

winchester business systems



Protocol ManagerTM

Clinical Trials Management System (CTMS)

CTMS Requirements

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Clinical Trials Management System

High-Level System Requirements

Overview of Requirements

1. Principal Modules of a CTMS
2. Relationship and Contact Information – Outside the Organization
3. Project Planning and Project Management
4. Project Planning and Project Management – Site Essential Document Specifications
5. Project Planning and Project Management – Trial Document Templates
6. Project Planning and Project Management – Human Resources
7. Project Planning and Project Management – Activity Reporting
8. Investigator Site Management
9. Patient Management
10. Inventory Management of Clinical Supplies
11. Linking to Other Systems
12. General User and Technical Requirements
13. Serious Adverse Events (SAE) reported within ongoing clinical trials

Clinical Trials Management System

High-Level System Requirements

Principal Modules of a Clinical Trials Management System

□ Relationship and Contact Information Management – Outside Organizations

- CROs
- Labs
- Suppliers
- Other Partners

□ Project Planning and Management

- Project Management, Budgeting, & Financials
- Site-Essential Document Specifications
- Trial Document Templates
- Human Resources
- Activity Reporting

□ Investigator Site Management

- Contact Management – Sites, IRBs/IECs
- Monitoring and Trip Reporting
- Regulatory Document Management

□ Patient Management

- Patient Recruiting
- Patient Scheduling
- Patient Tracking

□ Inventory Management of Clinical Supplies

□ Links to other Systems (ODBC Compatibility)

- Data Management System
- Electronic Data Capture
- Adverse Event Reporting System

Clinical Trials Management System

High-Level System Requirements

Relationship and Contact Information Management – Outside Organizations	
Requirement	Must or Want
▪ Manage unlimited categories of contacts	
▪ Manage organization names, contact names, titles, e-mail addresses, addresses	
▪ Manage call reports between company and contact	
▪ Manage action items	
▪ Generate and manage MS/Word-based correspondence	
▪ Comply with 21 CFR Part 11	
▪ Generate e-mail from system	
▪ Manage Vendor Contracts, Services, and Invoices	
▪ Manage Sponsor Contracts, Services, and Invoicing	
▪ Manage Sales Opportunities (for CROs)	
▪ Manage Bioanalytical Services and Central Labs	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management -- Project Management	
Requirement	Must or Want
▪ Provide adequate setup documents to plan a trial	
▪ Milestones	
▪ Services/Phases	
▪ Tasks/Activities	
▪ Budget Items – supplies, test kits, other trial costs	
▪ Overall trial-specific Investigator Contract specifications	
▪ Patient Setup	
▪ Patient Visits Setup(s)	
▪ CRF Setup(s)	
▪ Protocol-specified Items (Exclusions, Allergies, Patient Medical Questions, etc.)	
▪ Drug Registration Numbers (IND, NDA, etc.)	
▪ Provide ability to assign the project team	
▪ Project Manager(s)	
▪ CRAs	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management -- Project Management	
Requirement	Must or Want
▪ Data Management	
▪ Project Assistants	
▪ Manage, plan, and report on the utilization of personnel resources – employees and contractors	
▪ Provide ability to plan and manage trials in multiple countries including currencies and specific regulatory documents	
▪ Provide ability to monitor the on-line status of Trials	
▪ Provide ability to generate status reports	
▪ Provide ability to execute on-line, full-text queries	
▪ Provide ability to track budgets and actual costs	
▪ Comply with 21 CFR Part 11	
▪ Provide “instant” review of trial status – Investigator statuses, Patient Statuses, Document Statuses	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management -- Site-Essential Document Specifications	
Requirement	Must or Want
◆ Define what documents are required – medical licenses, 1572's, etc.	
◆ Define Trial-Specific Workflows for documents	
◆ Comply with 21 CFR Part 11	
◆ Provide “instant” review of trial document statuses	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management – Trial Document Templates	
Requirement	Must or Want
◆ Manage all documents as MS Word-based templates.	
◆ Manage Form Letter Templates – Trial and Country specific	
◆ Manage Trip Report Templates – Trial and Country specific [Monitoring Reports]	
◆ Site Evaluation Reports	
◆ Site Initiation Reports	
◆ Site Phone Monitoring Reports	
◆ Site Interim Monitoring Reports	
◆ Site Close Out Reports	
◆ Patient Monitoring Reports	
◆ Other reports that are trial specific	
◆ Define Trial-Specific Workflows for documents	
◆ Comply with 21 CFR Part 11	
◆ Provide “instant” review of trial document statuses	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management – Human Resources	
Requirement	Must or Want
◆ Manage Contact Information about company people and independent contractors	
◆ Define roles, departments, areas, etc.	
◆ Indicate assignments by trial	
◆ Illustrate Person-load by trial – hours or “Full-Time Equivalencies”	
◆ Track and manage costs by human resource	
◆ Comply with 21 CFR Part 11	
◆ Provide “instant” review of trial document statuses	

