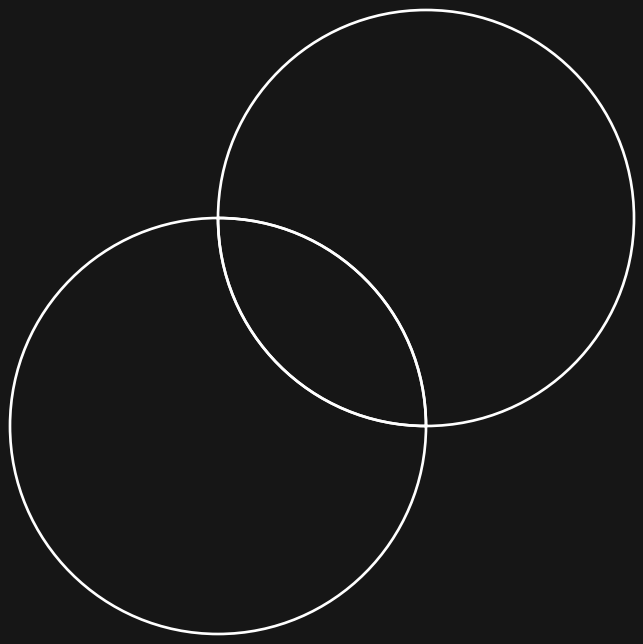
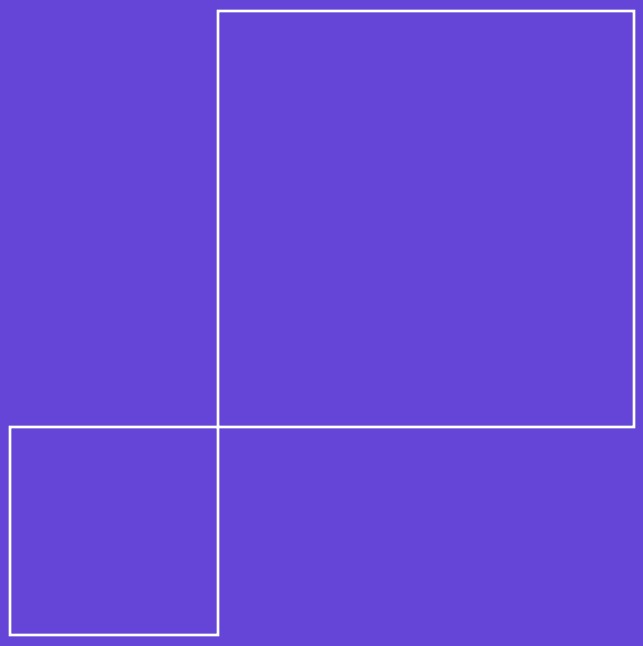
The building blocks of DCT

How to create a seamless experience across eConsent, eCOA and more





Medable

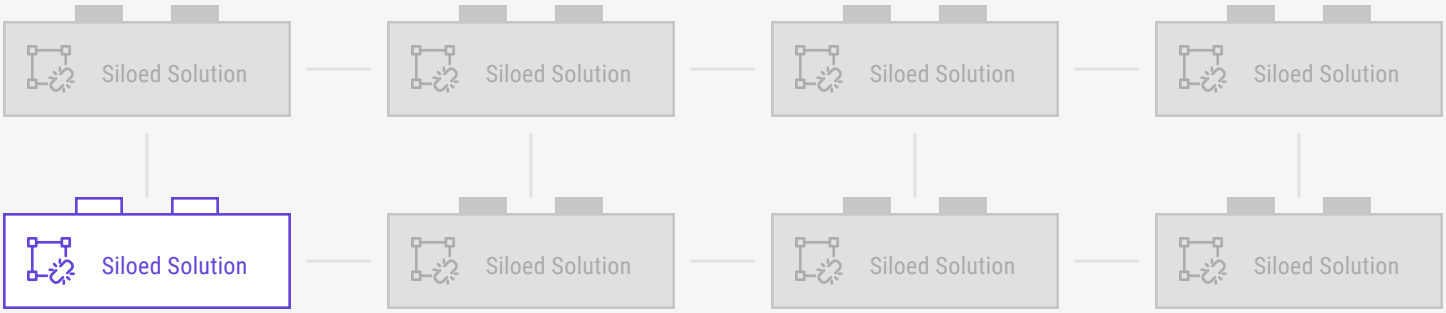
Over the past year, the Clinical Trials Enterprise (CTE) made tremendous progress digitizing and decentralizing various elements of the participant and site experience. As COVID continued to spread, sponsors rapidly digitized a number of key trial elements, replacing paper forms and physical visits with electronic consents (eConsent), electronic Clinical Outcome Assessments (eCOA's), and remote visits (TeleVisits).

