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# Future-Proofing MedTech: Leveraging Integrated Digital Health for Unprecedented Growth

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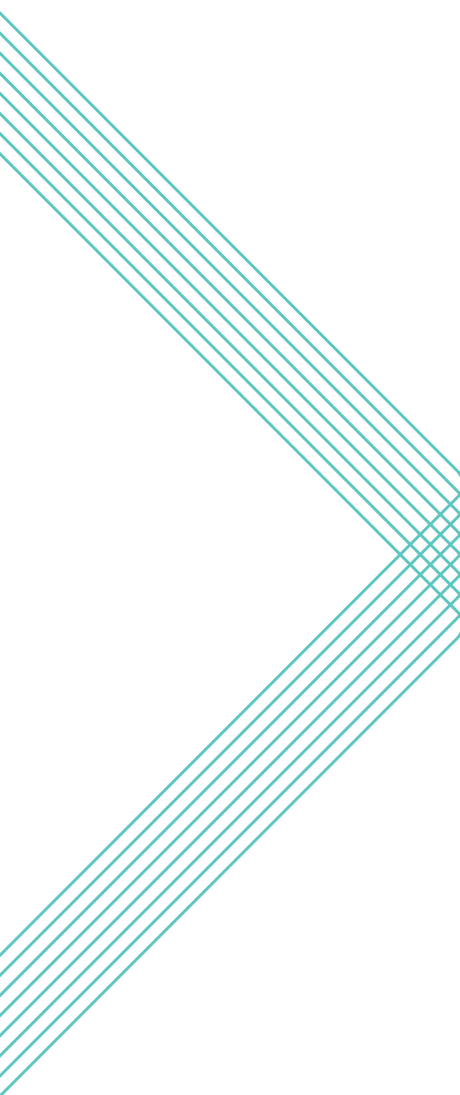


# Executive Summary

In this ongoing blog series, we delve into the dynamic MedTech industry, dissecting key trends, seizing opportunities, and tackling pressing challenges. Each article connects these insights with the power of the **digital thread**, revealing how it enables companies to innovate, optimize, improve patient outcomes, stay compliant and overcome challenges.

Building on previous discussions around digital health, this eBook delves deeper into what this transformative concept truly means for MedTech companies.

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## When examining industry growth, two distinct vectors emerge:

### Base Business:

This represents MedTech's traditional approach (e.g., manufacturing more hips, catheters, or diabetes tests). Currently a ~\$600-700 billion industry, it's expected to grow at a 6% CAGR due to macro trends like aging populations and increased disease states, projecting to approximately **1.2 trillion USD before 2035**.<sup>1</sup>

### Digital Health:

This involves integrating digital capabilities into products to elevate their function, enhance feedback loops, and ultimately improve patient outcomes. Currently a ~\$358 billion industry, it's projected to grow at an impressive 25% CAGR over the coming decade<sup>2</sup>. This industry will reach approximately **4.2 trillion USD by 2035**.

Together, these two vectors represent a potential combined global market worth well over **five trillion USD by 2035**, highlighting the increasingly blurry confluence of traditional MedTech and digital health.



<sup>1</sup> <https://www.mordorintelligence.com/industry-reports/global-medical-device-technologies-market-industry>

<sup>2</sup> <https://www.metatechinsights.com/industry-insights/digital-health-market-1015>

The race for market share in digital health is intensifying, with three primary categories of players poised to capitalize:



### Tech Giants:

Companies like Amazon, Apple, and Google are aggressively expanding their presence in this domain.



### Healthcare Providers:

Institutions such as hospitals, clinics, and pharmacy chains (e.g., CVS) are also innovating in the digital health arena.



### Life Sciences Industry:

The MedTech segment of Life Sciences is uniquely positioned to capitalize on this explosion by enhancing existing devices, seamlessly integrating them into clinical workflows, and developing new value-added services and data-driven solutions.

The following chart shows the confluence of Base MedTech and Digital Health. The clear reality is that the concept of MedTech is being redefined by this convergence.

