

**Clinical Trial
Management System**

DCRI

DUKE CLINICAL RESEARCH INSTITUTE

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CTMS Protocol Planning, Setup, and Maintenance

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CTMS Protocol Planning, Setup, and Maintenance

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Intended Audience

The primary audience for this session includes Project Leaders (PL), Clinical Trial Managers (CTM), and Lead Clinical Research Associates (Lead CRA). Although it is not required, Clinical Research Associates (CRA) and Clinical Trial Assistants (CTA) can also attend.

Training Summary

Previously named "CTMS Advanced Topics," this session discusses protocol setup options, steps for requesting data changes and template updates, close-out options, and trial team support.

Course Objectives

Upon completion of the CTMS Protocol Planning, Setup, and Maintenance training course, participants should be able to:

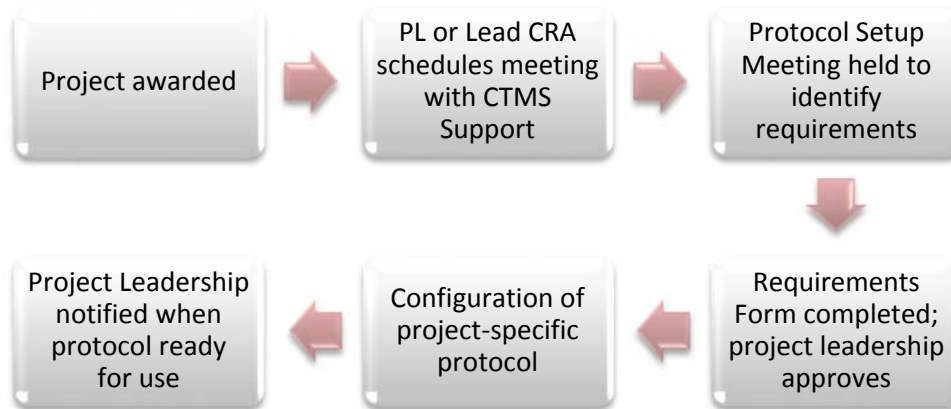
- Understand and follow the process to locate and complete the following documents.
 - Data Entry Guideline (DEG)
 - Protocol Setup Requirements Form
 - CTMS Access Request Form
 - CTMS Request Form (CTMSR)
- Identify and be able to communicate CTMS features and functions that can be turned on/off per protocol.
- Understand how CTMS is integrated with other applications at the DCRI.
- Locate and use the various CTMS reporting options.
- Communicate the different CTMS support options that are available.

PROTOCOL PLANNING AND SETUP

Protocol Set-Up Process

All projects that include DCRI-provided site management or site monitoring services are required to use CTMS. **The PL or Lead CRA (or designee) should schedule a meeting with CTMS Support to complete the Protocol Setup Requirements Form.** Prior to the meeting the form should be reviewed by the attendees to ensure the required information will be available at the meeting.

It typically takes two weeks to hold the Setup Meeting, complete the details, and approve the final requirements. This may be shorter or longer depending on the response time from the project leadership. Once the minimum required information is provided by the trial team, CTMS Support will need 2-3 days to configure, test, and release the protocol.



Protocol Setup Requirements Form

This document is used to record information required to configure a new protocol in CTMS. It is completed by the PL or Lead CRA based on information obtained at the Protocol Setup Meeting. The form is emailed to the PL or Lead CRA before the meeting, to allow time to prepare, and is located on the CTMS Learning Center.

Activity Plan

The Activity Plan is a pre-defined, protocol-specific, list of activities that are required to be tracked for all sites. Activity Plans are defined by the PL or Lead CRA and SSU, and are entered into CTMS by a CTMS Administrator. An Activity Plan template is available on the DCRI Intranet and is provided prior to the Protocol Setup Meeting, to allow time to prepare.

Activity Plan Options

A protocol can have one or more Activity Plans. An Activity Plan can be automatically applied by the system to all sites, or can be manually applied to individual sites by the user.

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Activity Plan Functionality

When an Activity Plan is applied, the appropriate view tabs (Milestones, Documents, Training, Other Requirements, and Safety Letters) are pre-populated with the items defined in the Activity Plan. After the Activity Plan is applied, data related to each item can then be added by the user.

Activity Plan Content

The following five view tabs are listed on the Site Management screen tab, and can be pre-populated via the protocol-specific Activity Plan. For a complete list of values, refer to the CTMS Standard List of Values located on the CTMS Learning Center.

