December 2016

CTMS
Site Management

User Reference Guide

Duke Clinical Research Institute

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REFERENCE GUIDE CONVENTIONS

What You Need to Know Before Using This Reference Guide

To gain maximum benefit from the material presented in this reference guide and the associated training course, you should have a working knowledge of personal computers (PCs), Microsoft Windows, and the DCRI network. If you need training in any of these areas, send an email message to IT Training (at *dcriittrain@dm.duke.edu*) requesting assistance.

Visual Aids Used in This Reference Guide

This reference guide uses the following visual aids to indicate notes, tips, and warnings.

NOTE: The note icon indicates a clarification or supplemental information. Content that is too extensive for a note appears inside a shaded box instead. Read a note or a shaded box if you want to learn more about a particular step or procedure.

TIP: The tip icon indicates a helpful hint or keyboard shortcut. Read a tip if you want to learn a quicker or easier way to perform a particular step or procedure.

WARNING: The warning icon indicates that performing a particular step or procedure under the stated conditions causes a significant problem or concern. Always read warnings.

SITE MANAGEMENT OVERVIEW

Site management within DCRI's Clinical Trial Management System (CTMS) includes many activities, such as creating sites, logging conversations, and tracking site statuses, milestones, and documents.

Before you begin, you must understand the data structure within the CTMS as well as the relationship between global and site data.

Defining Sites in the CTMS

In the CTMS:

♦ *Sites* are defined by the association of the principal investigator (contact), an account, and a protocol.

♦ A *contact* is a person related to the clinical research process, including site personnel (for example, principal investigator or study coordinator).

♦ An *account* is an organization or entity, such as a hospital or clinic, but can also be a sponsor, lab, or IRB.

♦ A *protocol* is a trial.
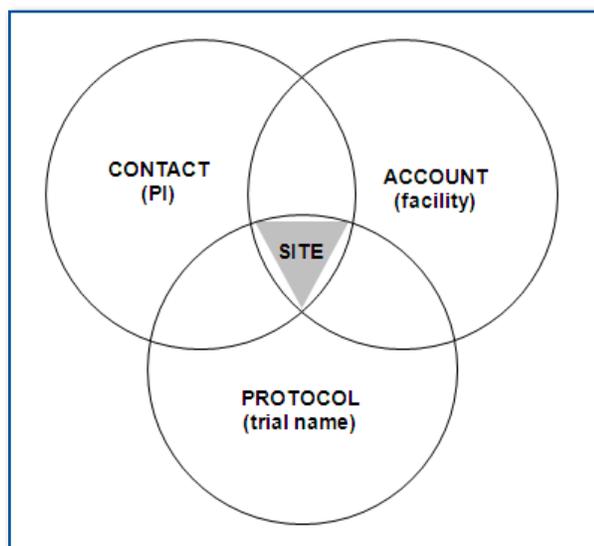
Global Data vs. Site Data

When you define a *site* by making contact and account associations, you are building connections to the *global* CTMS database. All related data elements, such as phone numbers and addresses, link to the global record.
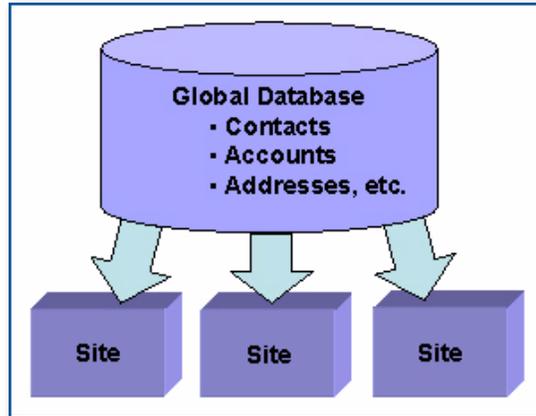
Additions and change requests (see "Requesting Changes to Global Contact & Account Information" on page 63) must be verified by the DCRI Service Desk because they are made at the global level and could affect other protocols and sites.

Data Entry Guideline

The Data Entry Guideline (DEG) provides protocol-specific instructions to the project team about CTMS data entry requirements, types of information needed, and who is responsible.

♦ The standard DEG template is mandatory for all protocols using DCRI-provided site management and/or site monitoring services.

♦ Some examples of data gathered in the DEG:

♦ Documents to be tracked (including version date definition and statuses to be tracked per document)

♦ Site Monitoring instructions (site visit naming convention, templates to be used)

Locating the Protocol-Specific DEG

The DEG is customized at the beginning of the protocol, by the Lead CRA and CTMS Support. It is then attached to **Protocols** screen tab > **Attachments** view tab, so that the entire team can access it anytime.

CREATING A SITE

Follow these steps to add a new site to the CTMS. Some steps are optional, depending on the specific site you are creating. For example, not all sites have additional accounts. Refer to your protocol's Data Entry Guideline (DEG) document for protocol-specific questions regarding data entry in the CTMS system.

