



THE FUTURE OF MEDTECH: WHY DIGITAL THREAD MATURITY MATTERS NOW

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Digital Thread Maturity in MedTech

Are You Ready for What's Next?

Is your organization prepared to navigate MedTech's rapid changes driven by AI, digital health, disruption, regulation, and complexity?

Connected cardiac implants, continuous glucose monitors, smart infusion pumps, and surgical robots are revolutionizing healthcare by enabling advanced diagnostics, real-time monitoring, and automated procedures. This innovation, increasingly powered by software and connectivity, enables superior patient outcomes but introduces greater complexity throughout the product lifecycle. Increased regulator, customer, and clinic expectations add further complexity.

As a result, teams now face greater coordination challenges as they bring new and updated devices to market. Unfortunately, disconnected data and siloed teams impede efficiency, impact quality, and complicate compliance even for less complex products. Yet, Top Performing MedTech companies are overcoming these challenges by investing in digital thread strategies that connect people, processes, and data to drive agility, resilience, and innovation.

About the Research

This study surveyed 206 MedTech professionals from diverse functions, including engineering, R&D, manufacturing, quality, regulatory affairs, and IT. The results highlight what differentiates Top Performers, especially around digital thread maturity. This report outlines executive pathways to advance digital thread maturity, empowering organizations to respond to new industry trends in AI, digital health, disruption, regulation, and increasing complexity.





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Executive Summary

MedTech Growth

Digital transformation is reshaping MedTech as Top Performing organizations find that digital thread maturity drives growth and competitiveness. With industry projections of 5-7% CAGR¹ over the next five years, MedTech companies need to be prepared to capitalize on this growth.

Complexity Slows Performance

With opportunity comes complexity. Devices increasingly integrate hardware, software, and data-driven services. Evolving regulations covering cybersecurity, data privacy, Software as a Medical Device (SaMD), and AI increase risk. Executives must also manage supply chain volatility, rising costs, and financial pressures. In this environment, effective product data management, collaboration, and

integrated lifecycle processes can differentiate performance. Still, 99% of MedTech organizations face major barriers like silos, limited traceability, manual workflows, and poor collaboration. These challenges delay time to market, increase compliance risk, raise costs, and limit innovation.

How to Overcome Challenges

To identify best practices, this research examines Top Performers, the top 20% excelling on time to market, quality, innovation, and profitability, and analyzes what sets them apart.

About This Report

This report explores:

- Challenges holding MedTech companies back
- How a digital thread helps to overcome them
- The digital thread's impact on responding to disruption, AI adoption, and digital health
- Best practices for implementing a digital thread
- The state of digital thread maturity

Top Performers are **nine times more likely** to have a more mature digital thread.



Key Findings

- **Digital thread adoption sets leaders apart.** 76% of Top Performers have a strategy, 46% more likely than Others.
- **Digital thread maturity drives performance.** Top Performers are nine times more likely to have a more mature digital thread.
- **Connected data increases agility.** 81% of organizations with a mature digital thread are well or fully prepared to respond to disruption.
- **AI success requires a strong data foundation.** While 97% plan to deploy AI, Top Performers prioritize connecting lifecycle data via a digital thread to support adoption.
- **Digital health success aligns with digital thread maturity.** 88% of companies with a digital thread strategy have made digital health central to their business.
- **Measurable business impact since starting their digital thread journey:**
 - 28% more on-time product launches
 - 27% more product introductions
 - 30% faster design transfer
 - 24% less ramp-up time
 - 24% less time on compliance documentation

The MedTech Business Environment

Growth Opportunity

The global MedTech industry is expected to see significant growth, with forecasts estimating a compound annual growth rate (CAGR) of 5-7%² over the next five years, reaching \$826 billion in 2030.³ Much of this growth is due to increasing demand from factors such as an aging population⁴ and an increase in chronic diseases,⁵ combined with a rise in novel treatments and therapy options.⁶

At the same time, the industry is undergoing a fundamental transformation as digital technologies reshape how care is delivered, monitored, and optimized. This delivers greater personalization, better patient outcomes, and improved operational efficiency. Over the next decade, the integration of artificial intelligence (AI), digital health solutions, and other technologies will further transform healthcare and help drive growth.⁷

Business Pressures

Growth and innovation are accompanied by increasing complexity. As medical devices become more sophisticated, integrating hardware, software, connectivity, robotics, and data-driven services, regulatory requirements also evolve. Regulators are responding to new technologies, cybersecurity risks, and the expansion of digital health solutions, adding further layers of complexity. Product development teams must manage greater technical, regulatory, and operational challenges throughout the product lifecycle. Meanwhile, MedTech companies face market

volatility and intensifying economic pressures. Increasing material, labor, and energy costs, combined with shifting pricing and reimbursement dynamics, affect profitability. Global supply chains also face disruption from geopolitical shifts, regionalization, and changing trade and sourcing policies, creating uncertainty even for established product lines.

Keys to Success

Navigating the evolving MedTech landscape requires new approaches to managing data, coordinating cross-functional teams, and connecting information from design through manufacturing, quality, and post-market activities. Agility is critical for responding to quality issues, adjusting production, adopting technology, ensuring compliance, and adapting to market dynamics.

To provide a comprehensive understanding of how to address these challenges, this report first examines challenges that make it hard to respond to ongoing industry pressures, followed by an investigation into how leading companies use a digital thread to be more agile, support advances in AI and digital health, and maintain strong performance in a complex, volatile market. Finally, the report examines how to mature and extend the digital thread maturity across the enterprise.



The **digital thread** ties product information,

decisions, and history together in a structured, integrated way that captures product innovation and knowledge throughout the product/device lifecycle. It establishes traceability early in the front end of innovation through development, manufacturing, service, and post-market surveillance.

*Navigating the evolving MedTech landscape requires **new approaches** to managing data, coordinating cross-functional teams, and connecting information.*

What's Holding MedTech Companies Back

Numerous Challenges

MedTech companies face many challenges that hold them back (see graph showing the top five). An overwhelming 99% report major challenges hindering success.

Siloed Data

The most cited challenge is siloed data and poor traceability. Data is often scattered across disconnected systems, documents, and spreadsheets, limiting visibility across design, manufacturing, quality, and regulatory functions. Without end-to-end traceability, assessing the impact of changes, nonconformances, or adverse events becomes difficult.

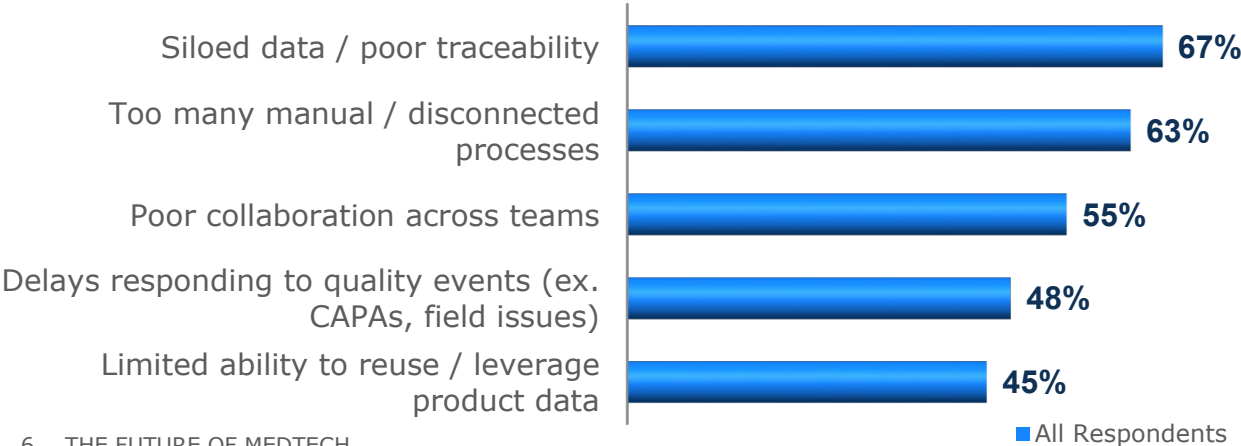
Manual Processes

Disconnected workflows compound the problem. Many teams manually transfer data between systems or departments, increasing the risk of errors and delays.

Ineffective Collaboration

Poor collaboration remains a major obstacle, impacting design transfer, change management, quality event resolution, and more. Many struggle to respond quickly to quality events. Limited product data reuse persists so teams waste time recreating and revalidating it, reducing productivity and increasing risk.

BIGGEST CHALLENGES LIMITING TEAMS' SUCCESS



BUSINESS IMPACTS OF THESE CHALLENGES



The Business Impact

These challenges have a substantial business impact (see graph). Delays are most common, affecting time to market and delaying the return on development investments. Added costs and margin pressure result from manual work, rework, and inefficiencies. Over half of respondents report increased compliance and audit risk—a critical concern in this regulated industry—largely due to poor traceability. Product quality and safety also suffer, adding more risk and potential downstream costs.

Nearly half cite lost innovation opportunities, a repercussion when resources must be shifted from value-added activities, illustrating a critical barrier to growth.

These findings highlight the significant business impact of lacking the operational foundation to thrive today. A connected, data-driven approach to manage the product lifecycle can enable better collaboration, traceability, and enterprise-wide decision-making.

Next, let's examine how Top Performing companies overcome these challenges.

