FAQs to Guide Your Decentralized Clinical Trials Strategy

What are decentralized trials?

Decentralized trials, also known as hybrid trials, virtual(ized) clinical trials, remote trials, and direct-to-patient trials, employ a method of conducting clinical trials where parts or all of the trial happen outside a traditional physical clinic or trial site.

What impacts can trial decentralization have on sites and patients?

When decentralizing any aspect of a clinical trial, the site and the patient are directly impacted by the use of technologies addressing patient-facing activities and site-based study oversight and management.

Innovative patient-facing solutions:

- lower the burden placed on trial participants to learn new technologies
- limit the number of devices to carry and multiple logins to track
- facilitate access to remote data capturing tools

At the site level, challenges arise when access to source data and documents is limited.

myMedidata, Medidata's patient portal, gives patients access to all of their clinical trial needs through one web-based portal, removing the need for provisioned devices.

Medidata's site-level solutions, such as Remote Source Review and Centralized Monitoring, solve the problems of data and document oversight by providing remote access to physical sites.

What are some key considerations when deciding if a trial can be decentralized?

Start with protocol review.

Ideally, the partner offering decentralization technologies will join the sponsor early enough to be involved in protocol development.

This ensures that the decentralization methods and potential impacts on sites and patients can be evaluated early on, removing the need for later protocol amendments to include these technologies. Protocol analysis should include:

- phase of the trial
- disease/condition being researched
- data analysis plan
- patient population and risk profile
- method of therapy administration and storage requirements of the treatment/drug
- visit schedule
- feasibility of collecting the endpoints (e.g., does it require technology not accessible from home)

Determine which procedures and oversight activities can be managed outside of the traditional trial setting.

Once the varying categories of remote procedures and activities have been determined, they must be operationalized using one or varying vendors.

Some of these activities include:

- Patient learning and consent to their trial through the use of eConsent

- Passive collection of endpoints through wearable devices or actively through eCOA/ePRO
- Remote review of critical data and documents via remote monitoring and source data verification
- Direct-to-patient (DtP) delivery of investigational medicinal product (IMP) via randomization trial supply management (RTSM)
- Automated site payment calculation and invoicing, decreasing manual touchpoints

Mobilize and enable decentralization technology.

It's often possible to integrate multiple point solutions through varying vendors; however, a robust platform offering an end-to-end range of technologies not only mitigates risk but also ensures consistent reliable data and a much better user experience for patients.

Medidata's myMedidata application, built on Rave EDC, enables a suite of decentralization technologies through one web-based portal for the patient while streamlining data capture directly into Rave EDC.

How are patients recruited and enrolled to participate in decentralized vs. traditional trials?

By removing geographic barriers to participation, patients gain access to trials from a broader range of channels including digital advertising, social media, advocacy groups, direct-to-patient advertising, and patient registries.

Broadening access also empowers patients to learn and register for research in which they are interested.

What are some key benefits of decentralized methods?

Patients engaging with Medidata's patient portal, myMedidata, experience a streamlined recruitment and enrollment process.

Within just one portal, patients can:

- Get informed about available trials
- Sign up to be part of an ongoing research registry for future research opportunities
- Provide information used for inclusion/exclusion or access to their electronic health records for faster pre-screening

By enabling virtual enrollment and participation, a larger ethnic, racial, and socioeconomic status range of participants is given the opportunity to participate.

This is in stark contrast to traditional approaches where geography plays a major role in enrollment and retention.

What does the patient journey look like in a decentralized trial?

The typical decentralized clinical trial path for patients involves enrollment, randomization, delivery of IMP, and capture of their data through wearable technology.

Decentralization capabilities empower patients to participate remotely with easier, more time efficient, and more secure experiences throughout their clinical trials.

Why does decentralization make the enrollment process easier?

In a decentralized trial, an electronic consent (eConsent) is used in lieu of traditional paper and wet signatures gathered at a site and enables patients to learn about their studies through an educational video, followed by written details and guidelines.

Medidata eConsent allows patients to flag areas they don't fully understand at any step to review with the study healthcare professional before consenting.