1 **Define the site associations** (page 10). Define the site number, project number (protocol), PI (principal investigator), region, account, and address.

2 **Complete the PI's contact record** (page 17). Associate the PI's address, email address, and phone/fax numbers to the site by selecting them from the global contact record. Also, specify the PI's preferred communication method and start date.

3 **Associate additional contacts to a site** (page 21). Associate additional site personnel, such as the study coordinator, to the site.

4 **Associate additional accounts to a site** (page 25). If your site uses additional accounts, associate them to the site.

5 **Verify Activity Plans applied to a site** (page 29). Verify that the pre-defined lists of required activities—milestones, documents, training, safety letters, and other requirements—have been applied and appear on the appropriate view tab for the site.

> **TIP**: When you begin to add new data, you must either complete all required fields or press the **Esc** key to get out of edit mode (no changes will be saved).

Querying the Site

Before you create a site, always query the database in your protocol to ensure it does not already exist, to avoid duplicate entries.

1 Click the **Site Management** screen tab.

2 To query for the site, do one of the following:

a At the Search box, click the drop-down arrow in the left field to select a category (column name), such as **Site #**, **PI**, or **Account**.

b On the right field, enter one or more words to narrow your search within that category.

> **TIP**: You can enter an asterisk (*) as a wildcard.

c Click the **Go** button.

Or

a On the screen toolbar, click the **Query** button (🔍).

b Define your query, most commonly using the **Site #**, **PI**, and **Account** fields. See "Query Basics" in IT Training's *CTMS Fundamentals* user reference guide, to further define your query.

c Click **Go** (➔) on the screen toolbar.

The results of your query appear beneath the Site Management screen toolbar. If no results are returned, the site does not currently exist in the global database and must be added.

1. Defining the Site Associations

If you query the database (see "Querying the Site") and do not find the correct site (site number/PI/account combination), then create the site by defining the main site associations: site number, project number (protocol), PI, region, account, and address.

1   Go to the **Site Management** screen.

2   Remember: to prevent duplicates, always query for the site first. (See previous procedure.)

3   On the site form, click the plus sign (**+**).

Empty fields appear for the new site record.

The next few pages detail how to complete the **Site Number**, **Protocol/Project Number**, **Region**, **PI Last Name/First Name**, **Account**, and **Account Address** fields.

Entering a Site Number

In the **Site #** field, enter the DCRI number unique within the protocol that identifies the site.

> **NOTE**: Refer to your protocol's DEG (see *Data Entry Guideline* on page 8) to determine the Site # naming convention you should use. Site numbers can be edited manually at any time to accommodate "renumbering" requests.

Selecting the Protocol and Project Number

1   Click the selection icon in the **Protocol** field.

The Pick Protocol window appears.

2   Select the correct protocol.

3   Click OK .

Selecting a protocol automatically populates the *Protocol*, *Project Number*, and a few other fields.

Selecting the Region

1   In the **Region** field, click the selection icon.

The Pick Region window appears.

2   Select the region (organizational designation used to group the protocol's sites).
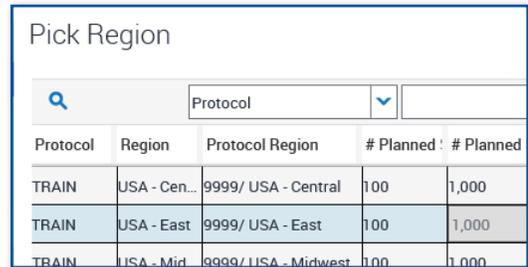
> **NOTE**: Refer to your protocol's DEG for protocol-specific regions.

3   Click OK .

Selecting the PI

1   In the **PI Last Name** field, click the selection icon.

The Pick Contacts window appears.

2   Query for the name, and then do one of the following:

♦   If the correct name is listed, select the contact, and then click **OK**. Proceed to "Selecting the Account" on page 14.

Or

♦   If the correct contact name is not listed, click the plus sign, complete the new row using the following guidelines, and then click **OK**.
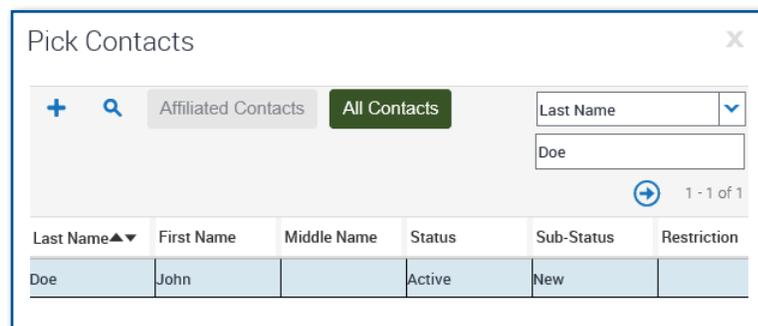
a Enter the PI's **Last Name** and **First Name**.

b In **Address Line 1**, click the selection icon to open the **Pick Address** window, query for the address using the **City** and **Prov/ State** fields, and then do one of the following:

◊ If the correct address *is* listed:

1 Select the address.

2 Click **Add** to add the address to the **Selected** pane.

3 Click the **Address Type** drop-down arrow to select the correct type of address.

4 If necessary, enter the correct date in the **Start Date** field.

5 Click **OK**.

The Pick Contact window reappears.

