Shredding Paper

Paper consent forms can cause misunderstandings for patients in clinical trials. However, the integration of eConsent in healthcare practices can limit, or completely remove, translation issues due to their informative and patient-oriented aspects

Eric Delente
at DrugDev
Patient Solutions

The informed consent process represents the keystone in a clinical trial, the space where science meets the patient. As healthcare began to globalise in the 1990s and 2000s, process and presentation flexibility became crucial. With technology spreading around the globe, the defects and difficulties in the use of text-only documents, reported internationally for 30 years, became even more apparent. Patients worldwide decreed that text-only paper consent forms were confusing, hard to read and sometimes in different languages. Patients frequently breezed through paper forms without truly understanding the material and were surprised by aspects of the trial once it started. This led to frustration and subjects often dropped out of the consent process or the trial itself.

With the globalisation of clinical research, creating a flexible system that works across international boundaries, yet respects the differences of countries and regions, is imperative. Today's world has 196 countries across six continents, populated by over 7.3 billion people speaking roughly 6,500 different languages. Members of the healthcare community must create one solution that works for all and paper was not cutting it. eConsent has proven to have the flexibility to address global differences and provide solutions to the myriad of clinical trial permutations present on an international basis. This new system presents many opportunities, helping patients and clinical sites worldwide.

Proven Benefits

eConsent is a modern, intuitive and interactive delivery of consent-related materials that effectively informs. Features and best practices, including animated videos, interim understanding acknowledgements, question flagging, audio narration and more – things paper could never do – have consistently shown to increase patient satisfaction and comprehension, which ultimately leads to higher retention rates. Additionally, this increase enables sites to recruit 25% fewer subjects while still meeting completion goals, simply through utilising eConsent (1-3). The system uses a variety of tools to ensure patients understand their clinical trial:

- An introductory video explaining the study process and patient expectations
- Narration of on-screen text, as well as scalable font
- Pop-up displays that explain unfamiliar terms
- Swipes to acknowledge each section is understood
- Highlights to identify sections of the form that patients would like to review with the principal investigator or qualified site staff
- An optional quiz or assessment at the end of the process

While eConsent was created as a tool for patients, sites and sponsors also benefit. Regardless of hardware or software differences, worldwide deployment of the system is effortless as it can be integrated into any internet-capable device. Additionally, sponsors' lives are made simpler through the documentation of every action taken in the system, which allows eConsent to capture learning metrics for patients, produce easily-digestible audit documentation, enables early remote monitoring of the consent process and consistently outperforms paper in record keeping, version control and regulatory compliance.

Patient Empowerment

eConsent offers an opportunity to empower patients and increase the worldwide understanding of an individual trial. Sponsors who use the system first should seek to understand the types of populations they will be recruiting. They can use video, narration, graphics and interactivity to overcome challenges posed by language, demographics, physical ailments or attitude. For instance, certain regional populations may be more reticent when making healthcare decisions. Often, these patients will not communicate whether they have queries or understand complex issues, yet they still complete the enrolment process, only to drop out later. To combat this, sponsors can tailor the introductory video to explain questions, helping hesitant patients to feel at ease. Sponsors should also consider incorporating periodic pop-up text bubbles or develop assessments that emphasise the importance of voicing questions.

Many studies have specific participation criteria, such as refraining from strenuous exercise or avoiding certain foods before lab visits. In these instances, eConsent's narration and graphics should be used to explain why these conditions exist and illustrate how best to comply, no matter the language or demographics of a patient.

Overcoming Attitudes

eConsent is gaining ground on its antiquated paper cousin, but unfortunately paper has had decades to build up a staggering head start. A 2016 survey showed that only 28% of global sites have ever used eConsent and the number one reason they provided was that they had never been asked (4). Thus, many patients are still missing out on the benefits of this modern system. The best way to remedy this situation quickly is for sponsors to mandate its use in clinical trials around the globe.

Different parts of the world have divergent attitudes towards technology in healthcare. In Scandinavian countries, patients are generally more open towards sharing their healthcare data with professionals through secure apps, email and patient portals.

Image 1: eConsent country experience

Other countries still have fears about transmitting sensitive information over the internet, as they are often concerned about privacy and protecting people who may not be viewed as 'tech savvy' (people with disabilities and the elderly).

In these areas, demonstrating that eConsent is flexible is important. To ease privacy concerns, healthcare members should consider storing data in servers that are based inside the country. Furthermore, sponsors should explain the system's narration tools, video capabilities and user-friendly options such as scalable text size to combat patient issues with accessibility. Studies have shown that these features make eConsent particularly popular among elderly patients and those with visual impairments. If challenging attitudes persist, healthcare members should try looking elsewhere for inspiration. Some countries that practice traditional healthcare are often ahead of the curve in other industries. For instance, highlighting the recent deployment and success of eConsent in the financial sector might illustrate how it can be a trustworthy solution for healthcare in that country as well.

Language Differences

Dialects will always provide a unique challenge to sponsors and sites. In most cases, they can opt to use the official language (or languages) of the country for text and narration, but differences in dialect may cause key components of the trial to be misunderstood. Using a local translator to provide audio for the introductory video is important to eliminate confusion at the start of the process. In certain instances, patients may speak a language that does not have a written form. eConsent presents an opportunity to overcome this by using video and narration for the entire length of the consent stage.

Local Ethics Boards

Different local ethics boards across the world have mostly been receptive of eConsent due to its ability to help patients. When meeting with these authorities, stressing the benefits of improved understanding and comprehension while showing the flexibility of its tool is recommended. In certain instances, boards have requested that inclusion or exclusion criteria be presented through pop-up boxes or that introductory videos are as diverse as possible. In their experience, this was the best way to ensure patients' attention was maintained. Essentially, patient-centred functionality typically appeals to ethics committees that are primarily concerned with ensuring that subjects are fully informed and engaged in the consent process. Firms should capitalise on these eConsent features when presenting to ethics boards.

Learn from the Past

The best organisations employ tools that can learn, adapt and improve. As sponsors continue to conduct trials, they should take advantage of eConsent's ability to identify where people may still be experiencing issues. For instance, the system allows patients to mark which trial aspects and concepts they do not understand. Sponsors should use this data to analyse what patients are commonly misunderstanding, then modify the language, videos and graphics appropriately. eConsent continues to prove its advantages worldwide for all involved. With improvements in patient satisfaction, comprehension and retention, the system cannot be ignored. Thus, sponsors will continue to look towards eConsent as a solution to streamline documentation, standardisation and monitoring in clinical trials. While site adoption rates still leave much to be desired, eConsent's value will cement its place as the one answer for 7.3 billion patients worldwide. After all, a global industry requires a global solution.

References

1. Madathil *et al*, An investigation of the efficacy of electronic consenting interfaces of research permissions management system in a hospital setting, *International Journal of Medical Informatics* 82(9): pp854-63, 2013
2. Moekel and Brady, *Centerwatch Study:* 2003
3. Rowbotham MC *et al*, Interactive informed consent: Randomised comparison with paper contents, *PLoS ONE* 8(3): e58603, 2013
4. Visit: www.centerwatch.com/news-online/2017/02/27/electronic-informed-consent-star-bench-warmer
5. Visit: www.ciscrp.org

About the author

Eric Delente, President at DrugDev Patient Solutions, has more than 20 years of experience leading technical and creative teams in the design and implementation of numerous award-winning online science, healthcare and clinical research web applications. Most recently, he led SecureConsent, the industry's definitive eConsent solution.

Email: eric.delente@drugdev.com