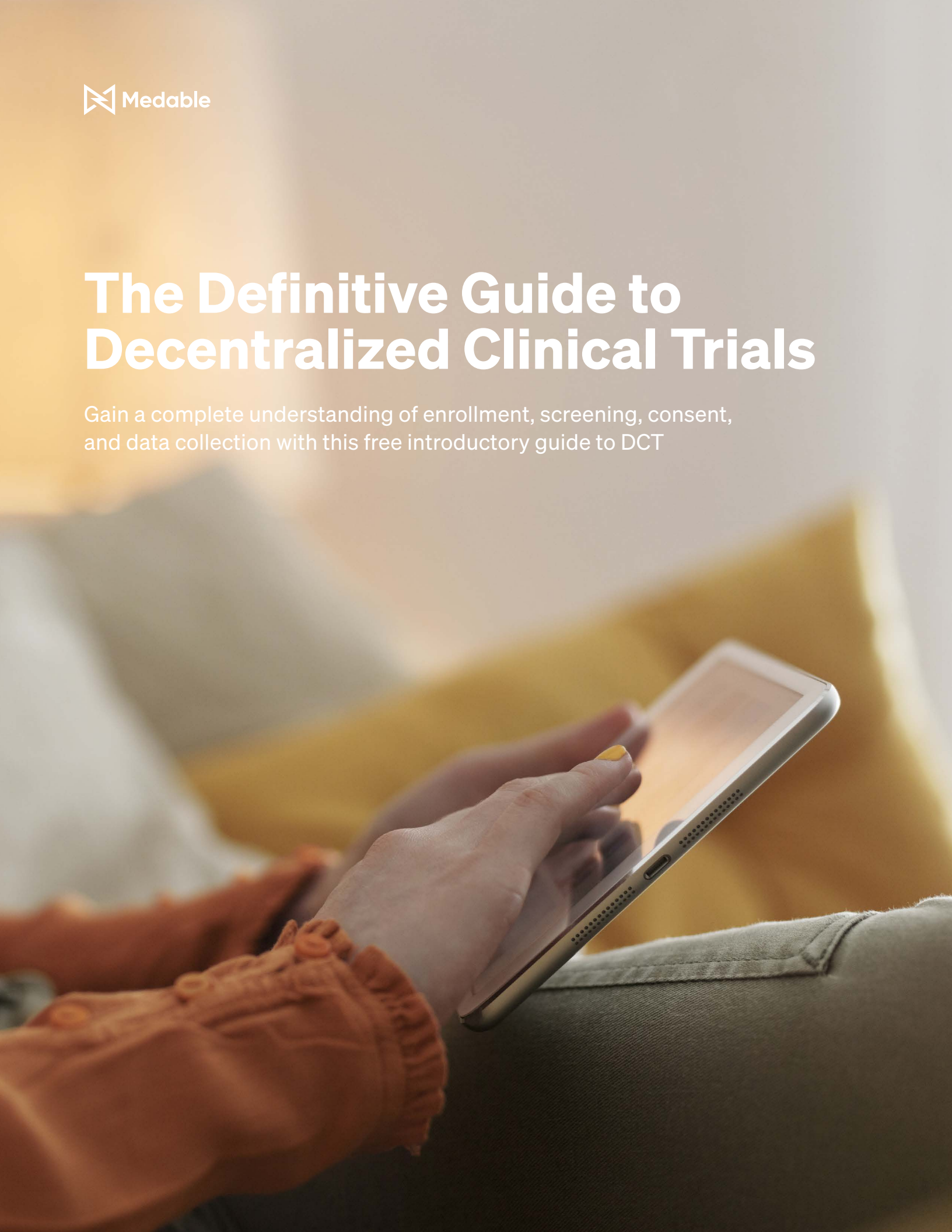
Medable

The Definitive Guide to Decentralized Clinical Trials

Gain a complete understanding of enrollment, screening, consent, and data collection with this free introductory guide to DCT



Contents

Patient screening

Electronic consent (eConsent)

Chapter one

What is a decentralized clinical trial?

The rise of decentralized clinical trials

Starting in the early 2000s, the life sciences industry began to envision a different way to conduct clinical trials. The rise of technology such as electronic data capture (EDC) helped pave the way for the first electronic clinical trial systems. And in the coming years, electronic clinical outcome assessments (eCOA) and electronic informed consent (eConsent) would be pioneered across the industry for the first time.

In 2011, Pfizer took the first step toward decentralization, conducting the first-ever "virtual" clinical trial.

Today, digital and decentralized trial components have become common in clinical drug development.

At Medable, we've conducted over 300+ decentralized clinical trials, the most of any decentralized trial company, with more than 1 million patients on our platform. As pioneers of decentralized trials, we help clients deploy solutions that best meet the needs of their protocols as well as their patients, no matter where they are located.

Defining decentralized clinical trials (DCTs)

A traditional clinical trial is where researchers test a new treatment on a group of people, usually at a single location, like a hospital or research center.

The FDA defines decentralized clinical trials as "those executed through telemedicine and mobile/local healthcare providers, using processes and technologies that differ from the traditional clinical trial model."

In a decentralized clinical trial, part or all of the protocol occurs away from the primary study site. Instead of patients traveling, often repeatedly, to a central site for enrollment, consent, data collection or symptom monitoring, they can participate in telehealth visits from their homes, often using familiar technologies, like smartphones, tablets and wearables to transmit pertinent information. Even medications and devices can increasingly be delivered directly to a patient's home, and a home visit from a health care professional can be arranged if necessary.

Though DCTs were first pioneered a decade ago, the advent of the COVID-19 pandemic catalyzed their use. Stay-at-home orders and, later, social distancing requirements, meant that study teams and participants alike could not effectively participate in on-site trials. In addition, technological advancements have created the Internet of Things (IoT), in which numerous devices, including wearables like fitness trackers, can all be connected through software and cloud computing. This enables seamless transmission of data of almost any kind.

In a fully-decentralized trial, every aspect from recruitment to treatment to data retrieval and analysis is done remotely.

In a hybrid trial, some of these steps will involve face-to-face or on-site interaction. Some trials, such as those that require frequent or complex imaging or surgical procedures, may be better suited for hybrid designs.

Tools and services employed in a DCT

Study teams can select which digital tools make the most sense to employ in their clinical trials; there's no need to implement them all at once, or even to use the same ones in different trials. Digital tools offer complete flexibility, as well as familiarity, since they can run on smartphones, tablets, or any other device you choose. These are the most common:

Telemedicine

Telemedicine enables clinical research staff to visit with trial participants remotely, through cell phones, computers, tablets, etc.

Virtual visits between patients and physicians help keep patients engaged and improve adherence to both the study schedule and dosing. With video-based televisits and interactive chat features, patients can consult with their physicians without leaving their homes, and physicians can easily monitor symptoms and health data. This results in greater peace of mind for patients and physicians alike.

eConsent

eConsent is an electronic version of the informed consent process which enables trial participants to consent either on-site or remotely. Using video and interactive graphics, patients can learn more about the intent of the study, see how a drug or device is designed to work, better understand what is expected of them, as well as any risks

participation may pose, and be kept appraised of any safety updates — all in less time than using traditional methods.