1. *Milestones*

A standard list of 28+ milestones is available for tracking. Milestones are used to track a site's progress throughout the lifecycle of the protocol, and are used to determine site metrics. Milestones required to be tracked for all protocols are:

- Regulatory Complete
- Activated for Enrollment
- Enrollment Complete

If the protocol is using the SSU Group, the following milestones will also be required:

- Contract Sent
- Contract Executed
- Reg Pack Sent
- Reg Pack Received
- Site Hand Off

Metrics Based Milestones are used to derive site performance metrics which are important to each project and to the DCRI as an organization, and are listed below. The PL and Lead CRA should ensure that these milestones are tracked as appropriate for each site.

- Regulatory Pack Sent
- Regulatory Complete
- Investigational Product Sent
- Activated for Enrollment
- Enrollment Complete

2. *Documents*

A standard list of 75+ documents is available for tracking. Documents that sites will be required to collect from every site should be included in the Activity Plan.

3. *Training*

A standard list of 20+ training events is available for tracking. Training events that sites will be required to track for every site should be included in the Activity Plan.

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4. Other Requirements

Information that cannot be tracked as a milestone, document, training event, or safety letter can be tracked on this tab. Any additional information that will need to be tracked for every site should be included on the Activity Plan.

5. Safety Letters

Trial Safety Letters and DSMB Letters are added to the Activity Plan by the CTMS Clinical Administrator and will be automatically added to each site that previously had the Activity Plan applied, as long as the site does not have a site status of "Stopped." *Site* Safety Letters can be added by the user to individual sites as needed.

Activity Plan Updates

Updates to an Activity Plan are requested using the CTMS Request (CTMSR) form, and are performed by a CTMS Clinical Administrator. Updates are automatically added to all sites that previously had the Activity Plan applied. The updated Activity Plan will be available for any new sites created, or any existing sites that have not previously had the Activity Plan applied.

Data Entry Guideline

A Data Entry Guideline (DEG), using the standard template, is mandatory for all projects where DCRI is responsible for site management or site monitoring activities. The DEG is written and maintained by the Lead CRA (or designee), in conjunction with CTMS Support. The DEG provides instruction to the project team about study-specific CTMS data entry requirements. The DEG identifies what type of information needs to be tracked and who is responsible. An electronic version of the project-specific DEG will be stored within CTMS on the Protocol Attachments tab. The DEG template is provided by CTMS Support for the Protocol Setup meeting, and is also available on the CTMS Learning Center. The approved standard DEG template is located on the DCRI Intranet.

Visit Tracking

All projects providing DCRI's site monitoring services are required to use CTMS to track planned and completed site monitoring visits and trip reports. Refer to the protocol-specific DEG for the list of fields that will be required.

Electronic Trip Report

CTMS provides a DCRI standard trip report format that is completed electronically. It is expected that this functionality will be used by all projects, with the exception being when a sponsor requires the use of a sponsor-specific trip report format. In that case, CTMS will not be used.

Trip Report Content

The CTMS trip report includes Checklist Activities (based on the DCRI Monitoring SOPs for each Visit Type), Follow-up Activities, Informed Consent Forms (ICF), Case Report Forms (CRF), and Protocol Deviations.

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Checklist Activities

Protocol-specific checklist activities can be added to the standard template. This requires submission of a CTMSR form, detailing the additional items to be added. Any changes should be reviewed and approved by the PL and Associate Director (AD) prior to submission.

Custom protocol-specific checklist item templates, not based on the standard template, can be requested. In addition to submission of a CTMSR form, an Excel spreadsheet of the checklist items, instructions, and annotations is required. **Approval by PL and AD is required for this type of request.**

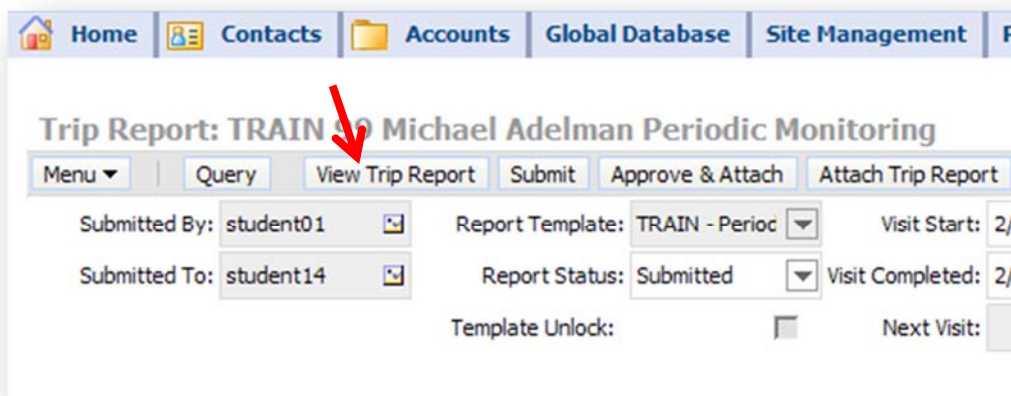
NOTE: It is the PL's responsibility to confirm that the requested revisions are in compliance with the applicable SOP. The PL should consult DCRI's QA/RC group, as needed.

