to a phase that can occur only after the build phase is complete. (One of the most well-known agile frameworks, Scrum, has

popularized this approach with the practice of small teams breaking their work down into goals that can be completed in two-week “sprints.”)

Reducing Waste and Risk

The ultimate benefit of agile is the ability for teams to dramatically improve customer engagement and satisfaction. However, agile methodologies, which often eschew overplanning and unnecessary meetings, have also been shown to reduce waste because the more iterative nature of the work minimizes defects in quality and low-value product features. The result is that companies can bring “the most valuable products and features to market faster and more predictably,” with much less risk.²

Agile Values

The authors of the Manifesto for Agile Software Development believe that while the items listed on the right do offer value, those on the left should be prioritized for better outcomes.

Individuals and interactions	OVER	Processes and tools
Working software		Comprehensive documentation
Customer collaboration		Contract negotiation
Responding to change		Following a plan

Mainstreaming of Agile Practices

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In the 20 years since the Agile Manifesto was written, various organizations and teams have adopted agile practices in order to improve outcomes. Disciplines such as warehousing and manufacturing are among the obvious early adopters, primarily because of the influence of lean manufacturing on agile software development.

However, agile has also influenced everything from the way organizations manage their people and finances to the execution of sales and marketing efforts. Agile frameworks, practices, and tools may differ across functions and departments, but the goal is consistent: remove organizational silos, leverage multidisciplinary teams, and remain hyper-focused on the customer.

According to Digital.ai's 14th State of Agile Report³, enterprise organizations that have adopted agile continue to realize significant benefits, such as the ability to:

- Respond to change
- Maintain insight into priority projects
- Ensure alignment between business and IT

In terms of measuring success, either for individual projects or an agile transformation, companies continue to focus on customer satisfaction as a primary measure of success, alongside the business value that is delivered.

Gaining a Foothold in Medtech Design and Development

Among the industries for which agile product design and development offers tremendous opportunity is medtech, especially given the increasing role that software plays in new medical devices and products. Whether the company is an established enterprise player or a new-to-the-scene startup, connected devices have moved medtech into the realm of the internet of things (IoT), while patients continue to demand a “more customer-centered health care experience.”⁴

Early concerns, such as agile lacking the rigor required by companies that operate in heavily-regulated industries and create complex products that have the potential to inadvertently pose risk to the health of patients, have largely been dispelled.

In fact, as early as 2012, the Association for the Advancement of Medical Instrumentation released standards for how product developers could leverage agile practices while still achieving regulatory compliance. Its most recent version was published in 2018, and includes “recommendations for complying with international standards and U.S. Food and Drug Administration guidance documents when using agile practices to develop medical device software.”⁵

As agile gains an even stronger foothold within medtech, new models for adapting its frameworks and processes continue to emerge. Among them is the concept of “fast feedback loops (or FFLs),” first

proposed by medical device design and development firm Orthogonal.io. The concept is to “take large, complex product development pipelines and break them down into a repeatable stream of highly effective build-measure-learn cycles.” Clearly, there are many benefits associated with FFLs. But the most critical success measure may be the ability to conduct “quick-controlled experiments” that help teams prove — or disprove — their ideas and assumptions so that they can pursue the ideas that are most likely to win as quickly as possible.⁶

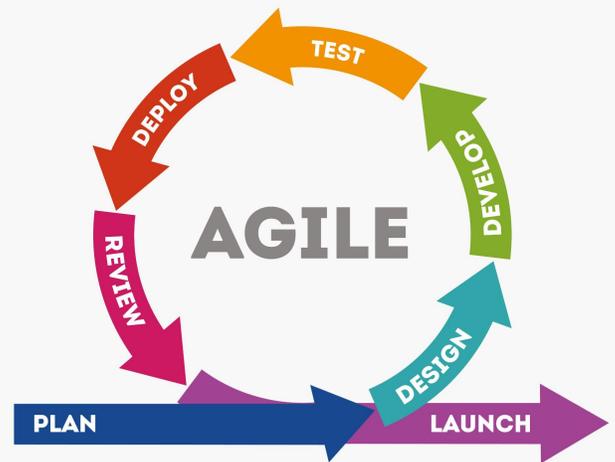
Spurring Faster Recovery for the Medtech Industry

Like all industries, medtech has been significantly impacted by COVID-19. As reported by EY in Pulse of the Industry: Medical Technology Report 2020, while some medtech companies did experience an increase in revenues (particularly those specializing in COVID-19-related diagnostics) two-thirds of medtech companies reported a

drop in revenue in the first half of 2020. In addition, annual R&D spending grew by only 8.1% in 2020 versus 11.5% in 2019. Venture capital funding fell 22% in 2020 after three years of record investment levels.

