Why eConsent Primes Patients and Studies for Success

Medable

As famed tennis player Arthur Ashe once said, “Success is a journey, not a destination. The doing is often more important than the outcome.”

There’s perhaps no greater application of this phrase in clinical research than with the informed consent process. This crucial process helps ensure trial participants are adequately educated about the trial and what will be required of them during the process, while confirming their willingness to enroll.

For almost 100 years, the informed consent process took place at a clinical trial site, with investigators briefing potential participants, in person, over large stacks of paper reminiscent of a car or housing loan. Thanks to technological innovations, refined processes, and decades of lessons learned, we have a better way of ensuring trial participants are educated and informed about their trial. This ”better way” is called eConsent, and it uses a combination of audio/visual presentation styles, proven educational techniques, and more to put the “informed” back into informed consent.

The Sudden Rise of eConsent

When COVID-19 spread across our globe at the beginning of 2020, clinical research was forced to change. During this time, eConsent adoption skyrocketed with sites adopting processes that would facilitate the remote continuation of clinical research.

According to a survey conducted by Florence Healthcare, 47% of research sites had adopted eConsent by December 2020, just eight months after the WHO declared an official pandemic.

By July 2021, 75% of research sites had either used it or were looking into it. Now, as the Journal of Nature reports, almost 60% of clinicians surveyed expect eConsent adoption to continue to rise post-pandemic.

The Move Away from Paper

While paper informed consent forms (ICFs) remain the most widely utilized method of consent, they have long been deemed inadequate, implemented primarily for cost and familiarity.

A recent survey of 179 different clinicians conducted by Chrysalis Advisory and CT:IQ showcases the negative clinical perception that prevails around paper consent forms. According to the survey:

- 72% considered paper consent forms to be too long
- 62% found paper consent forms to be too complex
- 38% thought that paper consent forms impaired participant comprehension

In stark contrast, the same survey showcased positive clinical perceptions around eConsent's ability to improve clinical research. Specifically:

- 67% expected eConsent to enhance patient comprehension
- 59% reported seeing eConsent as the solution to providing adequate information to culturally and linguistically diverse populations

Staying Power: How eConsent Fixes Age-Old Clinical Trial Issues

It's clear from the statistics from Nature and the greater industry that eConsent is here to stay. Part of the reason for eConsent's staying power is its ability to help solve long-standing problems within clinical research.

Challenge

Poor patient retention, understanding, and comprehension

For decades, sponsors and CROs have struggled with patient retention. As research protocols became more complex, consent documents became bloated. In fact, modern oncology ICFs can often exceed 12,000 words, which is greater than the number of words contained in the federal policy for the protection of human subjects in research.

Solution

eConsent helps patients better understand the importance of compliance

eConsent enables a consenting process that's tailored to feel more like a journey, utilizing multiple learning methods to reinforce main points, leading to greater patient comprehension, engagement, and ultimately, retention.

eConsent improves participant comprehension by:

- Tiering information into smaller, more digestible bites
- Deploying multi-media tools such as graphics, video, charts, and more to simplify clinical concepts
- Providing relevant key definitions, hyperlinks, and explanations live as patients consent, and by
- Facilitating a journey designed to better educate patients, while improving the informed consent conversation

Challenge

Patient burden due to site travel

With more than 70% of potential clinical trial participants living greater than two hours from a research site, many patients have expressed complaints about the travel burdens required by clinical research.

Solution

eConsent powers remote patient consent

eConsent helps eliminate these burdens by nature due to its remote capabilities. This not only gives patients and sites the ability to review consent forms and capture digital signatures remotely through video calls, but it also expands participation to populations that wouldn't normally have access to clinical trials.

Taking it one step further with **Medable Total Consent**

- **Web-based solution** enables patients to consent to clinical research from any web-enabled device (BYOD)
- **Built-in TeleVisit** enables a seamless and secure experience for both patients and sites
- **Seamless integrations** with other healthcare systems helps to automate workflows and reduce burden for sites and study teams

Challenge

Document management and re-consent burden

When clinical trial protocols change, patients are often required to re-consent to the amended protocol or sign additional consent forms due to changing scope. Unfortunately, re-consenting on paper means participants must make another, uneccessary visit to the site, while sites face an administrative nightmare managing multiple versions of paper consent forms, potentially leading to quality issues.

Solution

eConsent reduces site burden through automation

Sites can easily reissue additional consent documents to participants in just a few clicks using eConsent. With version control, digital signatures and TeleVisit being core capabilities of any eConsent system, sites can eliminate error-prone, manual tasks, while patients can eliminate uneccessary trips to the site.