As eConsent has become more popular, myths and misinformation around its use have cropped up. Explore the truth around eConsent, and reach a deeper understanding of decentralized clinical trials here.

eConsent enables organizations to customize consent workflows around the needs of your study, and they can even enable connections to physicians or other health care providers as necessary. Lastly, many robust eConsent systems, including Medable's, also provide wet-ink functionality in countries that require it, bringing the benefits of eConsent to countries that often rely on paper to properly inform participants.

Learn more about Total Consent management.

Remote screening

With remote screening, patients can be screened and enrolled with just a few clicks, using any device, anywhere. Screening modules can be customized to the specific needs of a study, and can allow data collection from almost any source and in any format, whether that's a medical image, blood work, or an EKG.

Home health coordination and management

Patients enrolled in digital clinical trials can access home delivery of all study supplies such as the investigational drug, relevant devices, and lab kits. If a trial requires blood pressure readings, blood draws, or other data collection that depends on professional assistance or expertise, home-health nursing visits can be arranged.

If biological specimens are required, home pickup can also be arranged. Home-health nurses can also be deployed for any drug administration that requires assistance or expertise.

DCTs, also known as virtual, remote or digital clinical trials, can easily be customized to the therapy, patient population or condition being studied. In fact, clinical trials can be fully decentralized or employ a hybrid model of virtual and in-person procedures.

Data collection and analysis

Through the use of wearables, apps, and other technologies, data collection can be frequent, continuous, time-stamped, and accurate. The primary benefit here is the data is captured for clinical interpretation in real-time, allowing the study team access to actionable data to make key decisions quicker than with traditional data collection.

Mobile devices and wearables

Consumers are becoming increasingly familiar with wearable devices, like fitness trackers and glucose monitors. In addition, 85 percent of Americans now own a smartphone. About three-quarters own a computer, and half own a tablet. These levels of connectivity have made remote data collection simpler and more convenient than ever before. With these mainstream devices (using either iOS or Android technology) and the rising familiarity in the use of wearables, patients and study teams can capture clinical outcome assessments electronically, either directly through a wearable sensor, or via the deployment of validated ePRO and eCOA instruments.

Remote monitoring

In addition to capturing key endpoint data and clinical outcome assessments, connected devices can also collect data on behavioral and physiological quality-of-life indicators such as sleep and vital signs. In some cases, connected devices can transmit data directly to patient portals.

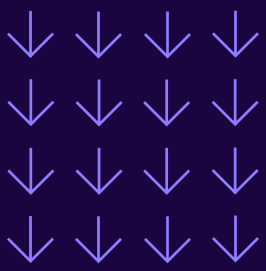
Patient interactive portals

In the past several years, patient portals have become commonplace among medical providers. They empower patients to schedule and keep appointments, interact with their healthcare team, review their health records, and engage with content related to their health conditions. In a DCT setting, an interactive portal helps guide patients through each step of the clinical trial protocol.

- Patients can be reminded to take medication and keep appointments.
- They can also be reminded to record any daily data or symptoms the study requires — something that's easy to forget when you're not feeling well. If a patient experiences an adverse event, physicians can intervene in real time.
- Patients can see results from lab tests and view their own health data at any time, which helps them learn more about their own health trends, manage their treatment and stay committed to participating in the trial for its duration.
- Patients may also be able to interact with other participants via the portal, and stay informed about upcoming clinical trial participation opportunities.

Investigational product and study supply logistics

In this era of pandemic-related production and shipment delays, it's critical to ensure that the supply chain for all study supplies is both robust and reliable. Smart and sustainable logistic solutions are integral to a direct-to-patient setting to ensure that investigational products, devices, wearables and lab kits arrive on time at patients' homes. Project managers help study teams accurately predict country-specific needs and tailor distribution plans to ensure the right supplies are delivered safely to the right place at the right time, with minimal waste.



Chapter resources:

Blog
Better engage patients with eConsent, using tips from patient advocates

Blog
How to use eConsent to reduce screen failures.

Blog
Where does patient recruitment end, and patient engagement begin? And, how are they intertwined? Find out. here

Blog
Learn how to design patient-friendly and inclusive ePRO instruments that improve your trials.

Blog
Learn more about remote monitoring here, with "Remote Patient Monitoring 101."

Blog
Learn how decentralized clinical technology impacts each phase of clinical research

Chapter two

Benefits and value drivers of DCTs

Participants, patients, and caregivers

Virtual clinical trials are, by design, patient-centric. Patients no longer bear the burden of arranging transportation to and from a study site, or of taking valuable time away from work and family to participate. They don't even need to live close to a study site. Instead, they can participate when it's convenient for them with a trial that fits readily into their daily lives.

In fact, when trials are conducted remotely, they become more inclusive accessible to a much broader — and often, more representative — patient population, including those in rural and underserved communities. A 2018 study found that decentralized studies recruited three times as many patients as traditional models, and did so three times faster.

Patients like virtual trials better, too. In 2019, the Center for Information and Study on Clinical Research Participation (CISCRP) found that 75 percent of patients liked the idea of collecting all data in their own home; 73 percent found a hybrid trial design appealing. Beyond the convenience factor, patients can communicate more frequently and more easily with physicians and investigators during a remote study. This heightened connectivity includes a remote patient monitoring modality that provides comfort to patient and clinician alike. It also boosts patients' engagement, satisfaction and compliance with data collection tools, including study diaries and questionnaires.

Sponsor benefits

Digitizing a clinical trial yields considerable benefits for sponsors. Recruitment becomes streamlined while also enabling faster enrollment of a broader and more representative patient population - thereby reducing the number of sites required to conduct the study. Once enrolled, patients in virtual studies have greater engagement and retention of key principles, as well as better adherence to the clinical trial protocol. That, in turn, leads to better retention of participants for the duration of the study.

Sponsors can specify whether data collection happens continuously or at specified times. In either case, with digital patient monitoring and unified workflows, data collection becomes standardized and more accurate. Real-time dashboards allow sponsors to track patient participation while televisits enhance communication and patient safety.

All this results in cost savings for sponsors, while opening up new opportunities to build organizational intelligence around innovative clinical trial conduct.

Site benefits

Decentralized trials offer a more efficient, effective, and integrated delivery solution for even the most complex studies when sites are properly trained and supported.

From a site perspective, these solutions eliminate redundancies, improve the quality of data, enhance connectivity with the trial participants and, ultimately, result in better clinical care. They also allow sites to expand the number of studies they conduct, so they can work on advancing medicine and helping patients get access to effective treatments faster.

CRO benefits

Contract research organizations that implement digital clinical trials can create competitive differentiation. By positioning themselves as experts in DCTs who can deliver better enrollment and retention, better quality data, and lower costs, they can drive more business to their brands. They can also position themselves as leaders in innovative clinical trial protocols.

Data considerations for DCTs

As a relatively new frontier, DCTs understandably raise questions about data capture and management and regulatory compliance. A number of organizations are

working to ensure these and other best-practice issues surrounding DCTs are addressed. These include:

- **Decentralized Trials & Research Alliance (DTRA)**
  Focused on accelerating the adoption of DCTs, this group has established four priority initiatives: defining key terms and performance benchmarks in DCTs; identifying and promoting best practices; building and sharing a knowledge repository, including an educational curriculum; and removing legal and regulatory barriers to DCTs.
- **Digital Medicine Society (DiME)**
  This group of collaborative healthcare and technology professionals focuses on establishing evidence-based standards for research, as well as building community and disseminating knowledge in the digital medicine arena.
- **Clinical Trials Transformation Initiative (CTTI)**
  CTTI offers an enormous cache of resources to the DCT community, ranging from trial design strategies and recommendations for mobile technology to guidance for working with IRBs.
- **Trials@Home**
  This European-focused organization works to develop standards, recommendations, and tools for DCTs throughout the continent.
- **American Telemedicine Association (ATA)**
  The ATA hosts frequent webinars, conferences, and other educational events and engages in advocacy, all in the name of advancing the efficient delivery of telehealth.

