THE SIGNAL
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Simplifying the Site eClinical Experience: Converged Workflow with Our Unified Platform

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In the complex landscape of clinical trials, sites need tools to facilitate smooth and simple workflows across the entire patient data journey. Here's a glimpse into how our Signant SmartSignals® Unified Platform transforms this journey, enhancing the experience for both patients and site staff, through a single site login.

In-clinic or Remote Consenting

Upon registration by the investigational site, participants receive access details to the patient portal via system-generated email or via a QR code or link provided directly by the investigator, allowing them to access and review necessary study information and sign the informed consent directly within our MyTrials patient portal.

While in-person consent remains the norm, some patients may have difficulty visiting the research site or prefer alternative ways of being informed. Our eConsent module offers flexibility, allowing for both in-clinic and remote consenting. When opting for remote consenting, patients can familiarize themselves with study details at their convenience or speak to the investigator via the integrated TeleVisit module.

After electronically signing the informed consent, patients automatically receive a copy via a system-generated email. They can also download the signed document from the MyTrials patient portal or receive it through their investigator. Of course, the solution supports wet-ink signature of paper informed consent forms (ICFs) in countries requiring this, with the ability to upload scans of completed forms.

Efficient Data Collection

After completion of the ICF, including countersignature by the investigator, Unified Platform automatically provides access to the required assessment visits and eCRF pages in the EDC module, allowing site users to commence screening assessments and

record data into the system. This seamless transition between activities eliminates the interrupted workflow associated with the need to log in and out of different modules.

Site staff can collect data using their preferred device. Guided workflows direct them through required study assessments, while dynamic and real-time data validations safeguard data quality. Optimized for any web-connected device, including mobile devices such as tablets, and enabling distinguishing between directly-entered source data and transcribed data, the EDC module supports direct data capture in a variety of scenarios including at site, via remote video consultation, and through home nurse visits.

Easy-to-use Video Connection for Remote Consultation

Using the integrated TeleVisit module, site staff can easily reach out to patients remotely, either ad hoc—if a patient is not feeling well—or via scheduled visits when no on-site assessments are required. This improves engagement and reduces travel burden for patients who may have difficulty visiting the research site.

Seamless Randomization & Medication Dispensation

Without leaving the Unified Platform, investigators can seamlessly randomize and dispense medication to patients during associated visits. This may include eligibility verification, and stratification using screening data recording in the eCRFs, and the integrated workflow guides them through rapid and simple randomization and identification of medication pack numbers to dispense—all without logging in and out or switching between modules.

Investigators can also verify their supplies and review medication order status from within the platform.

Patient-Reported Outcomes and eDiaries

Whenever patients need to complete daily diaries or other patient-reported outcomes, they use the MyTrials patient portal or MyTrials app. Having already used this module for consenting, they can reuse the login details and do not need to familiarize themselves with a new environment.

Our MyTrials module works seamlessly with other platform modules, presenting the right assessments at the appropriate times, whether during site visits or for recurring diaries between visits. Patients can complete assessments using a PC, tablet, or smartphone.

Through the app, patients receive alarms and reminders for home-based assessments, helping ensure compliance with the protocol. Site staff may also receive alerts for

compliance issues and can verify data and metrics in real-time through online reports.

Conclusion

Signant SmartSignals Unified Platform greatly simplifies study conduct for patients and site staff. By offering a truly seamless, integrated experience, we enable sites to focus on what truly matters—conducting successful clinical trials.

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