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eConsent Technology

Tips for tailoring eConsent for optimal patient centricity

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Clinical trials in a variety of therapeutic areas experience patient dropout rates close to 20%

While informed consent is a critical process for ensuring participant autonomy in clinical research, consent forms are too long, unclear, difficult to read, and frequently exceed 6th grade reading levels. This has been demonstrated in COVID-19 vaccination trials,[1] in oncology trials (where the average consent form has over 7,000 words),[2] and in many other settings.[3] Various stakeholders share this view, including IRB chairs, patients, advocates, caregivers, and care partners. Because the goal of informed consent is to assure that a participant can make a voluntary, well-informed decision regarding trial participation after carefully weighing potential risks and benefits, it is critical that the process be tailored to ensure that participants understand what's being asked of them and how their data will help further future disease treatment.

Failure to adequately inform participants such that they fully comprehend what is expected of them can also impact the success of a clinical trial and increase in drop-out rates. According to Tufts researchers, clinical trials in a variety of therapeutic areas experience patient dropout rates close to 20%. And, although every patient dropout cannot be attributed to failures of the consent process, Advarra's 2021 research titled "Retention in Clinical Trials" highlights a key link between consent and dropouts.

According to Advarra, "35% of patients who dropped out of a study early reported that it was difficult to understand the Informed Consent Form compared to just 16% who completed their trial." Advarra concluded that patients were more likely to continue the study if their expectations were appropriately set during the informed consent process, including what study participation entails, what actions are required to be taken by the participant, and most importantly, where to turn should questions arise; all areas that can be better addressed with the features of eConsent. Participant dropout is costly, with an average estimate of $42,000 per patient in phase 3 trials. If dropouts result in trial delays, the costs increase: estimated lost revenue for delaying a trial is 600k to 8M every day.

A Solution: eConsent

eConsent provides a solution to overly long and complex forms as it can be tailored to different audiences and have interactive, engaging elements. Additionally, eConsent can enable the enrollment of underrepresented and/or geographically diverse populations[1] through remote consenting, something that has been shown to reduce screening periods by up to 50%. In fact the potential use of technology in the informed consent process is something that is called out in the updated draft guidance from the International Council for Harmonisation (ICH) E(R) Good Clinical Practice (GCP) draft guidance.[11]

The features of eConsent combine to present the information in an easier-to-digest format, rather than offering patients the entire informed consent form at once. Table one illustrates some of the issues with the informed consent process and the potential solutions that eConsent provides.

Stakeholder issues with the informed consent process

Issue	Feedback from Medable's Patient Caregiver Network	eConsent Solutions
Complicated, lengthy, and jargon-heavy informed consent documents	If I had to describe the consent form, in one word, it would be mud. It's dense in terms of word choice, because it's heavy on the jargon, in terms of syntax, or complexity of the sentence structure. And also in terms of the layout, and how much text appears on the pages overall. ICFs often have a 'legal contract' feel to them that can be intimidating. Especially, when I think back to the 20-page documents of courier type font I've reviewed before. It has often felt like I was either left alone with consent documents that were overly wordy/dense.	eConsent allows distillation of information in ways that meet the needs of unique patient populations. Complex concepts and requirements can be transformed into audio and video, spoken in patients' local language. Actions can be demonstrated, which helps with accessibility and understanding. Hyperlinked terms or glossaries can provide additional context or explanations.
Lack of expectation setting	For me, knowing if and how I might be helping others with the same disease in the future would increase the likelihood of me being compliant with study procedures, particularly more nuanced aspects like taking medicine within a short window each day or spending genuine time answering daily measures.	Infographics, video, and audio narration demonstrate the study-specific clinical trial process, including the various phases, the participant journey, and what's expected of them. The consent form can also deliver information about the intended goals of research, the benefit for future patients, and what is known about the condition under study.
Lack of explanation around key concepts	Many study staff are not comfortable explaining the concept of randomization. The risks. I am not sure how to get around it but it's very intimidating and in some situations, frightening because you feel like you're signing your life away.	eConsent forms can be tiered to provide key summary information with expandable and retractable details if the patient is interested in learning more about a particular subject. Examples include videos explaining randomization, infographics displaying who has access to study data, or graphics of common side-effects and their likelihood.

The informed consent process offers an opportunity for site staff to build rapport with the patient, whether conducted in-person or remotely, and provides a first impression about the trial specifically, and research more broadly.

Thus, it's important for the patient to experience a two-pronged consent approach that uses engaging content tailored to their needs and facilitates a positive patient and site interaction.

How to create a tailored, engaging eConsent experience

To tailor a patient-friendly informed consent experience that meets the unique learning needs of varying patient populations, sponsors can use a mixed-media approach that includes key digital features such as:

- Audio
- Video
- Charts, graphics, infographics, and other visual displays
- Tiered content to provide information in easily digestible sections
- Hyperlinked terms that provide plain text definitions when clicked on
- Knowledge checks and interactive quizzes

Knowledge checks asking participants to confirm their knowledge about key study concepts, activities, and goals can guide site staff to facilitate conversations with the participant to clarify study details and misconceptions.

An informed consent approach should combine human interaction with engaging technology to make sure participants are comfortable with process and fully understand the information presented.

Tips from Patients, Patient Advocates, and Caregivers

Do

- Make eConsent interactive. Provide multimedia content that both engages and explains, and use knowledge checks to ensure comprehension and provide a guide for the consent discussion.
- Add glossaries or hyperlinks into eConsent. Terms should be clickable so participants are able to remember or refer to them as they interact with the tool.
- Depending on the participant population, multiple modalities should be used to help facilitate and match the common learning styles of the populations expected to consent.
- For example, to make studies accessible for the visually impaired, eConsent language should be optimized for screen readers, and use of video and audio should be optimized.
- If using video, then language, terminology, and dialect should be considered for your population.
- Use clear, simple language. Aim for a 6th or 7th grade reading level (approximately the level of a 12-year old.)
- Make information easy to share with loved ones, community leaders, and key stakeholders.
- Provide a mechanism for interaction. Treat this as an opportunity to build rapport and establish a strong relationship between site and patient.
- Keep paragraphs brief and use short words (1-2 syllables are best). Use words carefully. Don't define patients by their diagnosis.
- Use people first-language. For example, Barry is a patient with optic atrophy, not an optic atrophy patient.

Don't

- Use jargon or dense language patients don't understand.
- Treat the informed consent process as something to be done by the patient in a vacuum.
- Mimic a dense, jargon-filled paper consent.

Workflow

- Make the login process as simple as possible.
- Look and feel are important. Patients want to use apps that are engaging and warm.
- Progress bars, calendars with important dates/times, and reminders are important features in every solution.
- Be logical. If it doesn't make sense to you as the expert, it won't make sense to patients.

Imagery

- Be culturally appropriate and sensitive, and don't rely on stereotypes.
- Don't use images of an elderly, white woman to depict a typical patient with sickle cell disease.
- Steer clear of using imagery of a scruffy, old, down on their luck veteran when depicting a patient with hepatitis C

Conclusion

Studies have demonstrated increased comprehension with eConsent versus paper consent, especially when the interactive components are included, such, quizzes, tailored information, infographics, and links to definitions and more information.Additionally, eConsent has been shown to be an acceptable solution for ensuring patients are properly informed about a study.When paired properly with Good Clinical Practice and patient-centered goals, eConsent can help improve participant understanding of the trial and appropriately set expectations, and ultimately help improve recruitment and retention.

To see how Medable can help, contact us today for a demo.

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