The Digital Model for Clinical Research:

FOUR PILLARS OF RUNNING SUCCESSFUL MEDICAL DEVICE CLINICAL TRIALS

INTRODUCTION

The medtech industry constantly innovates to bring crucial therapies to patients, and this spirit of innovation has propelled the adoption of digital technologies for clinical trials. Medical device sponsors, during the past twenty years, have implemented digital technologies to connect clinical trial workflows, derive superior value from clinical and real-world data, and manage critical processes like study planning and regulatory submission.

Successfully leveraging digital technology for clinical trials requires a proven digital strategy. In this eBook, Medidata defines the four pillars of the digital model for clinical research that make for successful medical device clinical trials— digital leadership, a data-driven approach, patient centricity, and a culture of innovation. Fundamentally, this digital model for clinical research intrinsically links customer success with better experiences for patients to arrive at the best possible outcomes. For medical device companies looking to achieve clinical, regulatory, and commercial success, Medidata is a proven partner committed to serving the unique needs of medical device companies.

Implementing the digital model for clinical research also equips medical device companies for decentralized trials—a suite of capabilities defined in this eBook and adopted at an accelerated pace due to COVID-19. With the right digital strategy and technology infrastructure, you're ready for success under any operating conditions.

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THE SHIFT TOWARDS DIGITIZATION IN MEDICAL DEVICE CLINICAL TRIALS

Over the past two decades, technology has transformed almost every industry and altered the nature of daily life at an incredible pace. Internet connectivity, cloud computing and data storage, and digital platforms tailored for specific industries and tasks have fundamentally restructured how companies innovate and how people access services and products.

During this period of rapid digital transformation, the medtech industry found itself affected by a paradox: While the industry constantly innovates to discover and develop new life-saving therapies, the established processes for device development depended on pen and paper, and communication between study teams and patients typically happened in person. Consequently, the medtech sector has trailed behind other industries in digital innovation. According to an industry survey by EY, "While medical devices increasingly incorporate software and connectivity, many companies have hesitated to make significant investments into building the digital capabilities needed to access and use the ever-expanding wealth of real-world data."[1]

In the highly regulated and inherently risk-averse clinical research environment, medical device companies eyed digital strategies cautiously as they emerged. Twenty years ago, incipient digital strategies in clinical trials simply involved directing patients to a website for study information and gathering contact information for recruitment and retention purposes.[2] Since those early stirrings of digital transformation in clinical trials, digitization has begun to affect every step of the clinical development process, including study design, patient recruitment, communication, data collection, data analysis, and regulatory submission.

What Does Digital Mean for Medical Device Clinical Trials?

According to a survey of key industry stakeholders by Deloitte, "Most think of digital as a collection of technologies, platforms, and advanced analytics, such as connected devices, mobile applications, artificial intelligence, machine learning, and robotic processes." While this definition encapsulates a broad array of technology, the authors suggest it's "useful to conceptualize digital not simply as a platform or technology, but as a way of doing things differently."[3]

Fundamentally, digitization for medical device clinical trials means transferring processes from paper forms or manually managed spreadsheets to a system of connected technologies designed to automate workflows and generate novel insights from structured data. In terms of function, this transforms processes from static to dynamic— within a system of connected technologies, high-quality data continuously informs key stakeholders to accelerate the speed of clinical development.

What Factors Drive Digitization for Medical Device Clinical Trials?

Medical device companies contend with several major challenges, including finding regulatory pathways, managing disparate data sources, and reaching commercial success. A number of factors have applied significant pressure on medical device manufacturers to adopt digital technology, including an increased push toward trial decentralization and use of advanced analytics, continued fragmentation of clinical trial data collection, and ongoing significant changes in the international regulatory environment.

In addition to these long-standing pain points, The European Union's Medical Device Regulation (EU MDR), a set of updated regulations that oversees the production and distribution of medical devices in Europe, introduces a new set of challenges for companies to overcome. Any medical device company that plans to sell its products in Europe must comply.