Data capture

Because technology changes rapidly and DCTs are still relatively new, there is little standardization in data capture methodologies, though the Decentralized Trials & Research Alliance is working to prioritize that. Similarly, the Clinical Trials Transformation Initiative has developed a feasibility studies database that examines the technology used in hundreds of DCTs to date, in an effort to help sponsors and clinical operations teams select the best technology for specific endpoints. CTTI also has published a technology selection framework, which considers factors such as accuracy, resolution, sampling frequency, usability, data access and security, and more.

Regardless of what device you select — or even if your study operates in a BYOD (bring your own device) environment — one of the top considerations will be ensuring that every device is clinically validated and has all the regulatory approvals and certifications required in the countries where you're operating them. At the very least, it should integrate seamlessly with a 21 CFR Part 11 or GDPR-compliant database to eliminate security risks. It should also be a recent enough model that you can expect manufacturer support for it to last at least for the duration of the trial. Other regulations can be found here.

The usability of data capture devices also will be critical to any study's success. Patients should be able to easily enter or upload data without any external connections. Devices should not present obstacles to those with visual or dexterity impairments.

Allowing patients to see the data you capture during the trial on a dashboard — especially if it's something that occurs daily, as blood pressure readings or a number of steps walked — can help patients feel even more engaged with the study.

Data storage and management

Before initiating a DCT study, sponsors and CROs will need to determine how collected data will be stored and managed. Ensuring data integrity as well as maintaining data security and patient privacy should be at the forefront of concerns. Teams will need to map out their anticipated data flow and select solutions that maintain security at each step. The CTTI recommends that teams collect the minimum amount of data possible to meet the study endpoints. The group further encourages use of systems that provide "secure, computer-generated, time-stamped, electronic audit trails of users' actions and changes to data" during data transmission. Data security measures such as data encryption, tokenization and checksums should be implemented as well, the group says. It also recommends that teams regularly review and audit which users have rights and access to data.

Regulatory considerations for DCTs

In September 2018, CTTI published recommendations for conducting DCTs, with a focus on adhering to U.S. laws and regulations. Top among the group's suggestions were:

- Ensuring that trial investigators are licensed to practice telemedicine in each state where they provide medical services as part of the trial.
- If investigational medical products are being shipped directly to patients, investigators must be aware of the applicable laws in the pertinent states.
- DCTs must meet all relevant data security and privacy regulations, such as HIPAA, GDPR and safety monitoring plans must be well documented.
- Study protocols must take pains to clarify the roles of various health care providers so that "routine care" and "clinical trial–related activities" are distinct and meet FDA regulations.

In 2020, the FDA published nonbinding guidance in its document, "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency."

To assure patient safety in the wake of the pandemic, the paper granted approval for "immediate" implementation of telephone and video-based visits, with documentation of any deviations from the original protocol, and subject to review by the IRB and notification to the FDA. The document further outlined key best practices, such as

ensuring additional safety monitoring and obtaining informed consent.

In early 2023, the European Medicines Agency (EMA), European Commission (EC), and Heads of Medicines Agencies (HMA) acknowledged the growing role of decentralized elements in clinical trials and published a series of recommendations with a focus on data integrity, participant safety, and inclusion. The recommendation paper was published on December 13, 2022 but is not yet part of a harmonized approach with the national provisions of the individual EU member states, or with the United States. However, it is expected that the U.S. FDA will make similar recommendations later this year.

Pillars to success

Perhaps the most important consideration in launching a successful digital clinical trial is to keep the focus on the patient. Consider the patients' perspective in each decision so that every interaction they have, whether with study teams or technology, is positive.

Ensure that all the technology you've selected meets all benchmarks and requirements for validation and security before you begin. You'll want to make sure sites are ready, too, before trials begin. Conduct feasibility studies to ensure staff are prepared for changes in the way they interact with and collect data from patients.

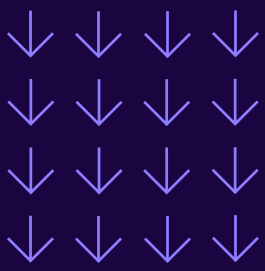
Now is the time for DCTs

While the COVID-19 pandemic may have been the spark that ignited more widespread adoption of decentralized clinical trials, we anticipate that the benefits of DCTs will endure long after the global health crisis ends. According to the American Telemedicine Association, an astonishing 97 percent of U.S. physicians were using telemedicine in some form by April 2020; what's more, 83 percent of patients expect to continue using telemedicine after the pandemic ends. Patients and physicians alike have clearly become comfortable with remote healthcare.

Clinical trial enrollment in a decentralized landscape

When conducting clinical trials, it's important to consider not only the methodology of the trial itself but also the process of enrolling participants. Digital and decentralized clinical trials, which rely on remote technology to collect data, have the potential to make trial participation more accessible and convenient for patients.

In order to effectively digitize a trial element, organizations must first understand the enrollment process, its complexities, nuances, and challenges. In this next chapter, you'll gain an overview of the enrollment process, and how to ensure your trials are set up for success.



Chapter resources:

Blog
Learn about Improving Diversity in Clinical Trials, with an interview from an industry leader as she discusses progress in diversity.

Blog
What does the new European Medicine Regulatory Network recommendation paper on decentralized elements in clinical trials tell us? Find out here!

Chapter three

Clinical trial recruitment

Patient recruitment is one of the most critical elements of a clinical trial. Without sufficient participation, studies will lack the power to demonstrate the statistical significance and efficacy of new treatments. Ultimately, poor patient enrollment will delay or prevent new therapies from reaching the market. Not only do such delays cost millions of dollars, but they also deprive patients of effective, potentially life-changing treatments.

Recruitment failures loom large across the industry, with 50 percent of trials delayed due to patient recruitment issues, according to a 2016 report in Pharmafile. Each day of delay costs an average of $600,000 but can go as high as $8 million a day for very complex studies. What's more, once the trial is underway, up to 30 percent of recruited patients drop out.

Considering that it costs an average of $6,533 to recruit one patient and $19,533 to replace a patient who drops out, study sponsors are motivated to find solutions that optimize enrollment of the right patients from the beginning, and minimize patient dropout after enrollment.

Designing a patient-centered protocol and consent

Keeping the patient's experience at the forefront of considerations can make patient recruitment, engagement, and retention more successful. Ideally, this begins the moment the team begins drafting the clinical trial protocol.

Chief among these is considering whether participating in the study will fit easily into a patient's life, or whether it will become a burden. It's easy to appreciate how traveling to and from a study site could be inconvenient, but that's just one piece of the time demands that trials often place on patients.

In a patient-centered approach, every aspect of the patient's journey, from their first interaction with recruitment materials to the final assessment should be considered.