Identifying Top Performers

How Top Performers Were Defined

Tech-Clarity identified Top Performing companies as the top 20% of survey respondents who outperform peers on key metrics that indicate greater success in bringing new devices and products to market. These leaders surpass competitors with a superior ability to:

- Meet time to market goals
- Design and/or produce high-quality products
- Develop innovative products
- Meet profit margin goals

Companies rating themselves highest were classified as Top Performers. Excelling in these areas reflects stronger overall business performance and indicates these organizations have the right combination of processes, technologies, and organizational alignment to succeed in a complex, regulated, and competitive environment. We then analyzed what Top Performers do differently to identify success factors.

Top Performers’ Advantage

Top Performers stand out through more effective, better-integrated product development and lifecycle practices. They are 30% more likely than peers to rate their data reuse processes across design, manufacturing, and quality as ‘very’ or ‘extremely’ effective. This helps explain why they are 61% more likely to rate their process for leveraging engineering data to efficiently ramp up production as highly effective and 43% more likely to rate their design transfer processes as working well.

These results highlight the benefits of stronger cross-functional coordination, better access to trusted data, and more mature approaches to managing product and process information across the lifecycle. Next, we will examine Top Performers’ practices to understand their success.

TOP PERFORMERS’ PROCESS EFFECTIVENESS ADVANTAGE

METRIC	PERCENT MORE LIKELY TO BE HIGHLY EFFECTIVE*
Compliance audit readiness	25%
Reusing data across design, manufacturing, and quality	30%
Responding quickly to quality events	23%
Leveraging engineering information to ramp up production efficiently	61%
Design transfer efficiency	43%

** Highly effective = Rated ‘Very’ or ‘Extremely’ effective*

Top Performers are **61% more likely** to rate their process for leveraging engineering data to efficiently ramp up production as highly effective, and 43% more likely to rate their design transfer processes as working well.

Strategies to Overcome Challenges

Digital Thread

The top strategy to overcome these challenges is implementing a digital thread. Among Top Performers, 76% have a digital thread strategy, 46% more likely than Others. They are also 88% more likely to have had this strategy for four or more years, giving them more time to realize benefits. By connecting data, processes, and stakeholders across the lifecycle, a digital thread addresses siloed data. It also improves visibility and traceability, enabling streamlined processes.

Empowering People

The digital thread lays the foundation for other strategies. To address delays and errors from poor collaboration, improving cross-functional teamwork is critical. The digital thread connects teams, streamlining access to data and allowing them to work from a consolidated view of product information. MedTech companies also seek to enhance decision-making through AI, analytics, simulation, and model-based approaches, although many are not there yet. Better decision-making is the top reported benefit of a digital thread, cited by 75%.

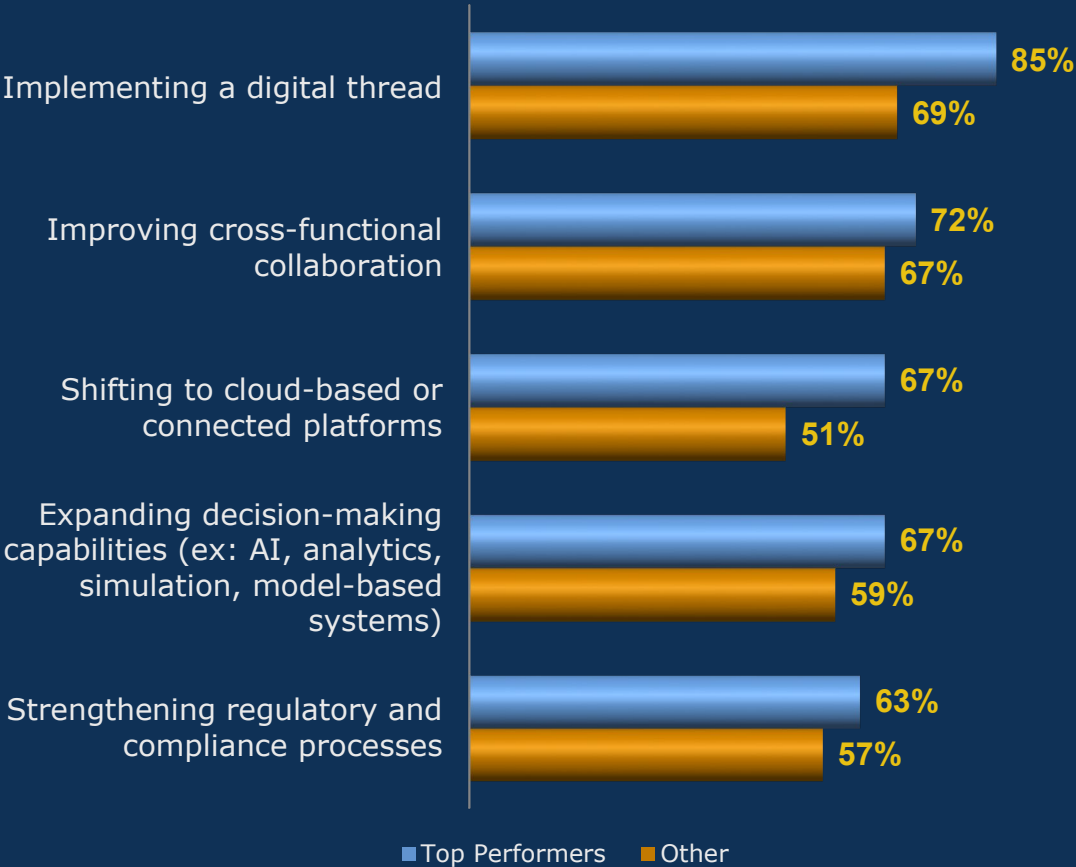
Right Technology

The right technology enables these strategies. Top Performers, in particular, are shifting toward cloud-based or connected platforms that provide the infrastructure to connect data. This doesn't mean existing effective solutions need to be replaced, but a platform that connects them will help.

Supporting Compliance

Strengthening regulatory and compliance processes is also critical for MedTech. The digital thread transforms compliance from a reactive, documentation-heavy task into a proactive, data-driven process. End-to-end traceability links and time-stamps every requirement, design decision, Design History File (DHF), Design Master Record (DMR), test result, change, and validation needed for regulatory compliance. Additionally, it supports post-market surveillance and enables rapid recall management by quickly identifying affected devices, facilitating targeted recalls, and improving patient safety. As post-market requirements evolve, organizations must rapidly find and assess data across the value chain to meet increasingly aggressive regulatory response deadlines.

ACTIONS TO OVERCOME CHALLENGES



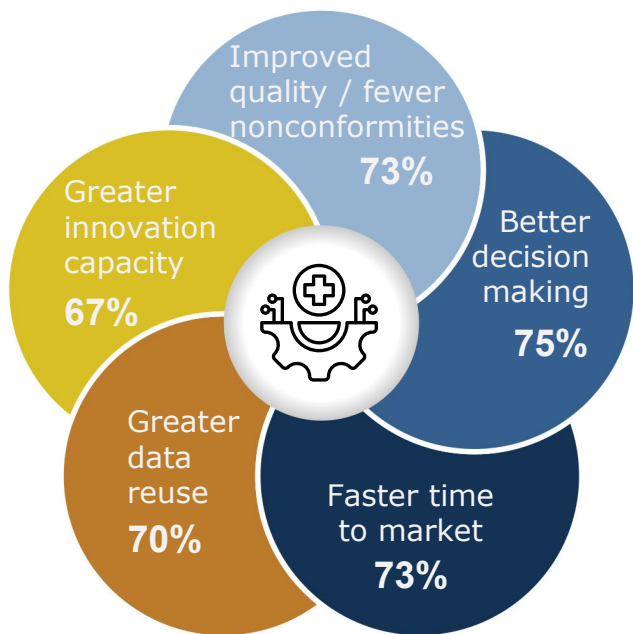
Top Performers are **88% more likely** than their peers to have had a digital thread strategy in place for four or more years.

The Business Value of a Digital Thread

Significant Benefit

An overwhelming 98% of companies with a digital thread report benefits, highlighting its advantages. MedTech companies note improvements in compliance, quality, efficiency, and innovation. The graph shows top reported benefits, and the table details percent improvements since implementing a digital thread. Respondents reported only on areas relevant to their roles.

HOW THE DIGITAL THREAD HAS HELPED



Better Decisions

Connected data enables faster, more informed decisions and greater adaptability to changing requirements or market conditions. With real-time visibility and a trusted source of product information, teams can have more confidence decisions are based on accurate information, ultimately improving device performance and patient outcomes.

Quality

Companies report improved product quality and fewer nonconformities. Standardized, connected workflows and data reuse across engineering, manufacturing, and quality reduce variability and lower the risk of errors, especially when teams don't work with outdated or incomplete data.

Efficiency and Innovation

Greater data accessibility eliminates time wasted searching for information. Traceability helps teams work more efficiently such as quickly assessing the impact of changes, contributing to measurable gains—including 28% more on-time launches and 27% more product introductions. Reuse of engineering data also accelerates downstream processes, reducing design transfer time by 30% and ramp-up time by 24%.

Regulatory Compliance

The digital thread enables automation that improves compliance efficiency, cutting

documentation preparation time by 24% and regulatory submission preparation time by 27%. End-to-end traceability also supports faster CAPA closure by helping to identify a root-cause faster.