The new MDR has a mandate for unique device identification, designed to help manufacturers trace all medical devices sold in the region and participate in new databases for clinical studies, product registration, and postmarket surveillance. This places an enormous new burden on medical device companies to continue tracking, monitoring, and registering medical devices after they are sold. Many medical devices may even have to be taken off the market, as companies might not have the resources to run the clinical trials required to produce the data.

These operational and financial pressures drive medical device companies to look for opportunities to accelerate timelines and reduce costs. Digitization introduces opportunities to automate formerly manual processes, freeing up valuable time and resources.

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THE DIGITAL MODEL

FOR MEDICAL DEVICE CLINICAL TRIALS

Digitization clearly has the potential to mitigate challenges for researchers and accelerate the pace of product development. But not all digital strategies bring the best benefits—so what does an ideal digital model for a medical device company look like? How do researchers benefit from best-in-class digital technology on a daily basis? And what digital strategies position researchers to achieve superior overall outcomes to meet critical endpoints?

An ideal digital model for clinical research involves digital leadership, a data-driven approach, patient centricity, and a culture of innovation. These four pillars equip researchers to succeed throughout every clinical workflow and to leverage novel insights from trial data.

Digital Leadership

According to analysis by Boston Consulting Group regarding digital innovation in the life science industry, "Two key factors may make companies reluctant to innovate: regulatory concerns and data privacy concerns."[10] These concerns reflect the medtech industry's commitment to safety and security, but they do not need to prevent medical device companies from becoming digital leaders.

Medical device companies face many challenges when it comes to developing their digital strategies. Understanding the different technology options helps medical device companies deliver the fastest and safest response to new priorities. Life sciences technology vendors deliver solutions that satisfy the industry's high threshold for safety and security. This creates the opportunity to deploy a digital strategy.

While technology provides the necessary infrastructure for a digital strategy, digital leadership means more than adopting great technology. To achieve digital leadership, the best medical device sponsors look for technology partners that also provide insights for study design and conduct, offer advanced data analytics, support regulatory submissions with established expertise, and deliver seamless experiences for study teams and patients.

Data-driven Approach

Today's clinical trials ingest data from numerous disparate sources, including electronic data capture (EDC) systems, patient reported outcomes, wearables, sensors, and other digital health devices. Along with new methods for data collection, the complexity and sheer amount of data has increased dramatically.

On an operational level, transitioning data collection from manual spreadsheet entry to a structured EDC solution with automated workflows lays the foundation for a data-driven approach. But a truly data-driven approach, on a strategic level, requires a connected technology system that delivers real-time insights to study teams and allows researchers to identify novel insights from holistic trial data with support from expert advisors. In a recent survey of current and former life sciences technology executives conducted by Medidata, 75% of respondents assessed the "availability of data across all clinical products" as a 9 or 10 on a 10-point scale intended to measure the most important drivers of adoption for unified platforms.[12]

An ideal data-driven approach takes this cross-application data availability even further by combining machine learning and AI capabilities with human subject matter experts for superior data analysis. With these capabilities, medical device sponsors can identify the best performing sites, craft effective patient recruitment and retention strategies, understand trial outcomes in new ways, and allocate resources efficiently to meet critical endpoints.

Patient Centricity

The medtech industry frequently uses patient centricity as a buzzword, but promoting the idea of patient centricity without action dilutes the term's meaning and frustrates patients. Patient centricity requires a formal process to infuse the patient perspective into the software development life cycle.

Medical device sponsors increasingly recognize patients as valued partners. Patients, based on their experiences, bring expertise to study design, planning, operations, and outcomes. Medical device sponsors committed to patient centricity establish channels for continuous collaborative communication between patients and study teams.

Patient-informed study designs ensure that patients receive the best possible care in the least burdensome manner. In practice, this could mean some data collection occurs through wearable sensors to reduce the number of in-person site visits, or that patients have the option to consent to studies electronically, or that patients have an opportunity to use their preferred technology to connect to a trial.

The future state of patient centricity depends on how well medical device companies balance the benefits of trials for their business and for patients. An emerging discussion in the medtech industry centers around access to data. Sharing trial data with patients whenever possible allows them to make the best informed decisions about their treatment beyond a trial.

