The Ultimate Guide to Decentralized Clinical Trials

CRO Edition

Four steps to shift, speed, and secure more trials in the age of decentralization

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INTRODUCTION

ATTRACT AND WIN MORE SPONSOR BIDS

"There is no doubt that virtual trials are going to become more prevalent. At the same time, clients will be looking to reduce costs. This means working with Medidata – where the scope of the platform can be adapted – will be critical to future project success."

Claude Price
Director, Clinical Data Management
Quanticate

Attract and win more sponsor bids

COVID-19 completely flipped the world of clinical trials on its head. While the pandemic put many facets of daily life on pause, clinical trials did not stand still. CROs were unsung heroes called upon to deliver quick solutions to navigate site closures, changing regulations, and enabling decentralized clinical trial solutions. In fact, quick pivots by CROs are one of the main reasons sponsors were able to launch COVID vaccines in record time.

Interrupted studies and delays in new trials pose challenges for patients, sites, and all key stakeholders throughout the entire clinical trial journey. When CROs invest in proven innovative technology that delivers a broad range of decentralization solutions, they put themselves in the best position to respond to the various needs of sponsors with a competitive edge.

Despite years of industry dialogue and widespread regulatory acceptance, decentralized clinical trial solutions were not widely adopted by the life science industry. But the acute challenges of the COVID-19 pandemic— limits to on-site activities, in particular— forced their hands in 2020. Many CROs recognized operational efficiencies and improvements in trial execution as a result of the risk-based approaches they took in 2020, and these benefits could continue to accrue long after the pandemic is over.

This eBook outlines four steps to consider when approaching decentralized clinical trials, and the value that adopting these technologies brings to CROs, their sponsors, sites, and ultimately patients:

1	Adapt to sponsors' desired levels of decentralization
2	Improve data quality control through digital oversight
3	Put patients at the core of trial activities
4	Leverage a unified platform to compliment sponsors' needs

Disruptions triggered by COVID-19 spurred innovations that have opened new, sustainable opportunities to increase margins and improve operations. Here is the path for CROs to excel at trial decentralization and digital transformation in the life sciences industry.

MEDIDATA DECENTRALIZED TRIALS EXPERIENCE

800+
Studies

600K+
Patients

44K+
Sites

10 of the top 12
pharma have used Medidata's decentralizing solutions

8 of the top 10
CROs have used Medidata's decentralizing solutions

STEP ONE

ADAPT TO SPONSORS' DESIRED LEVELS OF DECENTRALIZATION

"Working on the frontline of research development for COVID-19, we are excited to continue our partnership with Medidata to support our quality clinical research across the region. Novotech is well-positioned to drive research efforts across the Asia-Pacific region for COVID-19. Working with Medidata and the latest technology, we can deliver integrated clinical trial services in this extraordinary time."

Andries Claassen
Director Biometrics
Novotech

Adapt to sponsors' desired levels of decentralization

Sponsors depend on CROs to adapt—biopharmas outsource roughly 50% to CROs, and that percentage continues to grow each year. CROs who quickly adapt to decentralization using proven innovative technology complemented by an unmatched partnership experience gain a competitive edge, and the opportunity to rise above industry challenges. Required in-person monitoring and hospital visits, site closures due to a lack of enrollment and disruption in the clinical supply chain contribute heavily to delays. Add in the constant evolution of the study design during various phases and CROs experience lost revenue and smaller margins. Decentralized trials reduce some of those risk factors.

Address patient enrollment challenges by lowering the burden on patients to learn new technologies, limiting the number of devices they need to carry, and facilitating access to remote data capturing tools. Equip your study teams with control and visibility into site activities with remote monitoring technologies to access physical sites so they can continue to monitor source data and documents and other high-value activities. Remote stakeholders' engagement, ability to assess end-points virtually, shipment of investigational products directly to patients, and site-level outreach to ensure monitoring are a few of many decentralization initiatives promptly deployed, amidst assuring data and study integrity.

