



Digital Medical Device Innovation: A Prescription for Business and IT Success

A Digital Transformation is reshaping healthcare.

New technology, mobility, and advancements in computing are enabling innovation leaders to interact with patients at the touch of a button. Information collected from devices provides rapid insights and drives real-time decision making across organizations. Success in this space requires a shift in thinking and strategies to support these advancements.

How will your biopharmaceutical company respond to this revolution? This white paper provides a strategic blueprint to secure your spot as a digital medical device leader.

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Will Pharma Lead or Follow?

The digital health industry continues to explode with solutions and innovations. Investments, which topped \$5B USD in 2017¹, continue to climb with no sign of abating. Historical growth has been in consumer health information apps and other health care enablers. However, due to increasing patient, provider, and payer acceptance; technological advancements in genomics, artificial intelligence, and computing; and clearer regulatory guidance, we are seeing an acceleration of digital medical device solutions in disease diagnosis, disease monitoring, and cognitive behavioral therapies. This disruption is being largely driven by innovative startups and digital companies.

Many of our clients are experimenting with digital medical device pilots, but only the most discerning realize the significance of having a cogent strategy for bringing these products from concept to market.

—Susan Butler, Co-Founder and Managing Partner for Delivery, ResultWorks

It remains to be seen whether large biopharma companies will lead or follow in this space. Although they have an in depth understanding of disease progression and human biological

systems, some may lack the digital expertise and speed to effectively compete with their smaller, more agile counterparts. Prescient biopharmas are quickly securing their spots as first movers by building value-driven digital medical device portfolios. Rapid delivery of digital products at scale, underpinned by thoughtful, deliberate business and IT frameworks, ensure these companies remain relevant as this nascent market matures.

Understanding Digital Medical Devices



Industry have crafted a myriad of names for digital medical devices, including Software as a Medical Device (SaMD), mobile medical apps, digital diagnostics, digital health apps, digital therapies, digital prescription therapeutics, digital medications, and others. Regardless of

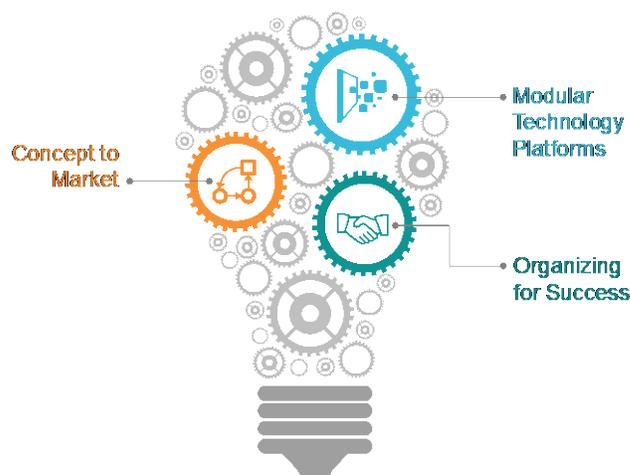
¹Zweig, M., and Tran, D., Q1 2018: Funding keeps climbing as digital health startups double down on validation, Rock Health, Retrieved from: <https://rockhealth.com/reports/q1-2018-funding-keeps-climbing-as-digital-health-startups-double-down-on-validation/>

what moniker your company adopts, it is important to align understanding of these commercial products internally. ResultWorks has adopted the name “digital medical device” to provide consistency with the regulatory term Software as a Medical Device², while also acknowledging that these digital products frequently integrate wearables, biosensors, mobile devices, other data sources (imaging, *in vitro* diagnostic results, EHR data, environmental data, etc.) and algorithms that deliver personalized, actionable results with validated clinical utility.