#### GLOBAL MEDTECH MARKET PROJECTIONS (2024-2035)

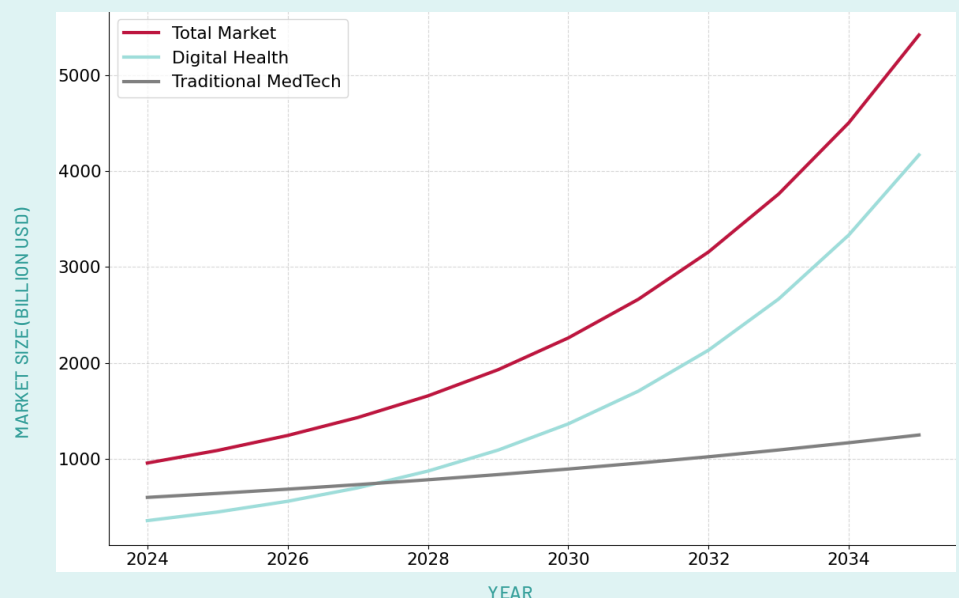


Figure 1: Estimated growth of MedTech (~6% CAGR) and Digital Health (~25% CAGR) and combination of both.

# Defining Digital Health

Digital Health can be defined simply as leveraging digital technology to provide a clinical benefit. Examples include connected medical devices to track a patient over time and provide greater insights to a physician. This will provide Real-World-Data back to the MedTech company enabling them to gain actual usage insights and allowing them to better improve their products over time. Another example might be a telehealth experience with a specialist (maybe in a distant geography that would otherwise have been impossible).

| TECHNOLOGY                             | DESCRIPTION                                                                                            |
|----------------------------------------|--------------------------------------------------------------------------------------------------------|
| Internet of Medical Things (IoMT)      | Network of connected medical devices that collect and exchange health data.                            |
| AI-Powered Devices                     | Devices that use artificial intelligence to analyze data and support clinical decisions.               |
| Software as a Medical Device (SaMD)    | Standalone software that performs medical functions without being part of a hardware device.           |
| Telemedicine/Telehealth Platforms      | Tools enabling remote clinical consultations and care delivery via digital channels.                   |
| Mobile Health (mHealth) Applications   | Health apps on smartphones for tracking, managing, or improving health.                                |
| Wearable Medical Devices               | Devices worn on the body that monitor health metrics like heart rate or activity.                      |
| Digital Therapeutics                   | Evidence-based software that delivers therapeutic interventions (e.g., for diabetes or mental health). |
| Electronic Health Records (EHR)        | Digital systems for storing and managing patient medical histories and data.                           |
| Blockchain Applications in Healthcare  | Use of blockchain to secure, share, and verify medical data and transactions.                          |
| Virtual/Augmented Reality Applications | Immersive technologies used for training, therapy, or patient engagement.                              |

Table 1: Evaluation of Digital Health Innovation

When working with clients, we ask executives what their plans are for digital health. Some of our clients are “all-in” and have been for several years, while others are reluctant due to the many technical challenges digital health brings.

The reluctance is understandable; there are many technical, safety, liability and business challenges that are introduced when connecting a device to the internet, which can be distracting for R&D and present a burden for clinics.

## Should a MedTech Company Invest in Digital Health?

In some categories of MedTech, digital health probably adds minimum clinical benefit and minimum competitive advantage, or the burden may be just too high whereas in other cases it may be necessary to survive against competitors. Each company needs to carefully weigh up the benefit vs. the burden.

The following framework might be a good starting point to analyze the benefits/risks associated with entering a digital health space:

|                                                                                    | CATEGORY                                       | QUESTION                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Strategic Alignment & Market Need              | Does this initiative align with our core business strategy and long-term vision?                                                                                                                                                                              |
|                                                                                    |                                                | Does it address a clear, unmet market need or pain point for patients, providers, or payers?                                                                                                                                                                  |
|                                                                                    |                                                | What is the competitive landscape?                                                                                                                                                                                                                            |
|                                                                                    |                                                | What is the potential market size and growth trajectory for this digital health solution?                                                                                                                                                                     |
|    | Clinical Value & Patient Impact                | Does this initiative genuinely improve patient outcomes, safety, or experience?                                                                                                                                                                               |
|                                                                                    |                                                | How will it integrate into existing clinical workflows without adding undue burden to healthcare professionals?                                                                                                                                               |
|                                                                                    |                                                | Is there a clear pathway for clinical validation or regulatory approval (e.g., FDA clearance/approval for SaMD, medical device data systems)?                                                                                                                 |
|   | Business Model & Financial Viability (ROI)     | What is the clear business model? (e.g., subscription fees, data monetization, increased device sales, reduced service costs, value-based care models).                                                                                                       |
|                                                                                    |                                                | What is the projected Return on Investment (ROI)?                                                                                                                                                                                                             |
|                                                                                    |                                                | What are the initial investment costs, ongoing operational costs, and potential revenue streams?                                                                                                                                                              |
|                                                                                    |                                                | How will this initiative affect our pricing strategy and existing product lines?                                                                                                                                                                              |
|  | Technical Feasibility & Integration            | Do we have the necessary technical capabilities in-house, or will we need strategic partnerships (e.g., AI expertise, cloud architecture, cybersecurity)?                                                                                                     |
|                                                                                    |                                                | Do we have a mature digital thread with the right capabilities necessary to support the technology, the product variants, integrated software/hardware and data collection mechanisms needed to support the device or devices on market? (more on this later) |
|                                                                                    |                                                | How easily can this digital health solution integrate with existing healthcare IT infrastructure (e.g., EHRs, hospital systems, other MedTech devices, personal health records)?                                                                              |
|                                                                                    |                                                | What is the data architecture plan for collection, storage, processing, and analysis?                                                                                                                                                                         |
|  | Regulatory Compliance, Data Security & Privacy | What are the relevant regulatory requirements and pathways (e.g., FDA, EU MDR, CE Mark, HIPAA, GDPR, state-specific regulations)?                                                                                                                             |
|                                                                                    |                                                | Is there a clear strategy for achieving and maintaining compliance?                                                                                                                                                                                           |
|                                                                                    |                                                | How will patient data be collected, stored, transmitted, and utilized securely?                                                                                                                                                                               |
|                                                                                    |                                                | How will patient privacy be protected?                                                                                                                                                                                                                        |
|  | Operational & Resource Capabilities            | Do we have internal talent (software engineers, data scientists, UX/UI designers, regulatory experts, clinical specialists) or will we need to hire or partner?                                                                                               |
|                                                                                    |                                                | What organizational changes or training will be required to support the new initiative?                                                                                                                                                                       |
|                                                                                    |                                                | Do we have a clear plan for ongoing support, maintenance, and future iterations of the digital health solution?                                                                                                                                               |
|  | Scalability & Future-Proofing                  | Can the solution scale to meet future demand and accommodate growth?                                                                                                                                                                                          |
|                                                                                    |                                                | How adaptable is the technology to future technological advancements (e.g., new sensors, AI algorithms) or evolving market needs/regulations?                                                                                                                 |
|                                                                                    |                                                | What is the long-term vision for this initiative, and how does it contribute to our company's sustained innovation?                                                                                                                                           |

Table 2: Evaluation of Digital Health Innovation

## Example Digital Health Case Study:

One of our clients, a top 10 global pharmaceutical and diagnostics company, sought to build an integrated **digital health ecosystem** around their blood diagnostic instruments, which are deployed in hospitals and clinics worldwide. These machines require a testing recipe, or “assay,” to learn how to detect new pathogens or antibodies. Historically, these updates were performed manually by field technicians during scheduled on-site visits.

As travel became hazardous during the COVID-19 pandemic, our client transitioned to fully remote assay releases.

This allowed them to push SARS-CoV-2 antibody updates over-the-air to their diagnostic machines across geographies, almost instantly reducing service costs while keeping both patients and staff safe.

After a failed initial implementation and the expenditure of tens of millions of dollars, the organization successfully reset its digital health strategy. Following this reset, we were engaged to develop a comprehensive strategy and build a scalable infrastructure. Today, the organization operates a robust platform with over 150,000 connected instruments spanning a diverse range of device types.

### The benefits have been substantial:

- ▶ **Remote Service:** A comprehensive remote monitoring and service capability saved significant costs in field-service fees while accelerating time to respond benefiting the health care facilities.
  - ▶ **Avoids Downtime:** Predictive maintenance of the devices reduced downtime risks, helping hospitals and clinics maintain volume and provide better/faster service to patients.
  - ▶ **Platform as an Added Business Line:** The success of the platform was so significant that the company is considering licensing the capability to other life sciences organizations.
  - ▶ **Closed Loop Quality:** Real-world-data and usage information fed upstream to the product development process solved immediate problems with remote sessions. This data also informed design decisions on the next generation of product. For example, the R&D team might assume a certain feature is utilized far more than in reality.
  - ▶ **Advances Medical Knowledge and Public Health:** The connected digital health infrastructure allowed the company to greatly accelerate and more accurately track new viruses and virus spread globally. It provided invaluable information to health authorities and put them on the forefront of treatment options.
- Further, the company was creative by providing financial incentives to enable connectivity. Instead of it being looked on as a risk, the model was flipped on its head to become a cost savings opportunity for the clinic. This resulted in a > 80 % healthcare facility connectivity compliance rate.