To accommodate hybrid and fully virtual study designs, CROs often work across multiple technology vendors and a host of digital tools. However, cross-functional risks may outweigh their ability to respond to their sponsors' demands. Limitations on interoperability and adaptability, congestion across data sources, and technology failure can result in slower deployments, scalability issues, and unexpected overhead costs. With proven innovative technology and operational agility,

CROs are equipped to:

- ☑ Rapidly reduce patient and site burden
- ☑ Support seamless data between key stakeholders
- ☑ Scale to desired levels of decentralization across
- ☑ Enable custom trial design, balancing onsite and virtual points for seamless patient experience
- ☑ Support remote electronic consent and remote use of eCOA tools by patients
- ☑ Ensure reduction in site visits with remote assessments

Medidata recognizes that trials rarely operate 100% virtually. That's why we equip CROs 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 CROs 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.

STEP TWO

IMPROVE CONTROL OF DATA QUALITY THROUGH DIGITAL OVERSIGHT

"Standardizing our trials with Medidata technology and enhancing our remote monitoring capabilities are critically important during the pandemic. Their scalable solutions will also take us beyond COVID-19. The future lies in minimizing disruptions to research, accelerating the move toward more virtual trial management, ensuring data collection and integrity, and managing source documents remotely, as needed."

Timothy Schroeder
Chief Executive Officer and Founder
CTI

Improve control of data quality through digital oversight

Faced with heightened challenges due to the pandemic, CROs have to navigate across the recovery of significantly impacted trials, the rapid launch of new studies, and the adoption of new technologies to counter patient and site disruptions.

In recent surveys, 69% of sites reported COVID-19 affected their ability to conduct ongoing trials and 78% responded that the pandemic impacted their ability to initiate new trials, leading to the need for real-time changes. In fact, over half of reporting sites have switched site patient visits to virtual or telemedicine formats. Additionally, more than 40% of sites are shipping investigational medicinal products (IMP) directly to patients. Sites demonstrated ingenuity by adopting new approaches to maintain patient safety and ensure data quality.

However, in order to match the pace and magnitude of the pandemic, these strategies require proven innovative technology to support and scale trial decentralization and virtual patient engagement to ensure:

- Greater flexibility, understanding, and response to protocol deviations
- Risk-based strategies embedded into workflows which identify and action the most critical sites for targeted monitoring visits
- Real time transparency and traceability of all data and activities

For CROs, decentralized clinical trials mean automatic digital data transmission, eliminating the chance for human error and relieving 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 CROs 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.

Medidata Digital Oversight enables continuous data monitoring from anywhere, allowing CROs 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.

Patient Centricity and Virtualizing Technologies

Read the results of an SCRS survey on Patient Centricity and Virtualizing Technologies to learn more about how the pandemic is driving adoption of digital tools in decentralized, hybrid, and traditional clinical trials.

Medidata Digital Oversight includes the following products, all leveraging both audit trail and eSignature functionality:

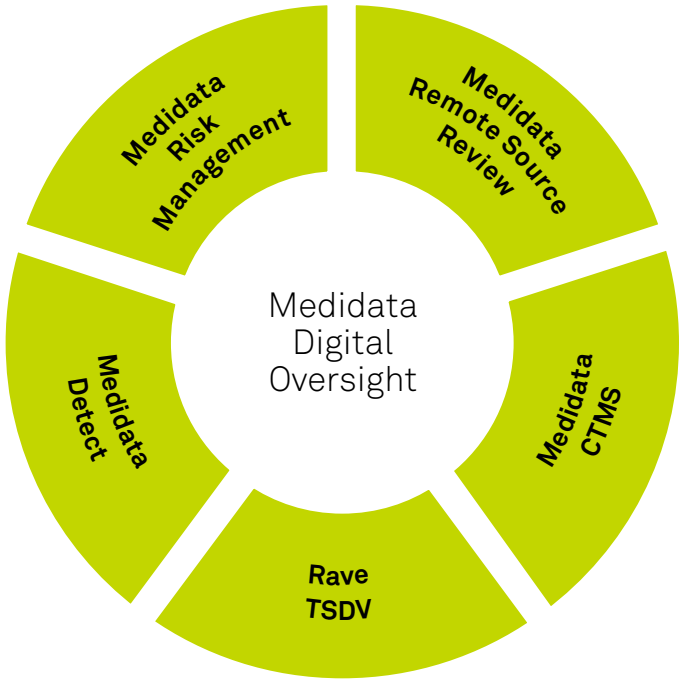
Medidata Risk Management enables study team members to identify, document, measure, and monitor the risk of a study protocol and devise a monitoring plan. The plan incorporates critical processes, critical data, source data review strategies, key risk indicators (KRIs), and quality tolerance limits (QTLs).