This shift not only kept trials running during the pandemic, but also presented participants with more choice about how they engage in studies. In fact, for perhaps the first time, the CTE presented participants with consumer-style engagements that offered convenience (any time, anywhere), reduced burden (removing transportation and paper burden and facilitating real-time data availability), and mirrored the lifestyle technologies they were already accustomed to using in their daily lives through smartphones and other technologies.

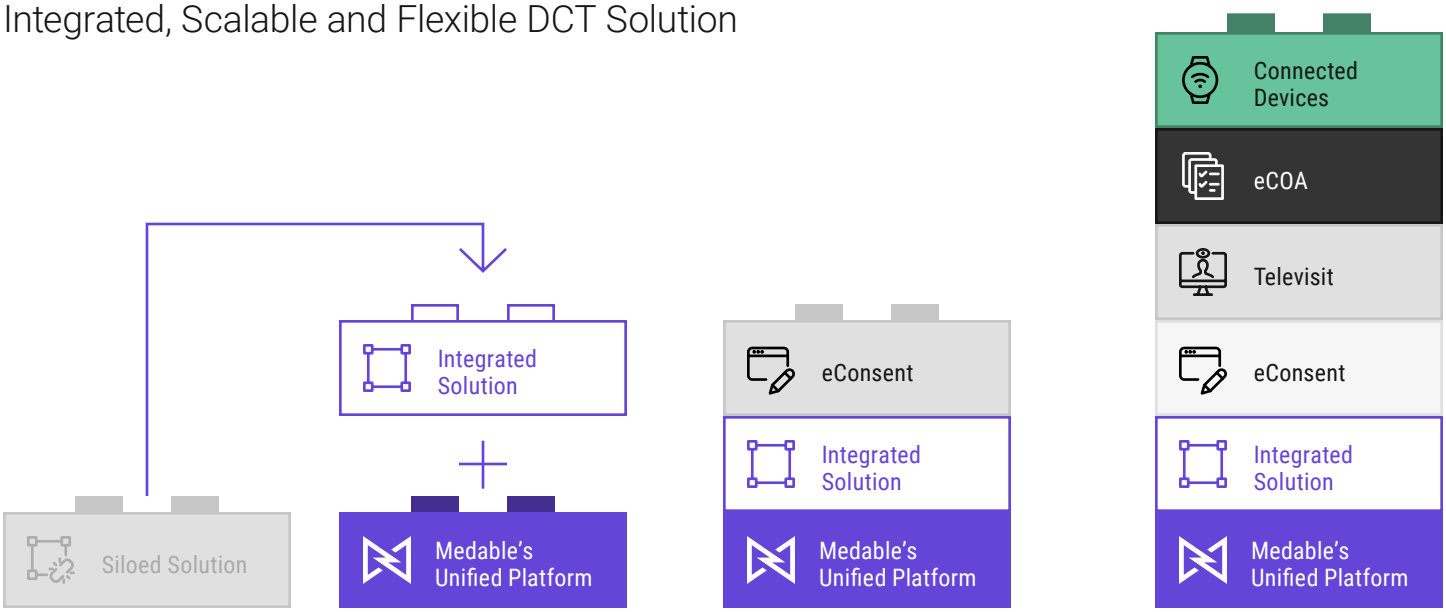
As the industry rushed to respond to the pandemic's demands, many study teams acquired individual point solutions to address a specific need in a study, such as an eConsent solution or ePRO offering. For those who are unfamiliar with the term, point solutions may be loosely defined as individual electronic systems that take the place of manual clinical trial processes.

Thus, many sponsors ended up with one system for electronic consents, another for ePRO's, and often another for TeleMedicine. While these e-solutions were instrumental in keeping trials afloat, they often combined in inefficient ways. For instance, when point solutions do not share common interfaces, devices, and underlying data structures, they create underlying data issues as a result of "siloization", while offering disparate and suboptimal trial experiences for patients, sites, or study teams.

Siloed Solutions



Integrated, Scalable and Flexible DCT Solution



1 Integrate your solution to Medable's Unified Platform

2 Configure the DCT process your way

3 Scale the DCT process your way

Thinking about data interoperability upfront

How to avoid data processing challenges and delays

For many years, the Medical Product Development industry has refined electronic systems to improve workflow and reduce manual activities. Despite individual improvements, these systems still maintain their own standards for data. Put simply, they don't "talk" to one another. In a decentralized clinical trial (DCT), the key to achieving optimal results starts with two steps. Step one requires identifying the data required to prove the hypothesis of the study protocol. Step two involves recognizing the digital options available (market solutions) and source location (location of patients/sites) of that data, with the intent to collect as much digitally from sources (patients/sites) as possible.