The bottom line: The platform provided substantial cost savings, new revenue models, and new innovation opportunities.

# How Does Digital Health Improve Patient Outcomes?

It’s exciting to think about the ways in which digital health can improve clinical outcomes. The following are publicly-cited additional examples of how MedTech companies have elevated the efficacy or safety of their devices:

| COMPANY NAME                                                                      | PRODUCT                                                                                                                                         | IMPROVEMENTS WITH DIGITAL HEALTH                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | FreeStyle Libre Continuous Glucose Monitoring (CGM) System <sup>3</sup>                                                                         | Digital health enables continuous, real-time glucose monitoring without routine finger sticks. Data is wirelessly transmitted to a smartphone app or reader, allowing patients and healthcare providers to view trends, patterns, and time-in-range. The system provides alerts for high/low glucose levels.                                                                                    |
|  | Cardiac Rhythm and Heart Failure Devices with Remote Monitoring (e.g., MyCareLink Heart™) Mobile App, CareLink Network) <sup>4</sup>            | Implantable cardiac devices (pacemakers, defibrillators) are paired with remote monitoring systems that wirelessly transmit data to clinics via mobile apps or home communicators. This allows for continuous surveillance of device function, cardiac rhythms, and patient physiological parameters from home. Clinicians receive alerts for critical events, enabling proactive intervention. |
|  | Philips IntelliSite Pathology Solution (Digital Pathology) with AI Integration (e.g., via partnership with Ibex Medical Analytics) <sup>5</sup> | This system digitizes traditional glass pathology slides into high-resolution images that can be viewed, analyzed, and shared digitally. Integration with AI algorithms assists pathologists in identifying areas of concern, quantifying features, and flagging potential discrepancies. It enables remote diagnosis and consultation.                                                         |

Table 3: Examples of Digital Health Improving Clinical Outcomes

# How Might a MedTech Company Generate New Forms of Revenue through Digital Health?

There are so many ways that a company might monetize digital health. The following table provides some ideas, related benefits, and tangible examples. When considering this content, it’s not hard to understand why the MedTech industry 10-year revenue potential jumps from \$1TN to over \$5TN.

| METHOD                                  | DESCRIPTION                                 | OTHER BENEFIT                                             | EXAMPLES                                                                                                                                                                                                         |
|-----------------------------------------|---------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SUBSCRIPTION MODELS                     | Generate recurring revenue                  | Access to software, platforms, data insights, or services | <ul style="list-style-type: none"><li>▪ <b>RPM platforms:</b> Monthly fees per patient</li><li>▪ <b>SaMD:</b> Monthly or annual licensing</li><li>▪ <b>Digital Therapeutics:</b> Per-treatment billing</li></ul> |
| VALUE-ADDED DEVICE SALES & MARKET SHARE | Digital features enhance core device appeal | Boost sales, differentiate products, build loyalty        | <ul style="list-style-type: none"><li>▪ <b>Smart insulin pen:</b> App improves adherence and drives sales</li><li>▪ <b>Connected surgical robots:</b> Data analytics boosts repeat purchases</li></ul>           |

<sup>3</sup> <https://provider.freestyle.abbott/ca-en/proven-outcomes.html>  
<sup>4</sup> <https://www.medtronic.com/ca-en/healthcare-professionals/products/cardiac-rhythm/managing-patients/improved-outcomes.html>  
<sup>5</sup> <https://www.philips.com/a-w/about/news/archive/standard/news/press/2025/philips-and-ibex-expand-partnership-to-enhance-ai-enabled-pathology-workflows-for-better-patient-care.html>