The number of procedures performed in phase 3 clinical studies has increased 6 percent each year since 2003, often driven by the sheer number of clinical endpoints. Since 2013, the average number of endpoints has grown to 20 per study, while the average number of primary endpoints is only 1.6, according to a recent study by the Tufts Center for the Study of Drug Development (CSDD). When a study becomes this complex, it may be worth reevaluating the protocol to ensure it is truly measuring what matters — that is, collecting data that answers the primary research question — and not inconveniencing patients unnecessarily to collect supplementary information.

Overly restrictive or expansive inclusion/exclusion criteria are another frequent pain point. The average trial has 31 criteria patients must meet for inclusion. Understanding the critical criteria to define eligibility in the context of patient safety, regulatory requirements, and existing standards of care is key. It's worth asking whether the pursuit of a "pure" sample is causing unnecessary delays or excluding patients who might benefit from the trial. Simplifying the inclusion/exclusion criteria not only helps resolve recruitment issues, but it can also reduce costs by more than 20 percent. Incorporating feedback from the patients for whom the treatment or device is intended can create greater transparency and trust between investigators and patients, and help patients feel more engaged in the study design.

Soliciting feedback from patients about other aspects of the study design — as well as from study coordinators and investigators — can help you achieve a more well-rounded perspective on what makes participation easier and what aspects complicate the experience. A patient advisory council can help illuminate these factors.

As you begin to view the patient as a colleague or collaborator it can help clarify which aspects of a clinical trial protocol are truly necessary versus which are extraneous. Patients will appreciate feeling that their insights, time, and contributions are valued and used efficiently, and will be more likely to remain engaged and enrolled.

Recruiting patients

A successful patient recruitment strategy is not just about ensuring the "right" patient is enrolled. The process also needs to support inclusivity and, of course, be time- and cost-efficient. The approach used to recruit patients is therefore critical to the success of patient enrollment campaigns.

A blueprint for how you will develop or leverage relationships with health care providers, advocacy groups, community organizations, and even trial-matching services is critical to ensure a rich source of patient referrals, particularly among diverse and underserved populations.

Prescreen and screen failure logs are becoming staple components of successful recruitment strategies. Together, they can alert study teams to trends that are keeping patients out of a study. Whether related to accessibility of the study, eligibility criteria or study design, these logs can serve as useful tools to highlight trends and enable staff to react quickly to address key barriers.

The innovative technology that powers Medable's Digital and DCT screening tools can help study teams create a unified recruitment strategy by identifying trial-ready participants across a broad geographical area and supporting a streamlined screening process.

Diversity, equity and inclusion in clinical research

While recruitment is in part a numbers game, enrolling participants who are truly representative of the patient population is the bigger goal.

Even social determinants of health such as economic status, education and family size can influence outcomes, and these factors should be considered when aiming to enroll a truly representative patient population.

We can never be confident in the broad applicability of new treatments without studying how novel therapies affect people across a wide range of racial, ethnic, gender, age, and social differences,. Additionally, it's critical we also work to ensure that all people have equal access to the potential benefits of participating in clinical trials.

Nothing has highlighted the disparities in health care and medical research more than the COVID-19 pandemic. People from the Black, Latin, and Pacific Islander communities, along with some homeless, incarcerated or otherwise institutionalized people, have been disproportionately affected by the disease, according to the MRCT Center of Brigham and Women's Hospital and Harvard. In addition to experiencing more severe symptoms and greater mortality from COVID-19, some people in these groups are less likely to be vaccinated, according to the Centers for Disease Control.

The fact that some people will require additional reassurance to participate in clinical trials should not deter our efforts. Recruitment teams should acknowledge this and work to rebuild trust by developing partnerships within the community.

The FDA has issued guidance for increasing diversity in clinical trials. Sponsors, too, are increasingly recognizing the role they can play in engaging a greater diversity of people in clinical trials. Additionally, the DEPICT Act requires "Investigational New Drug (IND) and Investigational Device Exemption (IDE) applicants to: Report clinical trial enrollment targets by demographic subgroup, including age, race, ethnicity, and sex, and provide a rationale for those targets," according to the bill's language.

Medical research is only meaningful if the trial population reflects the diversity of the population expected to use the medical product. Historically, clinical trials have excluded people of color, women, the elderly, and children — despite the fact that many health conditions affect these groups disproportionately.

The future of patient recruitment includes digital

Electronic communication has vastly expanded our social networks and our professional lives, so it's not surprising that digital marketing enables recruiters to reach patients in far greater numbers than traditional outreach efforts. As far back as 2013, the majority (53 percent) of people surveyed who were aware of clinical trials said they found out about them through the internet. In the nearly 10 years since then, digital connection has grown, particularly in the realm of social media, which is proving to be a powerful recruitment tool.

Recruiters who use social media must adhere to regulatory guidance, such as that distributed by FDA, NIH, and HHS when using such platforms. As long as companies are mindful of standard concepts like protecting data privacy, disclosing any necessary safety information, not promising specific results and obtaining IRB approval, leveraging digital communication opens up vast possibilities. And social media is hardly the only digital tool.

Recruiters can also leverage electronic health records and other digital platforms to identify patients who meet specific criteria for inclusion in a clinical trial. Currently, some pharmaceutical companies have created their own patient identification tools. In 2014, Novartis launched an app called "Clinical Trial Seek." Apple made the development of such apps even simpler in 2015 when it released ResearchKit, and now large numbers of such apps are available for patients to download.

Medable can help streamline the process with solutions like TeleConsent, ePRO and TeleVisit. These allow you to recruit patients anywhere, using any device, with a flexible

and modular technology platform. Even as the trial gets underway, these digital tools can make reporting symptoms and experiences fast and easy for patients.

The path toward better enrollment

Clinical trials are costly, and challenges in patient recruitment are among the primary causes of delays. Every day a trial is delayed increases the costs even more, and not just financially. Treatments that could improve the quality or quantity of life are held back, or only offered to a small subset of potentially eligible people. As an industry, we need to bring more effective treatments to the right patients, and we need to do it faster.

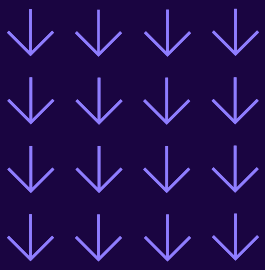
To accomplish this, we need to shorten research timelines, reduce costs and streamline patient recruitment. Patients are more likely to participate in a trial when it is designed with their experience in mind. Start with a patient-centered protocol, seek to include patients from diverse backgrounds, keep them engaged and empowered throughout the process, and make any necessary site visits convenient and accessible.

Screening for success: Why participant screening is as important as enrollment

Clinical trial enrollment is just the first step in the process of conducting a successful clinical trial. After participants have been identified and recruited, the next critical step is screening to ensure that they meet the eligibility criteria for the trial.

Proper screening is essential for ensuring the safety of participants and the accuracy of trial results.

Read on to learn how an intelligently designed patient-first approach to end-to-end screening can drive trial success—helping effective treatments reach the right patients, faster.



Chapter resources:

Blog
How to write clear and compelling patient recruitment material to drive enrollment and boost diversity

Blog
Where does patient recruitment end, and patient engagement begin?