Culture of Innovation

In an industry known for innovating life-saving therapies, leaders understand how digital innovation complements device development. In a survey of current and former life sciences tech executives conducted by Medidata, respondents cited several business-case benefits for using digital platform systems, including lower total cost of ownership, increased study speed, easier access to relevant data and reporting capabilities, and fewer manual processes.

MEDIDATA:
OVER 20 YEARS OF DIGITAL INNOVATION

A Proven Track Record of Digital Leadership

In 1999 Medidata introduced Rave and transformed the landscape of electronic data capture (EDC). Rave revolutionized the way clinical researchers gathered and tracked data. More than two decades later, our solutions comprise the most widely used end-to-end clinical trial technology platform worldwide.

TODAY MEDIDATA SUPPORTS

- More than 24,000 clinical studies and over 7 million patient experiences
- Over 160 medtech sponsors including 9 of the top 10
- Secure, scalable, and interoperable collaboration and communication among study teams and patients
- Clinical research across all geographies
- An experience designed to ease patient burden

A Data-driven Platform

A long history of trusted relationships with the medtech industry's largest players means Medidata has access to unparalleled historical data resources and extensive current insights. Our datasets cover 24,000+ historical trials and 22,000 healthcare facilities with associated investigators across 94 countries, including 6,000 live trials happening in real time.[13]

Medidata got a jump start in data analytics almost a decade ago. In 2010, we reached out to the biggest names in the business to invite them to share data in a coordinated way. In the spirit of cooperation, the companies agreed to let Medidata pool their data to provide analysis to improve clinical trials operations for everyone, while protecting the data privacy of individual patients and research organizations. No one else in the industry has access to clinical and operational data all in one place from hundreds of sponsors and multiple clinical research organizations.

And it's not just the quantity of data that makes Medidata's platform exceptional— it's also the level of detail. While publicly available clinical trial datasets exist, these do not provide the granular information that Medidata's datasets do. Our platform has information from the actual execution of each study, which gives deep insight into performance in different diseases, countries, and sites.

Medidata also enriches data through a two-step process unique to our business. Other companies use either algorithms or manual curation to structure their data, but Medidata's approach combines both. We let the machines do what they do best: learn from the data and apply systems of classification. Then we bring subject matter experts into the loop to adjudicate the findings and complete structuring the data before it is used in analysis. We also leverage publicly available data from all over the world including trial registries and publications.

For example, as the global impact of COVID-19 fluctuates, Medidata continuously analyzes the effect on patient study enrollment, the response by world regulatory bodies, and which Medidata solutions can help address your COVID 19-related challenges. Medidata publishes these reports regularly to make these insights available to the industry.[14]

Patient Centricity from Patient Insights

Medidata's award-winning Patient Centricity by Design (PCbD) initiative drives our Patient Insights program.[15] This is the formal process of infusing the patient perspective into the software development life cycle to create technical solutions that improve the overall patient experience in clinical research interactions. Medidata built PCbD around three core principles of patient centricity: design, engagement, and activation.

Develop and design products and solutions with the patient perspective at the forefront.

This requires understanding the patient journey to empathize, the patient perspective to define, patient goals to ideate, patient expectations for prototypes, and patient outcomes for product testing.

Build consistent points of interaction for patients.

Medidata hosts consistent events for patients to share their perspective at the beginning of the design process called Patient Design Studios.

Enable patients to be active participants in the clinical research process.

Medidata established a Patient Design Advisory Board composed of patient advocates, caregivers, leadership team members, and product team members. This group provides governance oversight for the software development life cycle methodology of PCbD.

In 2019, Medidata officially launched the PCbD program, ran two in-person Patient Design Studios with key internal team members, developed and published design principles, and evaluated our software development life cycle process for key points of patient inclusion. In 2020, we held our first virtual Patient Design Studio, and our eConsent product went through the PCbD review process. Medidata also launched the Patient Design Advisory Board to work with patients and sponsors on collaborative design studios for rare disease and oncology, and to publish research on our PCbD program in scientific journals.