| METHOD                                                                | DESCRIPTION                                                                                                       | OTHER BENEFIT                                                                                                  | EXAMPLES                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GEOGRAPHIC MARKET EXPANSION                                           | Digital tools overcome access barriers                                                                            | Enter new markets or deliver services remotely<br><br>Help serve patients with otherwise unmet clinical access | <ul style="list-style-type: none"> <li>▪ <b>Telehealth:</b> Consultations in rural/international areas</li> <li>▪ <b>Cloud-based diagnostics:</b> Reach global clinics without physical presence</li> <li>▪ <b>Remote therapeutic devices:</b> Perform remote robotic surgeries in hard-to-reach locations</li> </ul>                       |
| DIGITAL CLINICAL WORKFLOW INTEGRATION SERVICES                        | Monetize seamless integration into provider workflows                                                             | Enhance efficiency, patient management, care coordination                                                      | <ul style="list-style-type: none"> <li>▪ <b>EHR integration:</b> Push device data directly to clinical systems</li> <li>▪ <b>Telehealth platforms:</b> Tailored for hospital system use</li> <li>▪ <b>Planning:</b> Combine diagnostics and patient profiles with personalized treatment plans for patients</li> </ul>                      |
| REAL-WORLD DATA (RWD) MONETIZATION & INSIGHTS                         | Commercialize anonymized RWD from digital platforms                                                               | Generate new IP from derived insights or algorithms                                                            | <ul style="list-style-type: none"> <li>▪ <b>IP Licensing:</b> License de-identified patient data</li> <li>▪ <b>AI/Algorithm Licensing:</b> Develop/license AI algorithms (SaMD) from datasets</li> </ul>                                                                                                                                    |
| OUTCOME-BASED / VALUE-BASED PAYMENTS (A MACRO TREND IN AND OF ITSELF) | Revenue tied to specific clinical outcomes                                                                        | Payments based on cost savings or quality improvements                                                         | <ul style="list-style-type: none"> <li>▪ <b>Chronic disease platform:</b> Bonus for reduced A1C (Blood sugar)</li> <li>▪ <b>Heart failure platform:</b> Payment linked to reduced readmissions</li> </ul>                                                                                                                                   |
| HARDWARE-AS-A-SERVICE (HAAS) / DEVICE-AS-A-SERVICE (DAAS)             | Bundle device, software, service into subscription                                                                | Shifts customer from CapEx to OpEx paying smaller fees over time vs. large capital outlay upfront              | <ul style="list-style-type: none"> <li>▪ <b>Diagnostic scanner:</b> Monthly fee for device, software, maintenance</li> <li>▪ <b>Surgical robot:</b> Leased with digital service packages</li> </ul>                                                                                                                                         |
| PROFESSIONAL & IMPLEMENTATION SERVICES                                | Provide expert consulting for digital solution adoption                                                           | Offer integration, customization, ongoing support to clients                                                   | <ul style="list-style-type: none"> <li>▪ <b>IoMT Consulting:</b> Help hospitals integrate IoMT devices into EHRs; Consult on optimizing clinical workflows with new digital tools</li> </ul>                                                                                                                                                |
| DIGITAL EDUCATION & TRAINING PROGRAMS                                 | Monetize specialized training or certification-                                                                   | Focus on product use, data interpretation, digital care practices                                              | <ul style="list-style-type: none"> <li>▪ <b>Online modules for clinicians:</b> New AI diagnostic tools</li> <li>▪ <b>Training for IT staff:</b> Managing connected medical devices</li> </ul>                                                                                                                                               |
| API & PLATFORM LICENSING                                              | License access to proprietary APIs or platforms                                                                   | Allows third-party developers to build complementary solutions                                                 | <ul style="list-style-type: none"> <li>▪ <b>Data Exchanges:</b> License secure data exchange API to other health tech firms</li> <li>▪ <b>Development Toolkits:</b> Offer developer toolkit for building on MedTech platform</li> <li>▪ <b>Platform Licensing:</b> License IoMT platform capabilities to other MedTech companies</li> </ul> |
| "FREEMIUM" MODELS                                                     | Offer basic app features for free to attract users and charge for premium features, analytics, or personalization |                                                                                                                | <ul style="list-style-type: none"> <li>▪ <b>Free App:</b> Free medication reminder app</li> <li>▪ <b>Paid Add-On:</b> Upgrade for coaching/provider integration</li> <li>▪ <b>Basic RPM dashboard:</b> Paid tiers for advanced insights</li> </ul>                                                                                          |

Table 4: Monetizing Digital Health Capabilities

## Relevance to the Digital Thread

Venturing into digital health isn't a free pass to success; it presents a formidable challenge for MedTech companies. The ability to safely deliver a digital health system will be directly proportional to a MedTech company's digital thread maturity, an integrated framework for managing product data and processes across the entire lifecycle.

Without robust, integrated foundational systems – including Application Lifecycle Management (ALM), Product Lifecycle Management (PLM), Enterprise Resource Planning (ERP), Manufacturing Execution Systems (MES), Field Asset Management and IoMT Platforms and EHR integration – achieving success in this domain is incredibly difficult, if not impossible.

We have worked with many MedTech companies, developing strategies for implementing digital thread platforms. For some of these companies, despite their immature digital thread foundations, they have ventured prematurely and aggressively into the digital health market. The resulting struggle is not only obvious but often proves gravely concerning.

For instance, the sheer difficulty of accurately tracking and managing different product configurations including software variants, coupled with a lack of integrated change control, poor design transfer mechanisms, and high latency (if not absent) closed loop mechanisms, often leads to compliance risks, FDA Form 483s, warning letters, costly rework, and significant delays.