Medidata Detect is a data analysis and visualization solution that applies advanced statistical analytics on clinical study data to detect both known and unknown risks, anomalies, and trends. Medidata Detect continually analyzes patient and site data. Using machine learning and statistical algorithms, it identifies multi-level study areas of risk fast and accurately, providing immediate insight into study performance and data quality. Medidata Detect's findings help determine any necessary mitigating actions to take on study issues or risks to ensure study data quality and compliance.

Rave TSDV (Targeted Source Data Verification) is a tool that targets and reduces the amount of source data verification ("SDV") conducted in a clinical study by using a configurable, statistical algorithm without sacrificing regulatory compliance or data quality strategies.

Medidata Remote Source Review is a cloud-based solution that rapidly and remotely enables monitors to acquire critical documents, automates document workflows to the right monitor for the right study and site and allows him/her to review documents to support SDV and SDR. This allows for real-time assessment of subject safety and data quality compared to traditional onsite monitoring efforts. Sites simply upload source documents via a secure browser that has robust built-in Personally Identifiable Information (PII) and Protected Health Information (PHI) blinding capabilities, which removes the need to use error-prone, manual redaction techniques.

Medidata CTMS (Clinical Trial Management System) standardizes trial activity planning and management at the study, country, and site level. End-to-end trial activities are supported such as study startup, study conduct including enrollment and milestone tracking, site monitoring, and issue management. Rave CTMS integrates with Rave EDC (Electronic Data Capture), Rave eTMF (electronic Trial Master File), and Medidata RBQM (Risk-Based Quality Management) to streamline workflows and surface insights to drive decision-making.



STEP THREE

PUT PATIENTS AT THE CORE OF TRIAL ACTIVITIES

"We're excited to be part of the early engagement program with Medidata on [the new myMedidata platform]. I think it's really exciting and it's going to benefit lots of patients."

Rosamund Round
Vice President, Patient Innovation Center and Decentralized Trials
Parexel

Put patients at the core of trial activities

COVID-19 demonstrated that when CROs embrace decentralized technology, the patient is more likely to enroll, and remain enrolled, throughout the trial stages. To encourage participation, reduce burden, and decrease dropout rate, CROs need proven innovative technology to ensure that participation in clinical trials can be seamlessly integrated into each patient's life.

Decentralization technologies give CROs a competitive edge by ensuring better patient centricity and safety through recruitment, enrollment, and participation. CROs delivering end-to-end, streamlined, and unified technology will dramatically improve participant recruitment and retention by delivering a seamless flow of capabilities through the patient journey.

Decentralization removes geographic barriers, meaning 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%. For your sponsors, this has a serious financial impact—the median cost per patient in pivotal clinical trials between 2015 and 2017 was over $41,000.

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. In fact, last year the FDA included the use of decentralized clinical trials in its guidance on increasing patient diversity.

CRO CHALLENGES AND STRATEGIES

Read IDC's new report, CRO Challenges and Strategies: COVID-19 and Beyond where Medidata posed pressing questions to IDC analysts regarding key industry trends and pain points.

Patient Centricity from Patient Insights

The life science 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.

The future state of patient centricity depends on how well CROs balance the benefits of trials for their business and for patients. An emerging discussion in the 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.