Trip Report Functionality

Within CTMS, trip reports can be completed, submitted, reviewed, and approved electronically, using electronic signatures (e-sigs). The E-sig Submitted Date field and E-sig Approved Date field will display on screen in the time zone of the user. On the trip report PDF, these fields will always display in the US Eastern time zone.

CTMS offers the ability to export a trip report to a predefined Excel document. This allows the trip report to be completed while off-line and imported into CTMS when back on-line.

A trip report can be viewed on screen, saved, or printed as a PDF at any stage during the process, by clicking the View Trip Report button within the trip report window (see screenshot below).



The screenshot shows the CTMS interface for a trip report titled "Trip Report: TRAIN 09 Michael Adelman Periodic Monitoring". The navigation bar includes Home, Contacts, Accounts, Global Database, and Site Management. The main interface has a menu with options: Menu, Query, View Trip Report (highlighted with a red arrow), Submit, Approve & Attach, and Attach Trip Report. Below the menu, there are fields for Submitted By (student01), Submitted To (student14), Report Template (TRAIN - Period), Report Status (Submitted), and Template Unlock (checkbox). There are also fields for Visit Start and Visit Completed, both showing "2/3".

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The trip report PDF can also be attached at any time in the process, by clicking the Attach Trip Report button within the trip report window (see screenshot below). This attachment is added to the Attachments tab of the trip report and can be deleted prior to the report being approved.

By clicking the Approve & Attach button (see screenshot below), and entering the required authentication, your e-sig is applied, the trip report Status is updated to Approved and the approved trip report PDF is attached. This attachment is added to the Attachments tab of the trip report and cannot be deleted.

Home | Contacts | Accounts | Global Database | Site Management | P

Trip Report: TRAIN 99 Michael Adelman Periodic Monitoring

Menu | Query | View Trip Report | Submit | Approve & Attach | Attach Trip Report

Submitted By: student01 | Report Template: TRAIN - Periodic | Visit Start: 2/...

Submitted To: student14 | Report Status: Submitted | Visit Completed: 2/...

Template Unlock: | Next Visit: ...

Efficiency Tips for Preparing and Reviewing Trip Reports

- The reviewer can add Internal Comments at each checklist activity level as well as at the overall trip report level.
- To review the trip report and make comments in CTMS, generate the trip report using the View Trip Report button and toggle (alt + tab) between the PDF of the trip report and CTMS.
- Using the Select tool within the PDF, you can copy and paste from a previous trip report PDF to the current trip report being prepared in CTMS.
- Use the off-line trip report Export/Import functionality.

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Confirmation and Follow-Up Letters

Confirmation and Follow-Up letters can be attached by the click of a button at the trip report level using standard, or protocol-specific letter templates.

Standard Confirmation letter and Follow-Up letter templates are available by default for visit types of Site Selection, Site Initiation, Site Selection/Initiation, Periodic Monitoring, and Close-Out. Protocol-specific templates can be added. Completion of a CTMSR form is required, with a sample of the letter(s), indicating with brackets [] where data is to be populated from CTMS.

Fields that can be auto-populated, and which are included on the generic Confirmation and Follow-Up letter templates, include:

Current Date	CRA Full Name
Investigator Full Name	CRA Last Name
Investigator Last Name	CRA First Name
Investigator First Name	CRA Phone
Investigator Degree	CRA Email
Protocol Description	SC Full Name
Protocol Number	SC Last Name
Site Number	SC First Name
Site Address	Next Visit Date
Trip Report Attendees	List of Subjects in CRF Tab
Visit Actual Start Date	List of Subjects in ICF Tab
Visit Planned Start Date	List of Protocol Deviations
Visit Planned End Date	Follow-Up Items

In addition, the following fields can be included, if requested:

Site Manager Full Name	Site Manager Phone
Site Manager First Name	Site Manager Email
Site Manager Last Name	Additional Observations/Comments
Account Name	PI Address

Blinded vs. Unblinded

Protocols requiring Unblinded monitoring visits are identified at the Protocol Setup Meeting. Users are identified as Blinded or Unblinded per protocol. Trip report approvers are also identified as Blinded or Unblinded per Protocol. CTMS partitions Unblinded data so that only Unblinded users have access to trip report data, including Follow-Up items, and Conversation Logs.

