Your Path to Virtualization

Sponsor Edition

Eight parameters to accelerate and optimize your technology strategy

INTRODUCTION

The COVID-19 pandemic drove 45% of clinical trial sites to transition patients from in-person to remote visits using virtual trial solutions.[1]

Disruptions preventing or limiting site access to patients, monitors, and CRAs are propelling long-lasting changes in the research industry, supported by the adoption of virtualization technologies.

The urgency to adapt to evolving requirements for both patients and sites is prompting sponsors to engage in new discussions with their CROs.

Trial success relies on driving the pace, flexibility, and adoption of new capabilities.

The need for a rapid response is also creating new opportunities for sponsors to fundamentally evolve their technology strategy and leap into the next generation of clinical trials, far beyond COVID-19.

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

This eBook provides eight parameters to help sponsors optimize their path to virtualization across key site- and patient-centric capabilities.

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PARAMETER 1

URGENCY: COVID-19 RAPID RESPONSE

COVID-19 has intensified site access issues, accelerated the need for virtual clinical trials, and driven the urgency for remote patient participation and trial monitoring.

How urgent is it for you to support remote patient engagement, informed consent, and data capture using virtualization technologies?

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.

Sponsors must respond with hybrid and fully virtual study designs, often pressured to choose 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.

Sponsors need to invest in customizable technology to achieve long-term operational agility and performance to:

- Rapidly reduce patient and site burden
- Support seamless data flow from patient to clinician to site
- Scale to desired levels of virtualization across multiple trials
- Support remote electronic consent and remote use of eCOA tools by patients
- Ensure reduction in site visits with remote assessments

4
Critical Challenges to Solve

1 Understanding the Evolving Situation
2 Reconsidering Trial Design to Enable Data Capture
3 Maintaining Quality and Supply
4 Accelerating Study Start Up

Declining Trial Enrollment

-79%

April 2019 — Average Decline in New Patients Entering Trials — April 2020

13+
International Authorities

have provided updated emergency guidance on trial conduct during the pandemic.

While regulations and guidance differ from country to country, there has been an overall increase in:

- Promoting the use of technology in clinical trials
- Pragmatism and flexibility

Virtualizing Clinical Trials

Remote approaches can mitigate delays in drug development related to the pandemic - and push clinical trials in a more patient-centric direction.[1]

45%
trial sites are switching patients to virtual/ telemedicine

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

PARAMETER 2

MANAGING VIRTUAL PATIENT CONSENT

New patient enrollment has declined by 79% in the past 12 months.[1] How do you keep your trial on track when patients can no longer access sites?

Are you equipped to educate, enroll, and ensure patient consent with virtual capabilities?

Providing the capability for remote patients to learn about and enroll in a study virtually has become core to both trial continuity and new study launch.

myMedidata, a single-destination platform to enroll and participate in clinical trial activities, provides patients with an end-to-end experience to discover trials, review their benefits and risks, and start their enrollment process remotely.

A myMedidata account gives patients access to educational videos and written guidelines for every step of the study process. Once their eligibility is confirmed, patients are guided through an electronic consenting process, or eConsent.

eConsent is reviewed through a myMedidata LIVE visit with the patient and their study team. Patients can flag areas and access a study healthcare professional to get answers to all their queries.

Upon full understanding of the consent for participation, patients can virtually sign their web-based eConsent, or myMedidata eConsent when completed off site.

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

CHECKLIST

Are you looking to:

- ☐ Respond to limited site access
- ☐ Remove geographic barriers to participation
- ☐ Give patients a portal designed to help them learn about trials
- ☐ Educate patients with study video, written details, and guidelines
- ☐ Guide and monitor end-to-end Knowledge Review
- ☐ Facilitate guaranteed signature compliance and site screening metrics

PARAMETER 3

LEVERAGING WEARABLES

In the absence of in-office clinical consultations, collecting objective and timely data from off-site patients relies on wearable data management and reporting.

How critical is the use of wearables to collecting patient data in your trial?

Enabling the collection of critical, objective patient data through wearable and other biosensors is paramount to ensure study continuity and patient safety.