Chapter four

Patient screening

Patient screening, a vital step in the clinical trial recruitment process, is when interested participants are assessed for their eligibility for a given trial using select inclusion/exclusion criteria. These criteria help characterize the target patient profile to ensure patient safety, better efficacy, and optimized signal detection.

Traditionally, patient screening was done in person at a clinical trial site. Due to the current digital revolution in healthcare, which has recently accelerated in response to global health events, the ability to use cloud-based software and digital qualification steps to optimize patient screening and enrollment brings innovation, convenience, and sophistication to this process.

Effects of screen failures

The fundamental purpose of patient screening is to enable the successful enrollment of the target patient: in other words, ensuring the patient is qualified as a "good fit" for the study. Getting this process right while minimizing screen failure rates is a key industry challenge that is fundamental to efficient, effective, and successful enrollment. According to a commonly cited statistic from the Tufts Center for the Study of Drug Development (Tufts CSDD), some 11% of active sites will fail to enroll a single patient.

Screen failure rates are highest in interventional studies (Phase 2, 3, and pharmacokinetic) and impact enrollment across multiple therapy areas, from Alzheimer's disease where screen failure rates range from 15 to 35 percent, to genitourinary cancer trials where we see rates in the order of 20 and 30 percent.

The consequences of high screen failure rates are enrollment delays, increased cost due to longer delivery timelines, delays to endpoint generation, and in some cases termination of the study.

Key causes of screen failure

When we consider the key factors behind screen failures, it's clear that a well-designed, patient-centric screening strategy can significantly reduce screen failure rates. Two key contributing factors leading to screen failures are overly stringent inclusion/exclusion criteria and patient refusal due to concerns about potential risks and the logistical burden of participation.

As observed by Tufts CSDD executive director Ken Getz, a typical clinical trial is often forced to double the planned enrollment period just to reach recruitment targets. Furthermore, according to Getz roughly 1 in 10 sites will still fail to enroll any patients, even after such an enrollment window is extended. High screen failure rates can cost sponsors anywhere from $600,000 to $8 million every day the study is delayed, and study termination can hamper the pipeline of beneficial new treatments.

A 2016 study found 69% of screen failures occurred as a result of inclusion/exclusion criteria, and 16% of screen failures occurred when patients refused consent for reasons such as:

- Perceived severity of risk
- Concerns over the consent document, such as a lack of time to understand it or feeling overwhelmed by the information it contained
- Concerns over potential future expenses or the perceived burden of participation related to the number of required procedures (e.g. multiple blood draws)

These findings were supported by an eight-year study with the National Institute of Mental Health which found two-thirds of all patient refusals occurred because patients felt trial participation would be more burdensome than beneficial. In that study, 36% of patient refusals were due to protocol concerns, and 33% were concerned about potential inconvenience study participation might create.

When considering the factors driving the majority of screen failures, it's clear to see how issues of patient confusion and inconvenience are well within the control of the trial organizers.

A patient-centered clinical trial design can help to ensure studies are developed around the patient. This includes taking established care plans and treatment regimes into account, as well as the critical relationship a patient has with their healthcare providers.

Patient-facing material, including consent documents, need to ensure patients are well informed. By careful use of patient-friendly language that avoids overly technical information and makes use of multimedia methods to communicate relevant information in alternative ways, sponsors can aid comprehension, improve patient engagement, and avoid undue patient burden.

Additionally, while some complexity to protocols and criteria is certainly warranted, a closer look can help ensure protocols are meaningful and inclusion/exclusion criteria are chosen deliberately, avoiding unnecessarily limiting criteria.

Getting the design right

It's crucial to consider what type of patient the trial is looking for and whether, based on the inclusion/exclusion criteria, that target patient group is realistic—are such patients actually out there? For example, prerequisites for existing therapies (dosing, stability optimization, or line of treatment) are key to evaluating feasibility for enrollment and minimizing the potential for high screen failure.

Of course, there are times to be stringent to avoid unnecessary risk. But tightly defined criteria that are not practically meaningful can create a high number of avoidable screen failures. A more effective approach is to be pragmatic and realistic, taking the time to understand the patient and where they sit in the treatment pathway. It is critical that the study population is representative of the patient population for whom the treatment is intended (assuming market authorization is successful).

A successful clinical trial doesn't start with patient screening, or even at recruitment. It begins with the trial design. Intelligent trial design begins with the careful characterization of the target patient and the efficacy and safety measurements critical to success, while also considering the patient's perspective.

Identifying 3-4 critical characteristics that can help sites to profile the "right" patient will enable a more effective and efficient screening process. Keeping to discrete and targeted study measurements that are meaningful to both the research and the patient also fosters more convenience to participation and stronger patient engagement.

Using digital tools to optimize success

Prior to digital capabilities, trials were fully dependent on a brick-and-mortar site, the site's database of patients, and the proximity (or lack thereof) of those patients to that site. In addition to complicating initial screening, this also contributed to reduced participation over the course of the trial due to fatigue in attending rigid in-person clinic schedules.

The current digital enablement helps study teams optimize screening strategies and reduce the on-site screening burden for investigators by minimizing screen failure rates through the use of digital prequalification tools. Such strategies can help broaden the geographical reach of a study, provide access to previously underrepresented populations, and facilitate their participation in clinical trials so that sponsors can ensure the applicability of research findings to a more representative and diverse patient population.

Digital screening tools also have the ability to capture, standardize, and integrate vast amounts of patient-specific information from multiple sources, including clinical records, genomic testing, and centralized screening and prognostic tools, all of which help enrich the study population to improve safety and signal detection, as well as drive the need for fewer patients.

Whilst recent technological advances offer ways in which teams can bolster screening success, these tools must meet patients where they are. This means that the study process needs to fit into the patient's lifestyle while reducing the need to travel and take time away from home, school, or work.

By leveraging digital technologies, study teams can ease patient burden using intuitive and familiar technology. Gathering data from the comfort of a patient's home, for example, or using remote capabilities for patients who live a considerable distance from the site, or designing a study aligned to the patient's current treatment journey—in terms of the regularity of the visit schedule, for instance—all of these are effective ways to design the trial around and specifically for the patient.

Electronic consent tools go even further in streamlining and simplifying the consent process to minimize patient refusals. With electronic consent, teams can present a wealth of information in a richly engaging multimedia platform. At the same time, electronic consent empowers patients to proceed at their own pace and provides opportunities to ask questions or seek clarification at any point through the consenting process.

With all the possibilities afforded by accelerated digital health technologies comes a slew of new considerations: marrying a treatment schedule, visit schedule, and assessment schedule in a way that's convenient

for the patient; thoughtfully leveraging remote capabilities to gather data from a patient's home; and ensuring both clinician and patient still feel engaged and cared for when tasks and assessments are transitioned to a more virtual setting.

The wider net allowed by going digital with decentralized trials and democratized study participation promotes inclusive enrollment across geographic, racial, gender, age, income, and socioeconomic groups. This is crucial to ensuring the drug or device is tested in those individuals for whom the treatment is intended post-registration.

Recognize the larger implications of the screening process

Through the use of digital eScreening solutions, sponsors can now broaden the reach and accessibility of trials through a leaner trial footprint and recruit an enriched trial population—meaning fewer sites, fewer patients, fewer screen failures, and an acceleration of drug development cycle times.
Of course, recruiting sufficient eligible patients requires taking steps to minimize screen failures, which account for a substantial segment of study startup delays. Globally, 80% of trials do not enroll on time, and each screen failure costs the study sponsor an average of $1,200.