Next, we will explore what drives adoption.

IMPROVEMENT SINCE IMPLEMENTING A DIGITAL THREAD

METRIC	PERCENTAGE IMPROVEMENT
Time preparing compliance documentation	24% less time
Time preparing for submissions	27% less time
Average time to close a CAPA	28% less time
Number of nonconformities, audit findings, or recalls	26% reduction
Number of on-time product launches	28% increase
Number of new product introductions per year	27% increase
Reduction in design transfer time	30% less time
Reduction in ramp-up time	24% less time

Digital Thread Drivers

Strategic Value

The digital thread offers significant value, driving MedTech companies to adopt it. Several factors are especially relevant to top industry trends and are more common drivers for Top Performers than peers. The graph illustrates these drivers.

Traceability

The most cited driver is strengthening traceability across the product lifecycle. Connecting product, process, and quality data creates a single source of truth, reducing errors and nonconformities. Traceability lays the foundation for streamlined workflows, accelerated innovation, and improved audit readiness.

Agility

Improved agility is another major driver, especially for Top Performers. Amid market volatility, supply chain disruptions, and evolving regulations, companies need fast, reliable access to data to make informed decisions and adapt quickly. Organizations with mature digital threads report significantly improved ability to respond to disruption, demonstrating how connected data enhances operational resilience.

Data-Driven Decisions with AI

Improving decision-making is critical for MedTech companies given device complexity, market volatility, innovation pressure, and regulatory demands. Traditional data warehouse and BI approaches are too reactive, relying on complaints reports after issues occur. There's opportunity in real-time, in-workflow data and AI-assisted intelligence to inform decisions. A mature digital thread provides the foundation by linking and standardizing data across functions. This enables embedded decision support, predictive insights, and automation within workflows, shifting from reactive reporting to proactive, intelligence-driven processes.

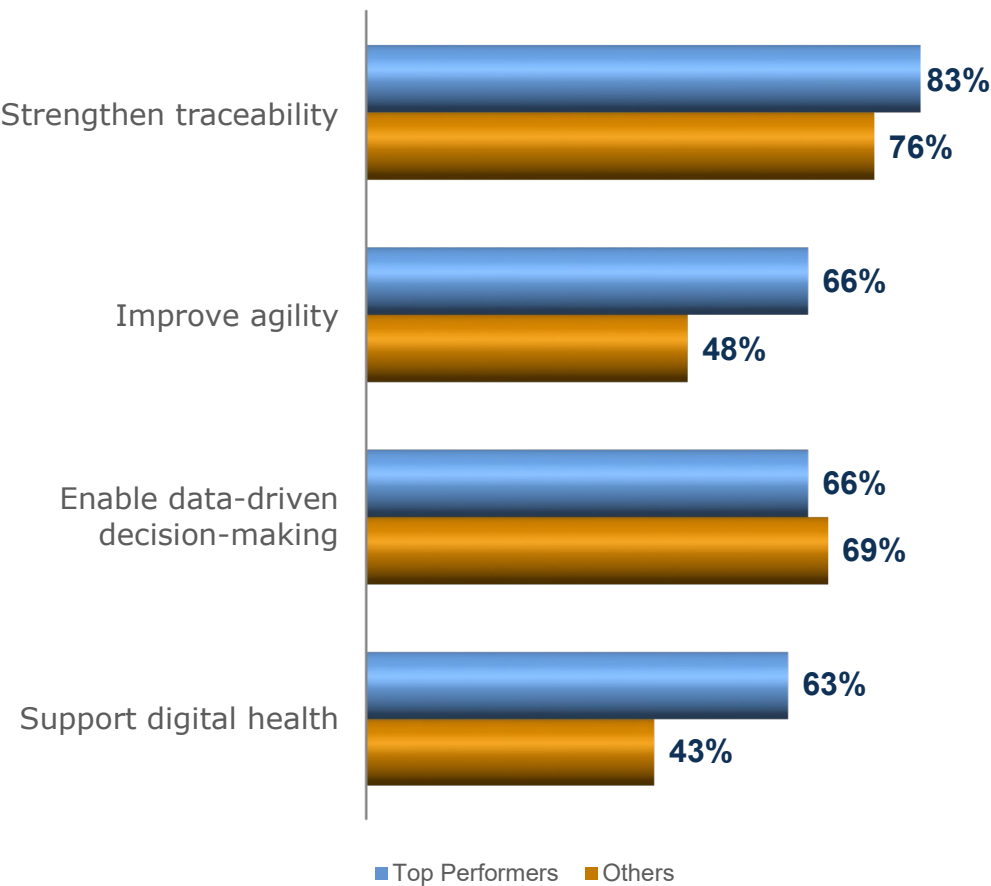
Digital Health

Many organizations see the digital thread as a key enabler of digital health initiatives. Connected data supports remote monitoring, wearables, predictive diagnostics, and personalized care. A digital thread positions companies to capitalize on this healthcare trend.

Addressing Key Market Trends

Let's dig deeper into how the digital thread enables agility, supports AI adoption, and positions companies to capitalize on the growing digital health market.

DRIVERS TO IMPLEMENT A DIGITAL THREAD



Traceability lays the foundation for streamlined workflows, accelerated innovation, and improved audit readiness.

Responding to Market Disruption

Market Volatility

MedTech companies face growing market volatility, supply chain challenges, rising costs, and evolving regulations. Only 23% report feeling fully prepared to respond to these disruptions.

Connected Data

Among those feeling prepared to respond to market disruption, the top factor cited was connected data. Connected data forms a digital thread that enables decision-makers to quickly access reliable information without having to search across disparate systems.

Digital Thread Impact

Digital thread maturity amplifies agility by creating real-time visibility across engineering, quality, manufacturing, and compliance functions. With seamless traceability, teams can respond faster to quality events, adjust design or process changes, and maintain regulatory compliance even under pressure. This level of operational resilience can help MedTech companies navigate geopolitical shifts, market uncertainty, and rising R&D pressures. The result is that 81% of those with a mature digital thread state they are either fully or well prepared to respond to market disruption.

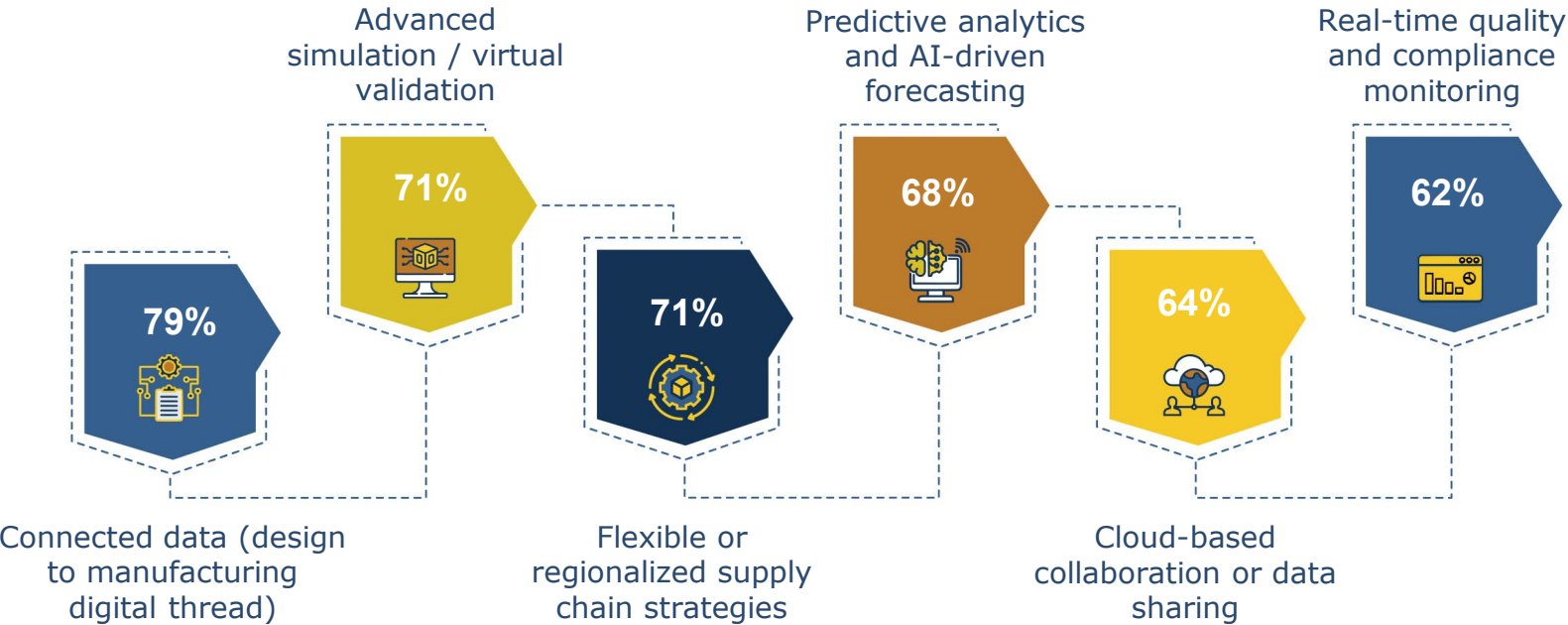
Other Capabilities

Additional helpful capabilities that support responding to disruption include advanced

simulation, virtual validation (such as with a digital twin), flexible regional supply chains, and predictive or AI-driven forecasting. These tools help MedTech companies adapt production, optimize resources, and mitigate risks. A digital thread provides the trusted data that enhances the effectiveness of these capabilities.

