medidata joins DASSAULT SYSTEMES

The Ultimate Guide to Trial Virtualization

CRO Edition

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

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Get ahead with virtualization. Stay ahead with transformation.

COVID-19 continues to drive profound disruptions in clinical trials. CROs are called upon to deliver rapid responses to unprecedented numbers of deviations across sites and patients.

The implications of interrupted studies and delayed new trials cause ever evolving challenges to patient experience, site enablement, data, and overall trial integrity.

CROs invested in technologies delivering a broad continuum of virtualization solutions are best positioned to respond to sponsors' urgent requirements. Rethinking tech capabilities and access to data solutions fueling performance is a CRO's priority and a path for immediate advantage to prepare for the next disruption and manage long-term growth.

> "... Medidata's unified platform is helping us put participants at the center of our efforts to develop a safe and effective vaccine against COVID-19."
>
> **Marcello Damiani**
> Chief Digital and Operational Excellence Officer
> Moderna

This eBook outlines four steps designed to start, scale, and accelerate a CRO's virtualization journey:

- Adapt to sponsors' desired levels of virtualization
- Become a site enabler through disruption and beyond
- Power patient participation and centricity
- Take the lead in growth and transformation

Disruptions triggered by the crisis spurred innovations that have opened new, sustainable opportunities. Here is the path for CROs to get and stay ahead of virtualization, the patient-centric paradigm, and our industry's overall digital transformation.

MEDIDATA KEY FACTS FOR PARTNERS

125+
CRO Partners

500K+
Site/Sponsor relationships

20K+
Clinical Trials

3,700+
Phase I trials to the largest ever virtual trial

One of the industry's
largest clinical trial data repositories

STEP ONE

ADAPT TO SPONSORS' DESIRED LEVELS OF VIRTUALIZATION

"[Medidata] technology allowed us to quickly pivot when the pandemic hit. We needed to change what we were doing, and we were able to leverage the technology and Medidata's expertise to meet the needs of our patients and sites."

Tommy Lee
VP of Clinical Operations
TissueTech

Adapt to sponsors' desired levels of virtualization

Sponsors depend on CROs to adapt.

Being first to adapt to virtualization is a CRO's edge to compete and outperform, and the opportunity to rise above industry challenges.

However, virtualization requirements are complex and constantly evolving as study teams adapt to ongoing disruptions such as: subjects missing hospital visits, sites closing or being overwhelmed with COVID-19 patients, or interruptions to the clinical supply chain.

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 virtualization 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.

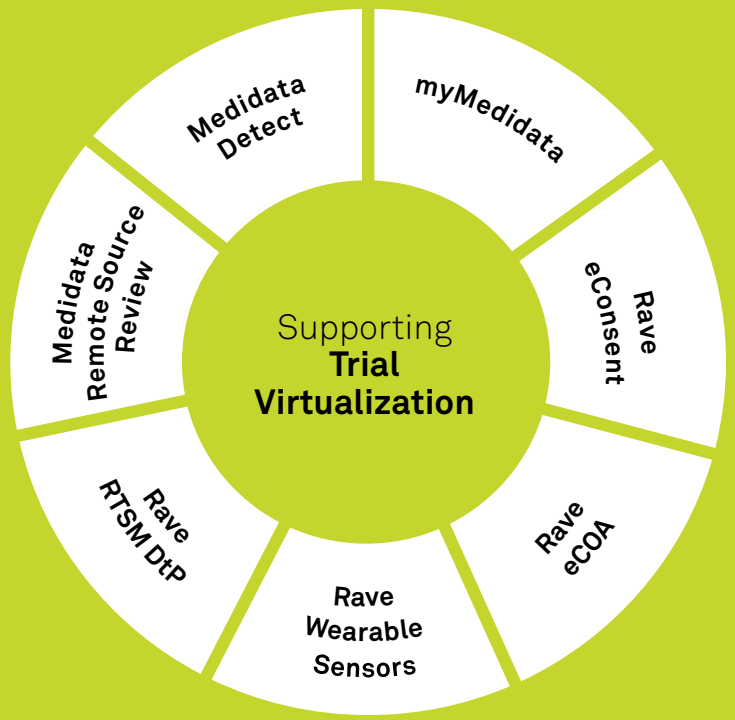
Limitations on interoperability and adaptability, congestion across data sources, and technology failure can result in slower deployments, scalability issues, and unexpected overhead costs.