When recruiting through digital media, it's important to be aware of bias-based factors such as limited access to or fluency with digital technologies. Otherwise, the individuals who are most appropriate for a certain trial, or who might most benefit from the trial's research, may be unintentionally excluded.

Accelerating research through a patient-first approach drives inclusivity in the research space, enabling more communities, and thus more people, to have access to the right health care.

The future of patient screening is now

Successful trials begin with successful patient screening. Failure to meet enrollment targets can lead to cost overruns, delayed endpoint capture, extended timelines, missed milestones, or even study termination.

Implementing flexible, scalable, and compliant tools enables teams to recruit patients no matter where they are — at the site or remotely. Electronic consent tools like Medable's Total Consent enhance patients' comprehension and help them feel more engaged with study goals and procedures, thereby increasing the likelihood they will grant consent and enroll.

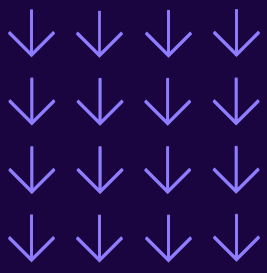
And resources like Medable's Patient Advisory Council provide ongoing insights regarding patient access, outcomes, and the practicality of the patient experience.

To meet your enrollment targets faster, drive inclusivity and diversity, enhance patient engagement and retention, and facilitate successful trial completion, consider integrating digital screening and consent tools into your study.

Retain screened participants by properly preparing them with a better consent experience

While enrollment and screening are crucial in obtaining participants for trials, the informed consent process is paramount in ensuring they stay enrolled in a trial.

Once a patient is deemed eligible for a clinical trial, they must be informed about the trial's purpose, procedures, risks, and benefits before they can enroll. This process is known as informed consent, and it ensures that patients understand what they are getting into before they agree to participate. Informed consent is a critical ethical and legal requirement for conducting clinical trials, and it plays a crucial role in protecting patients' rights and safety. Within the last twenty years, organizations like Medable have improved the informed consent process with electronic informed consent, a digital version of consent that's shown to improve education, comprehension, and retention in participants. Read ahead to see learn all about eConsent.



Chapter resources:

Blog
How to split risk and reduce patient screening failures

Chapter five

Electronic consent (eConsent)

Informed consent can be defined as providing a potential participant with enough information about a study to allow for an informed decision about their participation in a clinical trial.

The process is a vital one revolving around participant education and communication, and one that is highly controlled through local, country-specific, and global regulations.

While informed consent form (ICF) signatures traditionally have been collected on paper at a physical site, today's digital approach — electronic consent (eConsent) — offers more than high-tech signature collection. It provides an upgrade to patient education and communication as well, empowering participants in new ways. Moreover, eConsent can democratize clinical trial access, allowing researchers to recruit broader and more diverse participant groups through entirely remote consenting processes. This broader and less burdensome access also can increase the speed of recruitment and reduce drop-out rates.

In addition, when the eConsent solution is part of a larger platform for decentralized clinical trials (DCTs), it can facilitate automated workflows to further reduce both trial site and patient burden. Plus, as part of an interactive multimedia experience, eConsent offers the opportunity to present information in new and interesting ways to aid in reaching participants with various learning styles.

While the eConsent experience offers a number of opportunities for enhanced communication, it's important to recognize that it is not a replacement for discussions between clinical trial site staff and trial participants. This discussion, facilitated by the consent documents, will always remain the bedrock of the informed consent process.

eConsent Challenges

Informed consent forms (ICFs) can be difficult for some clinical trial participants to understand. For starters, today's ICFs are far longer than those of decades ago. In one review, ICFs averaged between 10 and 20 pages in length and were frequently written at higher-than-eighth-grade level. Clinical trial designs are increasingly complex, and the language often used on ICFs is often too technical for those with average or below-average literacy levels.

In a recent review of four COVID-19 vaccine trial ICFs, all ICFs were written above a ninth-grade reading level and required approximately 35 minutes to read. Further adding to the complexity of the informed consent documents is the environment in which they are presented. The experience of being presented with a complex 20-page document that often has a very legal appearance in a surgical center, hospital or doctor's waiting room was often described as intimidating during a discussion with the Medable Patient Advisory Council.

For trial sponsors that are committed to a better ICF experience, finding a way to communicate clearly with participants, and in a setting that is better suited to comprehension, is paramount. That can be accomplished by simplifying ICFs — that is, reducing the amount of pages to wade through and writing in plain language for readability. Another tool to improve comprehension is eConsent. The objectives of an eConsent process are:

- **Consistency.** A well-designed eConsent provides an opportunity for study designers to thoroughly and consistently explain the study to participants using a broader range of tools, including multimedia, interactive knowledge checks, tiered information, and links to websites.
- **Patient empowerment.** With clear explanations presented in an easier-to-understand format, eConsent empowers patients to make more knowledgeable, informed decisions and feel confident moving forward in the study. Plus, participants can digest information at their own pace in a comfortable setting of their choice.
- **Patient engagement.** The dynamic interface engages participants, which enhances patient recruitment and retention.
- **Less burden.** eConsent reduces the burden on clinical trial site staff by enabling a remote patient screening and paperless consent process.
- **Improved data management.** The digital process eases the retrieval of source documents for inspections, audits, and monitoring and enhances oversight with real-time data reporting to both sites and sponsors.
- **More efficient workflows.** Utilizing eConsent enables improved quality and efficiency for clinical trials through the automation of workflows, integrations, and reducing the administrative burden.

eConsent's impact on patient enrollment, recruitment, and retention

Adopting a remote consenting and screening process allows researchers to cast a wider net in recruiting participants. Minimizing the need for participants to travel also allows for a more diverse participant pool. Recent research has demonstrated the high travel burden experienced by clinical trial participants. This travel burden reduces the likelihood of participation, shining light on reasons why only an estimated 4% of patients participate in a trial. Using remote consent to reduce the initial burden can greatly enhance access to clinical research trials.

The average number of patient dropouts for clinical trials is roughly 30%, and participant dropout is costly — making the work of retention as critical as recruitment. The consent process is a major driver of keeping participants enrolled. Traditional informed consent forms can be confusing, and when patients don't understand what's required of them, they are more inclined to drop out of the study. In fact, one research review indicated that 35% of patients who dropped out of a study early said the ICF was hard to understand compared with 16% who completed the trial.

A paper consent process also carries a number of quality risks. Since 2018, over a third of all 483 FDA Warning Letters related to issues with the informed consent process, including when the consent process took place, who conducted the consent process, and who signed the consent form.

Patients are more likely to stay in a study if their informed consent process appropriately sets expectations, including what study participation will entail, what is required of the participant, and where to turn should questions arise — all of which can be better supported through eConsent than traditional paper.

Using eConsent to communicate with patients in an engaging way can help boost recruitment and retention, as potential participants feel informed, empowered, and confident in their choices.

Reducing quality risks with eConsent

Similar findings can be observed with EMA[AM1], and European Regulator Inspections, where issues with the informed consent process represent one of the most common reasons for critical issues as well as spontaneous notifications for GCP breaches. An eConsent aids in the accurate, real-time capture of these data points and makes it easy for trial staff to easily access participant consent forms should the need arise.