81% of those with a mature digital thread state they are either fully or well prepared to respond to market disruption.

WHAT THOSE WHO ARE MOST PREPARED FOR DISRUPTION HAVE FOUND TO BE MOST HELPFUL



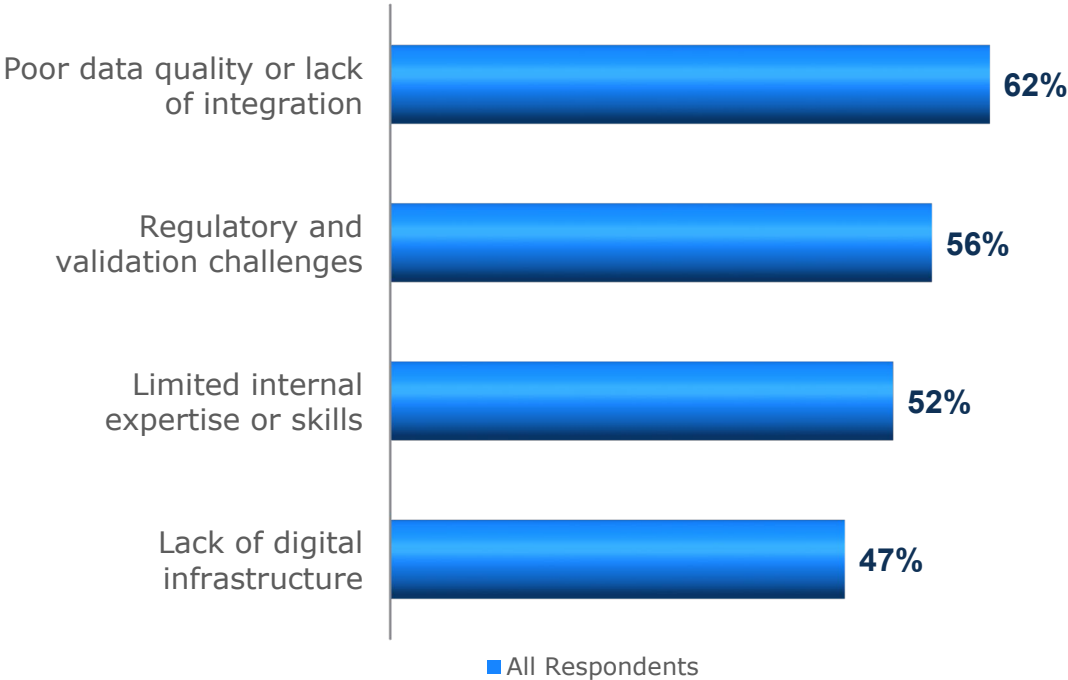
AI Adoption in MedTech

AI Plans

Artificial intelligence is emerging as a transformative tool for MedTech, supporting product innovation and operational efficiency. An overwhelming 97% of surveyed companies plan to deploy AI. Planned

uses span departments, simulation (65%), quality management (59%), digital health (55%), manufacturing optimization (55%), regulatory documentation automation (50%), predictive maintenance (48%), and supply chain planning (45%).

BIGGEST BARRIERS PREVENTING GREATER USE OF AI



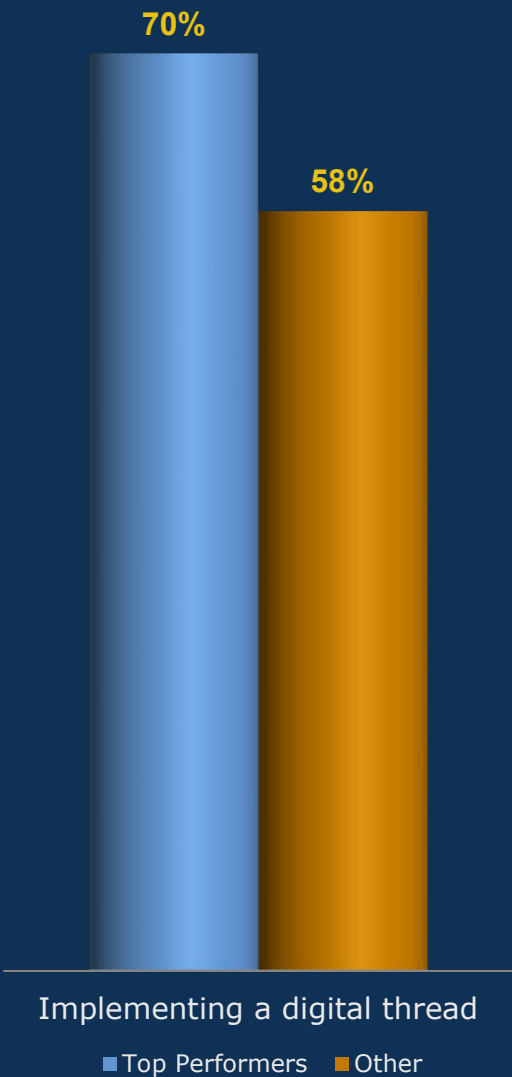
Adoption Challenges

Despite enthusiasm, adoption is often hindered by data quality challenges, disconnected systems, and a lack of digital infrastructure. Regulatory and validation concerns, as well as limited internal expertise, are also major barriers (see graph). While organizations recognize that strong data quality is critical for AI performance and contextualization, perfect data is not a prerequisite. Many are generating value by applying AI to targeted use cases, improving data along the way and building momentum over time.

Overcoming Barriers

The most common action Others take to support AI adoption is to invest in data management, reported by 71%. This is an important first step to improve data quality. However, Top Performers take this further and recognize that the data must be connected as well, so their top action is to adopt a digital thread. This integrated approach enables AI to deliver accurate insights, streamline workflows, and improve decision-making. It also provides the digital infrastructure they need to make AI a success. 82% of those with a more mature digital thread also partner with technology vendors or consultants to overcome their lack of expertise.

STEPS TO SUPPORT AI ADOPTION



Digital Health Enablement

Digital Health

Digital health initiatives—wearables, remote monitoring, telehealth integration, predictive analytics, AI-assisted diagnostics, and personalized medicine—are reshaping MedTech. Ninety-three percent of companies are pursuing digital health strategies, with Top Performers nearly twice as likely as peers to consider it core to their business. There is

a clear link between digital thread maturity and successful execution.

Digital Thread: An Enabler

Among companies with a digital thread strategy, 88% have made digital health critical to their business. Of those still implementing a digital thread strategy, 87% are in the pilot stage. Companies without a digital thread strategy are

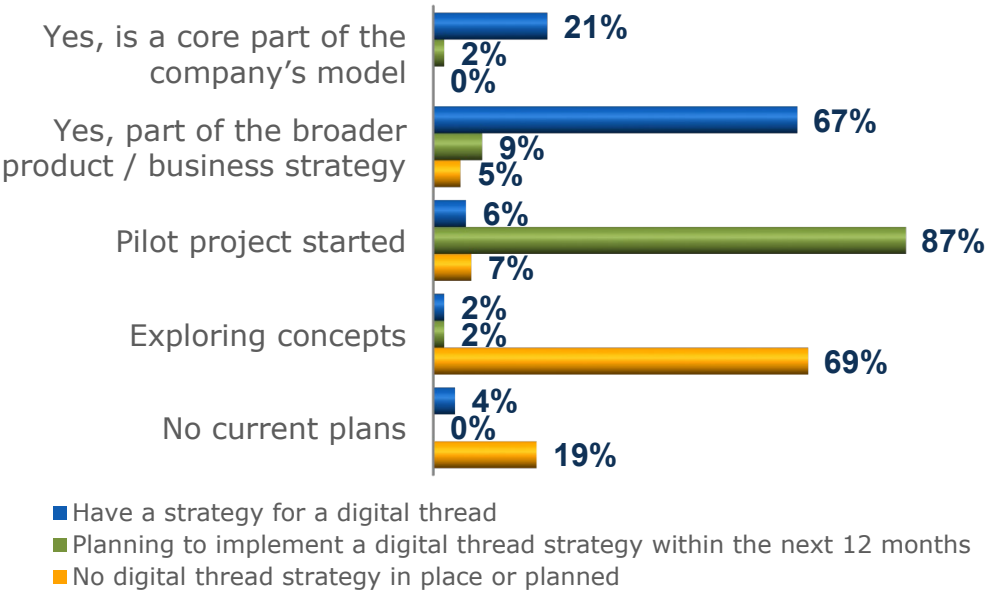
further behind with 88% either exploring concepts or lacking plans.

All companies with a mature digital thread recognize it as a key enabler for digital health, rating it critical or very important. Even 84% of those with less mature digital threads acknowledge its importance, showing that you don't need to be that far along in your digital thread journey to see its value for digital health.

