SIGNANT BIOTECH

Signant SmartSignals® Unified Platform

UNIFIED, INTEGRATED eCLINICAL RESEARCH SOLUTIONS

With rising costs and complexities in clinical development, research sponsors – especially emerging biopharma – and their contract research organization (CRO) partners require the right resources, expertise, and speed to succeed in an ever-changing, competitive environment.

Signant SmartSignals® Unified Platform is a single-source, integrated eClinical solution suite designed for efficient clinical trial digitalization and optimization, particularly tailored to the unique needs of small and mid-size biopharma organizations.

ONE BUILD, ONE DATABASE

Skip the back-end integration work with fully integrated solutions and reporting, out-of-the-box.

SINGLE SIGN ON

Reduce site burden with a single access point, and a single set of user credentials.

RAPID DESIGN AND LAUNCH

Setup in 4-6 weeks, even for studies including multiple platform components.

COMPREHENSIVE SOLUTION SUITE

Get all the solutions you need within our single Unified Platform: EDC/DDC, eCOA, RTSM, eConsent, TeleVisits, and Participant Tracker.

WHY CHOOSE OUR UNIFIED PLATFORM?

01 Leverage our single Unified Platform for evidence generation and study management.

02 Choose any combination of the eClinical solutions you need.

03 Launch in 4-6 weeks with one or many of the platform's solutions.

04 Enable your own team to implement using our configurable designer, or let us design and build your study using our team of experienced implementation specialists.

05 Supplement your team with our scientific, operational, and regulatory expertise.

06 Conduct trials anywhere with our mature operational infrastructure and processes.

07 Scale trials and programs from Phase I to Phase III and beyond.

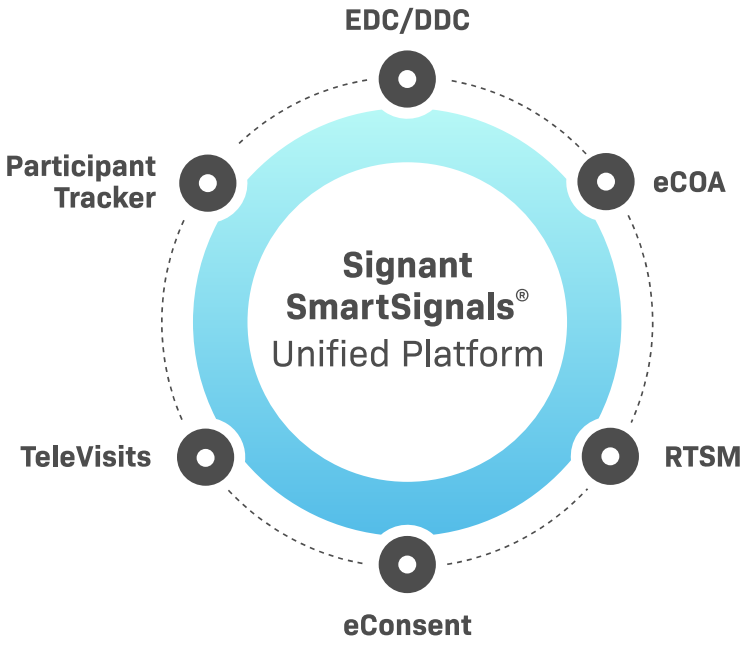
08 Work with 25+ year industry veterans.

A UNIFIED TECHNOLOGY SOLUTIONS PLATFORM FOR EFFICIENT PROTOCOL DIGITALIZATION

Signant SmartSignals Unified Platform contains all the key technology components for any clinical trial.

Take advantage of some or all of the eClinical technologies in this singular Unified Platform including fully integrated EDC, eCOA, eConsent, RTSM, TeleVisits, and Participant Tracker applications. Being part of the same unified platform means a streamlined experience for sites and sponsors: a single place to login, and a single set of access credentials; simpler, converged workflow across individual platform components; and a single database enabling consolidated oversight and reporting.

Empower your study team with rapid implementation, using full-service or self-service models, so they can optimize accurate data capture, and run any trial efficiently.