Rave Wearable Sensors capture frequent, continuous, and objective data directly from the patient during a clinical trial. This solution improves the patient experience by reducing the number of site visits, providing a less intrusive way to collect patient data, and boosting patient engagement, while securely storing sensor data for advanced analytics and reporting.

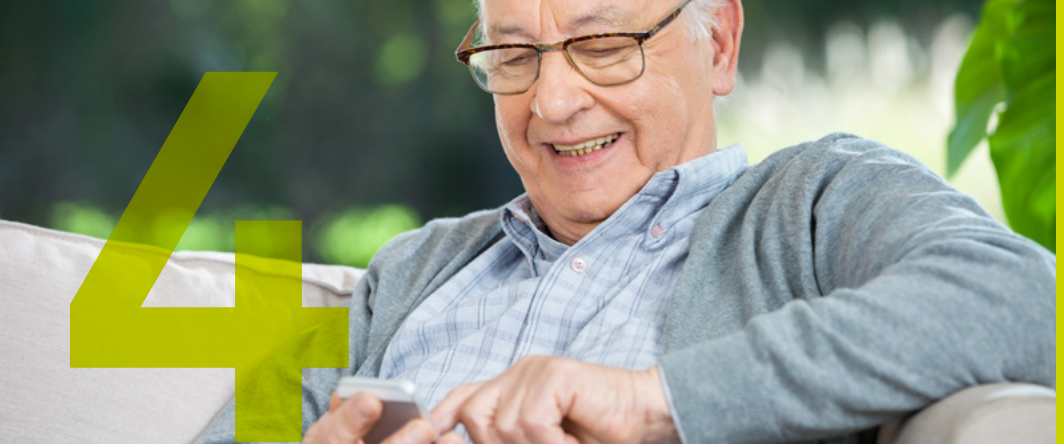
When Rave Wearable Sensors is used with other Rave Clinical Cloud solutions, data is compliant and highly accurate, while time spent on data entry and transcription is obsolete.

Efficient collection of structured and unstructured patient data enables real-time data review. It helps identify and address potential issues swiftly. Patient safety is also enhanced by immediately recognizing potential safety signals.

CHECKLIST

Are you looking to:

- ☐ Get full provisioning of mobile devices and sensors
- ☐ Process, store, and audit a high volume of data
- ☐ Manage across a variety of hardware and deployment models
- ☐ Transfer data for external analytics
- ☐ Route and integrate data while protecting clinical records from Personally Identifiable Information
- ☐ Access dashboards for compliance and operational oversight
- ☐ Meet evolving study requirements and local regulatory guidelines



PARAMETER 4

DEPLOYING REMOTE eCOA

Virtual patient participation introduces new trial complexities. How do you ensure patients respond accurately to surveys? Can you monitor patient safety and data integrity while off site?

Are you reliant on eCOA forms to ensure your trial integrity?

eCOA allows for patient data forms to be remotely filled out. Medidata's eCOA solution can be used to convert site-based data forms to remote data forms.

Patients can download the Medidata patient cloud app to access and provide remote patient data capture along with urgent data forms needed for missed visits.

Throughout the trial life cycle, patients also access their myMedidata accounts to virtually complete any necessary electronic clinical outcome assessments. Study teams configure the necessary forms and the patient logs into myMedidata to complete the web-based forms.

- Any Rave EDC study using eCOA can have additional data forms pulled into the eCOA app and made available to patients.
- Any Rave EDC studies not using eCOA can add eCOA to the project and immediately begin converting forms to remote-enabled forms.

YOUR EXPERIENCE WHETHER YOU ARE USING eCOA ON SITE OR AT HOME

WHAT DOES THE SITE STAFF SEE?

ClinRO
Clinician Reported Outcomes

ePRO in Site Mode
Patient or Caregiver Reported

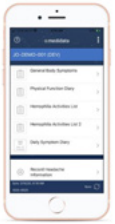
Reporting
Compliance Summaries

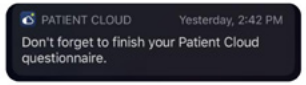
WHAT DOES THE PATIENT SEE?

ePRO
Questionnaires and QOL

Patient Diary
Symptoms, Meds, and tracking

Alerts / Reminders
Stay on track





PARAMETER 5

RELYING ON SITE REMOTE MONITORING

With limited or reduced access to clinical sites, sponsors are faced with an urgent need to evolve their monitoring execution models while ensuring patient safety and data quality.