Clinical Trials Management System

High-Level System Requirements

Project Planning and Management – Activity Reporting	
Requirement	Must or Want
<ul style="list-style-type: none">▪ Provide for the collection of timesheet and expense report data by employee by department, assignment, and:	
<ul style="list-style-type: none">▪ Trial	
<ul style="list-style-type: none">▪ Service	
<ul style="list-style-type: none">▪ Activity	
<ul style="list-style-type: none">▪ Responsibility	
<ul style="list-style-type: none">▪ Comply with 21 CFR Part 11	
<ul style="list-style-type: none">▪ Provide “instant” review of trial document statuses	

Clinical Trials Management System

High-Level System Requirements

Investigator Site Management	
Requirement	Must or Want
<ul style="list-style-type: none"> ▪ Provide ability to manage site, IRB, IEC, and other contact information: 	
<ul style="list-style-type: none"> ▪ Manage unlimited categories of contacts; e.g.: Principal Investigator, Financial Contact, Site Coordinator, etc. 	
<ul style="list-style-type: none"> ▪ Manage organization names, contact names, titles, e-mail addresses, addresses 	
<ul style="list-style-type: none"> ▪ Manage call reports between company and contact 	
<ul style="list-style-type: none"> ▪ Manage action items 	
<ul style="list-style-type: none"> ▪ Generate and manage MS/Word-based correspondence 	
<ul style="list-style-type: none"> ▪ Generate e-mail from system 	
<ul style="list-style-type: none"> ▪ Provide ability to assign sites and contacts to clinical trials 	
<ul style="list-style-type: none"> ▪ Automatically generate tracking documents for required regulatory documents 	
<ul style="list-style-type: none"> ▪ Manage all regulatory documents as MS Word-based files 	
<ul style="list-style-type: none"> ▪ Report on regulatory Documents that are ready to “expire” -- Where a regulated document is required to be renewed, the system should provide a flag or follow up identifier that is highlighted to the identified user (CRA, Project Assistant, etc.) 3 months prior to the renewal date. 	
<ul style="list-style-type: none"> ▪ Provide trial and country specific workflow 	
<ul style="list-style-type: none"> ▪ Manage Trip Reports [Monitoring Reports] 	

Clinical Trials Management System

High-Level System Requirements

Investigator Site Management	
Requirement	Must or Want
▪ Site Evaluation Reports	
▪ Site Initiation Reports	
▪ Site Phone Monitoring Reports	
▪ Site Interim Monitoring Reports	
▪ Site Close Out Reports	
▪ Patient Monitoring Reports	
▪ Other reports that are trial specific	
▪ Provide Trial- and Country-Specific Workflows for documents	
▪ Provide ability to manage Investigator Payments	
▪ Assign individual Investigator Site Contracts [based on Example Contract in Protocol]	
▪ Record Investigator Payment Item(s)	
▪ Record Investigator payment items based on Patient Tracking	
▪ Generate Investigator Invoices	
▪ Comply with 21 CFR Part 11	
▪ Provide ability to review and manage calendars for trail staff – appointments, actions items, and call reports	

Clinical Trials Management System

High-Level System Requirements

Investigator Site Management	
Requirement	Must or Want
▪ Provide “instant” review of trial document statuses – Regulatory Documents and Monitoring Reports	
▪ Store Approval status and comments in each document.	
▪ Free text field to enable a dialogue to be entered describing the reason for Not Approved or Conditional Approval	
▪ When approved, an electronic signature field is triggered to store who approved and when.	