MyMedidata Registries: Built with Patient Insights

myMedidata Registries was recently launched to expand and strengthen the myMedidata patient portal to engage patients before and after (i.e., long term follow up/safety surveillance) a clinical trial. This empowers patients to learn more about clinical trial opportunities and provides an experience that allows for active participation throughout their clinical trial journey. With increasing interest and adoption of decentralized clinical trials, myMedidata Registries gives patients continuous support in and out of a trial with access to one portal for all of their research needs — providing an everlasting engagement on one portal for life. myMedidata Registries was designed for patients by patients, in partnership with Medidata's Patient Insights team. Medidata's team of dedicated patient advocates use the Patient Centricity by Design (PCbD) process that infuses the patient perspective into the software development life cycle to create technical solutions that improve the overall patient experience in clinical research interactions. The PCbD initiative was **named the first-place** winner at the 2021 SCOPE Participant Engagement Awards.

Culture of Innovation: R&D and Customer Success

Medidata invests a significant portion of revenue every year to support research and development. Medidata's leadership promotes a culture of innovation and customer success throughout the organization and among partners. Forbes recognized Medidata co-founder and co-CEO Tarek Sherif as one of America's most innovative leaders in 2019.[16] In response to the recognition, Sherif emphasized that "Innovation and high growth require a team effort, and I've been lucky to be working with the best people in our industry."

While technology development and investment remains the backbone of any successful digital strategy, successful digital innovation in the competitive medtech industry depends on expertise, collaboration, and dedicated partnership.

Medidata continuously positions itself ready to support digital transformation of customer companies—not just focused on technology.

Our customer success program serves sponsors, CROs, sites, and patients.

READY ASSISTANCE FOR CUSTOMERS AND PATIENTS

In addition to the traditional product helpdesk that serves more than 1,700 customers, we offer a patient helpdesk. Patient calls get answered within five-seconds—a hold time unmatched in an industry where callers often have to wait fifteen minutes or more.

CUSTOMER-FIRST PRODUCT CONSIDERATIONS

We study customer usage behavior to improve the user experience. This contributes to the consideration of better product design for sponsors and patients.

With in-app satisfaction monitoring, customers provide feedback on features, functionality, and the overall user experience.

DEDICATED CUSTOMER ENGAGEMENT

1,700— the number of customers we have— represents more than just a number. It represents our culture of engaging customers at both macro- and micro-levels. These engagement activities allow customers to share their stories with the community. By sharing stories with peers through our engagement activities, our users learn how to address similar challenges and benefit from technology and best practices.

At a macro-level thousands of users come together at NEXT Global events to discuss their stories.

At a micro-level, we bring users together in purpose-built cohorts to learn and share a way to get the most out of their investment with Medidata. Some highlights include:

- Medidata's Client Engagement team heads the quarterly Data Management Roundtable which connects customers and offers resources. It is also launching a CTMS group shortly and looking for more trial decentralization user groups where customers can get together to discuss what went well, what didn't go so well, and how to tackle the ongoing challenges as they grow.
- Medidata's Product team currently heads the RBQM Voice of the Customer (VOC) group that meets quarterly.

WHAT'S NEXT:

DECENTRALIZED MEDICAL DEVICE CLINICAL TRIALS

What was once an emerging market trend is now an established market need: decentralized clinical trial technology. Decentralized clinical trials were already popular prior to the pandemic, but COVID-19 forced many medical device sponsors to rapidly accelerate adoption.

