Digital Equity in Clinical Trials: Lessons from an E-Consenting Pilot at IUSCCC

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The insights shared in this article are based on the author's firsthand experience implementing and evaluating the e-consent platform in a real-world clinical research setting.

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Abstract

E-consenting can transform clinical trial participation by improving accessibility, efficiency, and regulatory compliance. This reflection draws on my firsthand experience implementing an e-consent platform at the Indiana University Simon Comprehensive Cancer Center Clinical Trials Office. During the pilot, I observed increased patient engagement, more thorough consent review, secure centralized storage, and reduced paper usage. Challenges included assisting patients with limited technological experience and time-intensive staff training. These experiences underscore the importance of balancing security and efficiency with user-friendliness. Looking ahead, I believe there are opportunities to streamline verification, support participants with limited tech experience, introduce hybrid consent options, and strengthen community engagement. My experience highlights best practices for inclusive, patient-centered approaches, showing how e-consent can promote equitable access to clinical trials and improve the overall patient experience. This reflection also aims to inform the broader community about the impact of e-consent on clinical research.

Keywords: e-consent, clinical trials, digital equity, patient engagement, cancer research, community reflection

Introduction

Clinical trials are essential for advancing cancer treatment, providing patients access to innovative therapies, and contributing to improvements in care. However, patient participation is often limited by disparities in access, literacy, and geographic location. Digital tools, such as e-consent, can mitigate

these barriers, making trials more inclusive and patient-centered. The Clinical Trials Office (CTO) at Indiana University Simon Comprehensive Cancer Center implemented an e-consent platform to modernize the consent process, enhance accessibility, and promote digital equity. This platform allowed patients to review consent documents remotely, engage with study staff at their own pace, and participate in trials more comfortably and confidently.

By reflecting on this pilot, I aim to demonstrate how digital tools can support patient-centered care, inform policy and practice, and advance equitable access to clinical trials, while also highlighting lessons learned and forward-looking strategies for the field.

Pilot Implementation

We introduced e-consent to create a secure, efficient, and standardized consenting process across studies. The platform enabled patients to review documents on their own time, whether at home or during clinic visits, ask questions, and submit forms digitally. The centralized storage ensured accurate documentation, maintained data privacy, and supported compliance with regulatory requirements. Staff were trained extensively to support patients and navigate the platform effectively.

Additionally, the CTO partnered with a third-party provider to develop an e-consent platform compliant with 21 CFR Part 11, ensuring federal standards for electronic records and signatures were met. iPads were purchased and made available for patient use across multiple clinics as well. Patients could access the e-consent remotely via a secure link sent to their email, allowing them to complete the process on their personal home computers. A multi-step verification process was required to access and complete the e-consent on both personal computers and the iPads provided in the clinic. After reviewing the consent form, patients were guided through the necessary fields that needed to be completed before finalizing and signing the consent. This process ensured accurate completion of the consent and minimized errors.

The platform securely captured electronic signatures, auto-populated essential fields, and stored documents in a centralized library, supporting auditability and reducing paper use.

Inclusive practices were embedded throughout the pilot. Staff worked to identify and support patients who might face barriers due to limited digital literacy, language differences, or mobility challenges. Feedback from both patients and staff was continuously incorporated to improve navigation and enhance overall experience. The pilot also contributed to environmental sustainability by reducing paper usage, saving physical storage space, and promoting more eco-conscious research operations.

Observed Benefits

The e-consent pilot yielded several notable benefits. Remote consent capabilities allowed patients who had difficulty traveling to participate, increasing enrollment and expanding access to clinical trials. Patients were able to review documents thoroughly from the comfort of their homes, ask questions without time pressure, involve family members in decision-making, and foster greater understanding and engagement.

We also noticed improvements in workflow accuracy and efficiency through auto-populated dates and consent versions, which were previously common sources of errors on paper consent forms. One key advantage of the e-consent platform was that patients could not finalize the consent without completing all required fields, ensuring accuracy and preventing the common issues seen with paper consents—such as missed pages, signatures, or incomplete fields. Beyond operational advantages, e-consent facilitated more meaningful patient engagement, highlighting the positive impact of research participation on understanding cancer care. Importantly, patients reported feeling empowered by having greater autonomy in their participation, as they could make informed decisions after thoroughly reviewing the consent form at their own pace. The platform also allowed patients to receive an automatic electronic copy of the signed consent form via email for their reference.

Challenges and Lessons Learned

Despite the benefits, several challenges emerged. Patients with limited technological proficiency or lack of access to devices sometimes required additional support to complete consent forms, which often led to frustration and a sense of wasted time that hindered the process. In particular, the multi-step verification process proved cumbersome for many patients and frequently caused delays. This process required patients to input a phone number or email address to receive a verification code, which they then had to enter to proceed. However, delays in receiving the code, input errors like incorrect email addresses, or system glitches meant patients sometimes had to restart the entire process, often waiting on the phone with a coordinator to resolve the issue. Additionally, staff training was time-intensive, as it was critical to ensure proper use of the platform and adherence to study protocols. Integrating e-consent into clinic workflows required careful planning to maintain efficiency and compliance while supporting patient engagement.

With these challenges, many lessons were learned. These included highlighting the need to simplify verification processes while maintaining security, improving navigation for patients who may require remote assistance, and prioritizing inclusive design. Collecting feedback from patients and staff was essential for refining processes and fostering community-engaged practices. These experiences reinforced the importance of equity-focused strategies, demonstrating that thoughtful implementation can improve accessibility and empower diverse populations to participate in cancer research (Lunt et al., 2020).

Policy and Practice Implications

The implementation of e-consent carries several implications for institutional policies and broader research practices. Ensuring digital equity is paramount so that all patients, regardless of technological proficiency, can access clinical trials (Godwin-Smith, 2022). Institutions should adopt secure, user-friendly platforms that prioritize patient autonomy (Clinical Trials Arena, 2023), offer hybrid consent options to accommodate varying patient needs (Kaye et al., 2022), and invest in ongoing staff training and patient support resources (McMullan et al., 2022). Continuous evaluation of patient feedback

is necessary to refine processes and improve inclusivity (IQVIA, 2022).

Looking ahead, I believe future e-consent efforts have the potential to significantly shape patient engagement and research policy. Offering multilingual and mobile-friendly consent options is key to increasing accessibility, especially for populations that have been historically underrepresented. I've found that involving patient advocates in the design and evaluation process is essential for building trust and ensuring equitable access. These strategies not only improve the patient experience but also help inform policy by showing how technology can enhance regulatory compliance while supporting patient-centered research. By integrating these approaches, I see a path toward developing policies grounded in best practices for inclusive, community-engaged cancer research, ultimately contributing to broader efforts to reduce disparities in clinical trial participation.

Conclusion

The e-consent pilot at the CTO demonstrated meaningful improvements in patient engagement, accessibility, and workflow efficiency, teaching me the importance of balancing security, usability, and inclusivity. Looking ahead, I see great potential in hybrid and mobile-friendly platforms, streamlined verification, and patient-centered design. Reflecting on my experience, I believe incorporating adaptive tools like tutorials or chatbots can better support patients who need extra guidance, while real-time analytics could help identify bottlenecks in the consent process. Partnering with community organizations is also essential to ensure cultural sensitivity and equitable access. Ultimately, emphasizing inclusive, community-driven approaches is key to building trust and empowering patients, and I hope these insights guide future efforts to develop consent processes that are accessible, secure, and truly patient-centered, advancing equity and improving experiences across diverse populations.

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