Collecting data digitally from the source is key, as it removes one of the most common problems inherent in clinical trials - transcription errors that occur when paper sources are entered into digital applications such as an EDC. It also enables a shift away from source document verification (SDV), an activity known across the industry as a timesink, for Clinical Research Associates (CRA's).1

As mentioned, simply moving source data capture from manual to digital-first applications such as eConsent and ePRO will create challenges if these applications do not share data standards. The most common challenge is siloization. This is where manual data cleaning is needed in order to make data

interoperable order to create one clear picture of their trial. While manual cleaning can certainly be accomplished, any organization that's gone down this path will be quick to tell you that data cleaning is inefficient, prone to errors, and time-consuming. The result is often longer trial timelines and higher costs.3

Table 2.

Advantages of using non-CRF data

	Number of responses(%[a])
Less SVD	11 (91.7)
Higher quality data	10 (83.1)
Predefined format of incoming data	09 (75.0)
Resource savings	07 (58.3)
Timeline redutctionw	05 (41.7)
System platform flexiblity	03 (25.0)
Other responses	03 (25.0)

Abbreviations: CRF, Case Report Form; SVD, Source Data Verification

[a]Percentages are based on n=12 responses

[2] Transcelerate 2016. "Optimizing the Use of Electronic Data Sources in Clinical Trials."

The data advantages of decentralized clinical trial platforms

Contrast the above scenario with a flexible Decentralized Clinical Trial (DCT) platform. A unified DCT platform enables study teams to request, collect, and share data using a single master "data architecture" that not only works across the system but natively with other core clinical systems such as an EDC. Utilizing a DCT platform, therefore, can significantly reduce the challenges associated with data siloization mentioned above.

For sites and study teams, unified DCT platforms reduce burden by streamlining workflows and simplifying key trial processes. Here, much like it was for patients, a streamlined and simple workflow that doesn't require sites to leave the platform, re-login, or fumble between different interfaces is a must. It's also here where features and ecosystem integrations can make all the difference. For instance, real-time data feeds can alert sites of possible safety and efficacy issues. In addition, integrated workflows can also power

automatic reminders that help patients know what's coming up next in their visits and follow-up schedule. For patients, engaging in Decentralized Clinical Trials (DCT's) on a unified platform is attractive for the convenience of personal choice, the inclusivity options, and the ability to have real-time engagement with their clinical team from any location. With the increase in the collection of source data directly from patients, study team's must be cognizant of not inadvertently shifting the burden of data collection to the patients and ensure the experience is seamless, engaging, and well designed.

At Medable, we believe patient-centered research and design is a cornerstone to providing "patient first" experiences. Thus, our Patient Advisory Council (PAC) and Patient Champion Networks participate in functionality design, participant experience, and study solution workflow testing, among other activities. From a design standpoint, this means offering patients a simple, intuitive workflow that maintains all the engagement through one secure account, accessible via multiple modalities, such as mobile app and web, to accommodate cultural and personal comfort and preference. It also means creating logical connections, such as the ability to request an off-schedule Televisit with your investigator as you have questions about your study participation.

To illustrate a unified DCT platform, let's walk through an example:

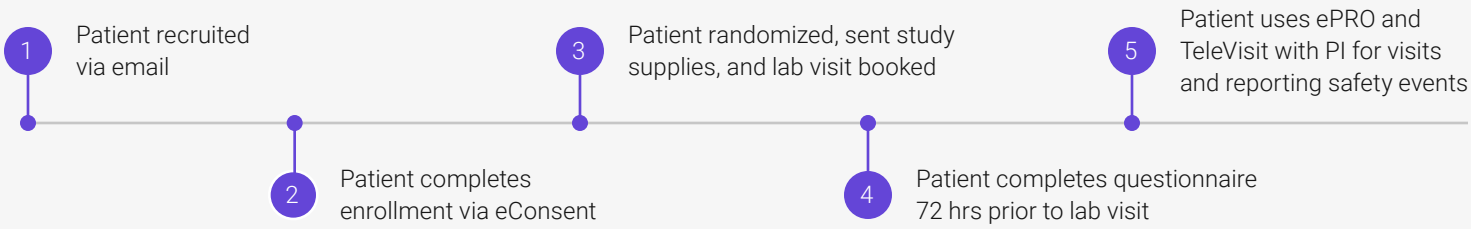
The situation

A top Pharmaceutical company was developing therapies for rare genetic diseases. They needed to access a rare patient population, and efficiently screen and enroll 1000 patients. The client required a single data architecture to capture key disease status information, plus randomization into 2 groups to obtain 2 blood samples across a 6-month period with AE follow-up and reporting. They had a single, central Principal Investigator and no physical sites. Medable needed to leverage the CRO's assets for a custom configured end-to-end decentralized delivery and management solution.

