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Consent Management: Moving Beyond Simple eConsent

Moving beyond eConsent alone to a more holistic consent management approach is a natural progression in the industry's push toward improving research through the delivery of better patient experiences.

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WHAT IS ECONSENT?

Even though it has been around for a number of years now, there are still some who mistake its function and potential. Many studies continue to view eConsent as:

- A digital version of paper consent
- Software that allows participants to sign consent remotely

For those with this mindset, eConsent is often treated as a box to check. The truth is, that eConsent can and should be viewed as part of an overall Consent Management strategy. In this vein, it is an important tool that can help transform the entire consent process from the initial design of the Informed Consent Forms (ICF) through to study close-out.

CONSENT MANAGEMENT

Moving beyond eConsent alone, or paper consent alone for that matter, to a more holistic consent management approach is a natural progression in the industry's push toward improving research through the delivery of better patient experiences.

Certainly, the ability for patients to consent remotely is a key principle of the industry's move toward patient-centered research designs meant to increase access to studies and improve trial experiences for broader more diverse groups of patients. But it is not just the patients that benefit.

Consent management is a key part of human-centered study design, helping to save time for all stakeholders – patients, caregivers, study coordinators, clinicians, translators, etc. This approach can result in better accuracy of all consent data over the course of the study, better regulatory compliance, and more transparency for all involved.

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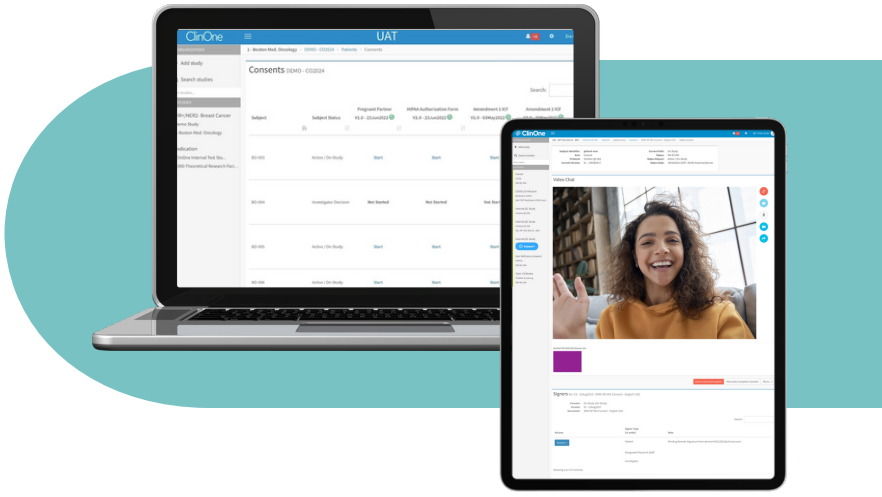
WHAT DO SITES WANT?

Site teams are often overwhelmed, so when it comes to adopting technology to help manage studies, they want something that helps to eliminate mistakes and allows them to spend more time focusing on patients.

Adopting a holistic consent management strategy provides site teams with:

- A consistent consent process across all trials
- A no-worries approach to version control & re-consent
- An easy way to remotely monitor the consent process

Some consent strategies, including paper, leave the door open for human error. These mistakes, like sharing the wrong version of the ICF, failure to re-consent, and missing signatures, cost study teams time and lead to frustration for both the coordination team and patients.



Using technologies that automate many of these processes increases efficiency and confidence in the data while decreasing stress levels for all involved.

For example, the eConsent process can be configured to recognize when the consent has been fully executed and generate a copy immediately to all parties. The fully executed consent, in this way, cannot be lost or accidentally destroyed by the patient. Patients and caregivers can also easily check the electronic form if they have questions, versus querying the study team for easily accessible information.

COMPONENTS OF A SUCCESSFUL CONSENT MANAGEMENT STRATEGY

AUTOMATIC ICF VERSION CONTROL
01

Changes to consent forms should be easily shared with all parties, ensuring that everyone is using the correct version

FLEXIBLE ON-SITE / REMOTE WORKFLOWS
02

With today's trials including both on-site and remote elements, consent management should accommodate all consent types

COMPREHENSIVE CONSENT LOGS
03

Study teams need the ability to easily check in on consent statuses to ensure compliance across all sites/patients

INTEGRATIONS THAT MATTER
04

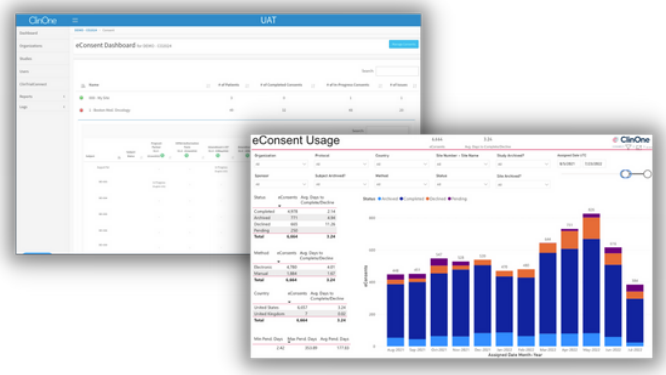
The eConsent system needs to work well with the EDC, clinical trial management system, and larger ecosystem as a whole

RAPID NO-CODE DEPLOYMENT
05

The system should allow users to configure the required features without coding to save time and increase quality

BEHAVIORAL INSIGHTS AND REPORTING
06

Insights like how much time is spent on the form helps study teams continuously refine the ICF & consent process



CONSENT MANAGMENT ROI

A comprehensive consent management strategy does what “digitized paper” could never do, providing measurable benefits for all research stakeholders.

- Allows for more rapid consent deployment, saving time during start-up
- Ensure everyone is working from the correct ICF, enhancing focus
- Automates time-consuming tasks while ensuring accuracy
- Reduces human errors that result in audit findings
- Enables further collaboration between study teams, patients, and caregivers
- Allows for remote monitoring of all studies
- Shares behavioral insights that help study teams improve the consent process

CONCLUSION

As researchers seek to make clinical trials more accessible to all patients and improve their experience, it is critical to seek out solutions that allow patients to participate in the ways they want.

Remote approaches help patients do more from home, but it should go further. Employing a robust consent management system allows patients to consent remotely, but also gives them more transparency into the consent process – ensuring they always have access to the most up-to-date consents.

Sites and other study leaders benefit as well, gaining better visibility into the consent process, more flexibility into how and where they can consent patients, and complete confidence in the audit trail.