# eConsent: Tearing Down Barriers to Oncology Trials

With huge leaps in the understanding of cancer resulting in an ever-expanding set of treatment targets, it's an exciting, yet fiercely competitive, time to be working in oncology.

Despite more people surviving the disease than ever before, a staggering 9.6 million people worldwide died from cancer in 2018[1], making the need for new drugs a global priority.

With the search for new treatments stepping up, patient technology and systems that can improve recruitment and retention while contributing to the collection of cleaner, more compliant data are in demand.

eConsent, when implemented well, has the potential to help companies rise to the challenge by removing some of the common barriers to clinical development.

## What is eConsent?

Traditionally, the patient consent process has been done in-clinic, on paper. Electronic informed consent, or eConsent, allows the processes to be carried out via an intuitive, interactive, collaborative online platform – both in-clinic and at home.

It uses a multimedia approach, incorporating pictures, videos and graphics, to convey study information to the patient in an accessible way. It then obtains and documents informed consent to participate in the trial.

## Why eConsent?

Failure in the clinical trial consent process can negatively impact regulatory compliance and data integrity, enrolment and retention, participant protection and costs.

We all know that informed consent is about more than securing a signature. It's about ensuring that patients fully understand what they are signing up for. And when they do, it's a win/win for trial sites and study participants alike.

**Benefits for Patients**

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| Greater convenience | The consenting process can be started, and in some cases completed, from the comfort of the patient's own home. |
| Greater consideration | The patient is in control of the process and can stop and start as they see fit. This puts them under less pressure to sign straight away. It also means they can speak to friends and family, resulting in a more considered decision. |
| More informed | eConsent allows for information to be presented in a variety of ways, including graphics, videos and infographics. It can also include links to further information and can incorporate approaches to test understanding. |
| Greater engagement | eConsent allows for two-way interaction i.e. participants can ask questions and sites can provide the answers. This ensures the patient-site interaction can cover all the areas patients have highlighted so they feel comfortable and confident before making the decision to participate. |

**Benefits for Sponsors/CROs/Investigators/IRBs**

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| Increased enrolment | Greater convenience and understanding of the study's requirements can increase enrolment rates. The consent document is the first main touchpoint for the study and providing this in an engaging format can aid enrolment. |
| Increased comprehension | By verifying that participants comprehend consent information, eConsent supports better information review with structured content, interactive assessments, rich media and support for interactive communication with study staff. |
| Increased retention | Increased comprehension reduces the risk of patient non-compliance to the protocol or early withdrawal from the study. In fact, industry research suggests that simply by using eConsent, clinical trials may enrol 25% fewer patients to achieve the same completion goals as those using paper consent.[2] |
| Decreased regulatory compliance risk | Documenting the consent process electronically helps ensure compliance through tools such as automated version control, date and time stamping, and an activity audit trail. |
| Streamlined development | eConsent can accelerate study timelines through the use of template libraries, reducing the time and cost of consent design and implementation for a faster study start-up process. |
| Enhanced collaboration | eConsent makes it easy for sponsors, sites, and IRBs/IECs to work together efficiently through online collaborative tools that facilitate form creation and deployment. |
| Increased geographical reach | Being able to consent patients remotely means sites can reach a wider participant base with ease. |
| Centralised remote monitoring | eConsent offers real-time monitoring dashboards that can result in cost savings on site and study monitoring – with instant insight into ongoing enrolment metrics. |

## Why e-Consent in Oncology?

One-fifth of oncology clinical trials fall at the first hurdle because they do not recruit enough patients[3]. In fact, just three per cent of people with cancer take part in research[4]. Of those who do, many drop out before their data can be utilised.

Oncology trials in the 21st century are complex, with complicated protocols and dosing regimens. Fortunately, eConsent can help.

**Patient Understanding**
Patients may simply decline to take part when faced with what they perceive to be an overwhelming level of information. Alternatively, they may sign up without understanding specifically what is expected of them, and this can impact drop-out rates if they find the protocol surprising and not to their liking.

With eConsent, information is presented in an accessible way and digested at the participant's own pace. Because they have the time and support to internalise the aim of the study and its requirements, they are prepared and ready for what is to come – leading to realistic expectations, higher satisfaction and lower drop-out rates.

**Consent Reliability**
As any cancer researcher knows, oncology trials are typically admin-heavy. There are multiple arms and consent doesn't stop at the front door — additional permissions are needed for investigations such as biopsies, tissue samples and more. Oncology studies tend to include multiple consent documents on these additional patient consenting requirements.

In paper consent processes, this leads to a complex process of managing their creation (including country and site variants, and associated languages) and implementation at sites. We know that sites sometimes use sticky notes to help manage the multiple forms and define the right set of forms per patient – even today, in 2019.