Having developed a digital thread strategy for a large MedTech company, it was clear they had been lured into digital health without first building the requisite digital thread for their devices to stay compliant and safe, let alone secure. They lacked configuration control, so it was nearly impossible to trace which HW/SW combination Device Master Record correlated to specific devices in the field. This rush to riches approach is not wise.

The following table is intended to help navigate this world. First, we consider the business outcomes we seek to resolve. Next, we look at the capabilities we should enable. Third, we determine the right type of tool to enable said capability. And, finally, we document the resulting impact to digital health.

| BUSINESS OUTCOMES SOUGHT                                                                                                                                                                                                             | ENABLING CAPABILITIES                                                                                                                                                                                                                                 | TOOLING TYPE        | IMPACT TO DIGITAL HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PRODUCT DEVELOPMENT OF DIGITAL HEALTH CAPABLE PLATFORMS                                                                                                                                                                              |                                                                                                                                                                                                                                                       |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <ul style="list-style-type: none"><li>Faster time-to-market</li><li>Improved product quality - regulatory compliance (FDA, MDR)</li><li>Reduced R&amp;D costs</li><li>Better clinical outcomes</li><li>Better traceability</li></ul> | <ul style="list-style-type: none"><li>Holistic system architecture (HW/SW/Service)</li><li>Requirements management</li><li>Risk management</li><li>Test management</li><li>Interface definition for complex systems (e.g., Device-to-Cloud)</li></ul> | Systems Engineering | <ul style="list-style-type: none"><li>Help ensure robust &amp; compliant development of integrated digital health solutions and products.</li><li>Critical for architecting a solution that interfaces with clinical workflows and provides interoperability for EHR integration and data exchange standards. e.g. incorporate FHIR requirements.</li><li>Foundation for managing complex systems that incorporate AI and connected devices. Increased font size to match subsequent rows</li></ul> |

| BUSINESS OUTCOMES SOUGHT                                                                                                                                                                                                                                      | ENABLING CAPABILITIES                                                                                                                                                                                                                                                                                                                                                                                                                                                       | TOOLING TYPE                                                                                                                  | IMPACT TO DIGITAL HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PRODUCT DEVELOPMENT OF DIGITAL HEALTH CAPABLE PLATFORMS</b>                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <ul style="list-style-type: none"> <li>Reduced development cycles</li> <li>Higher software quality</li> <li>Enhanced traceability for SaMD</li> <li>Regulatory compliance</li> <li>Improved cybersecurity</li> </ul>                                          | <ul style="list-style-type: none"> <li>Software requirements management</li> <li>Version control &amp; configuration management (SaMD, AI models)</li> <li>Defect tracking &amp; testing</li> <li>Release management for software (including OTA updates)</li> </ul>                                                                                                                                                                                                        | ALM (Application Lifecycle Management)                                                                                        | <ul style="list-style-type: none"> <li>Enables Agile &amp; Compliant development of Digital Health applications and SaMD.</li> <li>Facilitates secure and controlled Over-the-Air (OTA) software updates for connected medical devices.</li> <li>Crucial for managing the lifecycle and versioning of AI algorithms and their datasets for SaMD.</li> </ul>                                                                                                                              |
| <ul style="list-style-type: none"> <li>Faster hardware design &amp; prototyping</li> <li>Cost reduction in manufacturing</li> <li>Improved device aesthetics &amp; ergonomics</li> </ul>                                                                      | <ul style="list-style-type: none"> <li>Design of physical device components</li> <li>Model Based Enterprise (MBE) – use the model for downstream consumption</li> <li>Simulation &amp; analysis</li> <li>Data exchange with manufacturing tools</li> <li>Digital Twin of IoMT Enabled Product</li> </ul>                                                                                                                                                                    | <ul style="list-style-type: none"> <li>CAD (Computer-Aided Design)</li> <li>Integrated MBE Protocols (e.g. AP 242)</li> </ul> | <ul style="list-style-type: none"> <li>Supports the physical design and integration of IoMT devices and wearables, ensuring optimal form factor for patient use and robust sensor integration for data capture.</li> <li>Enables development of hardware compatible with digital health connectivity standards.</li> <li>Enables digital twinning of the medical device for on-going active monitoring and closed loop feedback.</li> </ul>                                              |
| <ul style="list-style-type: none"> <li>Streamlined regulatory submissions</li> <li>Efficient product variant management (HW/SW combos)</li> <li>Improved post market surveillance</li> <li>Reduced compliance risk</li> <li>Accelerated innovation</li> </ul> | <ul style="list-style-type: none"> <li>Enablement of product platform thinking vs. individual products</li> <li>Management of product data across lifecycle</li> <li>Change control &amp; traceability (from design to service)</li> <li>Configuration &amp; variant management (esp. for SaMD &amp; connected products)</li> <li>Design History File (DHF)</li> <li>Device Master Record (DMR) Generation</li> <li>Quality issues (CAPA, Complaints, NCR, etc.)</li> </ul> | <p>PLM (Product Lifecycle Management)</p> <p>With integrated QMS (Quality Management Systems Functionality)</p>               | <ul style="list-style-type: none"> <li>Provides the central backbone for managing the entire digital health product definition, including software, hardware, and service components.</li> <li>Helps ensure end-to-end traceability essential for medical devices, diagnostics, SaMD regulatory compliance and post-market monitoring of AI models.</li> <li>Critical for managing the numerous product variants arising from software/hardware combinations and OTA updates.</li> </ul> |