Innovation is essential to the industry's ongoing recovery, and agile practices present an opportunity to optimize innovation while reducing go-to-market costs and overall risk. For medtech companies that want to get their innovations to market faster and with far less risk, **an agile approach that involves gathering patient insights rapidly throughout all phases of the design and development process in an iterative manner represents the fastest route to success.**

Rapid Research to Support Agile Design & Development



Reducing Go-to-Market Risk by Asking — and Answering — Essential Questions

PLAN: *Do we know what patients want and need?*

DESIGN: *Which features/functions matter most? Least?*

DEVELOP: *Does our prototype align with patient expectations?*

TEST: *What's working? What's not working?*

DEPLOY: *How can we best convey our product's value?*

REVIEW: *Are there gaps to be addressed prior to launch?*

LAUNCH: *How does it perform once generally available?*

Using Rapid Research to Power Agile Design and Development

Using Rapid Research to Power Agile Design and Development

The essential role that rapid market research plays in an agile medtech design and development approach has grown increasingly clear over the past few years. Yet, those working in the medtech industry often cite the same barrier to success: *How do I connect with the patients whose voices are critical to launching our products faster and with less risk?*

Often, the biggest hurdle is limited access to the right patient population. Maintaining a community of engaged, high-quality panelists is a time-consuming endeavor. Most medtech companies, as well as the agencies serving them, lack the resources required to do so. This means they have to start from scratch every time a market research opportunity is identified. The patient recruitment process becomes lengthy and, often futile, as finding patients who meet the research criteria is like looking for a needle in a haystack.

The result is that traditional market research programs come with lengthy project timelines and fixed costs that exceed the budgets allocated for research. And they're often the reasons that medtech companies, especially startups faced with even tighter constraints, choose to forgo patient insights altogether.

The consequence is that medtech companies that delay efforts to gather patient insights, particularly in an iterative fashion, fail to realize the benefits of agile design and development. Costly changes and setbacks become the norm because the design and development process moved forward without a solid understanding of what patients actually want and need.

Eliminating Friction: The Value of Rapid Market Research

The majority of mass-market research vendors don't address the critical needs of medtech

companies because the current landscape remains fragmented and hasn't kept pace with either the generative or evaluative research needs of today's product-focused companies.⁷

As a result, rapid market research solutions are filling these gaps by prioritizing high-quality research outcomes alongside the reduction of waste.

However, there's an important distinction to make regarding rapid market research: It's not about cutting corners to arrive at results as quickly or as cheaply as possible. Rather, the focus is on eliminating the friction associated with prior market research models so that design and development teams have the flexibility they require to gather customer feedback through an iterative approach (agile) rather than waiting until development is complete (waterfall). This is achieved through:

- 1. Maintenance of a robust and engaged community of patients.** When a rapid market research solution invests in the maintenance of a robust and

engaged community of patients, it makes on-demand access for medtech companies a reality. Rapid research platforms are also proving adept at leveraging tech to ensure quality. This includes self-updating panelist profiling capabilities that automatically confirm the accuracy of patient criteria along with proactive screening technology that removes any panelist who provides low-quality responses or answers questions inconsistently or in ways that don't make sense given the specific health condition.

- 2. Seamless study creation and execution.** Friction is also eliminated when individuals, whether they are technical or not, can easily manage the design, program, and launch of surveys, focus groups, and usability studies. Self-service components provide further support to an agile design and development process because teams are more apt to implement an iterative market research approach that favors the FFLs that are critical to medtech innovation.

3. **Clear, automated reporting.**

Being able to tap into key learnings as soon as responses are received is another defining aspect of rapid market research. Clear, automated reporting reveals the insights that teams need to move forward, or pivot, with greater immediacy. It brings the effort full circle and allows medtech companies to make better decisions in support of improved product and business outcomes.

The benefits associated with the above rapid market research attributes are significant for both the companies and the patients they serve. To illustrate, one medtech company using the Thrivable platform reported that collecting early patient feedback helped them realize that one of the products in their pipeline was not likely to be a major value driver in their portfolio. This led

them to halt production on the product and redistribute resources, saving the company hundreds of hours and tens of thousands of dollars as they refocused efforts on products proven far more viable — and profitable. Similarly, surprising insights led a product development team to a novel conclusion: Merging two different product concepts into a single concept would allow them to serve a much larger audience.

Examples like these underscore the immense value derived from making rapid market research a key feature of agile design and development. In doing so, medtech companies will find it easier to realize one of the most important elements of the Agile Manifesto — keeping customers at the center of the work.

¹[Manifesto for Agile Software Development](#), 2001 (Retrieved April 2021)

²[Embracing Agile](#), Darrell K. Rigby, Jeff Sutherland, and Hirotaka Takeuchi, *Harvard Business Review*, May 2016

³[14th Annual State of Agile Report](#), Digital.ai, 2020

⁴[Pulse of the Industry: Medical Technology Report 2020](#), EY

⁵[AAMI TIR45: Guidance on the Use of AGILE Practices in the Development of Medical Device Software](#), Association for the Advancement of Medical Instrumentation, April 5, 2018

⁶[Four Success Factors for Accelerating Digital Health Solutions](#), Orthogonal.io, June 9, 2020

⁷[The Market for User Research Platforms](#), Andreessen Horowitz, April 6, 2021

About Thrivable

Thrivable connects patients and companies to create better products and services for the next generation of health care. Our real-time market research platform makes it easy for patients to be their own advocates by sharing their insights, stories, and perspectives via surveys, interviews, focus groups, and usability studies. Health care companies turn to Thrivable to ensure the voice of the customer drives important business decisions every day. Visit thrivable.app to learn more.

