Going Global with eConsent

The Novartis Journey

Scott Askin, Global Director in Digital Development at Novartis, paints the picture of why Novartis, determined to improve the patient experience, has begun to deploy eConsent… and what they've learned along the way.

The Journey Towards Change

It was early in 2014 when some in Novartis first thought they may need to make a big change. They were considering replacing one of their most basic trial processes, one they had used for over 20 years, with something entirely new.

The reason was simple. Like many other pharmaceutical companies, Novartis had become increasingly frustrated with the paper consent form process and the undue burden it placed on patients. Rather than intimidating and confusing potential trial participants, Novartis sought a patient friendly and intuitive way to help patients understand the material so they could make an informed enrollment decision.

They soon found their answer in eConsent. eConsent provided Novartis a way to easily introduce trials and consent by offering patients a familiar device, an intuitive interface and a patient friendly presentation. Patients reported that this helped them understand the material, guide them through the process, and make an informed decision., Novartis believed they had what they needed for change. The question was, what was the best way to make it happen?

A Better Patient Experience

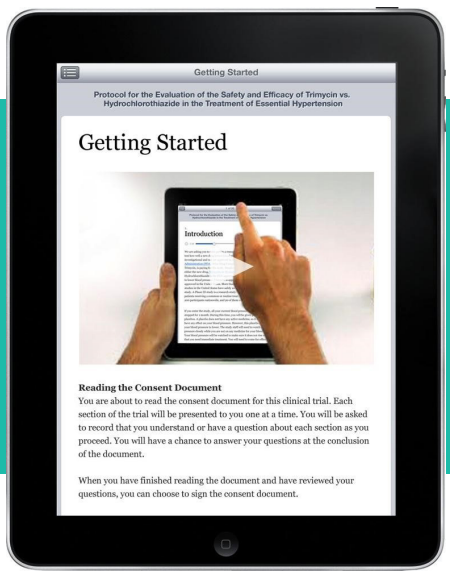
In its most elemental form, electronic informed patient consent forms, or eConsent, is the digital implementation of a traditional consent form. In practice however, it is a transformative experience for patients which has been shown to improve patient understanding, satisfaction and ultimately retention by making consent a more enjoyable and straightforward process.

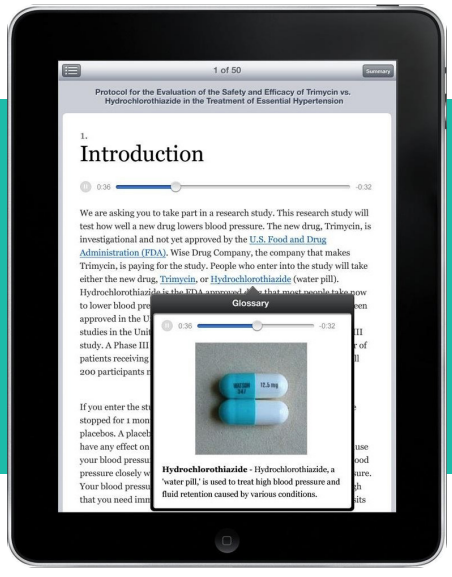
Instead of voluminous paper forms with no contextual assistance, patients use familiar devices such as tablets, or computers to learn about the trial and provide their consent to participate. “It simplifies the consent process for patients,” states Scott Askin, Global Director in Digital Development at Novartis in Switzerland. “As they read and swipe through the electronic consent documents they encounter pictures and diagrams, pop-up glossaries and educational animated videos that are tailored to explain complex terms in plain language, while the consent form itself is segmented into easily digestible sections,” he adds.

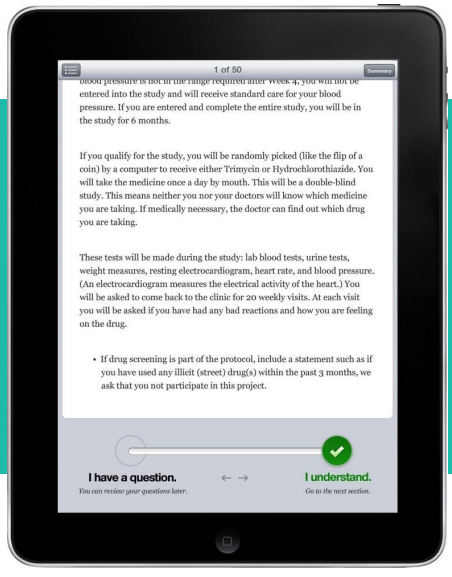
Even better, patients are required to acknowledge their understanding of each individual section, or tag areas of concern for discussion with qualified medical staff at the site, ensuring their questions are fully answered before consenting.