Clinical Trials Management System

High-Level System Requirements

Patient Management	
Requirement	Must or Want
Patient Recruiting:	
<ul style="list-style-type: none"> ▪ Provide contact management and full-demographic information on candidate patients 	
<ul style="list-style-type: none"> ▪ Provide ability to perform an initial “screen” of candidates against the medical questions included in the protocol 	
<ul style="list-style-type: none"> ▪ Screen for allergies, concomitant medications, and concomitant diseases 	
<ul style="list-style-type: none"> ▪ Forward screened candidates 	
Patient Scheduling:	
<ul style="list-style-type: none"> ▪ Provide a Patient Profile that can include trial-specific metrics and Patient “Status on Trial” 	
<ul style="list-style-type: none"> ▪ Automatically generate Patient “blank” Visit records according to the protocol 	
<ul style="list-style-type: none"> ▪ Allow scheduling to automatically occur once the patient has achieved the required criteria 	
<ul style="list-style-type: none"> ▪ Allow rescheduling 	
<ul style="list-style-type: none"> ▪ Allow for the management of “Multi-Leg Trials” 	
Patient Tracking:	
<ul style="list-style-type: none"> ▪ Track Patients through the visit cycle – as visits occur, update patient status 	
<ul style="list-style-type: none"> ▪ Provide a check-off for processing CRF pages 	

Clinical Trials Management System

High-Level System Requirements

Patient Management	
Requirement	Must or Want
<ul style="list-style-type: none"> Provide a test for visit actual attendance and schedule date for possible tolerance violations 	
<ul style="list-style-type: none"> Provide for the generation of a "Protocol Deviation" that may require CRA, Project Manager, and/or IRB/IEC approval to continue a patient on a trial -- Protocol violations and clarifications (date of event/violation, date received by CRA, report date, date sent to site, date of confirmation, report author,) 	
<ul style="list-style-type: none"> Provide for initiating and managing "queries" or <i>Data Clarification Forms</i> to involve CRAs, Investigators, and Data Management 	
<ul style="list-style-type: none"> Comply with 21 CFR Part 11 	
<ul style="list-style-type: none"> Provide "instant" review of trial document statuses 	

Clinical Trials Management System

High-Level System Requirements

Inventory Management of Clinical Supplies	
Requirement	Must or Want
Study supplies tracking for every site and supply item:	
▪ Number in-house	
▪ Number shipped to site	
▪ Date of site request	
▪ Date of order from company	
▪ Date of shipment to site	
▪ Date acknowledged received from site	
▪ Total returned from site/date returned	
▪ Predicted number of the supply remaining at site	
Study drug tracking:	
▪ Batch/lot numbers stored in-house	
▪ Expiry dates of batch/lot numbers	
▪ Batch/lot numbers sent to each site	
▪ Date sent to site/date received by site	

Clinical Trials Management System

High-Level System Requirements

Inventory Management of Clinical Supplies	
Requirement	Must or Want
▪ Batch/Lot numbers returned in-house	
▪ Date returned/received in-house	
▪ Storage of drug at each site	
▪ Blinding codes	
▪ Comply with 21 CFR Part 11	
▪ Provide “instant” review of trial document statuses	

Clinical Trials Management System

High-Level System Requirements

Linking to Other Systems	
Requirement	Must or Want
▪ Provides interfaces to, or integration with, the Data Management system to provide single data entry	
▪ Provides interfaces to, or integration with, the SAE/Medical Monitoring system to provide single data entry	
▪ Provides interfaces to the Financial System	

Clinical Trials Management System

High-Level System Requirements

General User and Technical Requirements	
Requirement	Must or Want
<ul style="list-style-type: none"> ▪ The system must be able to function so that staff can access data remotely and on a global basis, 24 hours per day, 7 days per week. 	
<ul style="list-style-type: none"> ▪ Store or link to documents related to the study including the CRF completion manual, study reference manual, the protocol and amendments. 	
<ul style="list-style-type: none"> ▪ Flexible in terms of organizing information according to numerous parameters. For example, information could be organized by patient, by site, by study, by CRA or by COA 	
<ul style="list-style-type: none"> ▪ “Ad hoc” query tool to assist in developing study-specific reports with output to products like MS Excel, Crystal Reports, among others 	
<ul style="list-style-type: none"> ▪ Solution must provide data conversion capabilities to avoid having to re-key existing data from Excel spreadsheets, and other systems. 	
<ul style="list-style-type: none"> ▪ Runs on Administration-friendly Platform 	
<ul style="list-style-type: none"> ▪ Detailed Training plan for a “Train the trainer” approach 	
<ul style="list-style-type: none"> ▪ Configurable Maintainable by internal staff 	
<ul style="list-style-type: none"> ▪ Support by vendor is available during implementation 	
<ul style="list-style-type: none"> ▪ The system needs to have varying levels of security to restrict who can view, edit, modify the database and the system defaults. Security may be definable to the “field” level. 	
<ul style="list-style-type: none"> ▪ Software vendor provide telephone support 	