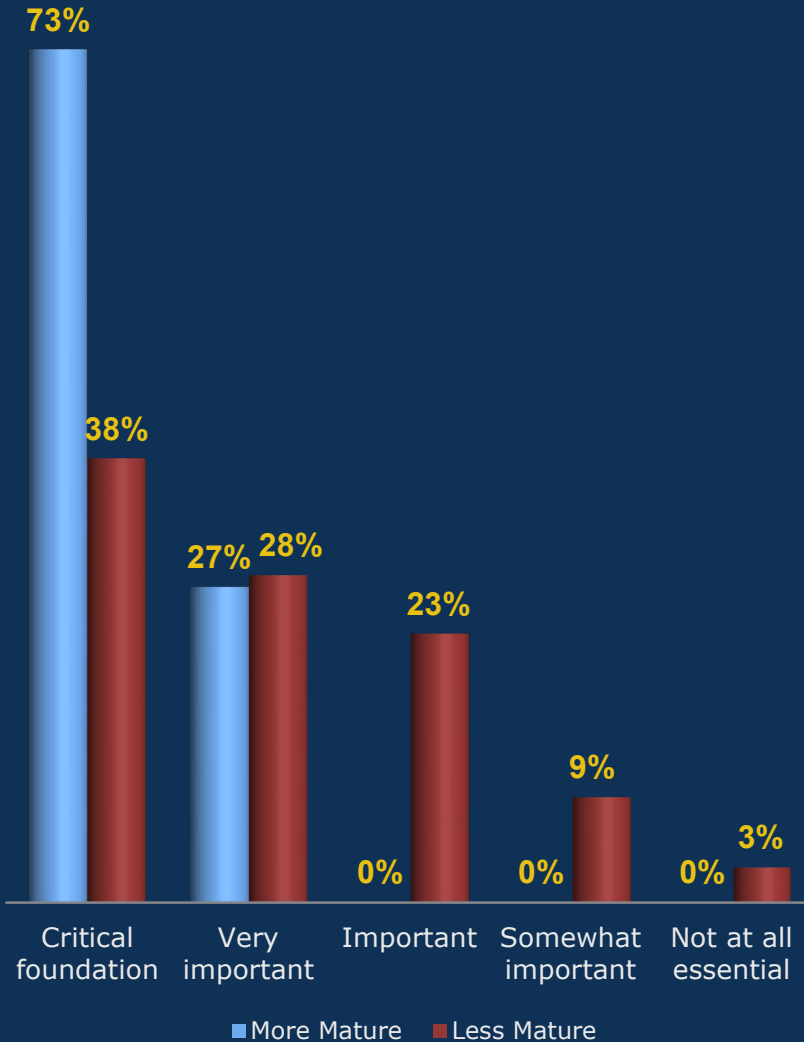
Digital Thread Value

A connected digital thread serves as the foundation for digital health by enabling the seamless flow of patient, device, and process data across engineering, manufacturing, and clinical functions. As digital health becomes a competitive differentiator, companies that couple it with a robust digital thread should be best positioned to capitalize on emerging opportunities and drive innovation across the healthcare ecosystem.

DO YOU HAVE A STRATEGY FOR DIGITAL HEALTH?



IMPORTANCE OF A CONNECTED DIGITAL THREAD TO ENABLE DIGITAL HEALTH



Implementing the Digital Thread

It's a Journey

Implementing a digital thread is a journey. Changing too much at once can be disruptive, so a phased, strategically sequenced, parallel approach improves success. Anticipating challenges upfront helps organizations plan effectively.

Top Challenges

Common challenges include integrating data across systems, standardizing processes across sites, and scaling pilots enterprise-wide. For example, different engineering teams may use separate PLM systems, creating inconsistency and complicating MES integration. Limited digital expertise and the need to justify ongoing investment add complexity.

Overcoming Challenges

Insights from companies with mature digital threads highlight best practices for scaling. Executive sponsorship is the most important success factor. Strong leadership drives cross-functional alignment, and secures resources, including

backfilling SMEs so they can focus on the program. A clear roadmap prioritizes high-value initiatives and supports scaling. Investment in platforms connects siloed systems and enables seamless data flow.

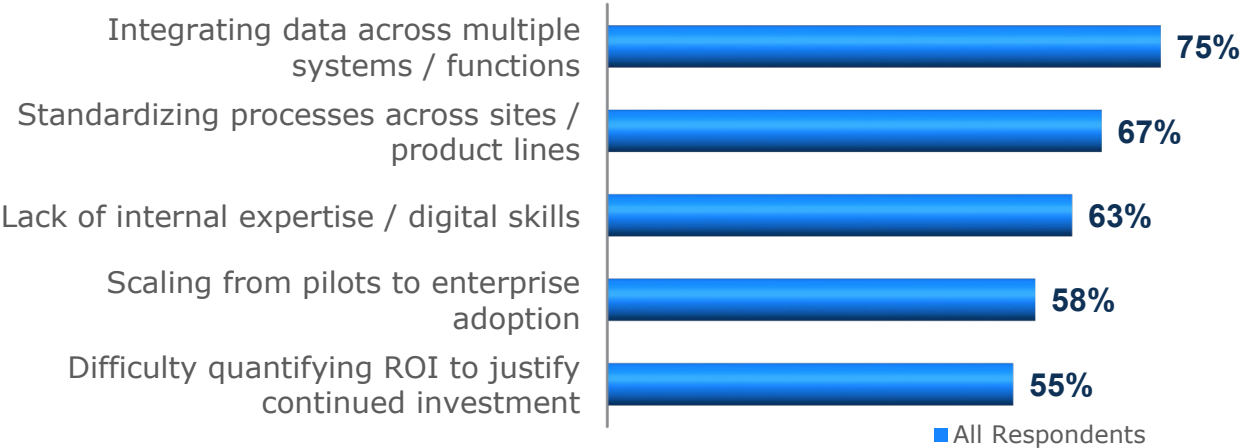
Select the Right Partner

External partners can address gaps in internal expertise. MedTech digital transformation experts can help avoid common pitfalls and ensure solutions support MedTech's unique regulatory, quality, and manufacturing requirements. Partners capable of integrating enterprise systems through factory and MedTech OT data further strengthen end-to-end connectivity.

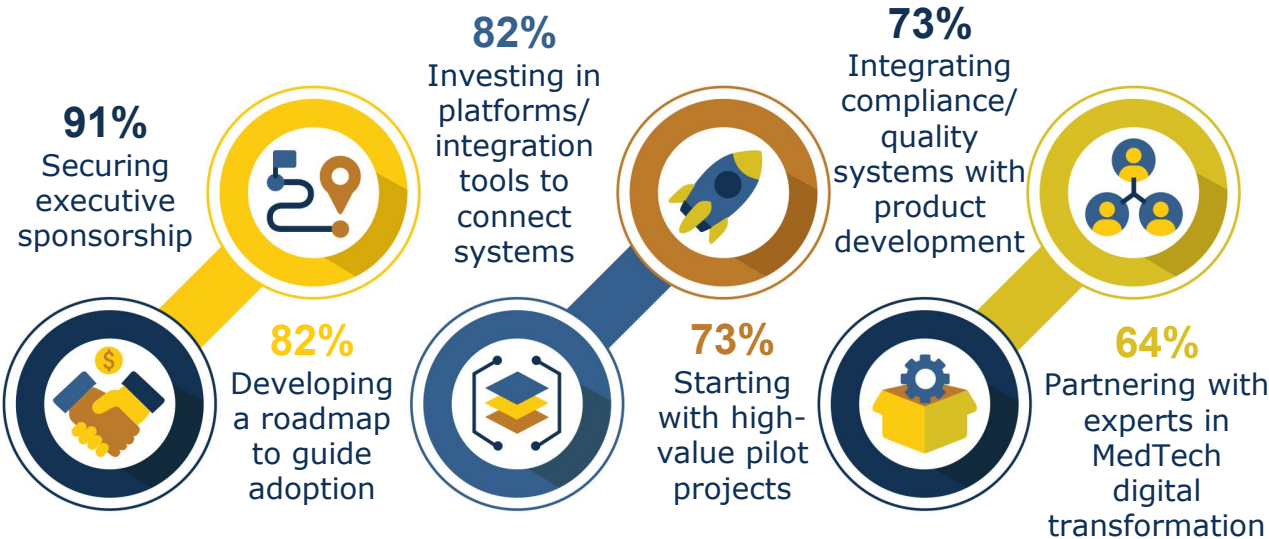
Maturity Journey

No organization has reached full maturity in their digital thread journey yet, but clear traits distinguish leaders. Top Performers are nine times more likely to have a more mature digital thread, making maturity a critical performance driver. Before exploring maturity further, we will define how maturity was measured in this research.

BIGGEST CHALLENGES IMPLEMENTING A DIGITAL THREAD



WHAT THOSE WITH A MORE MATURE DIGITAL THREAD FOUND MOST USEFUL TO SCALE THE DIGITAL THREAD ACROSS THE ENTERPRISE



Defining Digital Thread Maturity

Maturity Framework

In addition to performance benchmarking, the analysis for this report also looked at digital thread maturity. To clarify, the benchmarking analysis compared Top Performers to Others based on business outcomes. In contrast, a maturity model was defined separately to provide a state-of-the-market view of how MedTech organizations are progressing in their digital thread journey.

Maturity Definition

Digital thread maturity was defined across three foundational pillars: People, Process, and Technology.