FDA Warning Letters also called out trial sponsors for using old and out-of-date versions of the consent form and a lack of documentation. With eConsent, the risk of sending old or outdated forms is mitigated, as once an ICF is updated on the platform, sponsors are assured that all future participants will receive the latest version. Plus, the eConsent process is clearly defined in the platform, and documents are easy to pull for IRBs, regulators or others.

eConsent benefits

Electronic consent offers numerous benefits to everyone involved in the clinical trial process, specifically:

For patients. Electronic consent offers patients a more engaging experience. Videos, images, audio, charts, and diagrams help guide patients through the informed consent process, helping them understand the study's design and research objectives as well as what is expected of them as a study participant. Patients can review materials in the comfort of their over home in a low-stress environment. It's no wonder, then, that research shows patients prefer eConsent to traditional paper ICF.

For sites. For trial sites, an eConsent process reduces the burden on staff — eliminating paper burden and making documentation easier to find. While interaction and conversations with patients will always be important and necessary, stronger communication via eConsent reduces the number of questions patients have. Plus, eConsent allows for the automation of workflows and reduces administrative burden. Sites also benefit from broader recruitment and retention. When up to 50% of trials are not completed because of insufficient enrollment, a larger potential participant pool can be an important differentiator for sites. Such is the interest in eConsent that a recent survey published in Nature [AM2] showed that 59% of investigators expect the use of eConsent to increase and 40% rating it in the top 3 most valuable technologies.

For ethics committees/regulatory authorities. The digital process makes it easier to retrieve the source data for inspections, audits, and monitoring. eConsent can document patient comprehension, while capturing investigator and patient agreements to proceed. Having access to digital records helps set the foundation for ongoing digital engagement between sites and patients.

For sponsors. Study sponsors benefit from the ability to recruit and enroll a more diverse patient population, which enhances their research. Plus, they experience streamlined workflows and enhanced data quality and compliance, and they see increased transparency with real-time reporting and insight into study progress. eConsent also eliminates many of the quality issues noted in regulatory inspections, with the system controlling when and who conducts the process, automatically archiving the obsolete consent forms, and providing automated documentation of the consenting process.

eConsent misconceptions

There are a handful of misconceptions around eConsent, but they can be effectively overcome.

- **Initial investment.** Although the implementation of an eConsent process requires an initial investment of both time and money, neither should be a significant concern. When properly managed, the implementation of an eConsent system can be completed alongside the set-up of the trial, and the initial investment will be minimal compared with the return on investment gained through decreased recruitment time, reduced patient drop-out, and fewer issues with quality. With a risk-adjusted financial model[AM3] , sponsors can more effectively assess how patient engagement activities impact enrollment, adherence, and retention.
- **Stakeholder discomfort.** Moving to a digital consent process can be effectively managed with change management strategies. Clear communications with sites, patients, ethics committees or IRBs and health authorities can ensure all stakeholders understand the benefits of eConsent and support its use.
- **Technical requirements.** eConsent platforms can often require a specific device, such as a tablet, for both patient and site. But Medable's eConsent solution is offered across all web-enabled devices, such as smartphones, tablets, laptops, and desktop computers, and across all four major browsers. This flexibility significantly broadens access and minimizes the obstacles to this enhanced consenting process, especially with the increasing level of personal technology around the globe.

Regulatory considerations and adoption

As you consider whether eConsent makes sense for your study, it's wise to review the guidance from the U.S. Food & Drug Administration (FDA). According to the FDA's guidance, researchers can use eConsent to aid in the following:

- Protecting patients' rights and safety
- Facilitating patients' understanding of the information presented in the ICF
- Obtaining appropriate documentation of consent
- Ensuring data quality

The FDA's guidance provides information on how to present information in the eConsent, how to conduct the eConsent process, how to answer participants' questions and provide additional information, how to use eSignatures, and more.

ICH E6(R3) Good clinical practice

The International Council for Harmonisation (ICH) E6 Good Clinical Practice Guideline is a common reference for researchers. The ICH E6(R3) Expert Working Group released an initial draft [AM4] of their updated Good Clinical Practice guidelines in April 2021, which include guidance on informed consent. This guidance includes direction to sponsors to give consideration to the potential use of technology to inform participants and obtain informed consent, highlighting the acknowledgment of the benefits of eConsent and the expectation of its growing use.

International digital signature considerations

Another regulatory consideration is the acceptance of eSignatures around the world. Countries fall into a few categories:

- **eConsent is explicitly permitted.** These countries, which include the U.S. and the United Kingdom, have what is known as minimalist laws, allowing eSignatures to be enforceable in almost all situations and give the same weight to an eSignature as a handwritten signature.
- **eConsent is explicitly denied.** In a handful of countries, such as Austria, eConsent is not allowed.
- **eConsent guidance is vague.** In these countries, such as Spain and Italy, eSignatures might be accepted if compliant with eIDAS [AM5] requirements, but there isn't specific guidance on whether eConsent and eSignature can be used for clinical trials.

With Medable's extensive experience working in eConsent's mixed regulatory landscape, we can help trial sponsors navigate the international regulatory challenges that arise. Plus, the flexibility of the Medable platform enables the accommodation of multiple countries in a single deployment — allowing for a range of signature-collection methods based on each country's regulatory requirements.

IRB guidelines

Regulatory considerations also center around local Institutional Review Boards (IRB) or Ethics Committees (EC). The IRB or EC is responsible for reviewing the informed consent form and process to ensure compliance and patient safety, and it's important to understand what the IRB needs in order to grant its approval. The required elements of informed consent, for example, are essential regardless of whether you're using a traditional paper ICF or eConsent.

An IRB will often require review of the informed consent process as well as the informed consent content. IRBs tend to view eConsent systems quite favorably, acknowledging their benefits around participant comprehension and quality. Reviewing the platform from the perspective of a participant to assess the user experience before granting study is critical.

Through experience in deploying the eConsent platform across multiple global studies, Medable has developed both an experiential and regulatory insight knowledge set to help navigate the complex global landscape. Each study team implementing the Medable platform is provided access to our IRB/Regulatory Submission Pack designed to guide teams through the process.

What Are clinical outcome assessments (COAs/eCOAs)?

COAs (called eCOAs when captured electronically) are essential to understanding whether a drug is reducing symptoms, improving patients' quality of life, and improving patients' ability to perform activities they care about. There are several types of COAs, including:

- **Patient-reported outcomes (PROs or ePROs),** which are based on a report directly from the patient about the status of their own health condition, without interpretation from a clinician or anyone else.
- **Symptoms or other concepts** that are unobservable, known only to the patient, and can only be measured with PROs. For example, pain severity or headache intensity.
- **Clinician-reported outcomes (ClinROs, eClinROs),** based on a report from a trained healthcare professional after observation of a patient's health condition.
- **Observer-reported outcomes (ObsROs, eObsROs),** based on the report of observable signs, events, or behaviors related to a patient's health condition by someone other than the patient or a healthcare professional. ObsROs are most commonly reported by a parent, caregiver, or other non-healthcare professional who observes the patient in daily life. Importantly, these assessments do not include medical judgment or interpretation.
- **Performance outcomes (PerfOs, ePerfOs),** based on patient performance of standardized tasks, e.g. word recall or timed walking tests. These can be administered and evaluated by an appropriately trained individual or completed independently.