The significance of the results generated can vary greatly, from simple medication and health trackers, to disease risk prediction, diagnosis, and even therapeutic intervention.

digital environment or software products, such as digital medical devices. Organizations will need to adjust their approaches to:

- Move from concept to market
- Implement the right technology foundation
- Organize resources to create, sell, and support software products



Strategic Considerations

While strategies for drug development and digital medical device development can both use the ubiquitous People-Process-Technology framework, most similarities end there. We typically find that biopharma business processes, technology platforms, and organizational structures are finely tuned for drug development but not optimized for the

Forging a Path from Concept to Market

Biopharma companies will need to adopt processes and partnering strategies that blend the speed and agility needed to support digital markets with the unique requirements of a highly regulated industry. Strategies need to address effective screening of new ideas for

²IMDRF SaMD Working Group, Software as a Medical Device (SaMD): Key Definitions, International Medical Device Regulators Forum, 9 December 2013, IMDRF/SaMD WG/N10FINAL:2013, Retrieved from: <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>

potential value, quick determination of product feasibility, and acceptable quality and regulatory mechanisms. User feedback must be gathered and incorporated into design as early as possible, especially when dealing with novel, human contact biosensors. Right-sized quality management, as well as, the regulatory and pragmatic aspects of legal manufacturing, must be addressed in any digital strategy.

Historical, normative biopharma approaches may hinder the iterative learning needed to succeed in fast-moving digital markets. Visionary teams will disrupt these patterns, establishing unique methods for bringing digital medical devices from concept to market.

Laying the Technology Foundation with Modular Platforms

While the specifics of each digital medical device's target user base, disease area, and algorithms will differ, most will share common technology needs, such as data collection from wearables and biosensors, data storage, compute environment for use of algorithms, user identity and access management, etc. Innovative biopharma companies will deploy modular technology platforms that provide these common capabilities for leverage across the entire digital medical device product portfolio. By using state-of-the-art technologies such as microservices, cloud computing, and open architectures, these companies will enable their digital product delivery teams to quickly connect new wearables and biosensors, spin up

new digital prototypes for rapid user feedback, and iterate on algorithms.

Organizing for Success

Delivering digital medical devices requires a new organizational approach, oriented around the digital product.

Strategy Checklist

- ✓ Agile, iterative business process optimized for learning
- ✓ Product-oriented team structures and governance
- ✓ Modular technology platforms that minimize technical work
- ✓ Early and frequent user feedback on product design
- ✓ Right-sized quality and regulatory
- ✓ Post-marketing support and legal manufacturing

Much like with drug therapies, organizational structures and governance need to focus on the product and long-range goals. Continuity in vision and accountability needs to be maintained over the market life of the product, in contrast to projects, where teams form, execute, and disband. Consideration must be given to single point of accountability, cross-discipline subject matter expertise, multi-year funding, and the differing needs of digital medical device product governance. Successful companies will borrow what works well from

drug development—such as the use of a product lead and multi-disciplinary teams—and hone their organizational approaches for the unique needs in digital.

What Comes Next?

Biopharma companies cannot afford to ignore the significant digital transformation underway in health care. The question is not about whether or when to enter the digital medical device space, but rather how to successfully enter and compete. Although competitive threats from digital players (e.g., Amazon, Apple, Google) loom large, biopharmas should remember the immense health, disease, and regulated product expertise that they bring to bear. Successful biopharmas will quickly find ways to duplicate or acquire digital expertise and combine it with their core competencies in disease diagnosis, prevention, and cure.

Is your organization ready to build a digital medical device portfolio? Advance your thinking and accelerate your time to market by contacting ResultWorks to help you define a strategy for success.

About the Author



Karen Hiser is an executive leader with 30 years of experience in rapid-growth, technology environments, serving clients in the pharmaceutical, biotech, health care and government sectors.

She has extensive experience managing multi-disciplinary teams in change-intensive environments. Karen is a strong leader with world-class communication skills and the tenacity to unify teams to achieve transformational goals. Her roles have spanned domains including mobile health, clinical, analytics, manufacturing, and supply chain, and have encompassed a cross-section of skills: strategy development, complex project management, business and workflow analysis, and informatics and technical architecture design.

About ResultWorks

ResultWorks is a professional services company offering strategy innovation, integrated business analysis, information transformation, and knowledge management consulting services for the life sciences industry. Results are achieved through skilled facilitation and exceptional management leadership. The focus of our client engagements is optimizing life sciences effectiveness across research, development, clinical, regulatory, and manufacturing.

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“The [ResultWorks] strategy will prove to be invaluable to guide our path forward and take on the world in the exciting digital device space!

—Global Business Leader, Top 10 Biopharm