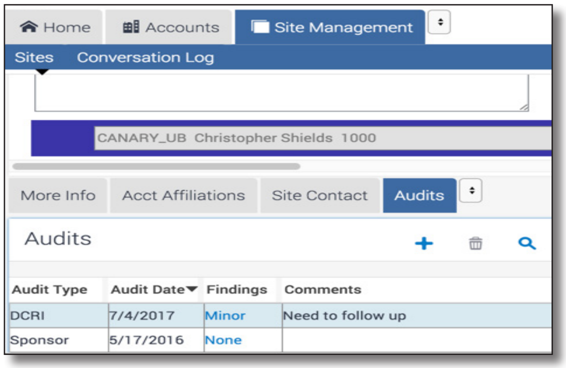
Duke Clinical Research Institute
Upgrade Bulletin

CTMS
3.14.1 Upgrade

The CTMS has been upgraded to version 3.14.1. This bulletin summarizes the key features and enhancements in this software release.

New Audits View Tab for Sites

On the Site Management screen tab, you can now use the new **Audits** view tab to track DCRI audits, FDA audits, sponsor audits, and 483s.



▶ To add an audit record

1. Click the **Site Management** screen tab.
2. Locate and highlight the site to which you would like to add an audit record.
3. Scroll down and click the **Audits** view tab (you might need to click the drop-down arrow to the right of the view tabs to locate the Audits tab).
4. Click the + button.
5. Use the following table as a guideline for completing an audit record. Fields marked with an asterisk are required.

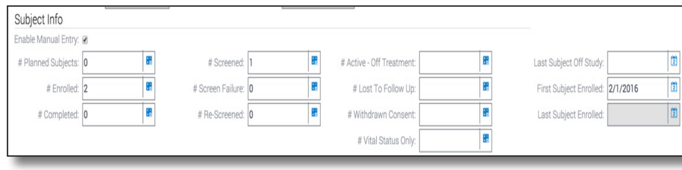
Field	Guidelines
Audit Type *	Select the type of audit from the drop-down list. Choices include *DCRI*, *FDA*, *IRB* and *Sponsor*.
Audit Date *	Enter the date when the audit occurred.
Findings	Enter the audit findings.
Comments	Enter additional comments, if needed.

6. Save your record, by pressing **Ctrl + S**.

Note: Refer to your protocol's *Data Entry Guideline (DEG)* for specific instructions regarding who is responsible for managing audit records and which details to capture.

Manually Tracking Enrollment Statuses on Site Form

On a site's **More Info** view tab, you can now manually track enrollment information in the **Subject Info** area.



Important! If your protocol is using automated enrollment via DCRI's Rando enrollment database, you should not change enrollment numbers in this area, as they will no longer match the actual numbers being tracked on the site's **Subjects** view tab.

▶ To manually enter enrollment status information at the site level

1. Click the **Site Management** screen tab.
2. Locate and highlight the site for which you would like to manually track enrollment status information.
3. Scroll down and click the **More Info** view tab (if needed).
4. Check the **Enable Manual Entry** check box, located just under the **Subject Info** section heading.
   All fields in this area are now open for editing.
5. Use the following table as a guideline for editing these fields.

Field	Guidelines
# Planned Subjects	Enter the number of planned subjects for the site.
# Enrolled	Enter the number of subjects that have enrolled at the site.
# Completed	Enter the number of subjects that have completed the site.
# Screened	Enter the number of subjects that have been screened for the site.
# Screen Failure	Enter the number of subjects that were screen failures at the site.

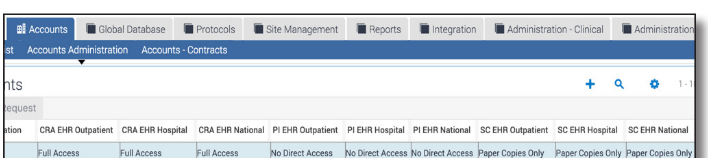
Field	Guidelines
# Re-Screened	Enter the number of subjects that were re-screened at the site.
# Active - Off Treat-ment	Enter the number of subjects that are active, but no longer receiving treat-ment a the site.
# Lost to Follow Up	Enter the number of subjects that were lost due to lack of follow-up at the site.
# Withdrawn Con-sent	Enter the number of subjects that with-drew from the study from the site.
# Vital Status Only	Enter the number of subjects at the site, that may only be contacted to confirm status of living or deceased.
Last Subject Off Study	Enter the date when the last subject went off of the study for the site.
First Subject En-rolled	Enter the date when the first subject was enrolled at the site.
Last Subject En-rolled	Enter the date when the last subject was enrolled at the site.

6 Save your record, by pressing **Ctrl** + **S**.

Note: Refer to your protocol's *DEG* for specific instructions regarding your site's **Subject Info** area.