Uncovering errors and addressing deviations before they corrupt your trial results is crucial. Ensuring continuous remote monitoring of site activities and data will remediate risks and keep your trial on track.

Are you able to review site data and documentation remotely?

Sponsors must assess current risks to subject safety and data integrity with as little impact to the site as possible. Medidata has developed a holistic remote monitoring solution encompassing three core activities: Centralized Statistical Monitoring, Central Data Monitoring, and Off-Site/Remote Site Monitoring.

Remote Source Review gives oversight on site activities by continuously monitoring source elements. By enabling the capture and upload of a photo of the source document to a portal, CRAs, unable to visit sites, are alerted when a data point is out of range and virtually access any necessary source documents for review and remediation.

As a hybrid solution to the on-site/off-site approach to study oversight, sponsors have the ability to shift from 100% on-site monitoring to remote monitoring activities.

Medidata Remote Source Review is a streamlined and quick-to-implement solution to collect, de-identify, manage, review, and verify critical study documents.

Study teams can also design, configure, and execute a highly targeted Source Data Verification (SDV). Rave TSDV prepares inspection-ready records of verified and unverified data points to ensure compliance.

CHECKLIST

Are you looking to:

- ☐ Support remote source document review and verification
- ☐ Target monitor's review on data endpoints
- ☐ Maintain de-identification and redaction of Personally Identifiable Information (PII) and Protected Health Information (PHI)
- ☐ Mitigate risk for studies with no secure option to manage critical documents
- ☐ Use a regulatory-supported method to perform reduced SDV
- ☐ Have a fully auditable solution
- ☐ Eliminate manual CRA determination of monitoring requirements
- ☐ Get real-time reporting capabilities for oversight responsibilities

PARAMETER 6

POWERING CENTRALIZED STATISTICAL MONITORING

As COVID-19 keeps driving remote and virtual trial activities, how do you identify and efficiently prioritize and remediate risks?

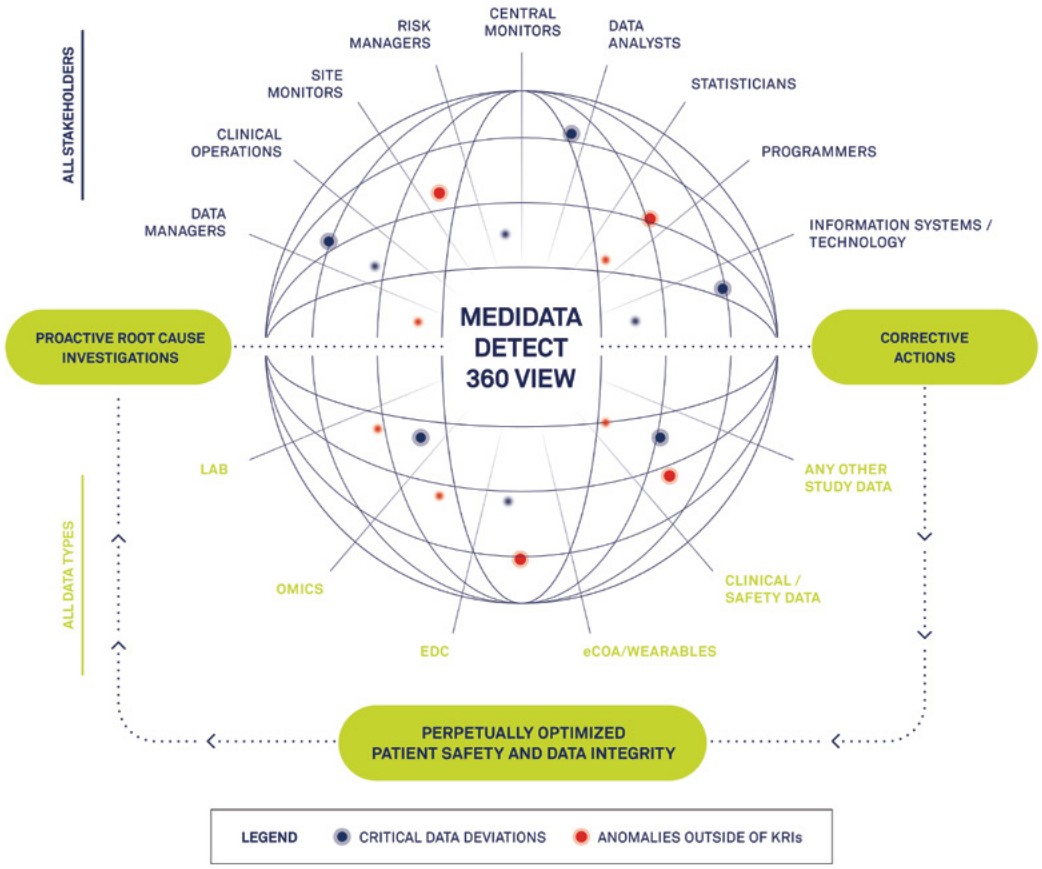
How important is it to detect and remediate errors, trends, and anomalies proactively in your trial?