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System Integration

The CTMS can be configured to integrate with various DCRI internal and external partner systems, including the following:

Interactive Voice Response System (IVRS)

DCRI's centralized enrollment system collects data from various Interactive Voice Response systems (IVRS), and loads subject enrollment data into CTMS nightly. Enrollment data must be identified as part of the data exchange process during budget negotiations and is managed by IT Operations.

Partners/External (funding required)

When project teams need to provide site contact information (name, address, telephone, etc.) to external systems, a data transfer mechanism is established. The cost for this service needs to be included during budget negotiations and is managed by IT Operations.

Example: Site contact information for shipment of investigational product is transferred with the roles from CTMS mapping as:

CTMS	External Partner System
Principal Investigator	PI
Study Coordinator	SC
Pharmacy Contact	DS (Drug Shipment)
All other CTMS Roles	AC (Additional Contact)

Trial Central (funding required)

Trial Central is built per project using a common / re-usable architecture. Basically, it is an external facing portal that receives common data from both sponsor and vendor systems to combine and display in a single view. The cost for this service needs to be included during budget negotiations and is managed by IT Operations.

Trial Payments

Several key milestones are key data points when determining site payments, and vary per protocol.

- Regulatory Complete
- Activated for Enrollment
- Contract Executed

Clintrial

DCRI's Clinical Data Management (CDM) database, Clintrial, can access information in CTMS for Data Clarification Form (DCF) Contacts. The IT Operations and Project Startup group is responsible for the initial setup of this integration. It is the responsibility of the PL, Lead CRA, or CDM specialist to request the setup of the DCF transfer process. The DCF transfer process is run on a weekly basis, usually on Tuesday or Wednesday.

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To populate DCFs that are sent to sites, the following information is required to be entered in CTMS for each site:

- Site Contact with role of DCF Contact and a DCF Fax Number marked as primary
- Site Manager Name and Phone Number

InForm

Trials can be set up to pull enrollment data from InForm to CTMS. The cost for this service needs to be included during budget negotiations and is managed by IT Operations.

The CDM group can collect Electronic Data Capture (EDC) training information from the CTMS Site Contact record, so that an InForm account can be set up based on training requirements being met. **There may be a charge for this service.**

Communicating with Vendors

CTMS allows email notification to a vendor when a site is ready to receive various supplies. This functionality is available for the following items:

- Regulatory Pack
- Starter Box
- Drug IP
- Device IP

The required Vendor information includes:

- Vendor name
- Vendor email
- Supply to be sent

Vendor information can be provided at the initial Protocol Setup Meeting or at a later time by completing a CTMSR form. Refer to the CTMS Site Management User Reference Guide for detailed information on communicating with vendors.

Other Protocol Options

Contracts

If DCRI is negotiating site contracts, CTMS will be used to track this information. The Contracts view tab is editable only by CTMS users who have attended CTMS Contracts training. The Contract Sent and Contract Executed milestones are auto-populated based on statuses entered for contract records.

If DCRI is not negotiating site contracts, the milestones of Contract Sent and Contract Executed will be available for tracking on the Milestone view tab, if required.

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Reporting

Standard Reports

Samples of the 30+ standard reports, including synopses of each, are located on the DCRI Intranet. Data in standard reports can be exported to Excel for sorting and filtering, or viewed as a PDF for printing or saving.

Custom Reports

Custom reports can be configured by IT. A CTMSR form and mock-up of the report are required. There is an additional charge by IT for custom reports.

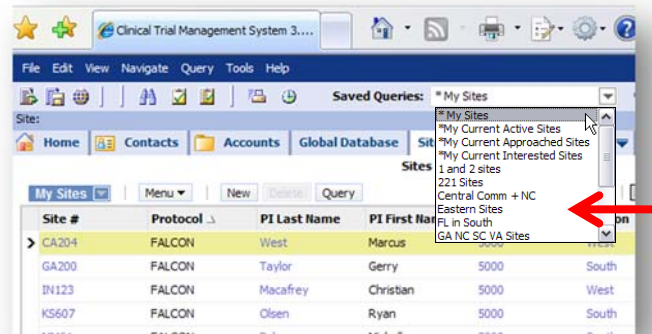
Exporting Data

Data presented in a list view can be exported to Excel for sorting and filtering. A list of data can be limited by querying on particular fields prior to exporting. Refer to the CTMS Fundamentals User Reference Guide, “Running Reports and Viewing Metrics” section.