View Types of Access to Patient Electronic Health Records (EHR)

There are new fields available on the **Accounts** screen tab that allow you to see what kind of access has been assigned to the Clinical Research Associate (CRA), Principal Investigator (PI), and Study Coordinator (SC) for viewing and/or editing patient Electronic Health Records (EHR).



The following categories are available to display access details for the CRA, PI, and SC:

EHR Category	Description
EHR Outpatient	Displays the type of access the CRA/PI/SC has to EHR outpatient information.
EHR Hospital	Displays the type of access the CRA/PI/SC has to EHR hospital information.
EHR National	Displays the type of access the CRA/PI/SC has to EHR national (typically Vet-eran's Administration) information.

The following access types are available for each category:

Access Type	Access Level
Full Access	User can view all EHR data via com-puter login.
No Direct Access	Also known as "over the shoulder" ac-cess, user can view records via computer only with a Full Access user who has logged into the EHR.
Paper Copies Only	Cannot access EHR data via computer. Can only view data on paper printouts.

Note: These fields are read-only with this release. Future enhancements will allow users to edit these fields.

New Physician Profile Fields on Contact Form

New fields have been added to the contact record to enhance search capabilities for the PI and SC.

► To view Physician Profile fields

1 On the **Contacts** screen tab, locate and highlight the contact record.

2 Scroll down to the form area to view the Physician Profile area. You can also add these fields to the list view by clicking the menu icon  and selecting **Columns Displayed**.

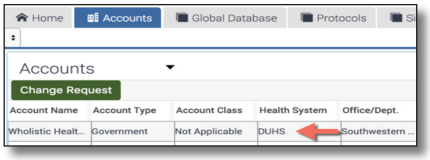
The following fields are available:

Field	Description
Date of Birth	Displays the contact's date of birth
Gender	Displays the contact's gender.
Race	Displays the contact's race.
Ethnicity	Displays the contact's *Hispanic or Latino* ethnicity.
Specialties	Displays the contact's specialties. To view the entire list of specialties for the contact, click the selection icon in this field.
Population	Displays the contact's population (*Adolescent, Adult, All Ages, Geriatric, Neonatal,* and/or *Pediatric*).
Areas of Interest	Displays the contact's areas
CV Received	Displays the date the contact's CV was received by DCRI.
PI Experience Since	Displays the year the contact began serving as a PI.
Sub I Experience Since	Displays the year the contact began serving as a Sub-Investigator.
SC Experience Since	Displays the year the contact began serving as an SC.
Clinical Background	Displays whether or not the contact has a clinical background (*Yes* or *No*).
Employed By	Displays by whom the contact is employed (*Contract Agency*, *Hospital*, *SMO*, or *Site*).
Research Availability	Displays the contact's research availability (*Full-time* or *Part-time*).
Networks	Displays the networks to which the contact belongs. Includes networks that are not necessarily tracked elsewhere in the CTMS. To view the entire list of networks for the contact, click the selection icon in this field.

Note: These fields are read-only with this release. Future enhancements will allow users to edit these fields..

Note: Refer to your protocol's *Data Entry Guideline (DEG)* for specific instructions regarding how these fields will be used.

New Health System Indication for Accounts



On the **Accounts** screen tab, there is a new field, **Health System**, which, if applicable, displays the name of the health system to which the account is affiliated.

Note: These fields are read-only with this release. Future enhancements will allow users to edit these fields..

Note: Refer to your protocol's *Data Entry Guideline (DEG)* for specific instructions regarding how these fields will be used.

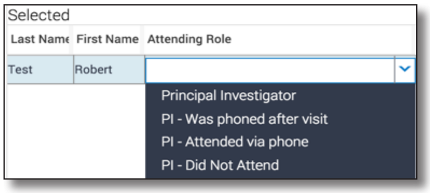
Ability to Track Networks

There are two kinds of networks that can now be tracked in the DCRI.

- On the **Protocols** screen tab, you can display the protocol's affiliated network, such as PTN or ARLG, in the new **Network** field. To populate this field, please contact *CTMS Support* via a *DCRI Service Desk* ticket.
- On the **Contacts** screen tab, you can track networks for those we don't track elsewhere in the CTMS, in the new **Networks** field. See the *New Physician Profile Fields on Contact Form* section of this Upgrade Bulletin.

Note: CTMS administrators are currently developing reports that will be able to capture both types of networks.

Updates to Trip Report Attendees List



There are new *PI* options in the **Attending Role** drop-down list when you are adding attendees to a trip report. These new roles allow you to capture the PI's level of involvement with the visit.

Getting Help

CTMS documentation, additional training and resources can be found on the **CTMS Learning Center** (https://dcri.org/education-training/ctms-learning-center).

If you have additional questions or issues that you would like to discuss with CTMS support representatives, please email your requests to the **DCRI Service Desk** (dcriservicedesk@dm.duke.edu).