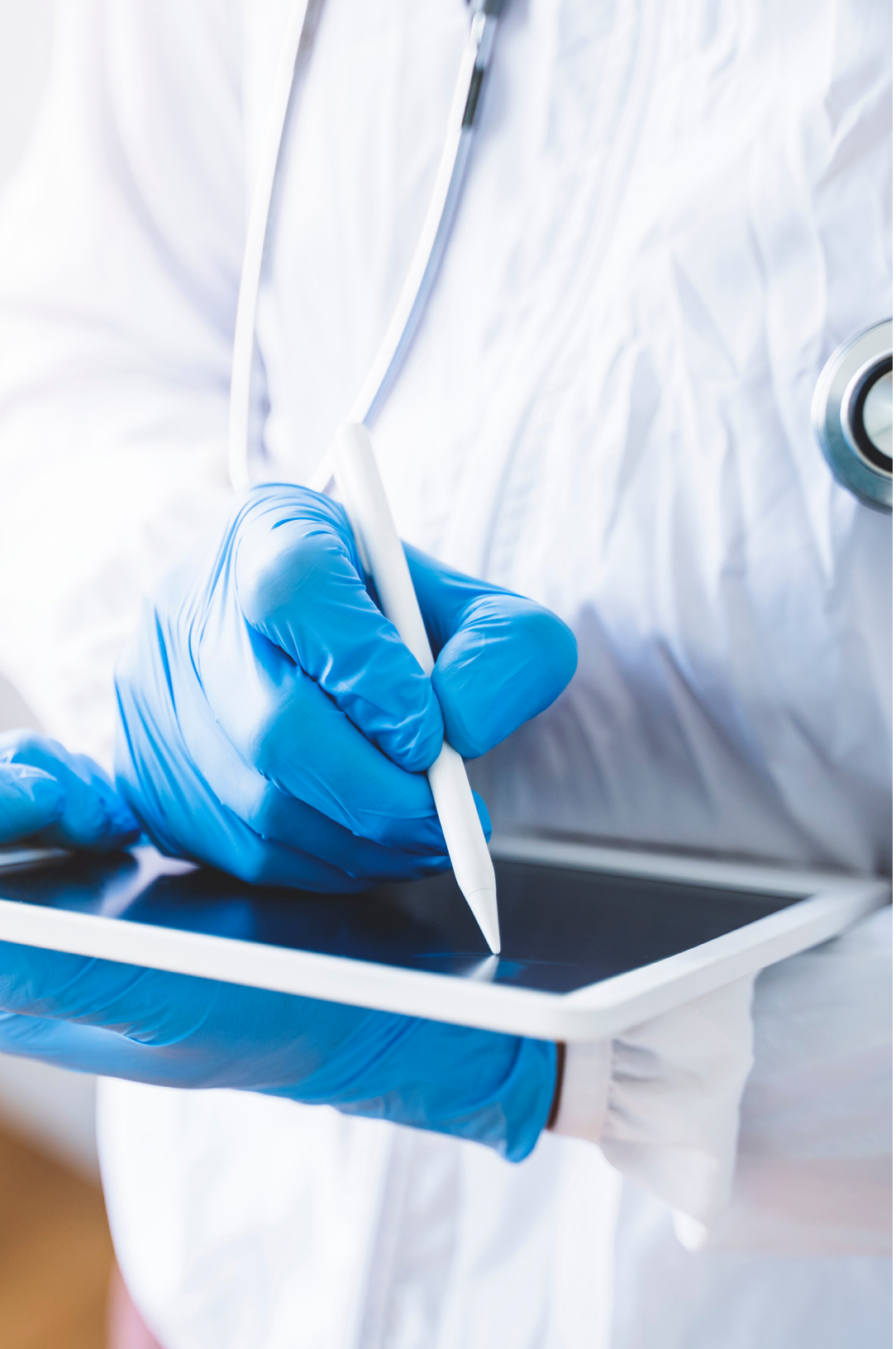
The need for decentralizing technology will certainly endure beyond the pandemic. According to a report from GlobalData published June 2020, approximately 35% of clinical health experts currently use virtual trials and 67% plan to use them in the future.[17]

What are Decentralized Clinical Trials?

In a decentralized clinical trial—also known as a hybrid trial, virtual trial, remote trial, or direct-to-patient trial—one or more elements of the trial occurs outside of a traditional investigator site. As patients have more opportunities to participate in trials virtually—using smartphones, sensors, wearables, or online patient data capturing tools—medtech decision makers need new technology to support ingestion and oversight of these novel data types.

While decentralized trials aim to minimize patient burden by enabling remote participation, working with independent point solutions without a unified platform can create significant challenges. With multiple logins and the need for device integration, it can become a burden on patients and sites to implement new tools. To minimize these risks and reduce data transcription workload for sites, look for decentralization tools already built on your preferred EDC. These tools must also be patient-centric in their design, reducing the number of devices and logins required to access virtually-captured data.

