SIGNANT SMARTSIGNALS®
UNIFIED PLATFORM

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

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's Unified Platform EDC delivers the perfect balance of power and simplicity—a comprehensive data capture solution that accelerates study timelines without sacrificing quality or compliance. Our modular approach puts you in control, with a robust EDC foundation and optional add-ons tailored to your study needs.

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

Studies in 4-6 weeks for EDC, with competitive timelines for inclusion of add-on modules

COMPREHENSIVE SOLUTION SUITE

Build from our comprehensive EDC foundation, with optional add-on modules for eConsent, eCOA, Randomization, and TeleVisits.

Why Choose Our Unified Platform?

01 Powerful EDC Foundation
Our comprehensive EDC solution serves as the backbone for all your clinical data capture needs, with functionality matching market-leading solutions.

02 Add Only What You Need
Enhance your EDC with optional modules for eConsent, eCOA, Randomization, and TeleVisits—only include what your study requires.

03 Rapid Implementation
Launch EDC in 4-6 weeks, significantly faster than industry averages.

04 Scientific Expertise
Access our experienced scientists and implementation specialists with 25+ years of therapeutic knowledge and regulatory experience.

05 Exceptional Service
Our experienced, attentive team designs the optimal solution to meet your protocol and study needs.

06 Global Infrastructure
Conduct trials anywhere with our mature operational infrastructure spanning 83 countries and 100,000+ sites.

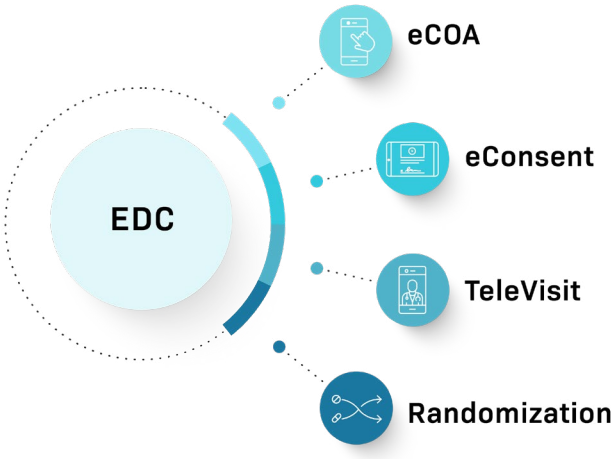
07 No-Downtime Changes
Implement mid-study amendments without disruption or data migration, to ensure continuous operations.

08 Complete Integration
All modules share a single database architecture, eliminating integration challenges and providing unified reporting across your entire study.

A Unified Technology Solutions Platform For Efficient Protocol Digitalization

Our EDC foundation contains all the functionality you'd expect from a leading EDC solution, including:

- Comprehensive capabilities
- Risk-based monitoring support
- Modular add-ons
- Optional eSource interface



eCOA

Capture patient-reported outcomes directly with our intuitive, device-agnostic interface using BYOD or provisioned devices.

eConsent

Streamline the consent process with digital forms, remote review options, and signature capture.

TeleVisit

Simplify patient follow-up with secure, compliant video visits.

Randomization

Easily implement patient randomization within the EDC workflow.

A Single Configurable Designer For Your Entire Study

Our Unified Platform is supported by our configurable designer. Utilize a single tool to configure your EDC and any add-on modules through a highly configurable build.

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 for EDC.

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

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 EDC and Add-On Modules

EDC CORE SOLUTION

- Full-featured EDC solution suitable for simple and complex study designs alike
- Traditional EDC and optional eSource direct data capture 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

ADD-ON MODULE: 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
- In-app notifications drive on-time completion

ADD-ON MODULE: RANDOMIZATION

- Robust, reliable randomization including stratification
- Effortless cohort management
- Convenient and transparent emergency unblinding
- In-house statistical expertise for methodology consulting and list generation

ADD-ON MODULE: 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

ADD-ON MODULE: TELEVISITS

- Secure and compliant video visits
- Optimized for low-bandwidth operation
- Ad-hoc or scheduled TeleVisits
- Optional video recording to facilitate compliance and adherence

Signant SmartSignals Unified Platform: A Proven Heritage of Success

TOP-3 THERAPEUTIC AREAS

CNS
DERMATOLOGY
ONCOLOGY

REGULATORY ACCEPTANCE

13
SUCCESSFUL FDA AUDITS

GLOBAL EXPERIENCE

30+
YEARS

83
COUNTRIES

100,000+
SITES

3,000+
STUDIES ACROSS ALL PHASES

540,000+
PATIENTS

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

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**.