CROs have to deliver on customizable technology and operational agility to:

- Rapidly reduce patient and site burden
- Support seamless data flow from patient to clinician to site to sponsor
- Scale to desired levels of virtualization across multiple trials
- 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

Leveraging a platform-as-a-service approach gives CROs access and control across all trial virtualization technologies. All categories of virtualization have been pre-identified and an end-to-end range of technologies delivers the required solutions across all sites, patients, and sponsors on one single platform.

On-demand, customizable, and scalable, the platform not only helps simplify processes, ensure consistent reliable data, mitigate risk, and improve efficiencies, it assures CROs are first to adapt and to respond to opportunities.



STEP TWO

BE A SITE ENABLER THROUGH DISRUPTION AND BEYOND

"When compared with traditional cardiovascular trials that engage hundreds or thousands of sites, this technology allowed us to enroll 15,000 participants from 40 centers."

Dr. William Schuyler Jones
Associate Professor of Medicine
Duke University Medical Center

Be a site enabler through disruption and beyond

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.

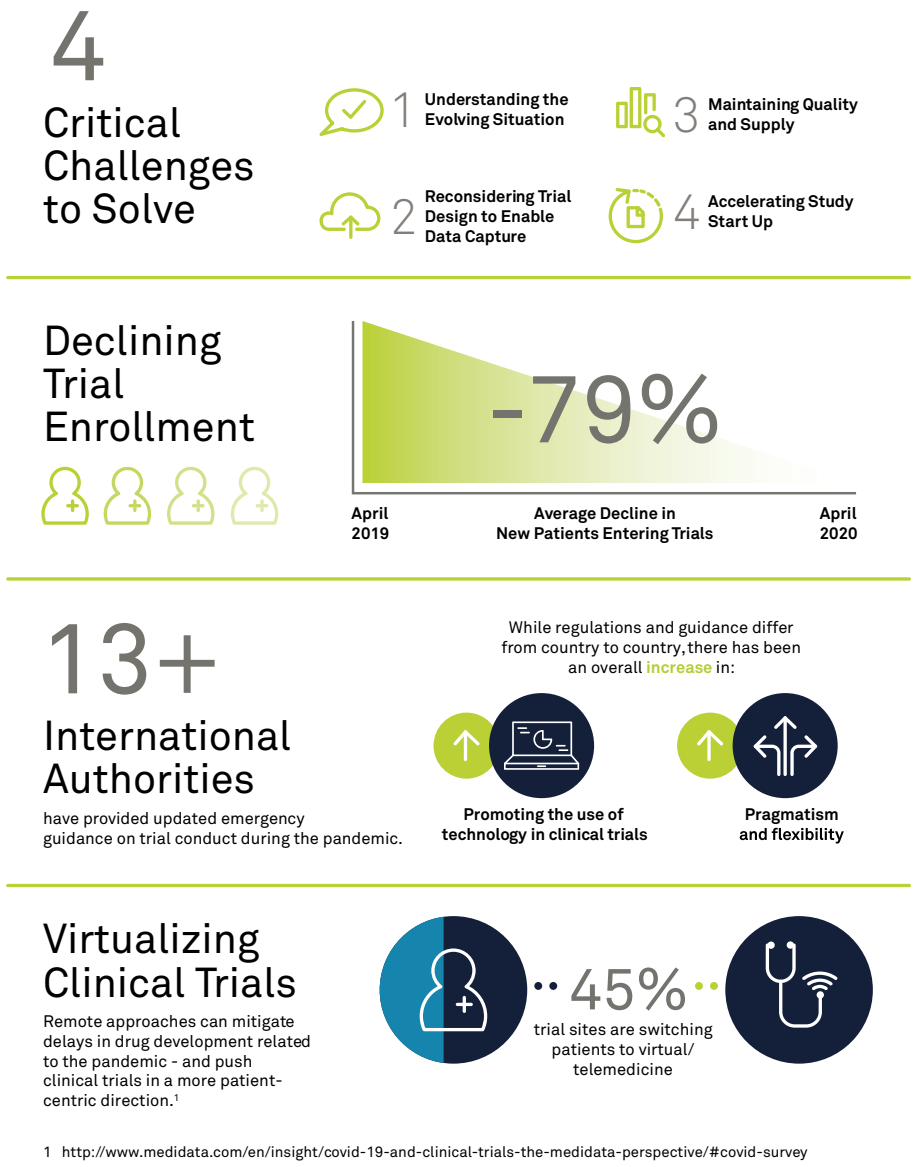
In recent surveys, 69% of sites reported COVID-19 affected their ability to conduct ongoing trials and 78% responded that the pandemic impacted their ability to initiate new trials, leading to the need for real-time changes.[1]

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. However, in order to match the pace and magnitude of the pandemic, they require technology that can support and scale virtual trials and decentralized patient engagement to ensure:

- Greater flexibility, understanding, and response to protocol deviations
- Immediate response to accommodate patients unable to visit research centers
- Real time transparency and traceability of all data and activities
- Improved study-specific virtualization contingency plans to prepare for the possibility of future outbreaks

When decentralizing operations and approaching virtualization, site-level interventions require site-centric technology solutions.