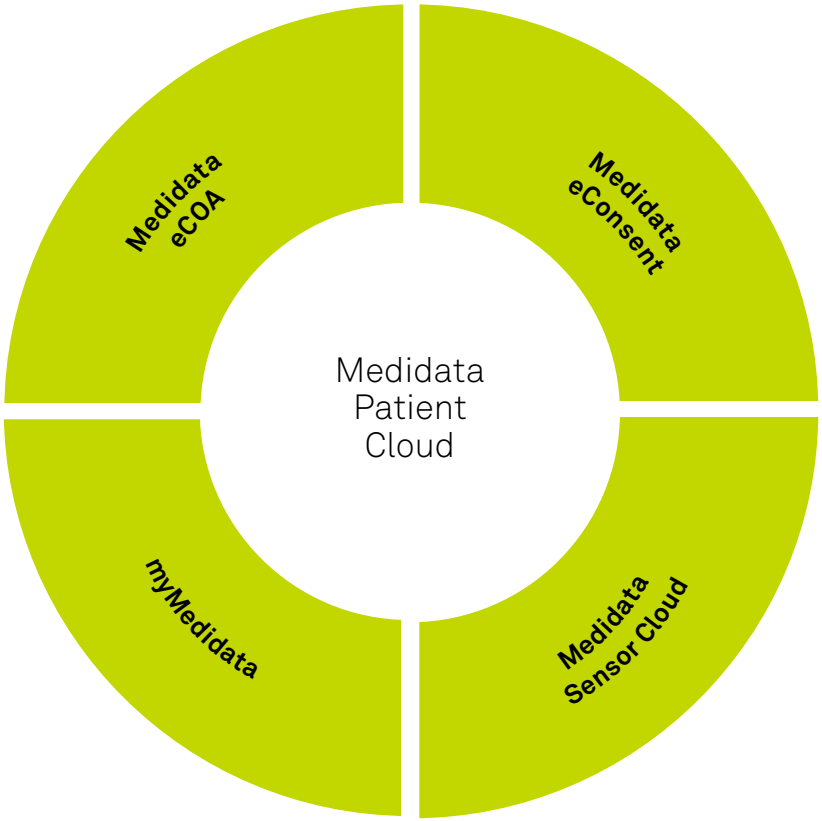
Medidata operates with a formal process called patient centricity by design (PCbD), part of our Patient Insights program. This is the formal process of infusing the patient perspective into the software development life cycle to create technical solutions that improve the overall patient experience in clinical research interactions. Medidata built PCbD around three core principles of patient centricity: design, engagement, and activation.

- **Design**: 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.
- **Engagement**: 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.
- **Activation**: 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.

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 Patient Cloud includes the following products:



Medidata eCOA (electronic Clinical Outcomes Assessment) is a full service, flexible solution that easily and accurately captures outcomes data from patients, caregivers and clinicians. Available as an iOS or Android app or web-based solution, Medidata eCOA improves your study experience with flexible deployment options, a groundbreaking global instrument library, and dedicated services and support. This product leverages audit trail functionality.

Medidata eConsent automates the patient enrollment process and onboards patients directly into Rave EDC and Rave RTSM. Whether onsite or remote, get started faster with our scalable platform supported by user friendly configuration tools that eliminate the need for customization. This product leverages both audit trail and e-signature functionality.

myMedidata is a single-destination patient portal, enables patients to virtually enroll and participate in pre, during, and post clinical trial activities. Built directly on the industry's leading Rave EDC platform, myMedidata extends all of the capabilities of Medidata's patient-facing solutions for electronic patient consent and clinical outcomes assessment (eCOA), collection of critical data through wearable and other biosensors, COVID-19 symptom tracking, live video investigator/patient visits, registries, and enablement of hybrid and virtual trials through a web-based portal. Using myMedidata, patients can easily complete forms, participate in video visits with their study team, receive reminders and notifications for study-related tasks, and access their results, using any device with an internet connection.