It also includes a Knowledge Review to ensure the patient's full understanding of the trial specifics. Complemented by myMedidata, the consenting process can be completed virtually from the patient's home.

How is randomization implemented when trials are decentralized?

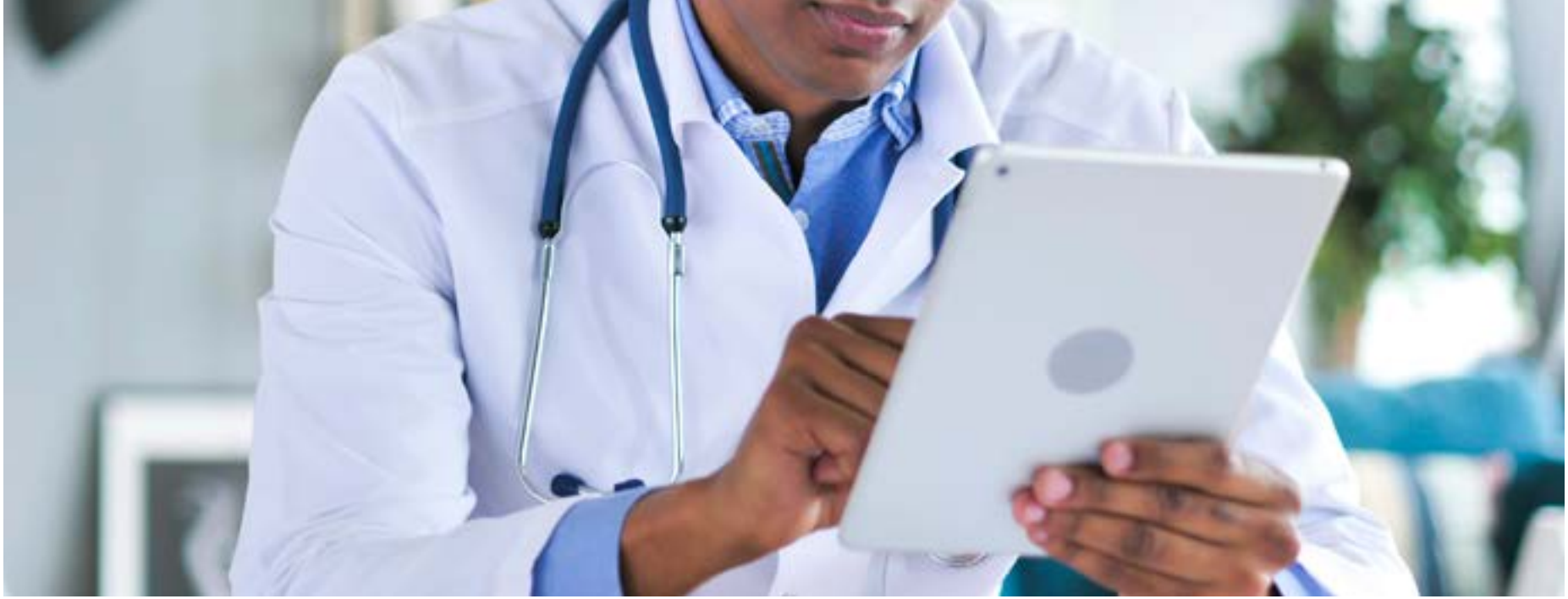
Post enrollment, patient information is entered into Medidata Rave EDC. Rave RTSM then automatically randomizes and automates the trial supply management, alleviating the site burden.

Additionally, randomization is controlled by an algorithm rather than a traditional paper envelope, creating a more secure and reliable method of trial randomization.

How does home delivery of IMP benefit patients in a hybrid or fully decentralized model?

The challenges of continued site visits and site supply accountability with multiple dispensations of trial IMP are solved when sites initiate IMP dispensation from a depot and enable Direct-to-Patient (DtP) shipments.

Removing the burden of travel from the patient also significantly decreases dropout rates.



How is the patient burden alleviated when data is captured using decentralization technologies?

In decentralized trials, patient data is captured through the use of wearable devices and biosensors in tandem with data-capturing tools such as eCOA and ePROs. These tools provide studies with faster and more accurate data with little to no transcription errors.

