



## Providing Clinical and Safety Data Management Solutions

### *SERVICE OVERVIEW*

ClinicalSoft is a leading provider of technical services and software solutions to the pharmaceutical and biotech industry. The company offers technical services and training for safety and Clinical Data Management Systems.

Our product expertise includes:

- Clintrial<sup>™</sup>
- Oracle<sup>™</sup> and Oracle Clinical<sup>™</sup>
- AE Reconciler<sup>™</sup>
- Integrated Review<sup>™</sup>
- Argus<sup>™</sup>
- Clintrace<sup>™</sup>
- dsNavigator<sup>™</sup>
- SAS<sup>™</sup>
- dsNavigator<sup>™</sup>

Our mission is to provide efficient and reliable solutions to meet the clinical and safety data management needs of Biotech & Pharmaceutical companies.

Expert technical solutions include:

- Software Installation
- Validation
- Training
- Applications Integration
- Study Design

### *OUR TEAM*

ClinicalSoft technical consultants and trainers have extensive industry experience, and technical knowledge and project management experience in implementing and validating clinical and safety data management systems.

### *OUR PRODUCTS*

#### **AE Reconciler<sup>™</sup>**

Our newest software offering *AE Reconciler* provides an effective method of comparing Adverse Event data collected in a Clinical Data Management System with SAE data collected in a Safety Data Management application.

The AE Reconciler<sup>™</sup> automates the adverse event reconciliation process. With AE Reconciler<sup>™</sup> sponsors can identify discrepancies between AE data and SAE data quickly, using a single reporting tool.

- Links CDMS and Safety systems
- Expedites reconciliation
- Easy to use and configure
- Compatible with most systems
- Dynamic report generation

#### **Coding Integration Bridge (to dsNavigator<sup>™</sup>)**

This innovative software provides a two-way bridge between Galt Associates dsNavigator, a web-based coding application and any CDMS or Safety system. dsNavigator incorporates functionality for searching, navigating, batch and interactive auto-encoding, and dictionary management in a single solution.

The Coding Integration Bridge can be customized to meet client specifications. ClinicalSoft also provides validation services for the dsNavigator coding integrations.

#### **CS Valset<sup>™</sup>**

Our expert programmers have created CDISC (version 3) compatible Clintrial objects, including items, panels, codelists and edit-checks. Using the CS Valset<sup>™</sup>, sponsors can more efficiently utilize time and resources with a library of validated Clintrial objects, functions and stored procedures.

Implementing CDISC standards during Clinical Database design improves data quality, reduces costs, and accelerates agency review.

## *OUR SERVICES*

### **Training Services**

ClinicalSoft offers on-site training services for Oracle™ SQL & PL/SQL programming, Clintrial™, Clintrace™ and Integrated Review™.

ClinicalSoft delivers superior training by utilizing highly qualified instructors and providing customized training materials. All of our training classes can be specifically tailored to meet individual client needs.

### **Validation services**

Our expert technical consultants guide the sponsor's team through the critical process of system validation. We have successfully performed comprehensive Clintrial/Clintrace system validation for more than ten sponsors.

Each validation project includes development of functional specifications, SOP's and SWP's. Using our complete set of Validation Script Templates (IQ, OQ & PQ), we develop comprehensive custom documentation to be retained by the sponsor.

### **Data Management Contract Services**

ClinicalSoft provides contract placement services for pharmaceutical and biotechnology companies looking for a full-time, temporary and temp-to-hire Clinical Database Managers, Programmers and Designers.

### **Technical Consulting Services**

Our team of expert consultants has a reputation for delivering superior quality services and extraordinary customer satisfaction.

Consulting Services include:

- Installation & Configuration
- Optimization & Tuning
- CDISC Standards Implementation
- System Assessment
- Upgrades
- Study Design
- Rules & Derivations
- PL/SQL Programming
- SQL Reports & Custom Queries
- Loading and configuring MedDRA, WHO Drug & other Dictionaries
- Standards Implementation (including CDISC version 3 Submission Data Model standards)
- System Administration
- Storage Area Customization
- DCF Customization (PowerBuilder)
- SOP and SWP Development
- System Validation
- EDC Consulting and Programming

## *CONTACT US*

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