

Clinical Data Management **Features**

GENERAL

- Role-based security management
- Full audit trail accessible (via right click) on all fields
- Customizable and extendible document tracking and data collection feature for any entity in system (e.g., sites, study, protocols, monitoring visits)
- Central document management capabilities for tracking common work documents or storing work documents directly in database with version control
- Support for sponsor logo on study correspondence

DATA DICTIONARY/SCREENS

- Universal coding dictionary supporting code trees and both character and numeric codes
- Re-usable data dictionary components (including edits, table structures and screens) for faster study development
- Manage study dictionary version and revisions
- Allow creation of patient-related CRFs or alternate forms for other purposes (e.g. CTMS) using same tool set
- Manage study dictionary version and revisions
- Totally customizable data entry screens
- Data entry screens can be generated directly from Word documents
- Industry Standard screen painter Sybase Infomaker used for screen painting
- Repeated or nested tabular CRF sections can be displayed on the same screen as non-nested data. i.e. Data entry screens can exactly match paper CRFs.
- CRFs can be directly linked to bitmaps and documents. Documents can be displayed directly on the data entry screen (e.g., MRI scan images)
- Data entry rule-based field skipping
- Support for default values, computed columns, pre-filled rows and columns either from a table or from a report
- Support for linked reports embedded on data entry screen, e.g., Display patient demographic info on each CRF after subject ID is filled in
- Multiple data entry screen sets allowed per CRF, which can be automatically selected based on user or CRF revision
- Support for automatic activities upon CRF save such as generation of a bar code label, automatically running a report, etc.

CRF DATA ENTRY

- Data entry performance and volume tracking reports
- Support for batch management of CRF data entry
- Support for 2nd pass data entry (interactive double-key verification or visual review)
- Randomization available on any CRF
- Floating data entry hints

CRF DATA QUALITY MANAGEMENT

- Data issue highlighting and generation directly on data entry screens
- Annotations highlighting and addition directly on data entry screens
- Simple range validations or complex cross-table/cross-CRF validations
- Manual or automatic creation of data issues (Queries/DCFs, etc.)
- Automatic generation of data issues based on complex edit rules (including simple intra-form or inter-form)
- Full documented audit trail on all CRF data modified after 1st pass entry and automatic audit trail on all data changes
- Term used for DCFs/Queries can be customized on a database by database basis to support sponsor requirements

DATA ACCESS/REPORTING

- Smart SQL auto-codes queries against data tables
- Smart SQL and Report results can be drilled down to open related CRFs or monitoring issues shown in results
- Smart SQL and Report results can be auto-linked to highlight results in multiple windows for the same subject
- CRFs can be automatically masked for specific recipients when printed (e.g. printing for a Clinical Events Committee)
- Over 150 standard system reports
- Source objects provided for most system reports so user can customize standard reports
- Users can develop and add their own reports and report folders to report menus
- Individual report level security allowing for customized report environment for individual users
- Industry Standard screen painter Sybase Infomaker used for report writing
- Automatically handles display of labels for all coded values in reports without the report writer having to write SQL joins
- Direct generation of SAS or SPSS files from any report or SQL query dataset. Includes all data dictionary information
- Automatic report runner that can automatically save reports to specific directories, email reports as PDF attachments or save SAS/SPSS datasets
- Batch reporting module for scheduling regular reports

AD HOC REPORTING

- Comprehensive and easy to use report environment
- Save any report in many formats (e.g., PDF, CSV, TXT)
- Save report underlying data as SAS/SPSS data sets
- End users can create custom reports
- Groups of reports can be run automatically and results emailed automatically as PDF attachment