Medidata Sensor Cloud takes a unique approach to managing a broad range of sensor and digital health technology data during clinical trials. Our common data model enables rapid ingestion and analysis of patient data resulting in better clinical decision making, faster timelines and a more patient-centric experience. This product leverages audit trail functionality.

STEP FOUR

LEVERAGE A UNIFIED PLATFORM TO COMPLIMENT SPONSORS' NEEDS

"[The Medidata Clinical Cloud], inclusive of CTMS, eTMF, and EDC, has offered tremendous advantages to Catalyst and our customers. The benefits and features we value are the ability to leverage multiple systems that are compatible, user friendly, and familiar to the end-user resulting in overall efficiencies for the sponsor, sites, and partners."

Keya Watkins
Global Head, Clinical Development
Catalyst Clinical Research

Leverage a unified platform to compliment sponsors' needs

Adaptive speed is an essential ingredient for optimal performance, growth, and transformation in times of unprecedented change. When investing in technology to support decentralization, a myriad of cloud technologies suites of capabilities are available. While evaluating options, consider a decentralization path built on proven innovative technology that offers adaptability, operational agility, patient-centricity, and speed.

Working with independent point solutions without a unified platform can create significant challenges for CROs. With multiple logins and the need for device integration, it can become a burden on sites to implement these tools. However, using decentralization tools already built on the EDC being used will mitigate risk and reduce data transcription workload for sites. Medidata decentralization solutions are all unified with Rave EDC, enabling direct eSource data capture to provide more information in real-time, with no opportunity for error. With Medidata Digital Oversight, there is no need to create a new login. Sites log into Rave EDC and access the data in near-real time for monitoring without the need for data reconciliation.

Unifying decentralization capabilities on a single platform delivers fast adaptation and performance with the following benefits:

- All scenarios of decentralization have been pre-identified
- An end-to-end range of technologies delivers solutions across all sites, patients, and sponsors on one single platform
- Solutions are designed to improve patient experience, safety, and centricity
- All capabilities are synchronized to deliver real time insights for remediation and secure data integrity

MEDIDATA PERFORMANCE METRICS

As reported by our customers

>70%

reduction in study build time over industry benchmarks

61%

higher reuse of eCRFs to reduce build and testing times

40%

improvement in CRA action item management productivity

50%

reduction in subject visit to query close cycle time

~70%

reduction in report generation time

25%

reduction in costs associated with visit report approval

How Medidata Customers Decentralize Trials

Your trusted partner for over 20 years, Medidata has been driving change and enabling innovation through a scalable cloud-based platform for clinical trials. Now, we are paving the way for you to deliver the future of clinical trials, giving you the ability to capture data from anywhere, anytime, and then analyze and harmonize all of that data to drive useful insights.

At a time when investment resources are at risk post-COVID, CROs are tasked with accelerating development of treatments and devices, driving fast approvals, and generating data that will stand up to regulatory scrutiny. Decentralized trials present an opportunity for CROs to recover lost revenue streams to attract and win more sponsor bids in a highly competitive industry.

Through our suite of decentralizing capabilities, you can dial your decentralized strategy up or down as needed, to optimize physical and virtual interactions with both patients and sites during a clinical trial. Realize truly virtual data capture and management, monitoring and analysis, and supply dispensation and management, so that your patients and sites have a better experience and your clinical trials run faster, without any compromise to patient safety or data quality.

The industry's only complete trial decentralization solution.

We are the only company that thinks about the whole trial, delivering novel decentralizing capabilities for both patient participation and study quality.

Let's build your path to decentralization, together.

Virtualize as much or as little as you need using the Medidata Trial Dial, our fully composable and customizable solution.

Any data, from anywhere, available everywhere.

Take a low-risk approach to decentralization by unifying all data on one platform, bridging the gap between data and workflows.

Advanced analytics power smarter, safer trials.

Continuously monitor and analyze your data, from anywhere, to realize the next generation of clinical operations.

THE ULTIMATE GUIDE TO DECENTRALIZED CLINICAL TRIALS

CRO EDITION

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**.

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