Query Function

User Specific Query

Users can create and save commonly used queries with predetermined criteria. A predefined query is specific to the Screen tab where it is created, and to the user who created it.



Refer to CTMS Fundamentals User Reference Guide, Section “Query Basics”

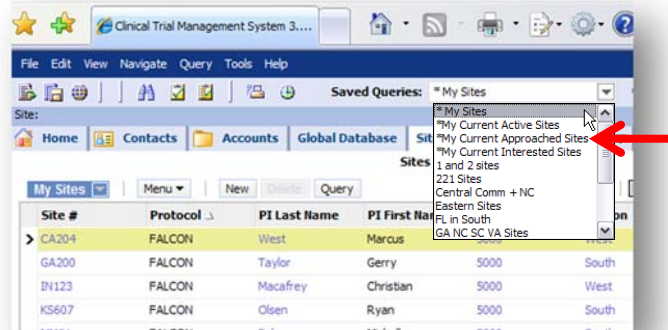
Protocol-Specific Queries

Queries that are determined to be needed by all users for a particular protocol can be published by a Clinical Administrator. A CTMSR form is required. There is no additional charge for this service.

Global Queries

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The Site Management and Site Visits screen tabs have predefined queries that are present by default for all protocols. If a determination is made that a new Global Query is necessary, it will be configured and made available on the appropriate screen tab for all protocols to use.

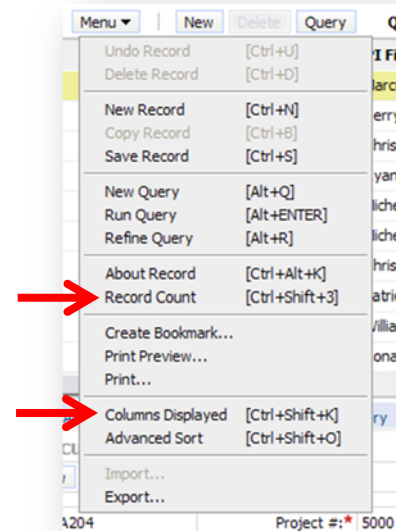


Data Roll-Up

Important data fields roll up from the site and region, to the protocol level. Screen tabs at the top of the window contain rolled up data. Look for view tabs within screen tabs to drill down into specific information. Refer to the CTMS Fundamentals User Reference Guide, "Running Reports and Viewing Metrics" section.

Helpful Tips

- To determine how many records are in a list, select Menu > Record Count.
- To view columns that are not currently visible, select Menu > Columns Displayed.



CTMS Project Leader Dashboard

Summary

DCRI's CTMS Project Leader Dashboard serves as a reporting tool to show key metrics for CTMS protocols. All new protocols using CTMS will be required to have a Dashboard unless an exemption is approved by the Director of Clinical Operations or the Assistant Director of the Therapeutic Area.

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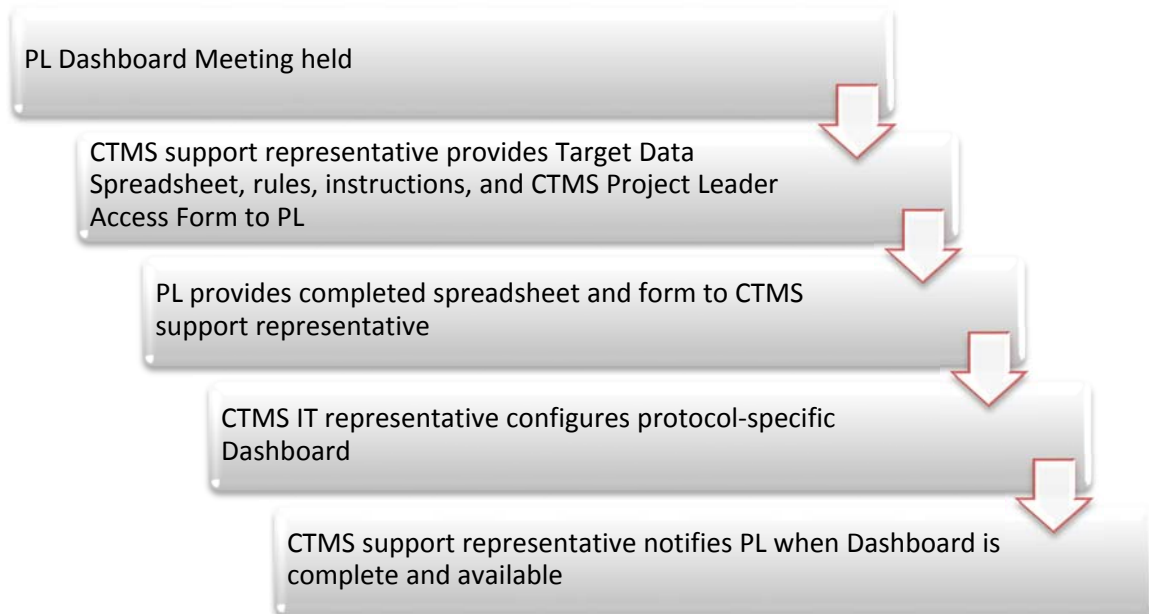
Reference Materials and Forms

