Adaptive Clinical Infrastructure

Clinical Technology Experts & Specialized Software Engineering

Bridging the gap between validated standard software and the unique protocol needs of clinical sponsors, contract research organizations (CROs), and academic institutions.

For over three decades, CISYS LifeSciences has delivered software for regulated clinical research. Our proprietary Sequence Platform provides the foundation, while our consultative approach helps study teams address requirements beyond standard configurations. Dedicated clinical engineering resources evaluate trial needs, resolve workflow challenges, and develop tailored solutions.

30+ Years
Clinical systems experience

GxP Focus
Validation & data integrity

Protocol-Specific
Configuration & engineering

A Solutions-First Engineering Approach

Standard software can place limits on complex clinical designs. CISYS works as a technology extension of study teams, combining proven platform modules with engineering support throughout the development lifecycle.

Comprehensive Trial Discovery

Our engineering leadership works directly with clinical operations to evaluate data intake from multiple sources, specialized endpoint criteria, central laboratory imports, and site workload before deployment.

Rapid Protocol Adaptation

From voting algorithms for rare disease studies and multi-panel consensus rules to external application programming interface (API) integrations, CISYS configures and develops solutions around your protocol and clinical charter.

The Sequence Platform

Custom solutions build on the established Sequence Platform, supporting efficient implementation and documented validation for the intended use.

Module	Core Functional Scope	Customization Options
WebEAS	Centralized endpoint adjudication	Multi-level voting rules, independent panel reviews, automated review packages, and real-time consensus logic.
WebPatient	Subject eligibility and enrollment	Qualification workflows to support review of complex inclusion and exclusion criteria before randomization.
WebCode	Standardized medical coding	MedDRA and WHODrug dictionary integration, automated term matching, and specialist review queues.
WebFXP	Secure communication and document exchange	Role-based document delivery, safety letter distribution, and collaboration among study stakeholders.
WebFormX	Clinical forms and targeted data capture	Dynamic electronic data capture tailored to study-specific forms and workflows.

Regulatory Integrity & Human Oversight

Technological flexibility must preserve data integrity and appropriate regulatory controls. CISYS develops, documents, and manages custom configurations, integrations, and deployments within its quality management processes.

Human Review of Automated Outputs

Workflows may use optical character recognition (OCR) and automated redaction of protected health information (PHI). Review and approval steps should be defined in study procedures, based on intended use and risk. Machine-assisted outputs are subject to appropriate human review before approval or finalization.

Validation, Privacy & Security

Validation is informed by GAMP 5 guidance, including Category 4 and 5 software as applicable. Controls support applicable 21 CFR Part 11, HIPAA, and GDPR requirements, with information security practices informed by ISO/IEC 27001. Audit trails support traceability of record changes and relevant administrative actions.

Collaborative Delivery Lifecycle

Our partnership model supports coordination from initial protocol review through final database lock, with clear responsibilities and documented handoffs.

01 → 02 → 03 → 04

Clinical Discovery

Protocol and charter review, data intake analysis, and site workload assessment with technical architects.

Targeted Build

Configuration of Sequence modules, API integrations, and study-specific decision logic.

Risk-Based Validation

Risk-based testing, IQ/OQ/PQ where applicable, user acceptance testing (UAT), and validation records.

Lifecycle Support

Impact assessment and controlled updates for protocol amendments, added sites, and evolving requirements.

Why Clinical Leaders Partner with CISYS

Direct Technical Collaboration: Work directly with clinical systems architects experienced in software engineering and regulated clinical operations.

Ecosystem Interoperability: Connect with electronic data capture (EDC) systems, imaging repositories, and central laboratories through APIs, based on study requirements and available interfaces.

Continuous Adaptability: In-house engineers evaluate emerging challenges and develop targeted solutions throughout the trial lifecycle.

Discuss Your Study

Share your protocol or adjudication charter for a technical review. Meet with CISYS solution architects to map custom workflows and integrations, then receive a functional specification, validation timeline, and implementation plan.

info@cisys.com | (888) 476-3133

Request a meeting: cisys.com/contact-us