DrugDev
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Why Isn't Your CRO Using eConsent?

Sponsors and CROs Worldwide Are Missing Out on eConsent Technology

In 2016, DrugDev's annual Investigator Survey uncovered the number one reason that sites hadn't used eConsent in their trial - they *hadn't been asked*. In fact, over 77% of sites in our survey self-reported that no sponsor or CRO had ever asked them to enroll patients with eConsent[4].

As the clinical technology ecosystem evolves to catch up with familiar consumer apps, missing out on the benefits of eConsent can have a significant detriment not only to patients, but to the sponsor's bottom line. eConsent helps patients understand the trial, set appropriate expectations, and create a more trusting relationship with the site from the beginning – leading to great satisfaction, and ultimately retention. In fact, research shows that studies using eConsent can enroll 25% fewer patients to achieve the same patient completion goal. Given how costly it is to recruit (and then lose) consented patients, this is an enormous opportunity cost that sponsors still using paper may be missing out on.

While DrugDev and industry experts believe that the number of sites using eConsent will continue to grow organically over the coming years (due to eConsent's focus on patient-centricity), it's important to note that there can be no change without first adoption. Thus, DrugDev is presenting five reasons why sponsors should ask themselves and their CROs "Why aren't we using eConsent?"

1 | Informed Patients Are Retained Patients

Studies show that patients who better understand the clinical trials process are more likely to complete it[3].

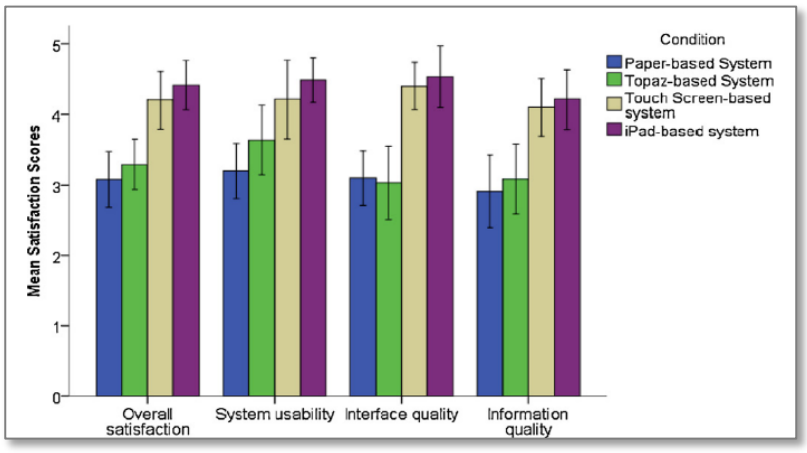
For sites and sponsors, this means that the informed consent process is their best chance at ensuring patients don't leave either part way through, or even pre-trial.

> Data suggests that 18 to 30% of patients in a trial will drop out, with 8% of disenrollment due to informed consent errors[5].

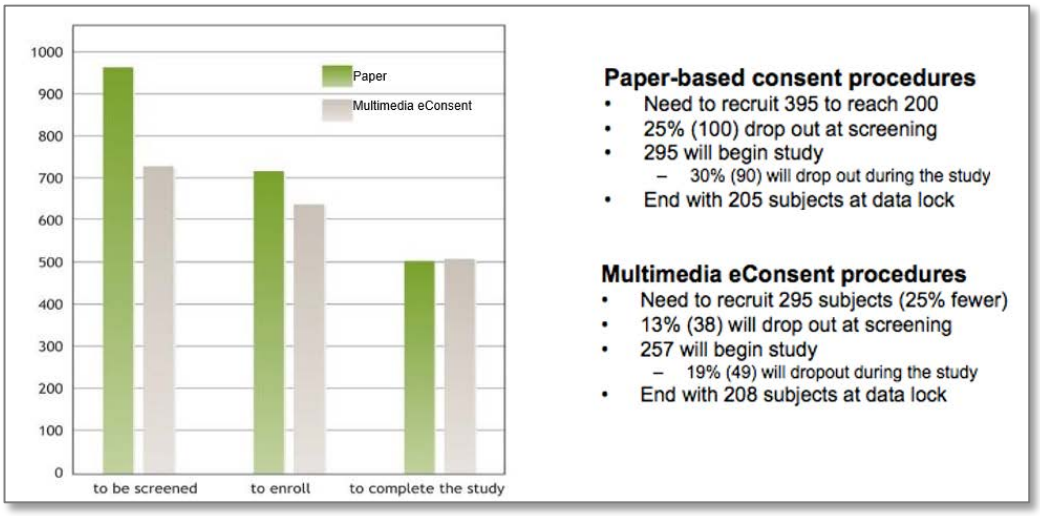
eConsent improves retention by offering sites and sponsors a simple tool that focuses on meeting the specific needs of each patient during the consent process. With eConsent, patients are first shown videos that explain the concept of informed consent and the basics of a clinical trial. They then move through each section of the electronic consent form at their own pace with added accessibilities capabilities such as large fonts and narration to help patients with specific needs (e.g. blindness, arthritis, etc.) participate in the trial.