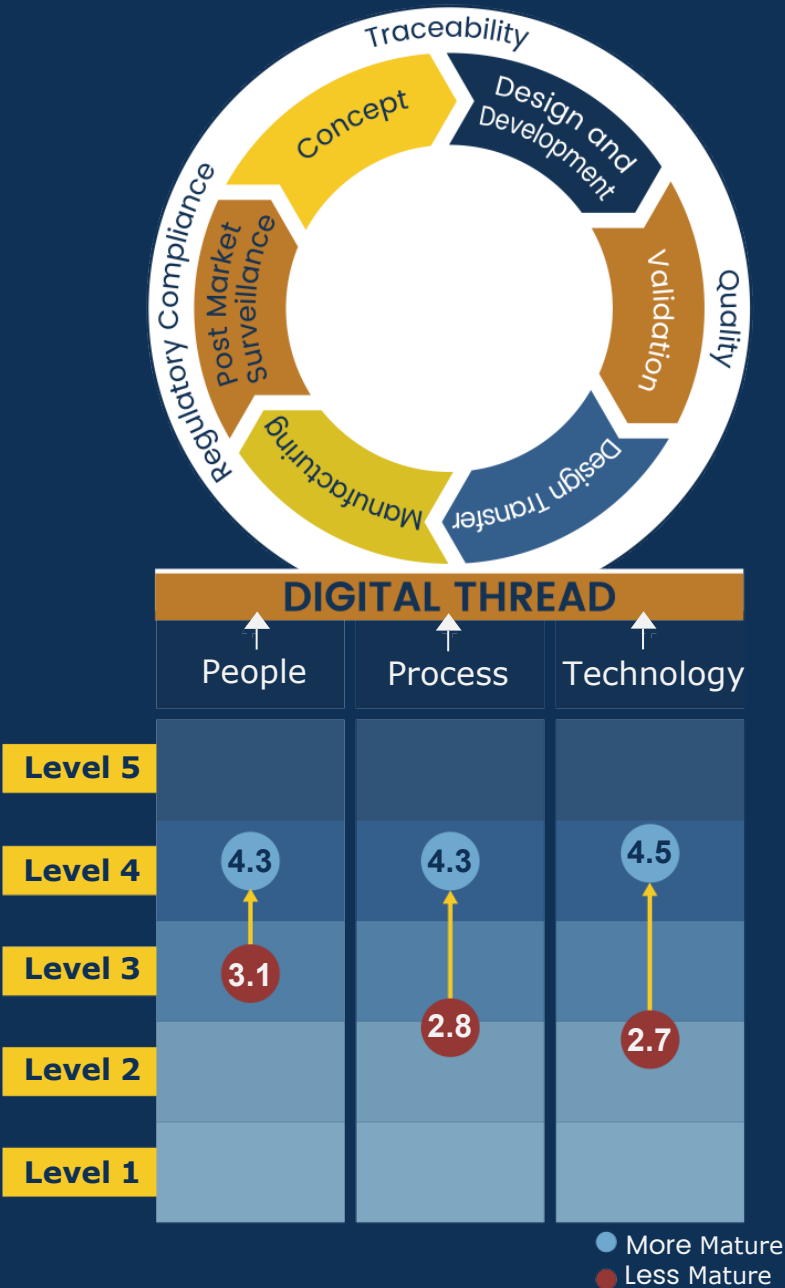
- **People** evaluates organizational alignment and readiness, including executive support, ownership and governance, and strategy visibility.
- **Process** examines how well key product lifecycle workflows are defined and connected, for product information access, change management, requirements management, design transfer, quality integration, and manufacturing planning and ramp-up.
- **Technology** assesses the degree to which enabling systems and solutions are integrated to support seamless data flow.

Scoring Maturity

Within each pillar and for each factor, survey respondents indicated their maturity level by selecting the description that best matched their company. These descriptions mapped to a five-level scale. Organizations that averaged Level 4 or higher across all pillars were classified as more mature. Everyone else was considered less mature. The scores shown in the graphics represent the average for each factor, reflecting respondents' current state.

The following sections present a state-of-the-market perspective on digital thread maturity across these three pillars. The graphics highlight where most companies are today relative to those furthest along in their journey, as well as the remaining gap to full maturity. Each section also describes the characteristics of a mature digital thread for the factors included in the model.

DIGITAL THREAD MATURITY



Digital Thread Maturity: People

Executive Support

The people dimension is foundational for a successful digital thread. Without strong leadership alignment, cross-functional collaboration, and clear accountability, even advanced technology and processes cannot deliver promised value.

Insights from companies with mature digital threads reinforce this point. Findings on the prior page show that 91% identified securing executive sponsorship as the most important factor for scaling digital thread initiatives. Strong leadership drives alignment, secures resources, and sustains enterprise-wide momentum. At more mature organizations, executive sponsorship is visible and active across engineering, manufacturing, quality, compliance, and R&D. However, while governance and strategy visibility most clearly differentiate leaders, executive support remains lower, indicating continued opportunity to strengthen leadership alignment.

Cross-Functional Alignment

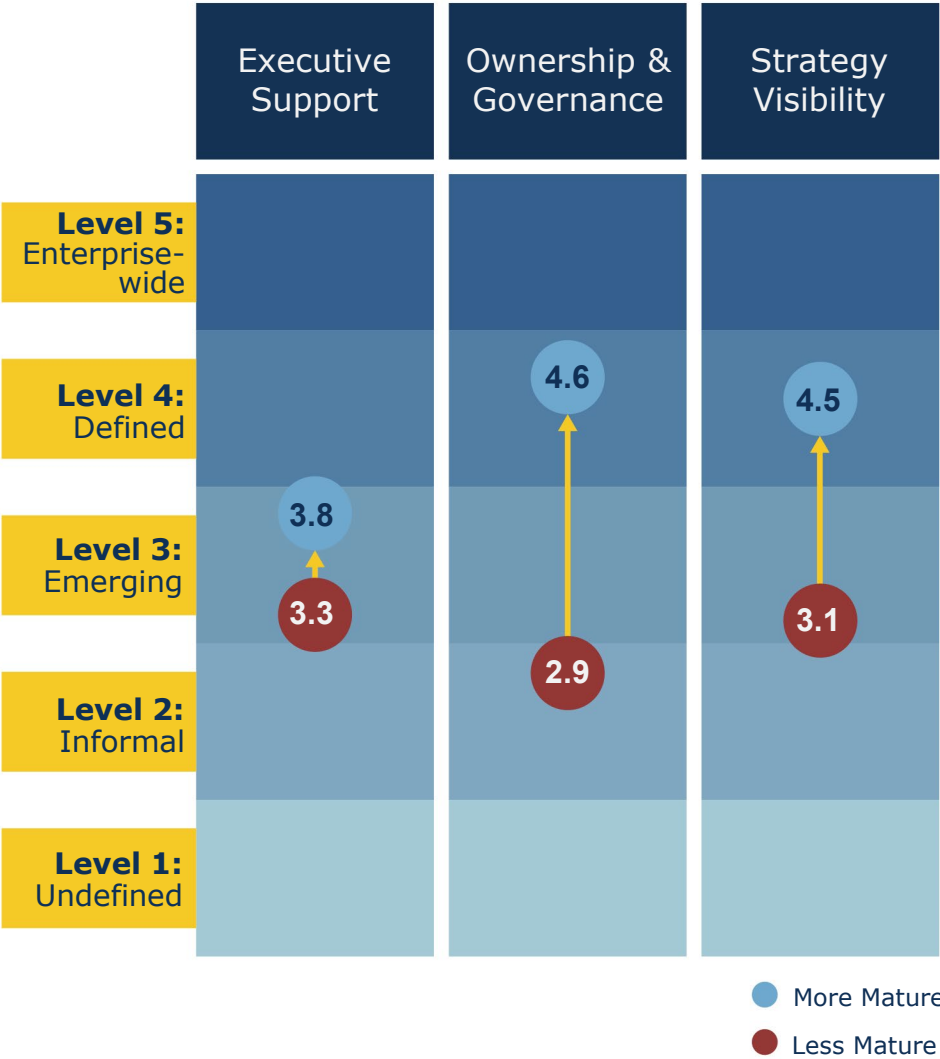
Cross-departmental alignment is equally critical. Mature digital thread strategies

involve multiple functions with shared visibility into goals, priorities, and responsibilities. All mature companies include IT, Engineering, Manufacturing, and Quality; most also include R&D and Compliance. This broad participation fosters clear ownership and governance of product and process data, ensuring accountability across the lifecycle. Less mature organizations often have siloed teams with fewer departments aligned and limited visibility beyond management. This fragmentation slows progress and makes it harder to overcome functional barriers.

Why It Matters

The people dimension determines whether the digital thread scales or stalls. Leadership commitment, enterprise visibility, and clear accountability enable organizations to move from fragmented pilots to coordinated, enterprise-wide adoption, driving agility, innovation, and operational excellence. With the people dimension established, the process and technology dimensions determine how organizations standardize workflows, connect systems, and extract value from their digital thread investments.

PEOPLE MATURITY FRAMEWORK



Digital Thread Maturity: Process

Better Visibility

Process maturity is critical to realizing digital thread value. Standardized, or harmonized to allow for regional or divisional variation, connected workflows improve collaboration, reduce errors, and accelerate decisions across the lifecycle. Companies with more mature digital threads enable seamless data flow across departments and domains. Top Performers are 22% more likely than peers to achieve this.

Change Management

Mature organizations have formalized, digitally integrated change processes providing cross-functional visibility and traceability. Linking engineering, manufacturing, and quality data allows teams to assess impacts and manage changes efficiently. Less mature companies rely on manual processes, increasing errors and slowing responses. Top Performers are 73% more likely to have digitally integrated change management.