1 http://www.medidata.com/en/insight/covid-19-and-clinical-trials-the-medidata-perspective/#covid-survey

For CROs and sites alike, the key to ensuring resilience in trial performance requires a shift toward virtual inspections to oversee all occurring offsite activities.

It requires leveraging technology to manage trial logistics – remote consultations for patients, telemedicine, directly shipping drugs to patients. As patients shift to alternate sites or at-home care, tracking protocol compliance becomes critical.

Remote Source Review enables remote monitoring of critical documents. It helps fill the gap when studies have critical timelines and no secure option to collect, de-identify, manage, review and verify critical study documents.

Platform-as-a-service technology enables CROs with streamlined access to a broad set of integrated, scalable, and virtualization capabilities.

Not only do CROs gain greater operational agility, they also achieve higher patient retention, better control of data integrity with real-world evidence, and protocol compliance.

SITE-CENTRIC SOLUTIONS

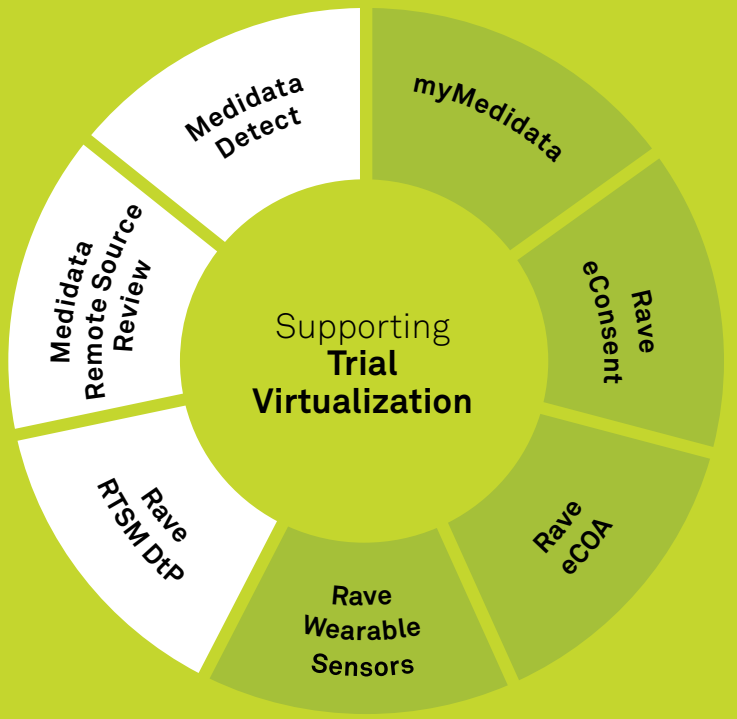
Medidata Detect
The solution enables virtualization of data review and alerts the CRA on out-of-range data points. It also removes the need for data collection, in person, from the site, and delivers real-time data review that proactively curates errors.

Rave RTSM Direct-to-Patient (DtP)

DtP allows the study of medications that are to be received and administered in a patient's home, simplifying the randomization and trial logistics like drug shipments, lab data collection etc. It also alleviates high trial costs and shortens clinical trial timelines.

Medidata Remote Source Review

A remote source review helps power sites by continuously monitoring source elements. It captures a photo of the source document and securely uploads it to a portal, enabling virtual access for the CRAs to source and review the document with ease.



STEP THREE

POWER PATIENT PARTICIPATION AND CENTRICITY

Pre-pandemic, the average patient dropout rate ranged around 30%, with approximately 40% of patients not adhering to trial protocols.[2] Patients' experience can make or break trial outcomes.

COVID-19 has caused CROs and sites to experience profound disruptions in patient enrollment and retention.

To encourage participation, reduce burden, and decrease dropout rate, CROs must deliver the technology to ensure that participation in clinical trials can be seamlessly integrated into each patient's life.

Virtualization technologies give CROs a competitive edge by ensuring better patient centricity and safety through recruitment, enrollment, and participation.

