

OVERVIEW

WHAT IS THE CLINICAL TRIALS MANAGEMENT TOOLBOX ?



It is a web-based Java application (accessed via a secure intranet) for managing all aspects of clinical trials, research protocols and outcomes initiatives. This research-based toolbox provides an integrated set of components for managing administrative and regulatory tracking (e.g., IRB submissions and approvals) and patient clinical data collections (e.g., tumor measurements, registrations / screenings).

The Clinical Trials Management Toolbox also provides support for study parameter definitions, including protocol schema / treatment calendars and financial management / event billing and mechanisms, for capturing study specific patient information.



THE WORKPLACE



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Clinical Trials Management Toolbox





ADMINISTRATION & REGULATORY

Administrative Summary

Provides the ability to collect and view information on status, study scope, population accruals, and IRB / other regulatory submission requirements.

Multi-Classifications

Allows the specification of multi-classification categories such as multiple disease sites and centers. Also, designations of multi-performance sites and resources can be specified.

Trial Researchers

Tracks and designates contact information for the various researchers and organizations. Includes primary investigator, co-investigators, coordinators, bio-statisticians, data manager and sponsoring organizations, CTOs, etc.



Electronic Document Integration

Provides access to all associated documents (e.g., consents, summaries) for quick viewing or editing. Includes support for MS Word, PDF, and other formats.



ENTERPRISE REPORTING

The Clinical Trials Management Toolbox utilizes a Business Objects (*formerly Crystal Decisions*) reporting solution for information delivery to a myriad of end users. Report templates are created and published on the Crystal Enterprise delivery platform, which allows users to run these reports on an ad hoc basis or by scheduling them as required. Reports can be viewed, printed or saved in multiple formats (i.e. Adobe Acrobat, MS Word, MS Excel, etc). Additionally, reports can be automatically scheduled to process and then be e-mailed to specific people or saved in specified directories. These reports cover a variety of topics, including accruals, regulatory reporting, financial reporting, specific protocols and/or patient-centric related activities, etc. Security is established to allow personnel access to only those reports which are required for their respective business purposes. There are presently in excess of 170 reports available for use.

Business Objects provides a flexible, scalable secure web-based reporting architecture. All components of the Enterprise are accessed via our intranet Web Application Server.



CLINICAL DATA MANAGEMENT

Electronic Data Capture

Using designated case report form, a variety of patient-related clinical data can be captured, including:

- Adverse Events
- Clinical Response
- Cultures
- Drug Administration / Concomitants
- Extent of Disease
- Lab Results / Skin Tests / Urinalysis / Vaccinations
- Physical Exams / Vitals / Hospitalizations
- Clinical Notes
- Patient / Family History / Prior Therapies
- Radiation / Surgical Data
- Tumor Markers
- Cancer Registry Data
- Integrated In-House Scheduling Calendar

Patient Enrollment/Screening Registry

Registers and tracks enrollment of patients onto trials. Pulls patient information from EMPI for registration. Collects treating and referring physician and vitals at the time of registration. Monitors patient accruals for enrollment compliancy.

Schedule Viewer

Interfaces with EPIC to display appointment information for a specific patient.

MARS Lab Results

Allows querying of the MARS repository for specified lab codes pertaining to a designated study subject. The returned results can then be reviewed and saved as a part of the overall study artifacts.

Custom Case Report Forms

This feature allows custom form creation to expand data collections to capture study-specific data elements.

Patient Calendar/Treatment Progress Chart

Provides a "day-planner" view of all patient activities, such as treatment start date. Allows treatment calendars to be generated and printed from the study Treatment Schedule. Integrated billing component to allow automated triggering of billable events.



FINANCIAL MANAGEMENT

Contract Info

Allows the collection and management of contract-related account information (i.e., account numbers, billing frequencies, etc.) associated with the sponsoring organization.

Treatment Schedule / Cost-Mapping

Allows financial data to be linked to the treatment events in a matrix-like format, utilizing a cost-mapping feature, which can be used for budget lists, or forecasting. Allows for the assignment of CPT codes to events and event payments.

Institutional Accounts

Allows the designation of institutional specific account numbers for linkage to ancillary billing systems.

Transaction Monitor / Payment Distribution

Monitors all itemized billing activity, from payments received to individual billable events. Allows payments received from sponsors to be tracked and distributed to the clinical trial account(s).



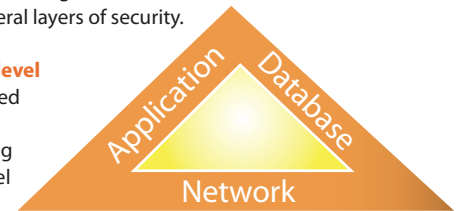
SECURITY

The Clinical Trials Management Toolbox was built on several layers of security.

An **application level** provides restricted access to menus and screens using a role/group level approach.

A **database level** provides table and view restricted access at the Oracle level, via login authentication.

A **network level** provides security using network authentication, using a single iPlanet™ account login.



STANDARDS

The Clinical Trials Management Toolbox supports a number of standardized code sets such as CTCAE, CPT-4 codes, ICD03 / 9, AJCC, CDUS, ECOG / Karnofsky, SNOMED, SEER and NAACCR. Future compatibility will include standardized vocabularies from the NCI Thesaurus and Common Data Elements.