| BUSINESS OUTCOMES SOUGHT                                                                                                                                                                                                                                           | ENABLING CAPABILITIES                                                                                                                                                                                                 | TOOLING TYPE                                                                     | IMPACT TO DIGITAL HEALTH                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>MANUFACTURING AND SUPPLY CHAIN OF DIGITAL HEALTH PLATFORMS</b>                                                                                                                                                                                                  |                                                                                                                                                                                                                       |                                                                                  |                                                                                                                                                                                                                                                                                                                                                                           |
| <ul style="list-style-type: none"> <li>Improved manufacturing efficiency</li> <li>Higher product quality</li> <li>Real-time production control</li> <li>Enhanced traceability &amp; compliance (eDHR)</li> </ul>                                                   | <ul style="list-style-type: none"> <li>Work order management &amp; scheduling</li> <li>Quality data collection - Electronic Device History Records (eDHR)</li> <li>Process validation &amp; control</li> </ul>        | MES (Manufacturing Execution System)                                             | <ul style="list-style-type: none"> <li>Helps ensure the manufacturing quality and traceability of connected medical devices (IoMT), which is foundational for reliable data collection and digital health functionality.</li> <li>Contributes to cybersecurity by ensuring secure device provisioning during manufacturing.</li> </ul>                                    |
| <ul style="list-style-type: none"> <li>Optimized resource allocation</li> <li>Cost savings &amp; financial control</li> <li>Streamlined business processes</li> <li>Improved supply chain management</li> </ul>                                                    | <ul style="list-style-type: none"> <li>Financial management - procurement &amp; inventory management</li> <li>Order processing &amp; Customer Relationship Management (CRM)</li> </ul>                                | ERP (Enterprise Resource Planning)<br><br>CRM (Customer Relationship Management) | <ul style="list-style-type: none"> <li>Manages the commercial aspects of digital health offerings, including subscription models, billing for digital services, inventory of connected devices, and the supply chain for hardware components.</li> <li>Supports the overall business infrastructure necessary for delivering digital health services at scale.</li> </ul> |
| <b>FIELD SERVICE AND ON MARKET/POST MARKET OF DIGITAL HEALTH PLATFORMS</b>                                                                                                                                                                                         |                                                                                                                                                                                                                       |                                                                                  |                                                                                                                                                                                                                                                                                                                                                                           |
| <ul style="list-style-type: none"> <li>Continuous patient monitoring</li> <li>Proactive intervention</li> <li>Enhanced clinical decision support</li> <li>New revenue streams (service models)</li> <li>Closed-loop real world evidence/data collection</li> </ul> | <ul style="list-style-type: none"> <li>Secure data collection from devices</li> <li>Remote monitoring &amp; alerts</li> <li>Connectivity &amp; interoperability with health ecosystem</li> <li>OTA Updates</li> </ul> | IoMT (Internet of Medical Things)<br><br>EHR Integration                         | <ul style="list-style-type: none"> <li>Directly enables the core of connected health, facilitating real-time patient data flow from medical devices.</li> <li>Supports the integration of device-generated data into EHRs and clinical decision support systems.</li> <li>Foundation for remote patient monitoring and virtual care delivery.</li> </ul>                  |
| <ul style="list-style-type: none"> <li>Improved user adoption</li> <li>Enhanced compliance</li> <li>Reduced training costs</li> <li>Better patient/clinician experience</li> </ul>                                                                                 | <ul style="list-style-type: none"> <li>Creation, storage, &amp; delivery of documentation (user manuals, training, release notes, IFU, regulatory content)</li> <li>Version control for content</li> </ul>            | CMS (Content Management System)                                                  | <ul style="list-style-type: none"> <li>Helps ensure patients and clinicians have access to accurate, up-to-date, and compliant information on how to use digital health devices, SaMD, and interpret data.</li> <li>Critical for supporting remote users and ensuring proper use of connected technologies and OTA updates.</li> </ul>                                    |