Taking it one step further with **Medable Total Consent**

- **Advanced version controls** automatically archive old versions of consent forms, preventing them from being used
- **Automated assignments** define a clear process for consents and re-consents, further reducing the burden on sites

Challenge

Missing data, poor data quality, and data delays

According to the FDA and EMA, informed consent issues are the cause of most inspection findings. These errors are costly, time-consuming, and can jeopardize the completion of a trial. Unfortunately, these issues are unlikely to be remediated by paper ICFs, as they stem from the physical properties of paper itself.

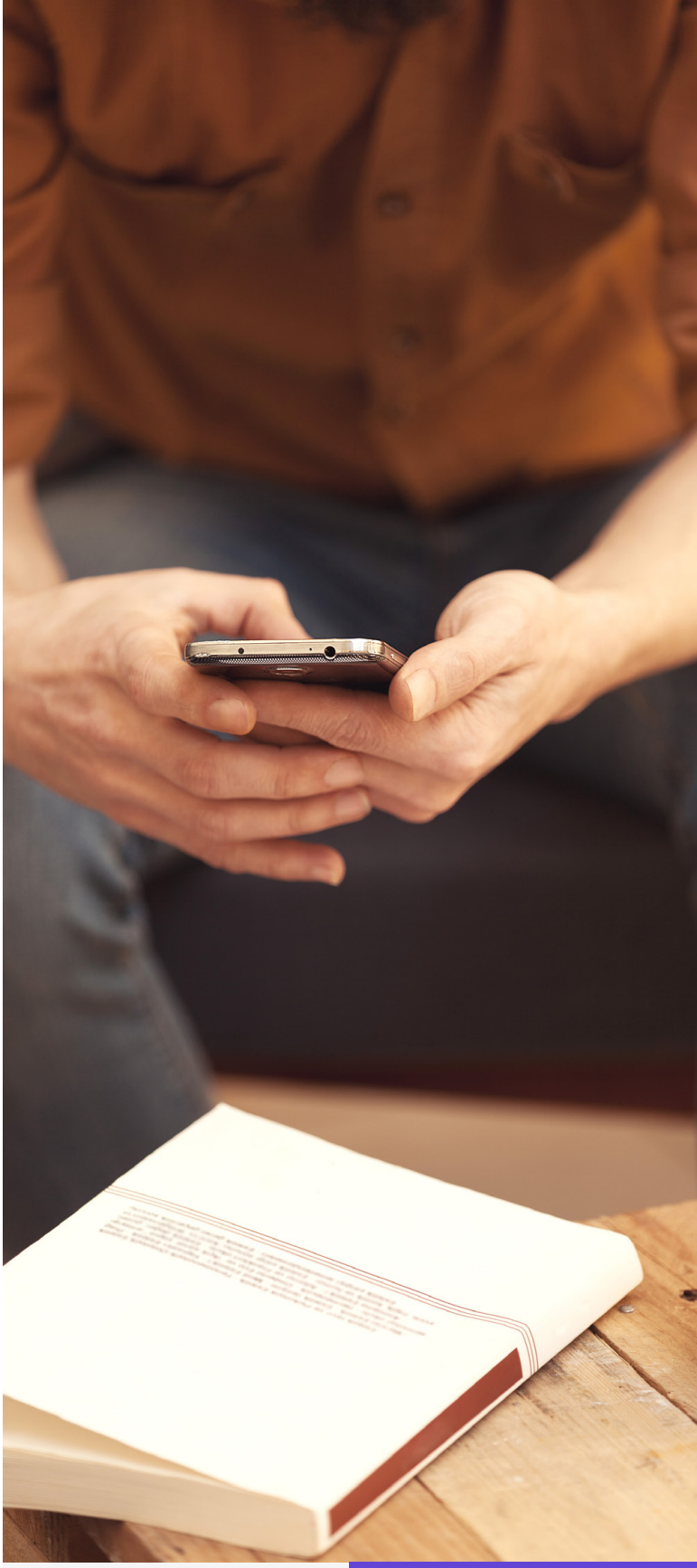
Solution

eConsent is designed to improve study quality

In addition to the core capabilities listed earlier, eConsent improves study quality by automatically documenting all consent activities and tracking consent statuses in near real-time, this gives study teams better trial oversight while ensuring sites obtain any and all needed signatures prior to data lock and submission.

Taking it one step further with **Medable Total Consent**

- **Gated system connections** ensure that the study at hand, cannot take place until all consent signatures have been collected
- **Multiple signature modalities** gives participants the ability to consent on-site with digital or wet-ink signatures or remotely through a tracked TeleVisit, depending on country regulations.



More Benefits Than Just Solving Problems

While some of eConsent's biggest benefits are mitigating long-standing clinical research issues, we can start redesigning clinical trials around the patient and their quality of life by using a **total consent management solution**.