By removing inefficiencies and the opportunity for human error, eConsent systems make this process easy and trustworthy while enabling full transparency and visibility of any additional consenting requirements.

**Amendments and Re-consent Management**
Oncology studies also tend to have frequent protocol amendments and updates. Because eConsent automatically provides the appropriate version of every document the moment it is updated, it ensures patients sign the current and correct consent form at all times. This unprecedented level of control which paper can never offer eliminates mistakes in the collection of patient consent, which otherwise result in regulatory compliance issues or data being rendered useless.

This is why the paper-based informed consent process is one of the most cited causes of regulatory deficiencies. It results in data integrity issues, spoiled reputation, delays, litigation and even trial failure. With eConsent, teams running oncology studies always have a clear process path and audit trail to ensure they can make the most of all patient data captured.

**How to Implement e-Consent**
Continually increasing sponsor, CRO and site adoption suggests the value and benefits of eConsent are well understood. Most of the world's largest pharma companies now have an eConsent strategy in place, ranging in scope from small pilot studies to enterprise-wide global platforms at the world's largest pharmaceutical companies.

One of the most overlooked advantages of eConsent is its ability to transform internal consent creation processes. Contrary to what some believe, eConsent is not about digitising paper consent forms. To the contrary, it unlocks potential for quality and efficiency and therefore deserves and requires careful planning to have maximum impact, not just on patients but on study teams and bottom-line ROI. To this end, there are several key considerations for stakeholders preparing to implement eConsent technologies:

**Data Security**
Data security is of the utmost importance, not least because it is a regulatory requirement. When choosing a system, it needs to protect patients' private health information and comply with all national and regional privacy laws.

**Business Processes**
eConsent needs to be part of, not overlay, current business processes. Before embarking on eConsent, stakeholders should map out how it will impact on all other business processes. For example, sites should think about how they currently schedule patients and perform the consent process, and how eConsent may impact on factors such as workflows or how teams work with ethics committees.

**Documentation**
Different systems offer widely variable functionality. Some will document patient questions or allow sites to store document notes. Others will not. Sponsors and vendors must assist sites in an outline of what will be automated by the eConsent system, and which steps staff will need to document manually. It will change depending on the study protocol, so both general and trial-by-trial advice is advised. This will avoid confusion and ensure compliance.

**Training**
To avoid delays in use or unexpected issues, sponsor and site teams should start preparing for system training early on. It's important to consider how training will be completed and documented, as well as how new users will be supported. Note that in some cases, the sponsor or eConsent vendor will offer to train site personnel.

**Inspection Readiness**
eConsent can mitigate the risk of regulatory deficiencies by providing a clear audit trail of digital timestamps, version control, real-time remote monitoring, and ongoing consent tracking. Consideration should be given to how direct access to this information can be provided if regulatory authorities request it during an inspection.

**Summary**
eConsent can help overcome many of the known barriers to effective clinical trials.

The poor recruitment and retention of study participants, especially in oncology trials, has long been an issue facing researchers, resulting in longer study durations and delayed completion, not to mention higher costs.

More than 40% of studies do not meet enrolment goals, and even when recruitment succeeds, 85% of trials fail to retain enough patients.[5] This leaves sponsors and sites struggling to conduct trials effectively.

eConsent represents a major advancement in clinical research programmes. It improves the presentation and flow of information, allowing for better patient support, comprehension, and experience.

When participants are fully informed and updated easily, study teams can yield better quality data while ensuring they meet regulatory requirements.

Recent medical advances have placed the medical community closer than ever to achieving the goal of beating cancer, but there is still work to be done. Tearing down the barriers to drug development, including those presented by the informed consent procedure, has never been so important.

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## Bill Byrom

Bill Byrom, PhD. VP, Product Strategy and Innovation, Signant Health. Bill has worked in the Pharmaceutical Industry for over 25 years, in clinical development and as an eClinical thought-leader and strategist. He has helped to develop and launch a range of innovative technology solutions and services across the industry, and has a rich, first-hand knowledge of clinical trial operation. Academically, Bill also has a strong track-record of contribution to the scientific advancement of the electronic clinical outcome assessments (eCOA) and the wearable technology disciplines.

## Neetu Pundir

Neetu Pundir, Go To Market Director, Signant Health. Neetu Pundir is an experienced product and brand manager with prior professional experiences across the globe in the healthcare and life sciences industry, working for companies such as Johnson & Johnson, BIOTRONIK Medical Devices, Henry Schein, and eResearch Technology. As the Go To Market Director at Signant Health, Neetu manages the product strategy for the company's electronic consent solution TrialConsent®. Neetu has a Master's in Business Administration with degrees from Northwestern University, USA and the University of New South Wales, Australia.