SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

CLINICAL TRIAL TECHNOLOGY SOLUTIONS AND SERVICES TAILORED FOR

PHASE I CLINICAL TRIALS

Phase I clinical trials provide vital early information on the safety and tolerability of new medicines, and help to inform early dosage and regimen considerations. Studies are typically small, and start and complete rapidly, with phase I units operating several studies concurrently. Technology solutions offer important operational efficiencies, but need to support rapid implementation and end-to-end processes. Signant's unified eClinical platform provides the perfect partner for Phase I research.

SIGNANT'S UNIFIED TECHNOLOGY SOLUTION ADDRESSES PHASE I TRIAL REQUIREMENTS:

COMPREHENSIVE TECHNOLOGY SUITE

Our Signant SmartSignals® Unified Platform contains all the essential technology components for Phase I research, fully integrated: Participant recruitment management, eConsent, direct data capture and EDC, randomization, and more...

RAPID SET UP

Rapid full platform solution set up, typically in 4-6 weeks or less, using our intuitive designer that requires no-software coding. Our extensive library of re-usable forms and study templates speeds study solution assembly.

SIMPLICITY FOR THE SITE

Site users love our truly unified platform. From a single sign on, sites can access all studies and all applications. Applications are integrated out-of-the-box, and site users enjoy seamless, converged, guided workflow between applications.

REDUCED TRAINING BURDEN

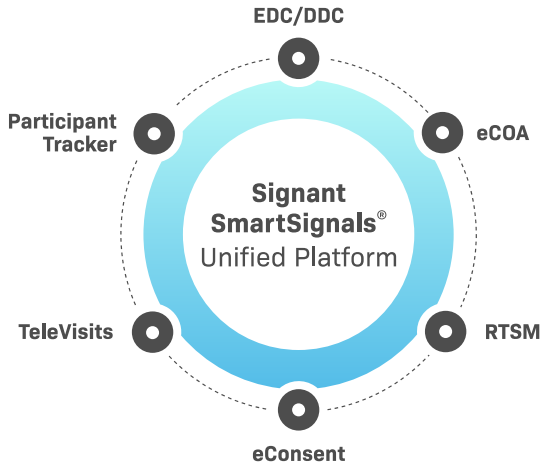
Our Unified Platform solutions are easy to use and intuitive. Guided workflow provides site operational efficiency. No need to learn multiple vendor solutions – all solutions are part of the same, single platform.

POWERED BY OUR UNIFIED eCLINICAL PLATFORM

Signant SmartSignals® Unified Platform delivers a unified and fully integrated platform of key technologies to streamline Phase I trial data capture and trial management. Studies can leverage some or all of the platform components including EDC/DDC, eCOA, eConsent, RTSM, Participant Tracker, and TeleVisits.

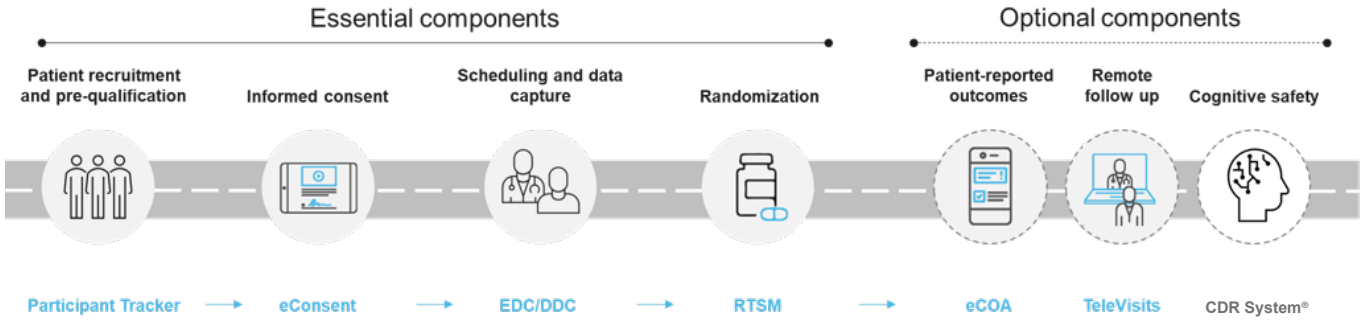
Built on a single database, there is no need to provide back-end integrations between platform solutions.

Customers can build their own study solutions using self-service, or Signant Health's experienced teams can provide full-service including study solution design and implementation.



WHY PARTNER WITH SIGNANT HEALTH?

Our unified solution suite provides a comprehensive end-to-end solution for Phase I research.



PARTICIPANT RECRUITMENT AND PRE-QUALIFICATION

Using **Participant Tracker**:

- Provide transparent management and oversight of patient recruitment and pre-screening activity/checks
- Easily import contact lists from unit candidate database
- Schedule site visits and auto-enroll in a selected study eConsent or EDC solution

SCHEDULING AND DATA CAPTURE

Using **EDC/DDC**:

- Leverage direct data capture, and reduce SDV, through modern responsive design that can be used on any mobile device
- Access study level and cross-study scheduling and activity calendars
- Enable remote SDV to reduce on-site CRA visits

PATIENT-REPORTED OUTCOMES

Using **eCOA**:

- Easily collect integrated ePRO data when needed by the study – such as pharmacodynamic measures, formulation acceptability and taste, and reactogenicity

INFORMED CONSENT

Using **eConsent**:

- Easily upload pdf ICF documents and include multimedia resources
- Provide participant access to study information and ICF ahead of / during site visit
- Improve transparency and quality of consenting documentation and eliminate inspection findings

RANDOMIZATION

Using **RTSM**:

- Include randomization within EDC workflow – one click randomization from the same common, intuitive interface
- Access rapid and transparent emergency unblinding
- Incorporate demand-driven medication supply chain management, as required

REMOTE FOLLOW UP

Using **TeleVisits**:

- Enable engaging follow up assessments using video meetings between site and participant

COGNITIVE SAFETY

Using **Signant SmartSignals® CDR System®**:

- Assess treatment-related changes in attention and processing speed

ABOUT 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 capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.