



5thPort for Clinical Trials – Video Transcript

Time: 4:34

<Silent Text on Screen> Helping Your Clinical Trials Succeed

Research shows that patients being recruited to participate in clinical trials are generally under-informed about clinical research and the specific details of the trial that they are being recruited for. Is it any surprise then that clinical trials experience an average patient dropout rate of 30%, with approximately 40% of patients becoming non-compliant with study protocols after just 150 days in a clinical trial?

This lack of understanding results in failure to recruit, convert and retain qualified participants contributing to trial failure.

So, what if you could improve Patient Conversion, protocol adherence and Retention while considerably simplifying your audit compliance?

5thPort's Patient Engagement and eConsent platform reduces cost, reduces trial delays and contributes to your trials' success.

When it comes to patients enrolled in a clinical trial, FDA guidelines are pretty clear. Patients should never say:

- I wasn't told,
- I didn't understand and
- I didn't have the opportunity to ask questions.

With 5thPort, providers can Inform patients using high quality videos and documents, Confirm their understanding through simple comprehension tests with teach-back and acknowledgements, then Engage in a meaningful consent process where patients can flag consent sections for enhanced follow up and capture patient experience or post-protocol compliance through follow-up surveys. These components can be combined in any sequence to create customized engagement plans for patients in their preferred language.

And, 5thPort can deliver the customized engagement plans over any device – mobile, tablet, laptop or desktop – securely storing the information in a HIPAA compliant cloud environment. Patients have the option to engage remotely by completing the process in the comfort of their own homes, in the providers office or a combination of both. Not only is it a more convenient approach for the patient, but also enables full remote interaction facilitating decentralized studies, limiting the potential exposure from face-to-face contact.

Every aspect of the patients' activity and progress through the engagement is digitally documented in great detail, providing your study an exceptional level of audit compliance.

5thPort is multi-lingual, allowing patients and caregivers to engage in their preferred language.

5thPort puts the “Informed” in Informed Consent.

With 5thPort, trial administrators can easily invite sites to participate in a trial. When sites accept the invitation to participate, they are then enrolled for the trial. Engagement plans and consents are easy to setup and once approved are automatically loaded to each participating site - locked, and ready to engage patients. Enrollment at each site is tracked in real-time and accessible through the management console providing complete transparency for trial administrators.

5thPort handles consent amendments seamlessly. Trial administrators update the engagement plan with the revised consent form, triggering notification of the change to enrolled sites. The amended engagement plans are automatically sent to patients who are still participating in the trial for re-consenting. New patients automatically get the amended engagement plan, ensuring that patients are always signing the most recent consent version. 5thPort eliminates the administrative burden and cost associated with the consent process while ensuring and improving compliance.

And, the 5thPort platform can be branded or white-labeled to enhance the value of your organization.

But, 5thPort’s value extends beyond consenting. Engagement throughout the course of the study can lead to better adherence and higher patient retention.

The 5thPort platform complies with 21 CFR Part 11 and other applicable US and international regulations and guidelines.

5thPort recognizes that “informed consent” is so much more than just getting a signature on a clipboard... it’s about engaging and educating the patient in order to improve clinical outcomes and trial success. That positive experience is all that matters to patients, their healthcare provider and ultimately you, as a study sponsor or contract research organization.

Patient engagement and Informed Consent made digital by 5thPort. Learn more about how to integrate the 5thPort platform into your next clinical research study.

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