- Removing geographic barriers to participation
- Expanding channels of recruitment: digital, social media, advocacy groups, or patient registries
- Giving patients a portal designed to help them learn about available trials and register for research in which they are interested
- Enabling virtual enrollment and participation for a more diverse set of patients, representing a broader range of ethnic, racial, and socioeconomic status

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.

For all its disruption, COVID-19 has, out of necessity, accelerated innovation.

CROs leveraging agile technology are not only enabling patients, they are also building on the momentum to transform in a rapidly changing patient centricity paradigm.

myMedidata

With myMedidata, a patient experience is powered by the industry's most comprehensive suite of virtual and remote technology capabilities – eConsent, eCOA, COVID-19 symptom tracker, LIVE video visits, and wearables.

ePRO and Rave Wearable Sensors

These solutions help real-time data capture digitally and analyze it through the wearable medical sensors. They also negate the need to manually monitor data transcription.

Rave eConsent and myMedidata eConsent

Regulatory-compliant, patient-friendly, electronic consent system automates the patient enrollment process and patient onboarding. The capabilities can speed start-up and studies from months to weeks.

eConsent is integrated with EDC, RTSM, and eCOA for a single-view, centralized monitoring. myMedidata eConsent extends this technology to be accessed virtually through the web, enabling remote patient enrollment.

Meeting global requirements and offering localization with configurable capabilities for multiple languages and regulatory environments, the solutions facilitate guaranteed signature compliance and site screening metrics.

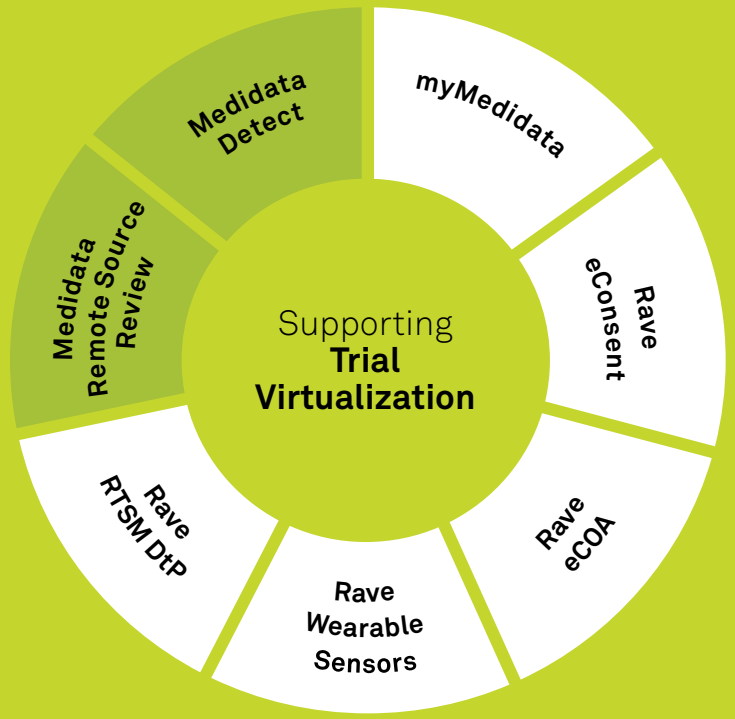
Rave RTSM Direct-to-Patient (DtP)