Solution and impact

Medable designed a flexible decentralized platform, including eConsent, ePRO and TeleVisit, with CRO, local labs, virtual PI network, and direct data capture.

Medable's decentralized workflow

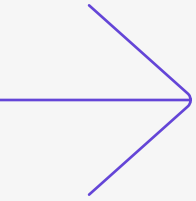


Solution and impact

The unified decentralized platform solution significantly increased access to what were seen as "hard to reach" patients, enrolling over 75 rare disease patients within 3 weeks. It also increased oversight with a single data architecture for a 'decentralized' site to enable study and patient monitoring. Lastly, it increased patient engagement by enabling seamless patient communication, blood sample, and signature collection from the comfort of their own home.

The experience advantages of a DCT platform

While there are several market solutions out there, such as eConsent and eCOA, that are great at solving individual sponsor problems, it's when disparate solutions are combined at the site level, that they present less than stellar experiences. In fact, according to a 2019 joint SCRS and Oracle report4, there is increasingly negative sentiment toward disparate systems. "Too many systems with different processes and login credentials," combined with redundant training was the number one issue listed by sites with more than a third of survey respon-dents---a growth of 65% from the previous survey. Additionally, sites in this survey reported that while there is an abundance of technology options for them to utilize, 70% of investigator sites wouldn't plan on using the solutions currently offered. While a further 33% of sites in the same survey stated that existing solutions were not solving their challenges.



"Too many systems with different processes and login credentials,"

How to present a unified decentralized clinical trial experience, utilizing eConsent, eCOA and TeleVisits.

As the Oracle/SCRS research showed, sites have quickly pointed out the increased burden that's inherent when using multiple point solutions. In this case, it's efficiency and usability that suffer as sites and study teams must switch between multiple systems, passwords, and most importantly, interfaces and workflows. Thus, in order to present a unified experience, study sponsors must ensure that their platform, as well as it's tools, maintain key features.

Of these key features, system connectivity is perhaps the most important. For instance, at Medable, our eConsent, eCOA, and TeleVisit systems are interwoven in a way that allows each system to "speak" to one another. This enables key benefits such as the ability for patients to outreach to their investigator with a TeleVisit call directly, during the time of consent, ensuring they can ask questions and get the information they need to feel comfortable Consenting.

However, it's not just interconnectedness across eCOA, eConsent, and TeleVisit that's needed. In order to present a patient-centered study experience that's unified in nature, the individual solutions themselves must offer some key benefits.

Patient engagement
The ideal DCT platform should guide users towards completing key trial tasks, such as diaries, logs, and sample collection, or remind them of upcoming appointments, without appearing too frequently throughout their day to day life.5

Patient monitoring using real-time data
In a DCT setting, eConsent, eCOA, and other tools must be armed with real-time data in order to effectively monitor patients for safety and efficacy concerns. Yet, this type of real-time data flow is almost impossible for organizations utilizing disparate point solutions.

TeleMedicine functionality
Telemedicine serves as an important bridge between the patient and the investigator, enabling the patient and investigator to connect during diary completion, consent, or at any other point during the trial journey.

Provide a consumer-grade interface
A simple, easy-to-navigate interface helps keep patients engaged and focused on your trial's key activities, preventing them from getting lost, frustrated, and missing or delaying key trial actions such as diaries, consent forms, and more.