The CTMS Project Leader Dashboard Reference Manual is located on the DCRI Intranet. This manual provides instruction on requesting, setting up and using the Dashboard.

The CTMS Project Leader Access Form is located on the DCRI Intranet. This form is used to request access for individuals, other than the ClinOps Director, Assistant Directors, and Site Startup Manager, who will have access to all protocols in the Dashboard.

Process

A discussion will be held during the initial CTMS Protocol Setup Meeting regarding the process for setting up a Dashboard. If necessary, a separate meeting will be held to explain and complete the Dashboard forms.



It typically takes between 2-3 weeks to hold the Setup Meeting, complete, and approve the final Target Data Spreadsheet. This may be shorter or longer depending on the response time from the PL. Once the Target Data Spreadsheet is approved, the CTMS IT representative will need 2-3 days to configure, test, and grant access to the Dashboard. Data will not populate the Dashboard until the milestone of Reg Pack Sent has been tracked for at least one site.

CTMS USER ACCESS

New Hire Process

Follow the steps outlined on the DCRI intranet's **Recruitment/Employment** page (<http://dcrihome.dcri.duke.edu/functional-groups/hr/recruitment>).

Non-DCRI Personnel System Access

CTMS is configured to allow external users access to only data they will manage. The same training requirements and access request procedures apply to both internal and external users. See *Appendix A* for more details.

CTMS Access Form

This document is used to request addition or removal of access *to protocols* for individuals. The form is located on the DCRI Intranet. The form must be approved by the PL, CTM or Lead CRA (signature is not required, but reference to the approver's name is requested). The completed form is submitted electronically to the DCRI Service Desk.

CTMS SOP - OP-S-019

The Clinical Trial Management System (CTMS) SOP provides instructions for standard administration, maintenance, and use of CTMS. All users of CTMS are required to be trained on, and comply with, this SOP as it relates to their role and responsibilities. This SOP is located on the DCRI Intranet (Groups > Clinical Operations > SOP Forms & Templates).

Training Requirements

Because the CTMS is a regulated environment, training requirements are verified before access is granted.

Users must attend the following core classes:

- **CTMS Fundamentals** (required for all CTMS users)
- **CTMS Site Management** or **CTMS Site Monitoring** (one or both required, depending on the user's role)

The requester is notified when access has been added or removed. This form is also located on the CTMS Home tab under Helpful Links.

