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The Research Site's Role in Supporting Patient Centricity with eConsent

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In "Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators and Sponsors" (2016), the FDA described eConsent as "the use of electronic systems and processes that may employ multiple electronic media…to convey information related to the study and to obtain and document informed consent."[1] In 2017, TransCelerate Biopharma published "eConsent: Implementation Guidance" for sponsors and CROs and "Introduction to eConsent for Sites" for research sites.[2,3] These are the three foundational documents of eConsent.

eConsent and Patient Centricity

A standardized paper informed consent form is inherently limited in its patient centricity, since, other than translations, every paper informed consent form is identical.

While some might say that a .pdf document that can be signed electronically constitutes eConsent, such an approach offers, at best, minimal benefit over paper, might actually *reduce* comprehension, and is certainly not patient centric. In contrast, eConsent, in its fully realized form, employs an intuitive, online experience involving a structured mixture of text, graphics, audio and video optimized for the patient according to modern learning theory.

eConsent can be highly patient centric. It can deliver the essential information and other information of interest to the patient in a manner tailored to that patient. Patients can navigate through the information as they wish. If a patient wants more information about a stent implantation, eConsent can deliver it, along with a video of a surgeon performing the procedure. If a patient wants more information about a ligament replacement, eConsent can deliver it, along with a photo of a torn ligament. If the patient wants more information about a drug's mechanism of action, eConsent can deliver it, along with an animation of the molecular interaction. If a patient prefers text, eConsent can deliver text. If a patient prefers a different language or a lower reading level, eConsent can deliver that. If a patient prefers audio, eConsent can deliver audio. If a patient prefers pictures, eConsent can deliver pictures.

Unlike with a paper document, eConsent does not allow patients to simply "turn the page" and skip over essential information — that information is not optional. Comprehension questions can even be built into eConsent, so patients can review information they missed the first time — another example of patient centricity.

For sites, the eConsent process is similar to the traditional, paper-based approach. With both approaches, the patient has plenty of time to go through the consent information. Patients can review the information online or on a portable device at home and with friends and relatives. If patients prefer a paper version entirely or to supplement the electronic version, the site can provide a paper version.

eConsent does not replace the consent discussion. Rather, it makes the discussion more patient-centric by allowing the patient to flag issues and questions that can then be addressed during the discussion.

As added benefits, by improving the patient experience, eConsent boosts patient recruitment, retention and adherence, thereby improving site performance. It ensures that

every patient sees the essential parts of the *current* consent information and that every participant is correctly reconsented when necessary. eConsent also reduces the site's paperwork management burden, allowing site personnel to spend more time with study participants. In addition, it automatically documents, in detail, the patient's interaction with the consent information, improving readiness for audits and inspections.

In a 2017 survey of mainly U.S. site personnel, 61% of the 105 respondents stated that eConsent would allow them to enroll more patients.[4] Several respondents indicated that many patients drop out of studies because they misunderstood what would be expected of them when they signed up. Respondents said that 5-25% of patients who currently decline to participate would agree to participate if there was a better way to access all the relevant information during the consent process.

Practical Considerations

eConsent requires the training of site personnel in the use of the eConsent system and, more importantly, in how to train patients in its use. However, a good eConsent system will require minimal training. The vendor should provide a user manual with FAQs and 24/7 helpdesk support to answer questions and address any issues that arise.

Depending on the technology, devices and WiFi access might be required.

eConsent systems should provide robust data privacy, with full compliance with privacy laws and regulations. Personal patient information should not be stored on portable devices that might be lost or stolen. Data storage and transmission of personal patient information should be secure.

Implementation

Assuming everything goes according to plan, implementation at the site should be very straightforward:

1. Site personnel receive training.
2. Site personnel verify the patient's identity, log into the eConsent system, and create an account for the patient.
3. Site personnel explain the eConsent system to the patient, and provide the patient with login credentials and any needed hardware.
4. The patient reviews the consent information at their own pace at the site or at home, flagging any questions or issues for later discussion with site personnel.
5. Site personnel confirm that the patient has completed their review of the consent information and then discuss it with the patient, addressing any flagged questions or issues.
6. Once the investigator is satisfied that the patient understands the consent information and study expectations, and is willing to give informed consent, both parties digitally sign to that effect.
7. Patient obtains a paper version of the consent information and/or continued electronic access.
8. If there is a significant update to the consent information, the process is repeated for the new information.
9. Upon completing the study, participants return any devices, as appropriate, and lose access to the eConsent system.
10. At study closeout, the site downloads archival documentation, including signed consent forms (or equivalent), audit trails, and notes, all suitable for regulatory inspection. The site returns any devices, as appropriate, to the sponsor and loses access to the eConsent system.

The Future of Consent is Electronic

eConsent offers numerous significant benefits to the site and the patient/participant. Perhaps the most important benefit is patient centricity and the benefits that flow from that: improved recruitment, retention and adherence, along with higher participant satisfaction and the resulting implications for future clinical studies.

References

1. "Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators and Sponsors," FDA, 2016, https://www.fda.gov/media/116850/download
2. "eConsent: Implementation Guidance," TransCelerate, http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/eConsent-Implementation-Guidance.pdf
3. "Introduction to eConsent for Sites," TransCelerate, https://transceleratebiopharmainc.com/Introduction-to-eConsent-for-Sites/
4. "Electronic Informed Consent: 2017 Industry Survey Results," Signant Health, https://insights.signanthealth.com/ebooks-whitepapers/state-of-econsent-2017-report-site-edition

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