Decentralization also occurs during study oversight, where teams can optimize their level of physical interaction with investigational sites. These teams increasingly rely on virtualized workflows for site and data monitoring, as trials move away from traditional data capture methods towards eSource. This approach can include technologies for risk management, central monitoring, remote site monitoring, and remote document review.



How do Decentralized Clinical Trials Benefit Patients, Sites, and Sponsors?

By removing geographic barriers, patients can participate in trials from anywhere. Tools for eConsent, electronic patient reporting, wearable sensors, and telehealth encourage active patient participation throughout their trial journey. In traditional clinical trials, the burden of traveling to and from sites often causes patients to drop out of studies. According to CenterWatch, the average dropout rate in traditional clinical trials is 30%.[18] For sponsors, this has a serious financial impact—the median cost per patient in pivotal clinical trials between 2015 and 2017 was over $41,000.[19]

Virtual elements help patients stay engaged for the duration of the trial. Technology like connected sensors and direct data capturing tools ultimately improve data quality, as a larger, more diverse set of patients previously unable to participate in traditional site-based studies can enroll.[20] In fact, last year the FDA included the use of decentralized clinical trials in its guidance on increasing patient diversity.

For sponsors, decentralized clinical trials mean less overhead, with fewer site management costs. Automatic digital data transmission also eliminates the chance for human error and relieves site burden by enabling them to focus more time on patient care. In the aftermath of site closures during the COVID-19 pandemic, decentralizing oversight technologies—like central monitoring and remote source document review—enable sponsors to stay agile when adapting to new trial environments. Modern study oversight strategies should support risk identification, mitigation, and monitoring—before and during the data capture process.

HOW MEDIDATA
CUSTOMERS DECENTRALIZE TRIALS

Medidata recognizes that trials rarely operate 100% virtually, especially for medical device companies. Medidata equips sponsors with a catalog of composable capabilities that can be turned "on" or "off" to optimize physical and virtual interactions with both patients and sites during a clinical trial. Our solution suite enables the decentralization of patient participation, data capture and management, and monitoring and analysis, so that patients have a better experience and clinical trials run faster, without any compromise to patient safety or data quality.

With Medidata technology, capture data from anywhere, anytime—then harmonize and analyze that data to drive useful insights. Using our Trial Dial™ continuum, you decide the level of decentralization that's right for your study. Medidata's Trial Dial is a way for sponsors to conduct 100% site-based studies, 100% virtual studies, and everywhere in between. There are no other vendors that can accommodate this hybrid type of study design for both patient data capture and study oversight on one unified data platform.

From a patient perspective, patients can virtually learn about their trials and consent using remote electronic consent, followed by collection of critical data through eCOA, which results in a direct-to-patient shipment of IMP based on data entered in eCOA, all before needing to visit a site for a scheduled visit.

Likewise, study oversight activities encompass start-up activities, central monitoring, and remote monitoring, including remote source document review, live-video monitoring visits, and flexible, targeted on-site visits. In some studies, there is a dramatic reduction in site visits with assessments and oversight being performed remotely.

Medidata's Trial Dial decentralization continuum includes Medidata Patient Cloud and Digital Oversight solutions.

Built using Medidata's award-winning Patient Centricity by Design process, Medidata Patient Cloud is a suite of digital health solutions designed to collect high-quality data from engaged patients regardless of their location. Whether your studies are primarily site-based or decentralized, Patient Cloud technologies help create a better overall study experience for patients and sites.

Medidata Digital Oversight enables continuous data monitoring from anywhere, allowing medical device companies to innovate and optimize their approach to trial design, physical and virtual interactions with sites, and holistic portfolio strategy. Digital Oversight leverages Medidata's experience in data acquisition and aggregation to contextually surface real-time insights at the patient, study, and industry benchmark level, improving clinical operations decision making. Digital Oversight takes risk-based approaches to monitoring and embeds them into workflows on a single transactional platform, infusing RBQM into day-to-day clinical operations.