COAs enable a well-rounded understanding of how a drug is working, its side effects, its impact on patients' lives, and more. Perhaps most notably, PROs/ePROs allow for the patient's voice to be heard. Capturing the patient's voice is particularly important because the clinician may not always see or express the patient's experience in the same way.

"It turns out that what is really bothering the patient and what is really bothering the doctor can be radically different things … patients are true experts in their disease," says Dr. Janet Woodcock, Director for the Center for Drug Evaluation and Research.

She adds: "It's clear you have to start with an understanding of the impact of the disease on the people who have it, and what they value most in terms of alleviation, before you set up a measurement and go forward with truly patient-focused drug development."

Benefits of electronic COAs/PROs

With advances to technological capabilities and the prevalence of personal electronic devices among the general public, electronic capture of clinical outcome assessments, including patient-reported outcomes, is preferred by study participants and recommended by regulatory agencies like the Food & Drug Administration (FDA).

The well-documented benefits of using digital solutions to collect eCOA data, including ePROs, include:

Data integrity. eCOA can help ensure data collection follows the fundamental principles of data integrity as defined by FDA: attributable, legible, contemporaneous, original and accurate, or ALCOA.

Data quality. With electronic data capture, researchers see enhanced data quality and accuracy, benefiting from real-time data flow and from automation—for example, automatic calculations, branching to appropriate subsequent items, reducing missing data, and avoiding transcription of data-entry errors.

Patient-centricity. Patients can use familiar (or even their own) devices to answer surveys or participate in televisits from the comfort of their own homes. Plus, data may be automatically collected and transmitted via digital health devices. With this patient-centered approach comes a reduction in travel, meaning researchers can gain access to a more diverse patient population and studies see higher rates of compliance.

Better protocol compliance. On-device reminders or alerts, timestamped data entries, and programmed eCOA workflow help ensure assessments are completed in the order and/or during the times specified in the protocol.

Reduced patient and site burden. Study participants and site staff input their responses directly into the eCOA system, reducing data entry time and the need to keep assessment forms and paper diaries as source documents.

Simpler regulatory submissions. With cleaner, higher-quality data, sponsors can experience a greater increase in the ease of submissions, which contributes to the continuing regulatory agency guidance for these digital tools.

Remote data collection. The COVID-19 pandemic highlighted the need to include remote and digital solutions as part of the clinical trial process. As decentralized clinical trials (DCTs) become more common, the industry has recognized patient data can be collected via televisit and/or mobile app where appropriate, rather than always requiring on-site study visits. Reducing travel can reduce potential patient burden. In addition, remote data collection enables more frequent collection of data outside the clinical setting, enabling greater insight into the impact of the drug on the patient's everyday life.

Better patient experience: eCOA connects users with large libraries of support materials, empowering them with up-to-date information on how to schedule a visit, how to use their devices, and with answers to frequently asked questions. The ability to access this wealth of information from their telephone or tablet, and in easy-to-view mediums such as videos, are also ideal.

Configurable reporting options. Having a robust reporting tool to connect with your eCOA system is a key advantage to DCTs. Electronic data capture solutions can help create an automatic series of questions with conditional

responses. They may also reduce the complexity of possible responses, an ability not easily obtained through paper surveys. And once created, eCOAs can be configured and deployed in numerous formats—providing further operational efficiencies.

Collaborative data creation and review. Electronic data capture solutions enable cross-functional groups to create, review, and approve data simultaneously. By deploying an ePRO solution participants can easily review and complete forms, providing a high level of patient adherence and engagement.

What to consider when implementing an eCOA solution

When you're ready to explore an eCOA solution, it's important to take into account the specific demands of the trial protocol and the patient and site staff experience, as well as regulatory requirements. Here are some things to consider:

Design your eCOA solution to fit your protocol needs. As you consider the appropriate eCOA solution for your clinical trial, be sure to consider what data you need to collect, how that data will be collected, and the age and characteristics of your study participants (for example, their physical/cognitive abilities).

Consider where data collection will take place. Regardless of modality, remote eCOAs need to provide valid, reliable, and meaningful endpoints equivalent to on-site eCOAs. Remember:

- eClinROs can be measured over a televisit or at site
- ePROs and eObsROs can be measured on a mobile app or web application, at site or remotely

Think about your device strategy: provisioned or bring-your-own -device (BYOD). A BYOD model allows participants to use their own smartphone or other device for data capture. When using a device with which they are already familiar, participants may be more likely to be compliant while not being burdened with multiple devices — ultimately leading to a better clinical trial experience. However, since some participants may be hesitant to download an app on their own device, or may not own a device that meets the requirements, it's important to anticipate a percentage of provisioned devices, even in trials adopting a BYOD strategy.

Understand the regulatory requirements. The eCOA solution should align with the regulatory guidelines put forth by the U.S. Food & Drug Administration (FDA) and the European Medicines Agency (EMA) to ensure the reliability, quality, integrity, and traceability of electronic data. Other regulatory agencies may have additional guidance specific to the indication.

Align eCOA solution design with study timelines. When considering timelines concerns for eCOA development, the design of your eCOA solution should enable sufficient lead time and alignment with vendor project schedules. Launching a project too soon may provide a platform that is obsolete at the start of a study, while deploying a solution too late may delay the ability of some subjects to participate: creating operational inefficiencies.

Ensure training and support for sites and subjects. Successful eCOA systems include the right amount of quality training for sites and subjects, provide avenues for additional retraining to combat potential issues that may emerge, and offer a comprehensive help desk to provide critical support to participants.

Conclusion

As telehealth solutions and mobile health devices help empower decentralized clinical trials, study sponsors look for ways to further improve the patient and site experience while delivering high-quality data. By deploying ePRO/eCOA solutions that allow the collection of patient-reported outcomes, clinician-reported outcomes, and other COAs both remotely and on-site, researchers can ascertain key quality-of-life data for labeling purposes and efficacy and safety testing.

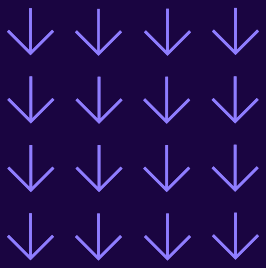
As you seek an ePRO/eCOA solution that's flexible, compliant, and modular, Medable is an ePRO/eCOA partner that can deliver.

Beyond trial startup: Collecting data in a digital and decentralized world

Once a participant has been enrolled, screened, and consented to a trial, their focus will be shifted from orientation to the completion of trial activities, including submitting their own data.

Collecting accurate and reliable data is critical to ensuring that trial results are meaningful and can be used to make informed decisions about the drug's safety and efficacy. In the past, this information was collected using paper forms. In today's digital world, this is commonly done using electronic Clinical Outcome Assessments (eCOA).

Read ahead to learn more about eCOAs, their benefits, and how they simplify data collection for all trial stakeholders.



Chapter resources:

Watch
This webinar about how a patient-first approach to informed consent can improve patient education, engagement, and comprehension, ultimately improving retention.

Blog
How the right eConsent solution can reduce screen failures

Watch
Learn how to overcome perceived eCOA adoption hurdles

Blog
How to design patient friendly eCOA and ePRO instruments

To learn more about decentralized clinical trials, speak with a Medable representative here.

www.medable.com

Sources:

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