COVID-19 challenges create limited onsite capacity, limited site staff, heightened safety precautions, and increased demand for onsite monitoring visits, which has limited the number of days that CRAs are allowed onsite.

Centralized Statistical Monitoring and Central Data Monitoring are supported via Medidata Detect. Driven by machine learning and automated algorithms, Detect ingests and unifies study data, identifies anomalies, and finds risks.

Data flows in real time and can be refreshed on demand, supporting the dynamic requirements for safety and quality review.

Medidata Detect 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.



PARAMETER 7

LEVERAGING RTSM DIRECT-TO-PATIENT

Patients can no longer access sites for their treatment. To ensure uninterrupted supply, and timely, accurate delivery, Investigational Medical Products (IMP) must directly reach patients in a safe and effective way.

How essential is delivering treatment directly to your patients?

With sites closed and visits reduced due to COVID-19, a Direct-to-Patient (DtP) solution enables IMP dispensation to be received and administered in a patient's home rather than at a clinical site.

Medidata RTSM Direct-to-Patient (DtP) delivers solutions across any dispensation scenario.

- Rave RTSM can be configured to send investigative product directly from the Depot to the patient's home.
- Sites can process dispensation through Rave EDC as a visit and courier the drug to the subject. Rave EDC then stores the courier tracking number (collected as text data).
- If a subject is transferred to an open site or if site users work remotely, they can register a visit in Rave EDC, then configure in RTSM to be Direct-to-Patient and have the dispensed items shipped from the Depot to the patient's home.

Beyond responding to COVID-19 disruptions, DtP trials are an opportunity for sponsors to address fundamental patient-centric issues that affect drug development programs.

DtP trials help engage a larger population of untapped prospective patients, reduce clinical development timelines, reduce trial costs, enhance patient retention, and deliver novel treatments to patients faster.

CHECKLIST

Are you looking to:

- ☐ Increase patient recruitment and retention
- ☐ Enable patients to access therapies from home
- ☐ Ship drug supplies direct to patients homes
- ☐ Integrate with depots and distribution facilities
- ☐ Track the chain of custody
- ☐ Ensure patient blinding and other logistical challenges
- ☐ Switch between site dispensation and DtP
- ☐ Accommodate mid study changes

PARAMETER 8

MEETING LONG-TERM COMPLIANCE

COVID-19 has accelerated adoption of virtual capabilities as an urgent response. Is your technology strategy designed to accommodate further disruptions in the long term?

Is your technology strategy designed to accommodate further disruptions in the long term?

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

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

When investing in technology to support virtualization, sponsors must consider a path that offers adaptability and operational agility. They have the opportunity to take command of their technology, ensuring they are building long-term capabilities to deliver on patient-centricity, compliance, and future disruptions.

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

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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.

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