Better informed consent conversation

eConsent's feature set is designed in a way that helps facilitate a better informed consent conversation. The combination of tiered information, knowledge checks, hyperlinked glossary and more, helps to ensure that the patient is better educated prior to their consent conversation.

Increased sponsor oversight

In traditional trial conduct, sponsors won't have insight into how a trial is performing until a sponsor's Clinical Research Associate (CRA) shows up to examine the consent process. Due to this time delay, any issues that are present are harder to correct.

Sponsors who adopt a total consent management solution gain complete visibility and oversight into how their study is progressing. With Total Consent, automated workflows and near real-time transmission of data enables researchers to quickly identify and correct issues.

A single platform for all consent activities

Unlike paper forms, eConsent provides a single system in which all consent activities for patients can be monitored. A total consent management solution streamlines all consent activities for maximum efficiency. This ranges from the creation and storage of consent templates, to automatically maintaining information on which version of the ICF was signed and stored, as well as the timestamps, location of consent, and more. These benefits coalesce to form an experience that's easy to use and exponentially more efficient while enabling clinicians to spend more time focused on critical study activities.

Device scalability

eConsent offers the ability to consent patients, their caregivers, children, and other patient populations that may face challenges offered by the traditional informed consent process. Built to scale, total consent management solutions are able to handle multiple signers (e.g.witness, LAR, child), multiple signature modalities (digital vs wet ink), and re-consenting with ease. Additionally, they're able to be used on any web-enabled device, unlocking the power to include new patient populations.

Pre-consent information sharing

One way to reinforce and retain patients is by providing trial information well in advance of the patient's consent appointment with the trial site. A total consent management solution packages and forwards trial information to patients to access remotely, such as explainer videos, key terms, glossaries, and more, all before the patient meets with the site.

Using Flexibility to Overcome Global Challenges

The varied global regulatory landscape around eConsent can still pose some challenges to sponsors, sites, and CROs. As it stands today, there are still a large number of countries where eSignatures aren't accepted and other eConsent features may be limited. Thankfully, a **total consent management solution** can mitigate these challenges.

		Total Consent Management Solution		
Regulatory Complexity		**eConsent + eSignature**	**eConsent + eSignature** (on-site)	**eConsent + wet-ink signature** (on-site)
Low	eConsent and eSignature are broadly accepted with regulatory guidance available *Examples: U.S., UK, Denmark, Singapore*	✓	✓	
Medium	eConsent and eSignature have been accepted however, there are considerations to account for *Examples: Netherlands, Belgium, Germany*	✓	✓	✓
High	eSignatures are not permitted however, eConsent can be used to present informed consent information *Examples: Switzerland, Austria, Bulgaria*			✓

Medable Total Consent enables the capture and upload of scanned wet-ink signature documents enabling you to meet global compliance requirements in all countries.

This flexibility allows for near real-time monitoring of all consent signatures, regardless of how they were captured, giving you what you never had before with a paper-based consenting process, complete visibility and oversight into your trial.

Bringing eConsent to Your Organization

As anyone working within a large company knows, bringing positive change to an organization can be hard. For those who are embarking on a journey to improve their organization's informed consent process with eConsent, we recommend you:

Find, understand, and deliver the key benefit for each of your organization's stakeholders

For instance, a Clinical Operations executive may care most about ensuring good clinical practice or reducing audit findings, whereas a Chief Information Officer may be more interested in standardizing study deployment.

Understand the best solution set for each study

eConsent cannot simply be shoehorned into an existing study. It must be tailored to the unique needs of its audience, sites, and study to succeed.

Assist sites in the adoption of eConsent

Training, documentation, on-site visits, and more can help speed up adoption and decrease tension.

At Medable, our Site Success Team ensures our products and technology meet the needs of site stakeholders while regularly reviewing training, workflows and user interfaces to ensure maximum site adoption and value.

Provide training to everyone involved

eConsent, like any new process, requires time to learn and master. Provide sites and study teams with eConsent Specialist Certification courses, create standard digital operating procedures, publish study-level training guides, and most of all try to alleviate some of the burden on sites and patients.

Summary: Consent is a journey, not a destination

As Advarra notes in their 2021 research titled "Retention in Clinical Trials", 35% of patients who dropped out of a study early reported that it was difficult to understand the informed consent form.

Advarra's research helps support a sentiment that we've long understood; that patients are more likely to complete clinical trials if their expectations were appropriately set during the informed consent process. This includes what study participation will entail, what actions are required to be taken by the participant, and most importantly, where to turn should they have questions.

Given that these are all features that eConsent can solve today, it's never been more apparent that a proper informed consent experience should lead to a fully informed patient, not just a signature.