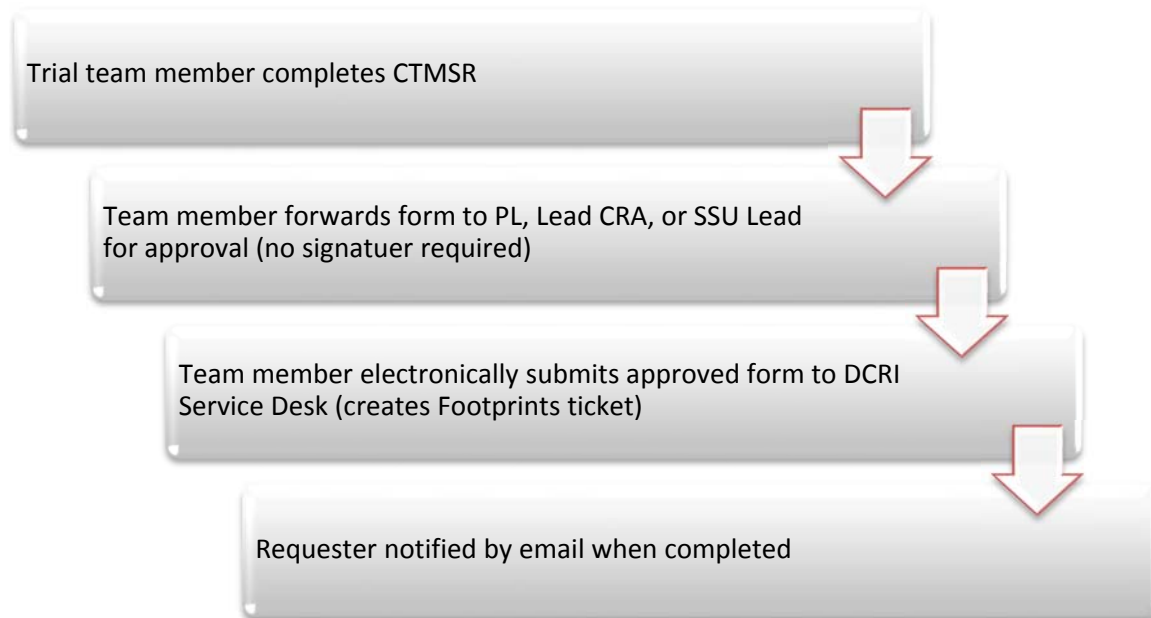
MAINTENANCE

Clinical Trial Management System Request (CTMSR) Form

A CTMSR form is required for addition, deletion or change of protocol configuration or data. The CTMSR form is located on the DCRI Intranet and on the CTMS Home tab under Helpful Links. Examples of items that can be included in the CTMSR include:

- Data changes (Row ID required)
- Activity Plan updates
- Trial Safety Letters
- Changes to custom templates

CTMSR Process



Associated Costs

Most requests can be handled without cost to the Project. The following requests will require funding by the Project:

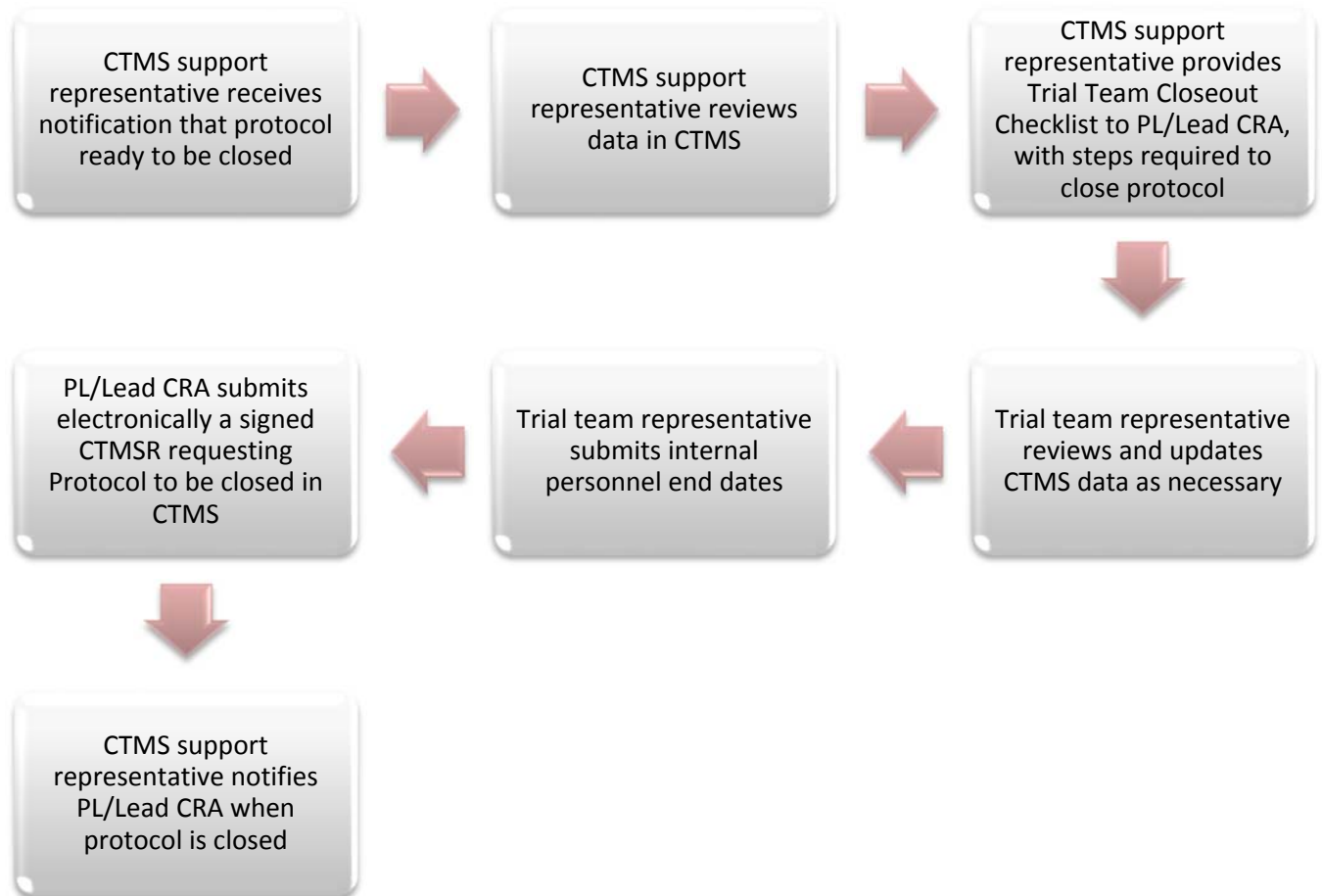
- Custom Report
- Data Transfers – During Protocol or at Protocol close-out
- Other – CTMS support representative will help determine if the request is Out of Scope