Consider Sensor Cloud

Medidata Sensor Cloud takes a unique approach to the ingestion, standardization, and scalability of data from any commercial or medical grade sensor device. Patient data delivered to Sensor Cloud can measure a wide array of information that includes sleep patterns, activity, posture, vital signs, and more. Data received using our common model infrastructure can be used by Medidata's biomarker data science team to discover and validate new algorithms or to leverage any of our dozens of existing FDA-approved algorithms. Most importantly, Sensor Cloud's integration with Rave EDC and myMedidata makes sensor data available, as appropriate, to both sites and patients during and after the study.

CASE STUDY:

DRIVING A PATIENT-CENTRIC TRIAL WITH ECONSENT

Boston Scientific, a top 20 global medical device manufacturer, chose to implement Medidata Rave eConsent in 2019. The company's core philosophies about the criticality of patient-centricity in study design and conduct were closely aligned with Medidata's own core tenets of driving patient-focused innovation through transformative technology.

Boston Scientific's core focus for implementing eConsent on their studies was patient driven. The goal was to provide patients with a better understanding of the purpose, risks, and benefits of each study and understand their rights and responsibilities from the very beginning. Their secondary focus was to recognize operational efficiencies through centralized monitoring, reconsenting, and enrollment reporting.

Through their partnership with Medidata, Boston Scientific's eConsent solution went live the first week of November 2019, meeting their timeline goals. They delivered a high-quality product for their patients, receiving positive feedback from several trial participants. Boston Scientific continues to use eConsent to help support and accelerate its clinical development across multiple studies.

"Medidata was great. They created user requirements. They drafted documents for us, and they really guided us every step of the way."

Shari Swanson
Principal Business Analyst, Clinical Programs, Boston Scientific

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SUMMARY:

DECIDE WHAT YOUR DIGITAL FUTURE LOOKS LIKE

Medical device companies have made significant digital transformation progress during the past two decades. Technology advances have improved operational efficiency, patient experiences, and data analysis for clinical trials. The future will bring more technology into clinical processes as decentralized trials proliferate.

But the future isn't just about technology—it's also about the strategic vision necessary to implement a holistic digital model for clinical research. As you strategize your company's future, consider:

1. HOW CAN DIGITAL LEADERSHIP CONTRIBUTE TO YOUR SUCCESS?

Does your technology infrastructure improve operations and automate workflows for your study teams? The best clinical trials technology platforms allow study teams to access data, connect workflows, and manage trials all in one place.

Learn More

2. WHAT VALUE CAN A DATA-DRIVEN APPROACH DELIVER?

Does your data inform your study design? Can your study teams access real-time insights to address risks and improve outcomes? While data informs the outcomes of critical endpoints, it can add even more value by informing researchers and decision-makers at every step along the way. Machine learning and AI combined with expert analysis derive superior value from every aspect of your data.

Learn More

3. WHAT DOES PATIENT CENTRICITY LOOK LIKE IN PRACTICE?

Do your protocols create the best experiences for patients? Are you struggling with high patient dropout rates or slow recruitment? Patient centricity requires continued collaboration—patients have the experience to inform trial designs, advise stakeholders, and benefit from data analytics. Creating the best experiences for patients also means offering convenience with virtual trial options like wearables, sensors, mobile data collection, and telehealth visits.

Learn More

4. HOW DOES YOUR COMPANY CREATE A CULTURE OF INNOVATION?

Do you work with a technology partner that dedicates resources to help you innovate? A trusted, experienced partner connects you with experts and peers who inform you to make the best decisions. Innovation requires commitment from the highest levels of an organization and an environment that fosters collaboration among partners and peers.

Learn More

These four pillars—digital leadership, a data-driven approach, patient centricity, and a culture of innovation—define a successful digital model for clinical research. For medical device companies looking to bring products to market faster and comply with changing regulations, this digital model for clinical research is the foundation of a successful digital strategy.

Achieve clinical, regulatory, and commercial success with a proven partner committed to serving the unique needs of medical device companies. Accelerate time to market and manage changing regulatory requirements with Medidata's innovative technology and 20+ years of industry experience. Together, we can achieve our shared goal of getting products to patients faster.

Notes

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THE DIGITAL MODEL FOR CLINICAL RESEARCH: FOUR PILLARS OF RUNNING SUCCESSFUL MEDICAL DEVICE CLINICAL TRIALS

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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