Using myMedidata, patients can easily log in from any WiFi-enabled device to access these tools for at-home data capture.

Additionally, patient data is captured directly into Rave EDC, giving sites access to data in near real time.

Patients can also meet with their study teams and PIs virtually, from enrollment to end of study participation, via live video visits using myMedidata LIVE.

How do decentralized technologies enable data capture and remote monitoring?

Early in the pandemic, a Medidata-led study reported an 80% drop in new patient enrollment rates, making data capture of those enrolled even more imperative.

By using ePRO synched into EDC, patient data is captured digitally, removing the need for monitors to ensure proper transcription of traditional paper diaries.

In addition, Medidata Detect, a centralized statistical monitoring solution, powers real time proactive remote monitoring to uncover unanticipated data anomalies and trigger corrective actions.

How can CRAs retain oversight of site activities?

Source Document Review

During the pandemic, CRAs were unable to visit sites to perform critical source document review activities.

Medidata's Remote Source Review allows CRAs to virtually complete these activities and ensures seamless access to source documents throughout decentralized trials.

With Remote Source Review, the CRA is alerted as errors are detected and can virtually access and review the source document.

As a result of the pandemic, remote monitoring of site activities and documents has been accepted by global regulatory authorities, including the FDA, since early 2020.

What are the regulatory bodies saying about the adoption of these technologies?

The use of digital technologies to facilitate trials during the pandemic was discussed in guidance documents that describe how new processes and methods can be implemented to protect patients and facilitate continued trial execution while maintaining GCP standards.

Components include remote site monitoring, handling informed consent, conducting remote trial visits, and maintaining data integrity and an audit trail (FDA, 2020a; EMA, 2020; MHRA, 2020; HSA, 2020; Taylor, 2020).

These documents were provided by many of the world's regulatory agencies, including the FDA, the European Medicines Agency (EMA), the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), Singapore's Health Science Authority (HSA), and China's Center for Drug Evaluation (CDE).

Between logins and trainings, does the use of multiple tools increase patient and site burden?

A recent study conducted by SCRS showed that tool complexity and need for training were two of the leading factors in why sites were not implementing a tool such as eCOA.

When a site is running studies on an EDC system with multiple independent point solutions integrated into the system, with multiple logins, and the need for device integration, it can become a burden both on the site and the patient to utilize these tools.

However, when a site incorporates decentralized capabilities built on the EDC being used, patient data flows into EDC, manual work to transcribe data at the sites is minimized, and risks are mitigated.

Medidata's solutions are all unified on the Medidata Clinical Cloud, with Rave EDC at the core of data capture. It provides a single source of truth, with no opportunity for error.

Interoperable with myMedidata, patients create one login to access all the tools needed to enroll and participate in their studies. It also allows sites to access patient data in near real time for monitoring, without the need for reconciliation of data.

What are the options for partially decentralized trials?

Medidata recognizes that trials rarely operate 100% virtually. Sponsors and CROs can strike the right balance between site-based and virtual visits that still delivers a truly patient-centric clinical trial with our Trial Dial decentralization continuum approach.

Trial Dial enables Sponsors and CROs to design each trial to reflect the ideal mix of onsite and decentralized touchpoints for the best patient experience.

Driven by the increased focus on lowering patient burden and minimizing study risk, the Trial Dial approach introduces various levels of decentralization into more trials.

What is the patient experience in a partially decentralized trial?

From a patient perspective, this might include remote e-consent, followed by a site visit, followed by the remote use of eCOA tools by the patient, and a DtP shipment of IMP based on data entered in eCOA before returning to the site for lab tests or treatment.

How do sponsors and CROs benefit from partially decentralized trials?

In some studies, there is a dramatic reduction in site visits with assessments and oversight being provided remotely.

From a sponsor or CRO study monitoring perspective, oversight activities can begin with on-site study startup activities, followed by central statistical data monitoring and data review with virtual remote source review and live-video monitoring visits, and targeted, risk-based, onsite visits.

FAQs TO GUIDE YOUR DECENTRALIZED CLINICAL TRIALS STRATEGY

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™.

info@medidata.com | +1 866 515 6044

MEDIDATA