Perhaps most importantly, rather than flipping through a large paper document and signing at the bottom, patients must acknowledge they understand each section before moving on - or mark sections they don't understand for follow-up discussions with qualified medical professionals at the site. Embedded in the process are pop-up glossary terms, additional videos, animations, and quizzes that are used to explain difficult concepts and help patients of all ages, cultures, languages and education levels retain trial information regardless of their personal exposure to technology.

The result is a system that is flexible, easy-to-understand, and ensures each patient finishes the consent process informed and with all questions answered. Not surprisingly, patients who complete the eConsent process have been proven to be more satisfied than those who used traditional paper consent forms [1]. This is important, because satisfaction has a direct impact on patient retention.



As mentioned above, a CenterWatch report measured the enrollment rates of two identical trials – one using eConsent and one using paper. The study found that simply using eConsent instead of paper meant sites would have to enroll 25% fewer patients to reach the same goal of patients completing the study – which would deliver significant time and cost benefits on a global trial scale[2].



2 | Addressing Patients Worldwide

With eConsent, sites and sponsors can localize any part of the consent process information to meet the needs of their patients, no matter how niche. For instance, users can switch the voice actors in their audio narrations as needed, allowing them to speak to patients using their local dialect and accent.

eConsent can also be used to tackle regional differences in healthcare culture. For example, certain regional populations may be more reticent when making healthcare decisions. Often, these patients will not communicate whether they have questions or understand complex issues. Therefore, they complete the enrollment process only to drop out later. eConsent offers solutions to this as sponsors can tailor introductory videos, spoken materials, or interactive quizzes to stress that patients should have questions for their investigators, putting their reticent concerns at ease.

Similarly, introductory eConsent videos can be used to explain how the system keeps patient information safe when transmitting it electronically, which is a common concern globally, especially in Europe. These features and more ensure eConsent can be used to educate patients worldwide in a way paper never could.

3 | Monitoring

eConsent offers sponsors and CROs conducting multiple studies the ability to track and monitor the progress of sites during enrollment. Sponsors/CROs can view how far along their sites are in the enrollment process, ensuring sites are meeting timelines. They can also ensure that patients are consenting to the correct documents and amendments in cases where multiple consent forms exist, or where additional addendums are required.

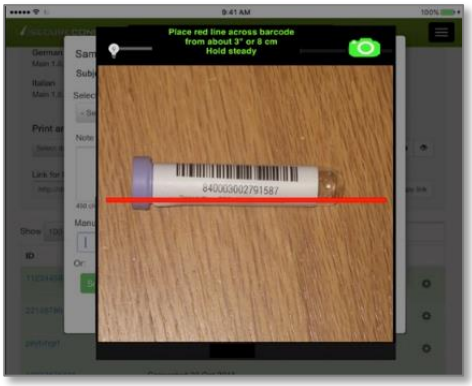
4 | Learn and Adapt

One of eConsent's great advantages is its ability to "learn" from the needs of its patients. The system does so by keeping track of almost every action taken in the system. Study teams can then use this information to analyze their eConsent program and make changes as necessary.

For instance, when patients take longer to read through a section, users should look to see where they can improve readability. If patients continually flag a section as "misunderstood," sponsors should see if the section can be re-written. Doing so allows sponsors to continually learn from their patients, improving the consent process with each refinement.

5 | Additional Benefits

Occasionally, sponsors, CROs and sites will conduct studies that extend beyond the typical consenting process. For instance, perhaps there are multiple consent forms that a local IRB has required. Or, perhaps sites must collect various biological samples, and their accompanying consent forms. For scenarios like this, eConsent offers a simple solution.



eConsent's document control options allow it simultaneously receive and manage multiple consent forms for trials that require them. The document control methods automatically file and index multiple consent forms per patient, making them easy to manage. In addition, eConsent has the flexibility to scan and document any necessary attachments such as biological samples, indexing them as well.

It's Time to Start

If your study team isn't using eConsent, it's time to see the benefits for yourself. Keep in mind that not all systems are created equally, so you must find the solution that works best for you, your CRO and your sites.

DrugDev has been pioneering eConsent since 2008 with market-leading experience on over 100 clinical trials worldwide. Request a demo of eConsent on the DrugDev Spark™ clinical operations suite at www.drugdev.com.

Sources:

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4. Elisa Cascade, Electronic informed consent: The star bench-warmer?, February 2017
5. The 2013 CISCRP Perceptions & Insights Study Report on Ineligible Participants & Those Who Terminate Participation Early - http://www.ciscrp.org