

The Signal

Hybrid Trials: Supporting Remote Consent

Informed consent is one of the most complex processes within clinical operations. Explaining the highly technical and specialized material so that all participants fully understand the study is no easy feat. Thankfully, today's digital solutions can improve the process and even prevent regulatory findings.

The adoption of electronic consent (eConsent) will only continue to grow with the proliferation of hybrid and decentralized clinical trials (DCTs). But what do sponsors and study teams need to know before implementing this technology in a remote setting?

We've outlined the potential challenges and best practices for utilizing eConsent within these modern study models.

What is the benefit of remote consent for clinical trial participants?

An electronic consent solution, thoughtfully designed for remote use, empowers participants to make an informed decision by allowing them to learn at their own pace and consider the study without the pressure of a clinician present. An eConsent solution breaks down the dense information into smaller, more digestible sections, and much like web flow interfaces common online, the technology enables participants to start and stop when needed.

Some consent solutions, such as [Signant's SmartSignals eConsent](#), facilitate text flagging to clarify sections prior to enrollment. Remote consent also allows participants who may be experiencing debilitating symptoms or mobility issues to consent from the comforts of their own home.

In some situations, remote consent has the power to save a life. For certain indications, participating emergency rooms can offer investigative treatment to incoming and eligible participants or their legally authorized representative (LAR).

How does remote consent benefit clinical sites and study teams?

Clinical trials that employ remote consent can access and enroll a larger population who may otherwise be overlooked due to where they live. By allowing participants to flag specific sections, sites can intervene and enhance comprehension through customized, one-on-one discussions. This feature also helps them improve consent forms for future use.

At-home consent reduces burdens for site staff since they no longer need to worry about collecting, managing, or storing each consent form – the technology does it for them. In fact, eConsent ensures correct versions of the consent forms used by suppressing old, unapproved, or wrong versions of the documents.

Unlike the traditional, paper-based forms, a digital consent tool gives study teams real-time visibility via intuitive dashboards and progress reports for optimal, ongoing monitoring. Paper consent forms, on the other hand, could take weeks to arrive by mail.

What are the regulatory benefits of remote consent?

Electronic consent capture supports faster regulatory submission and often, faster approval. The tool keeps the various forms for each participant organized and easily accessible. Time and date stamps establish a transparency that paper forms simply can't.

Unlike paper forms, electronic consent requires less time and effort to address special configurations to meet local requirements – think font size, target reading level, and the signature type. Digitally, these configurations can be saved settings for effortless use in the future.

The technology shows real-time edits made on documents by sponsors and regulatory authorities. Document version history and older versions are available for inspection at later times. Finally, eConsent ensures that all the required signatures are captured and in the right order.

What are the expected challenges for remote consent?

As with the adoption of any new technology, eConsent challenges all stakeholders – even the regulatory agencies reviewing the documents – to learn something new. This makes it even more important to find an eConsent provider who offers an intuitive design, possesses extensive experience in global logistics, and stays abreast on regulatory needs.

Sponsors who remain apprehensive to implement eConsent solutions, often cite privacy concerns. However, a digital consent tool uses encrypted, secure platforms to safeguard confidential information. Paper consent forms, on the other hand, could be intercepted and compromised when in transit.

Finally, there is a misconception that older participants prefer paper over digital technologies. According to our [study on the use of mobile technologies among older patients](#), this couldn't be further from the truth.

Do sponsors need to do anything differently for remote consent forms?

Sponsors should be aware that the review process is a bit different for remote consent, including:

- Account access information is sent via email.
- Sites are notified when participants are ready for discussion and will need to use technology to virtually discuss consent.
- A participant's ID needs to be verified remotely.
- An eConsent solution handles a synchronized flow between investigator and study participant to go through the form. This is split into two separate streams: one for the participant and one for the investigator.

Best practices for supporting eConsent remotely

The most important consideration for supporting remote studies regardless of what tools you employ is engagement. Sponsors should put significant effort into site-participant interactions, including training users on system navigation. A bring-your-own-device (BYOD) model, in which participants use their own personal smartphone or tablet, can accelerate this since they will be familiar with the hardware.

With remote participants, it's important to keep them invested in the study and on track to complete questionnaires or diary entries. An engagement solution, like [Signant's Patient Concierge](#), can be integrated to do just that via gentle reminders.

For additional considerations, review the [Electronic Informed Consent Implementation Guide](#).

How does Signant Health's eConsent support hybrid and decentralized clinical trials?

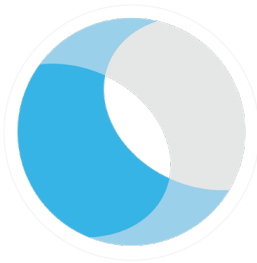
As the evidence generation company, Signant ensures sponsors and study teams capture the required consent. We have experience guiding sponsors and study teams on how to implement a study-appropriate eConsent solution for any model, including hybrid and DCTs.

Our SmartSignals eConsent:

- Supplies participant accounts with unique usernames and passwords for effortless, remote log in
- Uses a portal that allows documents to be reviewed at any time
- Offers remote consent options with an off-site Q&A process and electronic signature

- Provides ongoing monitoring on participant status – from the date they consented to pending reconsents
- Comes with experienced support who has implemented the solution in over 40 countries and in various languages

If you're interested in launching a hybrid study and don't know where to start, [contact our team](#). We're happy to review your protocol and make recommendations.



Signant Health

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently generate quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all of Top 20 pharma – have trusted Signant Health solutions for remote and site-based eCOA, eConsent, IRT, supply chain management, and data quality analytics.