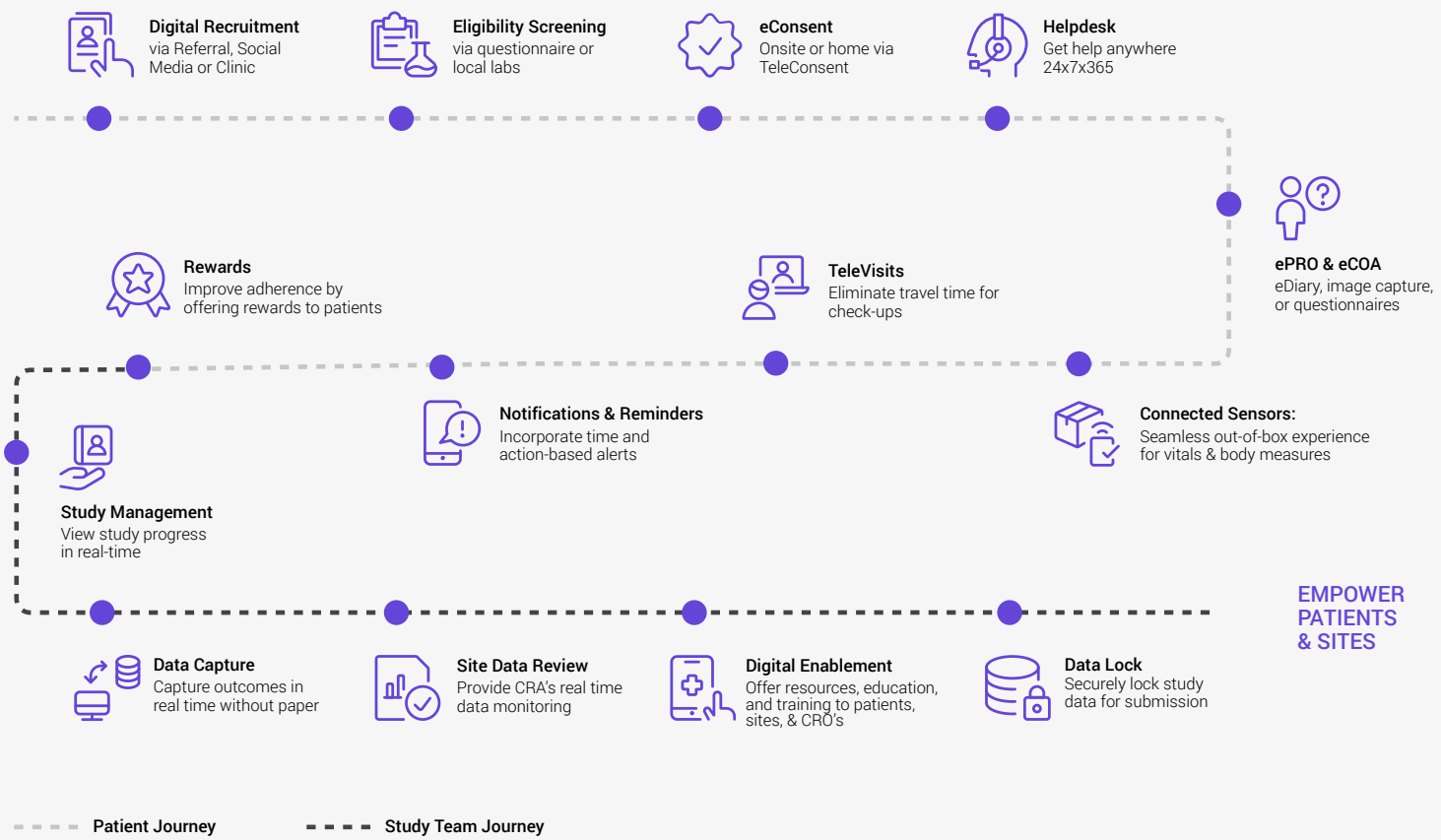
Pre-enrollment connectivity
Pre-enrollment and enrollment consent agreements are the gateway between trial participants and your study. Thus, it's imperative that your eConsent and DCT tools prep patients in a manner that prepares them for the upcoming trial.

Localization
A proper unified experience must be presented in a manner that's able to connect with patients and sites, no matter where they are across the globe.

It's when all of these features combine, that patients and sites begin to perceive the trial as a single stream, rather than a series of disjointed activities.

Medable was able to deliver a single experience for each participant and stakeholder, supporting enrollment of over 11,000 patients in 50% of the time anticipated from a traditional model.

How? By working with a sponsor and CRO partner to design the workflow for patient recruitment and consent in a fully decentralized model.



Closing Thoughts

The continued digitization of clinical trials has been a net positive for the CTE, as more patients gain access to trials, and sponsors and CROs gain new capabilities. Yet, as industry research notes, multiple systems can often combine in a way that creates new burdens for patients, sites, and study teams.

Thus, those who are seeking either their first or a continued form of trial digitization should heavily consider a decentralized system, in order to present all users with an optimized experience that saves time and cost.

If you have questions about digitization, decentralization, or the best way to tackle the needs of your patients, sites, and study teams, **click here** to speak to a Medable decentralized specialist and receive a free assessment of your organization.

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