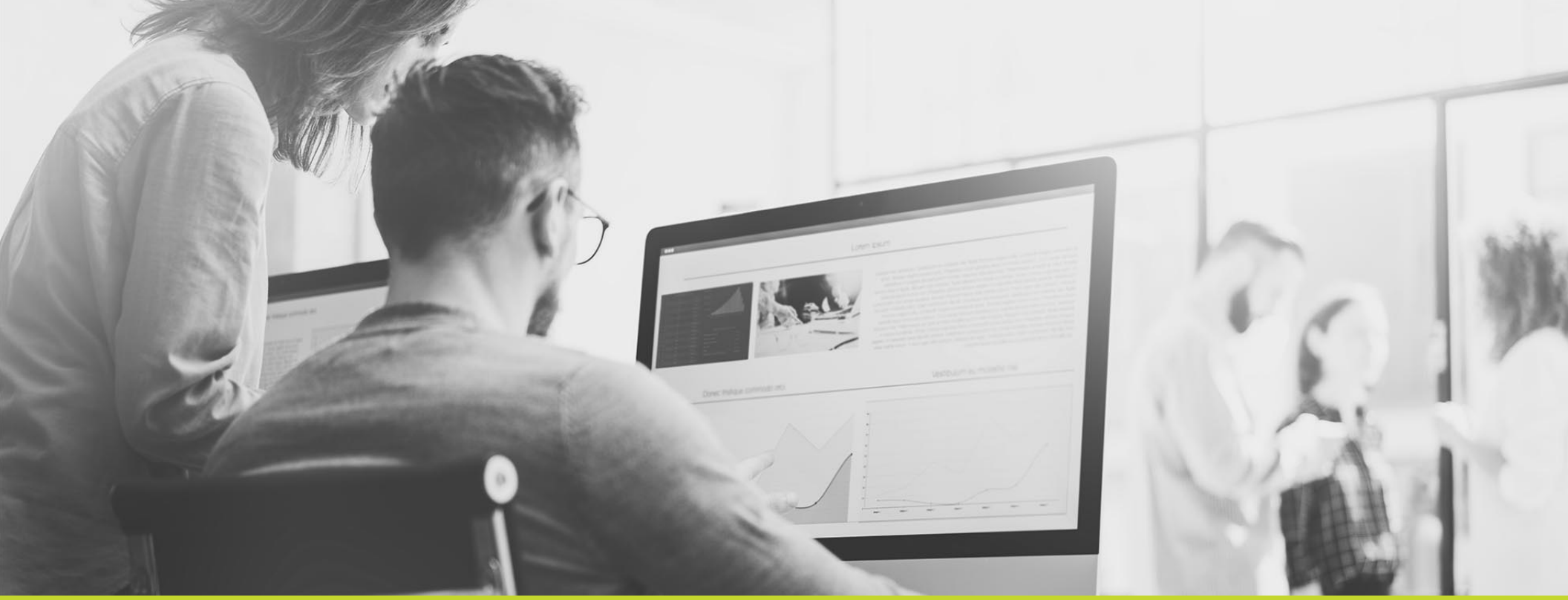
Rave RTSM for DtP makes getting the right treatment directly to the right patient at the right time thereby supporting virtualization and hybrid trial approaches. This solution removes the need for the patient to travel directly to a site and instead access customized care and novel therapies from the comfort of their homes.

CROs are able to facilitate patient enrollment and increase patient adherence, which are central to the success of clinical trials.

With Medidata's Rave RTSM, sponsors and CROs can manage DtP shipments for clinical trials or medical device trials, all while maintaining patient confidentiality since patient addresses are never stored in Rave RTSM.

PATIENT-CENTRIC SOLUTIONS





STEP FOUR

TAKE THE LEAD IN GROWTH AND TRANSFORMATION

"Working with Medidata and the latest technology, we can deliver integrated clinical trial services in this extraordinary time."

Andries Claassen
Director Biometrics
Novotech

Take the lead in growth and transformation

Adaptive speed is an essential ingredient for optimal performance, growth, and transformation in times of unprecedented change.

When investing in technology to support virtualization, a myriad of cloud technologies suites of capabilities are available.

While evaluating options, consider a virtualization path that offers adaptability, operational agility, patient-centricity, and speed.

Our platform-as-a-service path to virtualization empowers CROs to drive growth beyond delivering virtualization, safely and speedily.

The platform model also keeps CROs abreast of expanded revenue opportunities as it enables them to uncover new bids, identify fit-for-use data, and improve patient recruitment and retention.

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

- All scenarios of virtualization 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

Finally, CROs can mitigate risks when adopting new technologies by leveraging the right solutions at the right time, with the ability to unify virtualization plans and trial data through integrated data sets and product capabilities.

MEDIDATA PERFORMANCE METRICS

>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

Virtualization: Why Medidata for CROs

Medidata offers CROs a proven, streamlined approach to virtualizing clinical trials.

Our platform-as-a-service model, supported by the expertise of our Professional Services team, enables flexible hybrid virtualization to meet a CRO's specific requirements, ensuring the following key benefits:

- Adaptive capabilities to match degree of virtualization required
- Enhanced patient-centricity through engaged and dynamic participation
- Reduced integration burden from disparate solutions and data
- Streamlined operations and minimization of the complexity and costs of maintaining multiple systems
- Risk mitigation through the unified Medidata Rave Clinical Cloud™, using patient data capture at the site on the same platform used to capture patient data on myMedidata

As the adrenaline from the crisis-response period wears off, CROs must figure out how to continue building a technology edge that will set them apart and gain speed to get ahead, and stay ahead of the next disruption.

THE ULTIMATE GUIDE TO TRIAL VIRTUALIZATION

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 1,500 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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1 https://www.medidata.com/wp-content/uploads/2020/08/COVID19-Response8.0_Clinical-Trials_2020824_v1.pdf

2 Tufts Center for the Study of Drug Development and Forte Research3

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