A SINGLE CONFIGURABLE DESIGNER FOR ALL PLATFORM SOLUTIONS

Our Unified Platform is supported by our configurable designer. Utilize one tool to configure any combination of platform solutions through a highly configurable build, with no software coding.

The simple-to-use designer, its underlying CDISC ODM database, along with our library of preset forms, reusable study layouts and standards, makes it easy to deliver studies rapidly – typically in 4-6 weeks.

This Unified Platform is easy for sites and sponsors, with a **single access point**, **one set of login credentials** per user, and a **converged guided workflow** allowing users to move seamlessly between solutions.

Signant SmartSignals® Unified Platform

BACKED BY SIGNANT HEALTH EXPERTISE

Leverage Signant Biotech's 25-year heritage of scientific, regulatory, technical, and operational excellence supporting our integrated eClinical technologies platform. We ensure optimal solution design and implementation to ensure high quality studies and data.

SCIENCE

Study designs are supported by our experienced science team that ensures optimal design and industry best-practices.

LOGISTICS

Our in-house logistics team prepares and distributes provisioned devices for all studies, as needed.

TRANSLATIONS

Our experienced team manages any new or adapted translations required, working with experienced, preferred translation vendors.

PATIENT HELPDESK

Patients can call our 24/7 multilingual helpdesk to gain help downloading or using our solutions.

SCALE MANAGEMENT

Our experienced scale management team leverages relationships with instrument owners and authors to ensure current and approved versions are implemented.

SCALE

We support study operations anywhere with our global infrastructure and project delivery teams.

EXPLORE PLATFORM SOLUTIONS

EDC/DDC

- Full-featured EDC solution suitable for simple and complex study designs alike
- Traditional EDC and eSource direct data capture (DDC) within a single solution
- Modern, responsive design supports mobile use for site and home-visit data collection
- Remote SDV capabilities reduce CRA travel burden
- Risk-based monitoring enables targeted SDV
- Intuitive, guided workflow for sites and CRAs
- No downtime for mid-study updates

eCOA

- Simple, intuitive solution to capture accurate, timely data from patients, caregivers, and clinicians at-site or at-home
- Device-agnostic, patient-centric experience with biometric authentication and engagement tools to optimize compliance
- Standard design and instrument library supports rapid study setup
- In-app notifications and alarms drive on-time completion

RTSM

- Robust, reliable randomization including stratification and cohort management
- Demand-driven medication supply chain management including a resupply algorithm informed by real-time EDC data
- Easy, configurable integrations with depots and CMOs, and other eClinical systems
- Full chain of custody visibility and drug accountability

eCONSENT

- Secure, remote, or site-based informed consent management with multimedia content support
- Configurable workflow for consent and reconsent, including signatures of legally authorized representatives and witnesses
- Rapid mid-study changes and consent version updates deployed real-time at site, country, and study level
- Multilingual support for site-specific forms and amendments

TELEVISITS

- Secure and compliant video visits available alongside EDC, eConsent, and eCOA
- Simple user experience enables participants to use any device and join with one click, even in low-bandwidth environments
- Ad-hoc or scheduled TeleVisits
- Optional video recording to facilitate compliance and adherence

PARTICIPANT TRACKER

- Transparent management and oversight of pre-screening activity
- Centralized tracking and management of patient enrollment
- Integration with recruitment vendors to drive site contact and follow up through a single management interface
- Real-time sponsor visibility into site recruitment activity performance

SIGNANT SMARTSIGNALS UNIFIED PLATFORM: A PROVEN HERITAGE OF SUCCESS

THERAPEUTIC AREAS

TOP-3 THERAPEUTIC AREAS

CNS

DERMATOLOGY

ONCOLOGY

REGULATORY ACCEPTANCE

13

SUCCESSFUL FDA AUDITS

GLOBAL EXPERIENCE

30+

YEARS

3,000+

STUDIES ACROSS ALL PHASES

83

COUNTRIES

100,000+

SITES

540,000+

PATIENTS

SIGNANT HEALTH

THE EVIDENCE GENERATION COMPANY™

Signant Biotech is part of Signant Health, 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.