The PL will need to coordinate with their BD Associate to ensure the cost is/was included in the original budget or if a Change Order needs to be created. The time it takes to complete each Out of Scope (OOS) request will vary, based on the request.

PROTOCOL CLOSE-OUT

All protocols that have been configured in CTMS must be closed out appropriately at the end of the study.

Process



Note: Data still available through CTMS support representative after close-out

Conversation Log

By email request to DCRI Service Desk from the PL or Lead CRA, at close-out of the Protocol, a CD of all conversations tracked for the protocol can be provided.

TRIAL TEAM SUPPORT

CTMS Super Users

CTMS Super Users are available to help solve problems as they arise. Refer to the CTMS Learning Center on the DCRI intranet for a list of Super Users.

CTMS Training

Besides monthly offerings of the basic CTMS training, Refresher training and Lunch & Learn Sessions are held regularly. These one-hour sessions cover a wide range of CTMS topics and offer a question-and-answer period.

CTMS Learning Center

The CTMS Learning Center on the DCRI Intranet provides a central location to access CTMS reference materials, forms, FAQs, and more.

DCRI Service Desk

Submit **all** CTMS requests to the DCRI Service Desk. As needed, requests will be routed to a CTMS support person for handling.

APPENDIX A – CTMS ACCESS FOR EXTERNAL, NON-DCRI PERSONNEL

The first step in the process for obtaining CTMS access for external personnel (non-DCRI employees) is to complete and submit the External New Hire Notification Form (EENF). This form is also referred to as the External Employee Notification Form (EENHF). The new hire process can take up to 3 weeks to complete.

Note: This form is located on the HR page of the DCRI Intranet (DCRI Home>Groups>Human Resources). Click “Recruitment/Employment” at the top of the page; scroll down to Step Five 5, “Non-Traditional Employee” and then click the link “External Employee Notification Form (EENHF).

Required fields for external personnel requiring a generic DCRI Network Account are:

- First Name, Middle Name, Last Name
- Last 4 digits of Social Security # **OR** first 4 digits of Date of Birth (preferred)
- Start Date
- DCRI Contact/Sponsor - (PL/CTM at DCRI who is requesting this account)
- Additional Notes - Include in this section the justification for the network account. State that this person needs a generic DCRI network account only; (access will not be needed to Time Tracking and a Lotus Notes account will not be needed).
- If access to DCRI network resources (i.e., public folders on K: drive) is needed, the user must have a DHE account and must set up their challenge-response and unique Net ID password through the OIT web site. These users will be logging on to the DHE domain rather than the DCRI domain. If access to DCRI network resources will be needed, this information may be included on this form.

Email the completed form to DCRINHF. It must be emailed by an internal DCRI Contact/Sponsor - CTM, PL or Lead CRA. After approval by the DCRI Chief Human Resources Officer, it will be distributed to the necessary departments for completion of the DCRI Network Account. A completion notification will be sent from IT Operations and Project Startup to the requester. This notification will provide detailed instructions for accessing the DCRI Network.

Note: Network passwords must be changed every 3 months using through Citrix. In addition, Generic DCRI Network Accounts expire every 6 months and must be renewed if the account is to remain active. Email notification to the DCRI Service Desk from the DCRI Sponsor/Contact, including the required information listed above, is sufficient to renew the account. If the password is not changed within 3 months and expires, the DCRI Sponsor/Contact must call the DCRI Service Desk and request the password change on behalf of the user.

In addition to the above process, the training requirements for CTMS access, and a CTMS Access form must be completed prior to CTMS access being granted. Questions about completion of this form should be directed to DCRI Human Resources.

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