Clinical Trials Management System

High-Level System Requirements

Serious Adverse Events (SAE) reported within ongoing clinical trials	
Requirement	Must or Want
<ul style="list-style-type: none"> ▪ Provide for the identification of the protocol, patient, investigator, research site and study drug 	
<ul style="list-style-type: none"> ▪ Link to CTMS for critical data 	
<ul style="list-style-type: none"> ▪ Document temporary or permanent discontinuation of the study drug including relevant dates 	
<ul style="list-style-type: none"> ▪ Provide a detailed description of the event including randomization date, onset date, the date when the event became serious, how long the patient had been on the study drug and an estimation of the event intensity 	
<ul style="list-style-type: none"> ▪ Describe all investigations, diagnoses and treatments (surgical and medical) during the event 	
<ul style="list-style-type: none"> ▪ Determine event causality and drug-event relationship 	
<ul style="list-style-type: none"> ▪ Determine if the SAE is unexpected and if regulatory 	
<ul style="list-style-type: none"> ▪ Provide for the use of various coding dictionaries; such as: MedDRA, WHOART, COSTART, and company specific coding dictionaries 	
<ul style="list-style-type: none"> ▪ Provide for country-specific regulatory information 	
<ul style="list-style-type: none"> ▪ Describe event resolution and resolved date 	
<ul style="list-style-type: none"> ▪ Provide a pick list for event resolution which can be added to dynamically 	
<ul style="list-style-type: none"> ▪ Outline the concomitant medications and relevant past medical history by pick-list and free-form 	

Clinical Trials Management System

High-Level System Requirements

Serious Adverse Events (SAE) reported within ongoing clinical trials	
Requirement	Must or Want
<ul style="list-style-type: none"> The database must be “validated” for audit purposes. All changes or additions to the database must be traceable. (Who changed what when) 	
<ul style="list-style-type: none"> Provide for regulatory and contract timelines to generate “flags” or messages reminding staff of report status and time requirements. 	
<ul style="list-style-type: none"> Allow for at least 4 “differing opinions” to be documented (e.g. the Primary Investigator has made a certain decision but the Medical Monitor or the sponsor does not agree). -- Include dates and names along with these “opinions” 	
<ul style="list-style-type: none"> Provide for electronic tracking summaries to be generated as needed (e.g. weekly) for each study in the form of a report that can be sent to the sponsor, regulatory agency or used in-house by the project team as E-mail attachments. The timing of these items must be settable. 	
<ul style="list-style-type: none"> Provide a written Medical Narrative for each SAE based on the information in the database directly or exportable into MS Word. This must allow multiple versions of the narrative to be stored. 	
<ul style="list-style-type: none"> Allow or facilitate the completion of standard SAE reporting forms such as the CIOMS, MedWatch 3500A using the information from the database if the reporting needs to be expedited. 	
<ul style="list-style-type: none"> An unlimited number of countries should be included for global operations 	
<ul style="list-style-type: none"> Multiple copies, versioned and dated separately must be stored. 	
<ul style="list-style-type: none"> It must include reporting capabilities to review the database for patterns and trends. 	
<ul style="list-style-type: none"> The system must be able to function so that staff can access data remotely and on a global basis, 24 hours per day, 7 days per week. 	
<ul style="list-style-type: none"> Provide capability to create standard “dictionaries” or “Glossary of Terms” for common concomitant medications, 	

Clinical Trials Management System

High-Level System Requirements

Serious Adverse Events (SAE) reported within ongoing clinical trials	
Requirement	Must or Want
Medical history terms available on drop down lists or auto field link to minimize the need to type them in each time.	
<ul style="list-style-type: none">▪ User must be able to enter Modification and Transmission dates that are locked, auditable and electronically signed.	