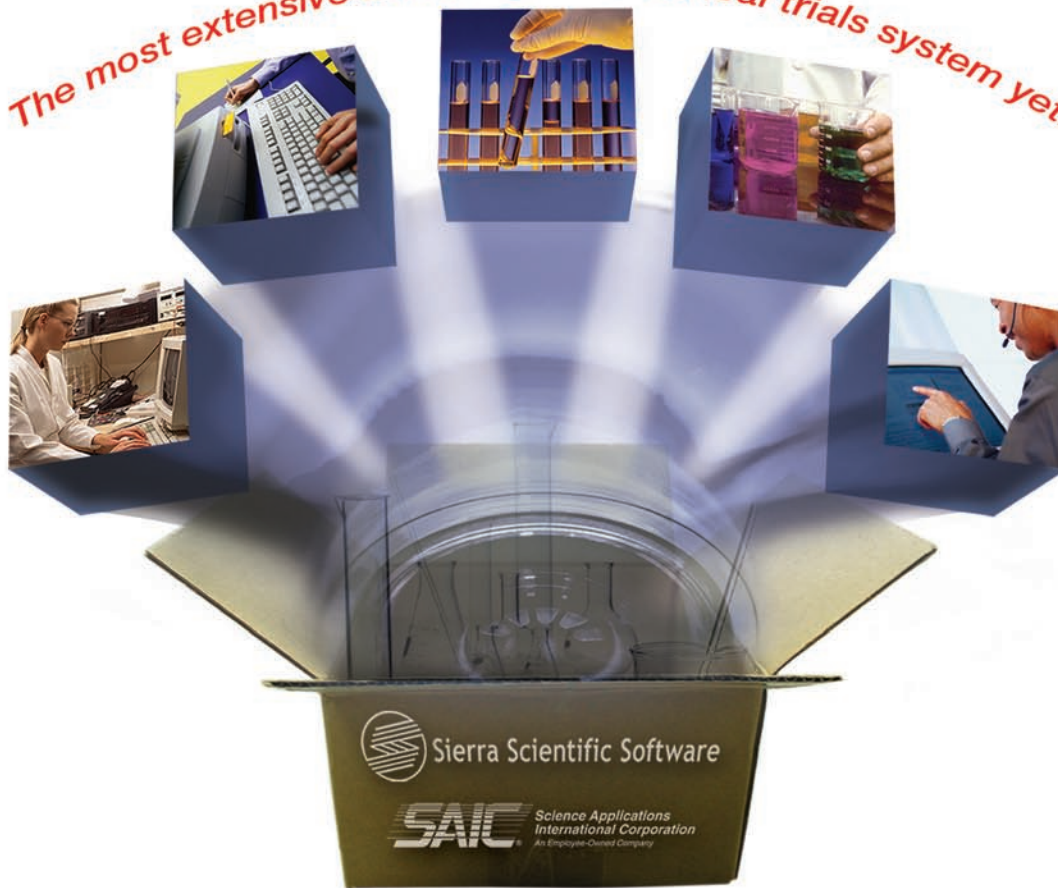


*The most extensive and integrated clinical trials system yet!*



Why not work right out of our box?

## CRISv8 offers

unprecedented speed of input, and access to all your important trial-protocol-project data, when you need it, and how you want to see it, in real-time via the Web or your network.

## CRISv8 is

a highly cost effective, fully-integrated solution that meets all your CTMS, CDMS, Safety and Investigational Materials tracking requirements.

## ▶ What's New in CRISv8?

**SAIC and Sierra Scientific Software — together we are reinventing software, service and support for the Pharma, Biotech and Medical Products Industry.**

For more information visit  
[www.sierraware.net](http://www.sierraware.net) or  
[www.SAIC.com/healthcare](http://www.SAIC.com/healthcare)  
or email us at  
[info@sierraware.net](mailto:info@sierraware.net)  
or call at 1.510.655.2441

- ▶ Intuitive, easy-to-use Web-enabled interface
- ▶ Secure portal for EDC and all site access and communications
- ▶ "Project View" to aggregate information across multiple studies
- ▶ User configurable graphic dashboards
- ▶ Configurable workflow management, with active alerts to identify events such as document expiration dates, safety reporting deadlines, interactive communications with clinical sites
- ▶ Data mining across all your studies and data
- ▶ Enhanced Safety Tracking, including support for MedDRA coding, E2B electronic submission, and ever-changing regulatory standards
- ▶ Integrates with other enterprise applications, including: Project Management, Document Management, MRP, Finance, as well as other Clinical applications
- ▶ Support for key data interchange standards, including CDISC LABS and ODM

## Modules of CRISv8

### Clinical Trials Management

- ▶ Stores all study contact information; captures all necessary GCP documentation, including IRB approvals, lab certifications and customer-defined documents; creates links to electronic versions of all documents
- ▶ Creates protocol and study center budgets; tracks actual expenses and compares between planned/actual costs
- ▶ Maintains a central repository of all study communications and monitoring visit reports

### Clinical Data Management

- ▶ Captures and tracks real-time and projected study enrollment for review over time
- ▶ Provides True 3rd Generation EDC functionality
- ▶ Enables input of CRF data via virtually any mode (EDC, fax, paper, phone, electronic import) with full audit trail to accommodate the study type and each site's capabilities

### Safety Data Management

- ▶ Manages sponsor notification, reporting and review of serious adverse events with links to CRF data
- ▶ Prints MedWatch and other mandated safety reports

### Investigational Materials Tracking

- ▶ Tracks inventory and shipment of investigational materials by lot, serial number and patient, including end-of-study reconciliation

## Security, Configuration and Compatibility

- ▶ Detailed security matrix allows the sponsor to permit limited access by regional monitors, investigators, CROs and corporate partners
- ▶ Supports all data-exchange standards
- ▶ Efficiently integrates with legacy solutions and related systems (e.g., MRP, project management, document management and finance)

## CRISv8 Service and Support

- ▶ World-class global customer support for implementation, validation and life-cycle management
- ▶ Hosting services, either through licensing or on an ASP basis
- ▶ 24/7 global help-desk in multiple languages

User Configured Dashboard

EDC Portal Clinical Site Communication

EDC Data Entry

Safety Alerts and Task List