All this adds up to create a solution that’s been proven effective in increasing patient satisfaction, preservation of information, and ultimately patient retention as shown in research published in CenterWatch, the Journal of Medical Informatics, and PLOS Medicine over the past decade.

Naturally, Novartis became very interested in eConsent. Knowing they had to try the technology themselves before trusting it, Novartis began to pilot eConsent on the DrugDev Spark clinical operations suite across a small set of trials in early 2014. Within a few months they realized what they had. And, after three years of strategizing, piloting and executing, Novartis would decide to begin using eConsent through the DrugDev Spark™ Suite of Solutions in selected future trials in Summer of 2017.







Making the Business Case

Novartis recognized the benefits of providing their patients with a modern interactive experience on a platform familiar to most people. In fact, they knew that many different segments of people had become more and more reliant on smartphones and tablets and understood that eConsent takes advantage of this level of familiarity by presenting trial information through video, pictures and diagrams, while offering accessibility features such as zooming, and audio narration to help specific patient groups (e.g. visually impaired, elderly) complete the process themselves.

"When you see the tool, its value is instant and obvious," added Askin. "The multimedia interactivity goes way beyond what we give to patients today" While this all adds for patients, it also presents benefits for both sites and sponsors.

One of these chief benefits is transparency. eConsent provides the ability to track the progress of patient consent at every site in real time, anywhere in the world, with just a few clicks. This helps not only with building the audit trail, but with improving the consent experience.

"As the patient works through the form, the information is tracked, so that we can see where they slowed down or had trouble and make improvements wherever needed," Askin explained. It also helps sites get quick insights into what consent work still needs to be done. "Investigators can see much easier, who still needs to be consented. It's much easier to look at a dashboard or a report than it is looking through a stack of papers."

While the benefits of eConsent to patients may be seen as a "no-brainer," Askin and his team had to ork closely with key stakeholders to change the status quo. Even though there are significant time and cost savings to be realized from improved patient retention, the most impactful benefit for securing buy-in on a wide basis was the qualitative improvement of the patient experience.

> "When you see the tool, its value is instant and obvious"
>
> *– Scott Askin*

Askin promoted those qualities to key senior Novartis staff and stakeholders who supported the transition to eConsent. He adds, "Every sponsor talks about becoming more patient-centric, and I think they were able to see that we had found a great way to actually do it in one of the most important parts of the trial process."

In the summer of 2017 Novartis decided to implement eConsent in order to improve the patient experience. After learning lessons during their pilot program, Novartis is now implementing the technology together with sites, and while most companies are still talking about becoming patient-centric, Novartis has gone ahead and done it.

This article is a summary of the information presented in an October 10, 2017 webinar titled "Going Global with eConsent: The Novartis Journey." You can view the full webinar here.

eConsent at Novartis:

Four Lessons Learned for Successful Implementations

As with any transformative process, change management was also an important consideration. During its first 10 trials across 38 different countries over a three-year period, Novartis learned a few lessons while implementing eConsent:

1

There is no "right" pilot trial

All trials, short or long, big or small, come with their own challenges, so there is no perfect trial for piloting eConsent. Instead, they learned that they needed a mix of each type of trial to truly understand the benefits, drawbacks, and challenges of eConsent for their organization. The key takeaway is that it would be a mistake to wait for that perfect trial, and instead to get started with several different types of trials.

2

Change management is essential – so start early

Because eConsent is digital, it comes with the reluctance to change that is commonly associated with new technology (especially at sites). Novartis commonly encountered stakeholders who were reticent towards adopting the technology because they were familiar with the existing process, reluctant of technology, or had concerns over possible limitations. Novartis mitigated this reluctance by internally involving and educating as many people as possible early in the process - specifically addressing technical, process, and user concerns with demonstrations of the technology, established research, and anecdotes from experienced patients and sites.

3

Make it clear that patients can take information home

One of the common misconceptions Novartis encountered was that eConsent was only to be used "in office." Fortunately, this is not accurate as patients can take physical materials home in addition to viewing consent information from the comfort of their own devices. Novartis ensured that both sites and internal stakeholders were aware of this, as it was key in eConsent's acceptance.

4

Listen to site feedback

Sites are honest, making them the best resource for getting feedback about the consent process. Novartis spoke regularly with sites to refine the process, making changes that went a long way in improving the experience for sites and patients. It also ensured sites were invested in the technology by giving them a voice and making them stronger users from the beginning.