Securing informed consent from clinical trial participants involves more than a signature – sponsors and investigators need to ensure participants truly understand what they are signing, and that the process is well documented in order to reconstruct and evaluate that the subjects’ rights have been upheld. A critical first step, informed consent has a major impact on regulatory compliance, enrolment and retention rates, and expenses across a study’s lifecycle. Like many processes in clinical research, informed consent has traditionally been collected via paper-based methods, but this can lead to inefficient consent development and management, poor consent documentation, data loss, lack of participant understanding, reduced site regulatory compliance, lower subject compliance and retention levels, as well as increased study costs for monitoring and issues management.

To combat these issues, electronic informed consent (eConsent) solutions have been introduced in recent years, representing a major advancement in improving information delivery to study participants in clinical research. eConsent utilises electronic systems and multimedia, such as audio and video features, to communicate study information to participants to securely obtain and document informed consent. eConsent offers researchers numerous benefits, including the capability to:

- Solicit and track study participant questions about participation and document that they have been answered
- Mitigate regulatory risk of data loss due to inadequate consent through systems that enforce certain activities be completed prior to achieving a “consented” status
- Improve study participants’ understanding by delivering information in a way which supports comprehension at the patient level through tiered information delivery
- Provide a more efficient way of developing and collecting informed consent; therefore saving time and money

In addition, the oversight of the consent process by investigators, sponsors and ethics committees can be very challenging when using a paper-based process. Deficiencies related to informed consent have not improved in many years; in fact, the European Medicines Agency’s (EMA) ‘Annual report of the Good Clinical Practice Inspectors Working Group’, released in June 2016, found that informed consent deficiencies are still in the top 10 for overall and #2 in Asia.2

Despite clear benefits, integrating eConsent within a clinical trial requires a shift in practice to accommodate the new system and its associated processes. This can be a major hurdle when it comes to adoption. Working Closely with Ethics Committees
In order to meet regulatory requirements and avoid slowing down the research and approval process, sponsors must gain acceptance by the applicable institutional review board/independent ethics committee (IRB/IEC) as early as possible. They need to ensure the ethics committees are satisfied that the informed consent meets the regulatory requirements for consent and supports their review process, and so for that reason, involving them as early as possible in the process is crucial.

An ethics committee should conduct an assessment on how integrating multimedia and electronic systems for various activities around the informed consent process impacts their current processes. This should consider what needs to be added or edited to make sure they have a clear message to investigators, health authorities and sponsors about their requirements related to their role in trials that wish to include electronic consent. For example, what they require for submissions, and any additional content required related to the use of technology. In December of 2016, the US Food and Drug Administration released its final guidance document for the use of electronic consent in clinical trials, which addresses the responsibilities of ethics committees.3 While this guidance is applicable to studies that are under the US Food and Drug Administration (FDA) jurisdiction, it may serve as a suitable reference document as ethics committees around the world consider how they will work with eConsent.

Sponsors and sites should find out how the ethics committee will review and approve the eConsent process, and provide them with precisely what they need to do this. For example, will they want to actually demo the eConsent on a device to get the patient experience, or will the ethics committee review the eConsent in a similar way to eCOA by examining screen shots? Getting this information early on is key to facilitating a quick and successful review process. As mentioned above, it is likely that some ethics committees have not finalised the ways they will or will not work with eConsent. This is an opportunity for the sponsors and vendors to work together with ethics committees to support and establish best practices for trials that are wanting to use eConsent.

Consider All Stakeholders from the Outset
As with the adoption of any new technology, the introduction of eConsent will have an impact on a multitude of stakeholders. As well as engaging with the relevant ethics committees, it is vital for sponsors to consider the needs of other stakeholders, too, and how they will be impacted. For example, in a large, multi-site study, there will be various research institution requirements when working with electronic systems such as acceptance and requirements for eSignatures or collection of protected health information (PHI) and level of security. As such, selecting an eConsent solution that has the flexibility to meet the requirements of various stakeholders is crucial. Additionally, eConsent vendors and sponsors must work with sites or ethics committees to evaluate adoption of alternative ways to meet these requirements.
Think About Integrating eConsent with Existing Technology

Sponsors opting to introduce eConsent face the task of replacing existing paper-based consent processes with a new electronic system and supporting processes. Coupled with this, it is likely that many sponsors would like to integrate eConsent with other current electronic platforms, such as trial management or eCOA solutions.

Additionally, many ethics committees use portals to review and post-review decisions, and therefore, would likely benefit from integration with eConsent trial management systems. Finally, research institutions with electronic health records (EHR) may also wish for the signed consents and associated data to be easily uploaded to the participant’s EHR. To ensure a smooth transition and improve clinical trial operations and oversight, sponsors, ethics committees and research sites should evaluate which systems offer the most benefits for integration.

To help sponsors and other stakeholders overcome the challenge of technology integration, the industry is seeing the emergence of solutions which have been designed to easily integrate with existing platforms. By integrating informed consent with existing solutions, for example, eCOA technology on a single platform and on the same device, study teams can gain all the benefits associated with eConsent, while removing the additional burden that would be inherent with the use of a separate system. This also provides considerable savings to researchers by removing the need to purchase an additional system, as well as the time and cost associated with integration procedures and training.