Requirements Management

Mature companies connect patient needs, design inputs and outputs, and test results within integrated systems. This traceability is a regulatory expectation, as authorities like the FDA emphasize a Total Product Lifecycle approach leveraging real-world data to continuously assess devices. Lower maturity organizations often depend on spreadsheets, documents, or siloed systems, creating fragmented records that inhibit traceability and decision-making.

Manufacturing

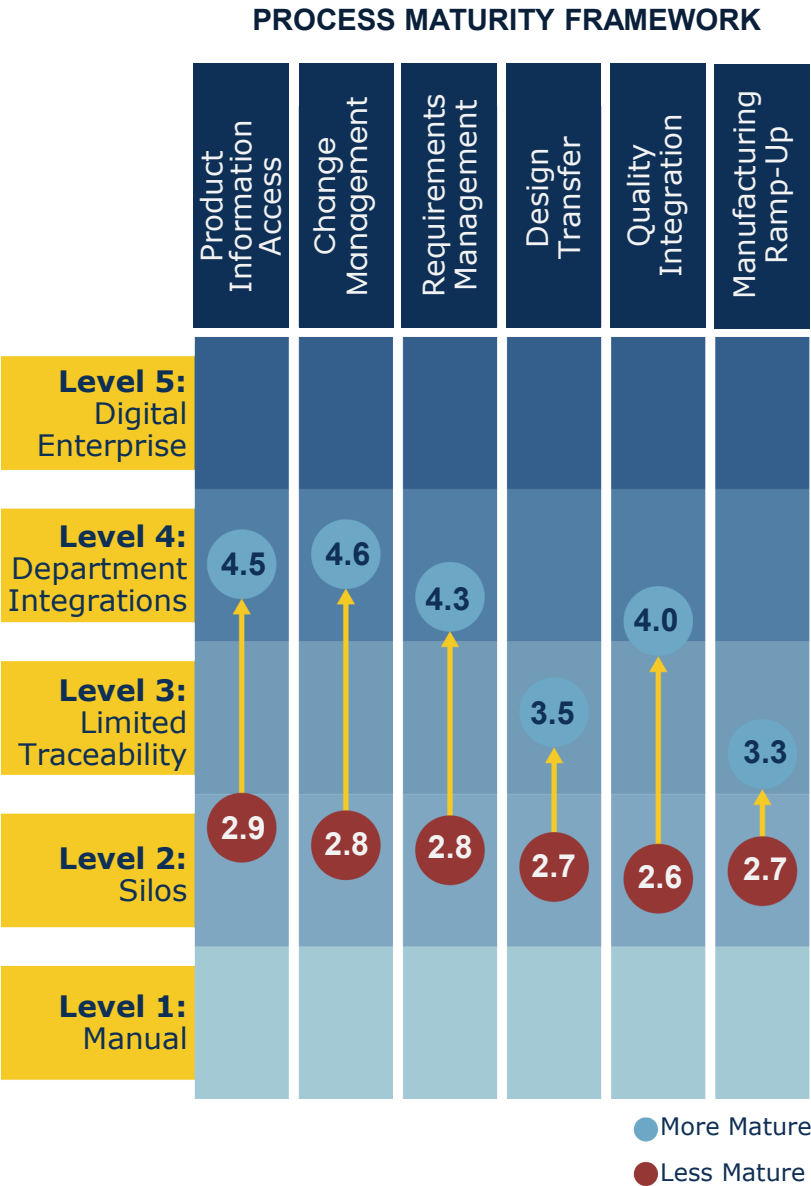
High-maturity organizations transfer design data (Device Master Record data) to manufacturing through standardized workflows that connect product and quality information, reducing rework and improving time to market. However, manufacturing-related processes still represent one of the greatest opportunities to advance digital thread maturity, even among more mature companies. Less mature organizations frequently recreate data, leading to inefficiencies and higher costs.

Quality

In mature environments, complaints, deviations, and change records are integrated with product data, enabling faster response and stronger compliance. Top Performers score 38% higher than Others in integrating product quality data. Still, quality and product-process integration remain a significant opportunity, particularly in linking design artifacts to downstream quality processes such as CAPA and complaints.

Why It Matters

Process maturity ensures workflows are consistent, traceable, and efficient, forming the backbone of digital thread value and enabling enterprise-wide data flow. Next, we examine how technology enables seamless data flow across the enterprise.



Digital Thread Maturity: Technology

Seamless Data Flow

Technology provides the foundation enabling people and processes to fully leverage a digital thread. MedTech organizations with a mature digital thread have an integrated system that connects engineering, manufacturing, quality, and regulatory functions, creating a seamless product and process data flow across the enterprise.

Lifecycle Solutions

Key technology enablers include ERP, MES, PLM, Quality Management Systems (QMS), and Regulatory Information Management Systems (RIMS). Mature companies use PLM not just for data storage, but as a collaborative platform that supports version control, workflow management, and cross-functional access. Engineering, manufacturing, regulatory, quality, compliance, R&D, and even procurement teams have shared visibility into the same data, enabling faster decision-making and more efficient operations. Less mature organizations often underutilize their PLM systems, limiting them to basic document storage, which restricts the benefits of a digital thread.

Integration across lifecycle systems is critical. Mature organizations enable

automatic data flow between ERP, MES, PLM, RIMS, and QMS, reducing manual work, minimizing errors, and providing real-time visibility. Less mature companies rely on partial integrations or manual data sharing, which slows workflows and limits agility.

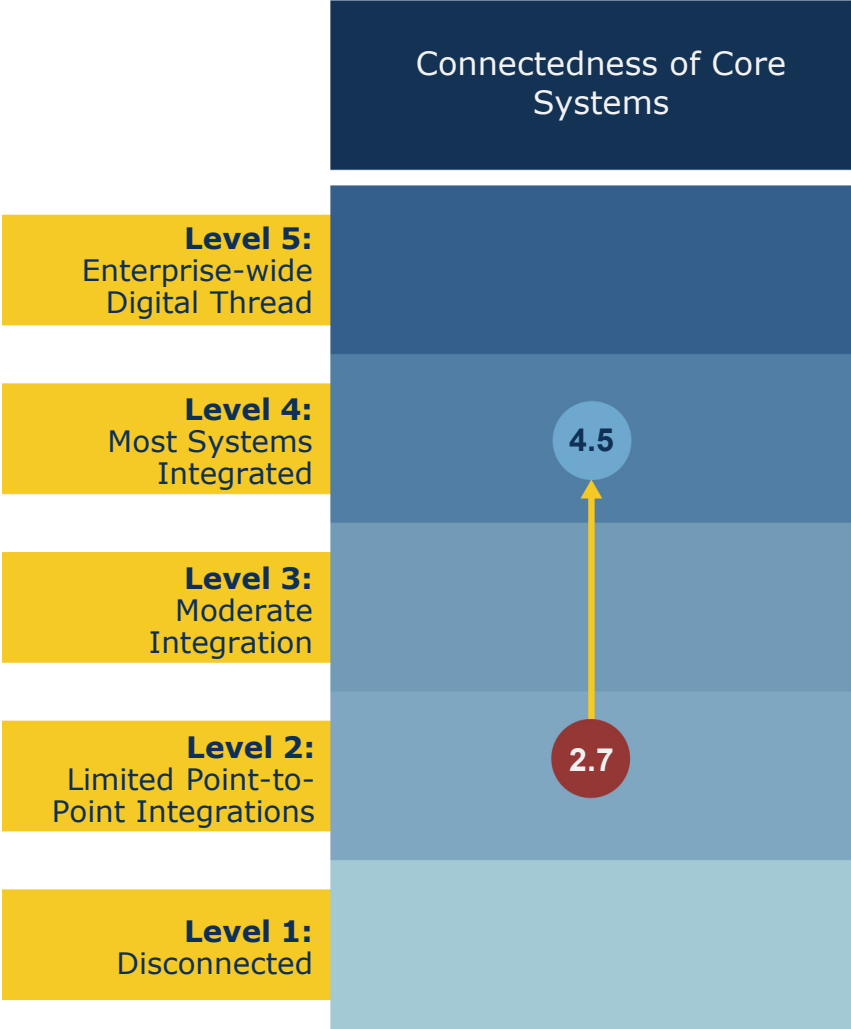
Compliance

The technology dimension also supports compliance and traceability. Connected systems enable rapid generation of audit-ready documentation by linking design, manufacturing, and quality data to efficiently meet regulatory requirements. Organizations that have fully integrated technologies report faster time to market, improved product quality, and higher innovation capacity because teams can reuse validated data across products and projects.

Why It Matters

In summary, integrated technology is the backbone of a digital thread. Combined with mature people and process elements, it enables a fully connected product lifecycle, supports regulatory compliance, and drives operational efficiency.

