FAQs to Guide Your Decentralized Clinical Trials Strategy

Copyright 2023 Medidata Solutions, Inc., a Dassault Systèmes company

- Passive collection of endpoints through wearable

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

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.

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 □ows into EDC, manual work to transcribe data at the sites is minimized, and risks are mitigated.

Medidata's solutions are all uni□ed on the Medidata Clinical Cloud, with Ravhe Mllb ae m(n)-30Dni15(s i)7.8(h)-7.3 (e n)ll un Co, ae

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™.

Medidata, Medidata Rave and Medidata AI are registered trademarks of Medidata Solutions, Inc., a wholly owned subsidiary of Dassault Systèmes.
info@medidata.com | +1 866 515 6044

Copyright 2023 Medidata Solutions, Inc., a Dassault Systèmes company

MEDIDATA