Decide upon Roles and Responsibilities

It is important to agree upon roles and responsibilities for each member of the study team, including the sponsor, research sites, IRBs and IECs that are responsible for the development and implementation of eConsent from the very beginning to ensure integration runs as smoothly as possible. A collaborative system design approach can really support this.

Keeping the end result front-of-mind when considering integration is also useful. For example, as previously mentioned, study teams should consider how the IRB/IEC will review and approve the consent process per site/region. They should also think about how the consent process will be monitored and, crucially, how it will be audited by the regulatory authority, and how the data will be documented so that they are defensible to regulators. By creating the process with the end goal in mind, and working in collaboration with partners to agree to responsibilities within a study team and between sponsors and other stakeholders, a smooth integration of eConsent can be ensured.

In addition, during the development process for a paper-based consent solution, there is typically a lot of back and forth between the many stakeholders to reach agreement of content for each site before IRB/IEC review. This process can be very risky and uncontrolled but by using an eConsent approach, sponsors can take advantage of the electronic system for version control to better manage the back and forth communication between stakeholders. There are differences between what each eConsent vendor offers, so choosing a vendor that better supports the consent development is ideal. Most vendors add complexity to the consent development process, because the approach is too founded in distance and asynchronous training development. An eConsent is not meant to be an eLearning session with added components. Rather it facilitates improved informed consent processes using multimedia and trial management technology.
Ensure Buy-in from Research Sites

An important part of the successful introduction of any new process or technology is achieving buy-in from site teams. However, they are typically very busy and can often feel over-stretched and detached from decision-making, so this can be difficult.

Sponsors need to work on sites’ confidence with eConsent and ensure they understand the benefits or they might feel additional burden because of its introduction and required use. If not, sites are more likely to revert back to previous paper processes and be more resistant to change. Therefore, sponsors should engage sites as early as possible in the process. They should take the time to make sure they understand the technology, the reasons for implementation and how the sponsor is going to be using various components (i.e., monitoring). Sponsors should also ensure sites understand how eConsent can improve the consent process and decrease issues by offering comprehensive training and support before and during implementation. eConsent can support more timely monitoring and feedback about why participants are choosing not to consent and the areas they are having most difficulty understanding, ultimately improving subject recruitment and retention.

In an attempt to better understand some of the barriers to adoption, and encourage uptake of eConsent, CRF Health has carried out demonstrations of its solution with a number of different research sites. The investigative sites we met with expressed concerns at the increasing burden to them by adding an additional log-in and system to manage. Ensuring that the eConsent solution has been designed with the user in mind and integrates with other systems as much as possible is essential. Additionally, ease-of-use and technical support are also key to gaining acceptance of a technology system that replaces the method that some subjects are familiar with (paper), even when it is not working. Look at the slow acceptance of electronic case report forms (eCRFs) in the past, and now they have become the preferred path. You have to prove there is some “what is in it for me (WIIFM)”.

Pilot Your Solution

The introduction of eConsent will represent a major process change for researchers, and has the potential to have a significant positive impact on study outcomes, so it is only logical to pilot the technology before implementing it across a large multi-centre study or all studies.

Ideally, test the solution within a small study with a healthy subject population and relatively simple study design. In addition, choose a study that is geographically more condensed, e.g., early phase research. The idea of piloting is to test the effectiveness of the set-up process and training, check the functionality of various features, and identify any process gaps before introducing the solution into larger and more complex studies. This allows sponsors to involve other stakeholders in the set-up and approval, and provides the opportunity to incorporate valuable feedback into the design process. For all stakeholders, eConsent should continue to get better and better with each trial.

Moving Forward

During a time when technology is becoming ever more present in clinical research practice, it is no wonder that some in the industry are cautious of introducing yet another new solution. From the cost of adoption to integration challenges, there are still a number of perceived barriers stopping researchers from embracing technology with the same enthusiasm as those in other industries.

It is important for anyone still in doubt to consider with an open mind the clear benefits for making eConsent common practice within clinical trials. It has the potential to drive significant operational efficiencies, minimise regulatory risk, ensure participant comprehension and deliver long-term cost savings, which point to the kind of transformative budgetary impact that could be achieved by implementing this solution across multiple trials. In fact, far from adding extra costs to already tight budgets, it is estimated that the costs dedicated to implementing eConsent will be much more economical compared to the amount of money that companies spend rectifying issues arising from paper-based forms further down the line.

REFERENCES


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With just over two decades in software product management in the global environment, Mika’s breadth of experience spans from product and portfolio management, strategy and business development, and heading a product line at Nokia, to revenue and business relationship development at Digia. Mika is a specialist in developing and managing relationships both internal and external to his organisation, as evidenced by his varied roles in team motivation, change management, and customer relationship development.

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She has over 30 years of clinical experience, has a Bachelor of Science degree in Nursing and a Master of Science degree in Education with a Specialization in Training and Performance Improvement. SAM has been dual certified by the Association for Clinical Research Professionals (ACRP) for over 10 years as a CCRA and CCRC. She is a current member of the ACRP Academy Board of Trustees, and ACRP Regulatory Affairs Committee (RAC). SAM has been a clinical research coordinator, site manager, sponsor and CRO monitor, auditor, trainer and quality manager.

She has had multiple training, monitoring and project management experiences of diverse size and objectives, with a variety of global clients. She is a frequent speaker at industry conferences and has authored dozens of courses for clinical research training programmes. In 2002 she co-founded Clinical Pathways (CP), LLC.