TECHNOLOGY MATURITY FRAMEWORK



● More Mature
● Less Mature

Recommendations

Recommendations and Next Steps

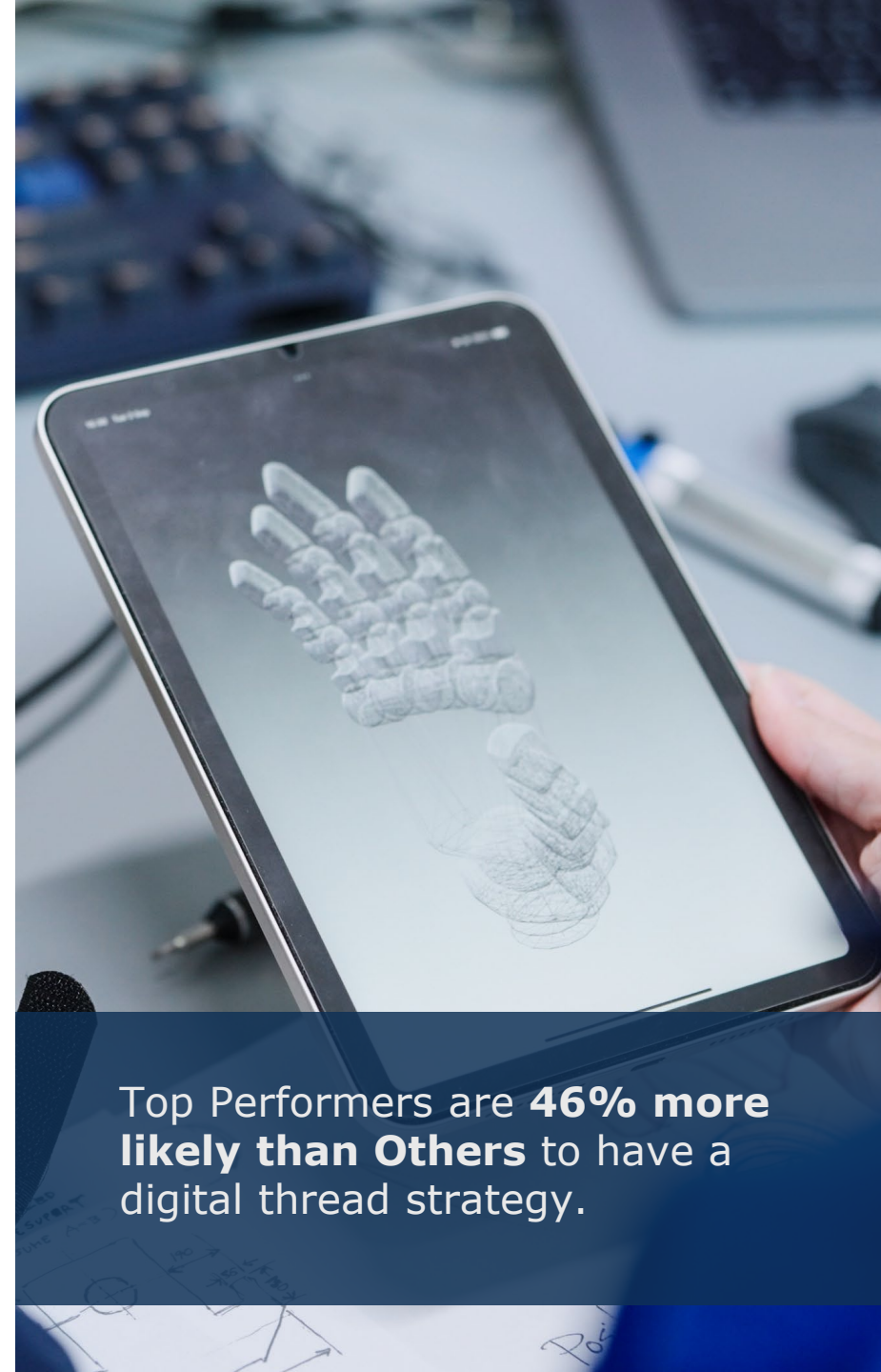
Based on industry experience and research for this report, Tech-Clarity offers the following recommendations to MedTech companies:

- **Establish a clear digital thread strategy.** Top Performers are 46% more likely than Others to have a digital thread strategy. Define a roadmap that connects product data, processes, and stakeholders across the lifecycle—from concept and design through manufacturing, quality, service, and regulatory submission. Sequence initiatives strategically, but execute in parallel where possible to accelerate value.
- **Secure executive sponsorship.** Digital thread success requires cross-functional collaboration to overcome silos. Executive support empowers teams, secures resources, and enables backfilling SMEs so the program is not treated as a side effort.
- **Prioritize high-impact use cases.** Focus on areas delivering tangible value, such as digital change management, design transfer, product quality integration, and regulatory documentation automation. Early wins build momentum and executive support.
- **Break down data silos.** Integrate engineering, manufacturing, quality, and regulatory systems to create a single, trusted

source of product information. Improve traceability and enable seamless data flow.

- **Strengthen governance and compliance readiness.** Embed traceability, risk management, and documentation controls into digital processes to reduce audit risk and streamline submissions.
- **Build a scalable foundation for AI and digital health.** Ensure lifecycle data is structured and accessible to support AI initiatives and connected device strategies. AI success depends on high-quality, contextualized data.
- **Invest in corporate change management and cross-functional alignment.** Technology alone is insufficient. Foster collaboration among engineering, quality, manufacturing, IT, and regulatory teams to drive adoption and sustain value.
- **Measure and continuously improve.** Track KPIs such as on-time launches, design transfer cycle time, ramp-up duration, and compliance documentation time to quantify progress and refine strategy.

By adopting a strategic, phased—yet parallel—approach to digital thread maturity, MedTech companies can reduce operational friction, enhance compliance, accelerate innovation, and build resilience in a complex market.



Top Performers are **46% more likely than Others** to have a digital thread strategy.

About the Research

Data Gathering

Tech-Clarity gathered and analyzed responses to a web-based survey from 206 manufacturers. Survey responses were collected by direct email, social media, partners, and online postings by Tech-Clarity.

Company Size

The respondents represent a mix of company sizes, including 33% between \$100 million to \$250 million, 29% between \$251 million to \$499 million, 11% \$500 million

to \$1 billion, 15% \$1.1 billion to \$5 billion, and 12% greater than \$5 billion. Company sizes were reported in US dollar equivalent.

Geographies

Responding companies report managing projects in North America (47%), Western Europe (48%), Asia (17%), Eastern Europe (1%), Australia/Oceania (1%), Africa (1%), and Middle East (1%).*

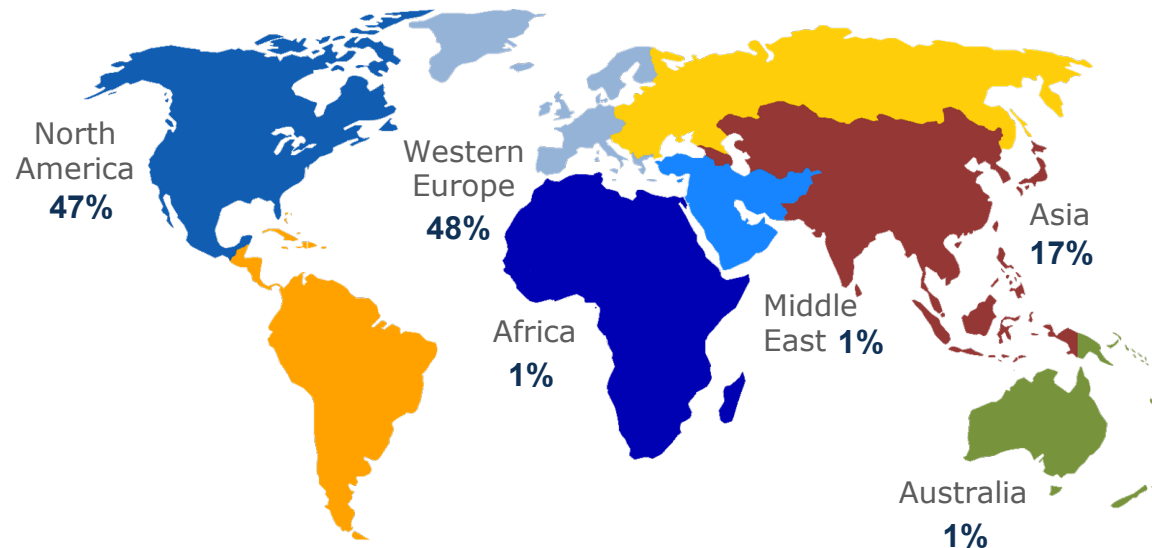
Title

The respondents comprised 10% Executive Level, 15% VPs, 35% Directors, 25% Managers, and 15% individual contributors.

Organizational Function

Of the respondents, 16% were in R&D/Engineering, 16% Industrial/Manufacturing Engineering, 20% Manufacturing, 17% Quality, 13% Regulatory Affairs/Compliance, 10% Information Technology (IT), and 8% General Management.

* Note that the values may total greater than 100% because companies reported doing business in multiple industries and geographies.



Acknowledgements



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About the Author

Michelle Boucher is the Vice President of Research for Engineering Software for Tech-Clarity. Michelle has spent over 20 years in various roles in engineering, marketing, management, and as an analyst.

Michelle graduated magna cum laude with an MBA from Babson College and earned a BS in Mechanical Engineering, with distinction, from Worcester Polytechnic Institute. She is an experienced researcher and author, having benchmarked over 7000 product development professionals and published over 90 reports on product development best practices.

Tech-Clarity is an independent research firm dedicated to making the business value of technology clear. We analyze how companies improve innovation, product development, design, engineering, manufacturing, and service performance through the use of digital transformation, best practices, software technology, industrial automation, and IT services.



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