| BUSINESS OUTCOMES SOUGHT                                                                                                                                                                                                      | ENABLING CAPABILITIES                                                                                                                                                                                                   | TOOLING TYPE                                                                                                                               | IMPACT TO DIGITAL HEALTH                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>FIELD SERVICE AND ON MARKET/POST MARKET OF DIGITAL HEALTH PLATFORMS</b>                                                                                                                                                    |                                                                                                                                                                                                                         |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <ul style="list-style-type: none"> <li>• Reduced equipment downtime</li> <li>• Extended asset life</li> <li>• Optimized maintenance costs</li> <li>• Improved equipment reliability</li> </ul>                                | <ul style="list-style-type: none"> <li>• Preventive &amp; predictive maintenance scheduling</li> <li>• Work order management for assets</li> <li>• Spare parts management</li> </ul>                                    | <p>CMMS (Computerized Maintenance Management System)</p> <p>Note: CMMS can apply to both manufacturing equipment and on-market devices</p> | <ul style="list-style-type: none"> <li>• Helps guarantee the continuous uptime and reliability of physical medical devices, especially IoMT devices and the IT infrastructure supporting digital health services.</li> <li>• Similarly applicable to plant equipment.</li> <li>• Helps ensure uninterrupted data flow for clinical insights and patient care.</li> </ul>                                                                                                                            |
| <ul style="list-style-type: none"> <li>• Faster service response - increased customer satisfaction</li> <li>• Reduced service costs</li> <li>• Optimized spare parts inventory</li> </ul>                                     | <ul style="list-style-type: none"> <li>• Field service management</li> <li>• Repair &amp; returns management</li> <li>• Service parts logistics</li> </ul>                                                              | <p>SERVICE LOGISTICS (Service Logistics Management)</p>                                                                                    | <ul style="list-style-type: none"> <li>• Essential for post-market support of physical connected devices, minimizing downtime and ensuring continuity of digital health services.</li> <li>• Facilitates efficient distribution of replacement parts for IoMT devices, supporting the ongoing integrity of the digital health ecosystem.</li> </ul>                                                                                                                                                 |
| <ul style="list-style-type: none"> <li>• Increased revenue from value-added services</li> <li>• Improved patient outcomes; stronger competitive edge</li> <li>• Enhanced coordinated care; further differentiation</li> </ul> | <ul style="list-style-type: none"> <li>• Autonomous decision making and action execution</li> <li>• Intelligent coordination with medical devices and EHR data</li> <li>• Continuous learning and adaptation</li> </ul> | <p><u><a href="#">Agentic AI Platform</a></u></p>                                                                                          | <ul style="list-style-type: none"> <li>• Enhances real-time patient and device monitoring with autonomous, predictive insights.</li> <li>• Delivers precise, actionable recommendations directly to clinical staff or patients.</li> <li>• Automates aspects of care pathways for improved efficiency and outcomes</li> <li>• Strengthens safety, trustworthiness, and regulatory compliance through explainable AI, robust validation, and adherence to evolving AI/ML SaMD frameworks.</li> </ul> |

Table 5: Digital Thread Capabilities that Support Digital Health Platforms

<sup>6</sup> <https://www.darpa.mil/research/programs/explainable-artificial-intelligence#:~:text=Enable%20human%20users%20to%20understand,generation%20of%20artificially%20intelligent%20partners.>

Developing a digital thread strategy to support all these enabling capabilities for a digital health program is essential. Rome was not built in a day, and not all these components are necessary to begin assessing the increased revenues that might be awarded because of digital health. But, a digital thread program is ground-zero essential for any MedTech company wanting to enter this space and do it in a safe and compliant manner that drives business outcomes.

## **CONCLUSION:**

Digital health represents a transformative opportunity, offering up to 5x revenue expansion compared to traditional MedTech. By 2035, the digital health market is projected to exceed \$5 trillion, far surpassing the estimated \$1 trillion for base MedTech device sales. This growth unlocks entirely new revenue streams that extend well beyond traditional lifecycle services.

MedTech companies are uniquely positioned to capture this value, but only if they invest in the foundational capabilities required to scale. Central to this is building a robust digital thread that enables digital twins of active devices in the field. Achieving this demands disciplined execution across systems engineering, change management, and configuration management. Start with a digital thread strategy that challenges traditional thinking and use it as an opportunity to energize the organization.

Interested in elevating your MedTech to access the exploding Digital Health market and building a robust Digital Thread ecosystem to support it?

**Scan the QR code for our Digital Value Accelerator and Digital Health Maturity Checklist.**



# About Kalypso

Kalypso, a Rockwell Automation business, helps companies bring digital solutions to product problems. Whether it's weaving a digital thread from product ideation all the way through manufacturing and service, or advancing operations from automation to autonomy, Kalypso specializes in improving what's being made and how it's made. Kalypso serves the largest names in the discrete, hybrid and process industries, around the world. Visit our website to learn more about Kalypso and our services.

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