6 Click **OK**.

The new site window reappears.

◊ If the correct address is *not* listed:

1 Click **New**.

A new row appears.

2 Complete the fields, and then click **OK**.

The Pick Contact window reappears.

3 Click **OK**.

The new site window reappears.

c In **Primary Phone**, click the selection icon, select the correct phone number, and then click **OK**. If the phone number is not listed, click **New** to complete a new row.

d In **Primary Fax**, click the selection icon, select the correct fax number, and then click **OK**. If the fax number is not listed, click **New** to complete a new row.

e In **Primary Email**, click the selection icon, select the correct email address, and then click **OK**. If the email address is not listed, click **New** to complete a new row.

f In **Type**, select the appropriate contact record (not site affiliation) in the drop-down list.

When you click **OK**, you submit the new contact information to the DCRI Service Desk for verification, and the new site setup window reappears.

Selecting the Account

1 Click the selection icon in the Account field.

The Pick Account window appears.

2 Query for the account, using the City and Prov/State fields.

3 Do one of the following:

♦ If the correct account is listed, select the account, and then click **OK** . Proceed to Step 4.

Or

♦ If the correct account is not listed, click the plus sign, complete the new row using the following guidelines, and then click **OK**.

a Enter the **Account Name**.

b Select the **Account Type** from the drop-down list.

c If applicable, based on the Account Type, select the appropriate **Account Class** from the drop-down list.

d In **Address Line 1**, click the selection icon to open the **Pick Address** window, query for the address using the **City** and **Prov/State** fields, and then do one of the following:

♦ If the correct address for the account is listed, select it, and then click **OK**.

Or

♦ If the correct address is not listed, click **New**, complete the new address record, and then click **OK**.

e In **Primary Phone**, click the selection icon to open the **Account Phone Numbers** window, select the correct phone number, and then click **OK**. If the correct phone number is not listed, click **New**, enter the new phone number record, and then click **OK**.

f In **Primary Fax**, click the selection icon to open the **Account Phone Numbers** window, select the correct fax number, and then click **OK**. If the correct fax number is not listed, click **New**, enter the new fax number record, and then click **OK**.

NOTE: Two fields are read-only.

♦ The **Account Status** field shows the status set by the DCRI Service Desk. This can be *Active* (can be associated to a site) or *Inactive* (cannot be associated to a site).

♦ The **Account Sub-Status** field shows the sub-status set by the DCRI Service Desk. This can be *New* (recently added to the global database), *Unverified* (change requested to the Service Desk, but not yet verified), or *Verified* (CTMS Administrator has verified account information).

When you click OK, you submit the new account information to the DCRI Service Desk for verification, and the new site setup window reappears.

4 Save the record by pressing **Ctrl+S**.

Verifying the Account Address

1 If the account address fields are not automatically populated after selecting the account or do not show the correct address for the site, click the selection icon in the **Address Line 1** field.

The Pick Address window appears, listing addresses that are already associated to the account.

2 Select the correct address for the site.

NOTE: If the correct address is not listed in the **Pick Address** window, click **Cancel**, and then submit a change request to add the new address (see "Adding or Updating Account Information" on page 67).

3 Click **OK**.

Selecting an address automatically populates the Office/Dept, Address Line 1, Address Line 2, Address Line 3, City, Prov/State, Postal Code, and Country fields.

4 Save the record by pressing **Ctrl+S**.

TIP: To view additional information about a site, click the **More Info** view tab in the lower portion of the window.

Additional Fields in the Site Record

The following table defines additional fields that appear in the site record. These fields, not required at site creation, are explained further throughout this guide.

Field	Guidelines
SM First/Last Name	Click the selection icon in the **SM Last Name** field to select the Site Manager (person primarily responsible for site management of a site) from the list of **Internal Personnel**.
CRA First/Last Name	Click the selection icon in the **CRA Last Name** field to select the site's primary Site Monitor from the list of **Internal Personnel**.
SSU First/Last Name	Click the selection icon in the **SSU Last Name** field to select the Site Startup (SSU) representative assigned to your protocol.
Site Source	If applicable, select the source of the site referral from the drop-down list.
Last PI/Account Visit	Automatically calculated from the PI and account records to indicate when the last visit occurred.
Status	Click the selection icon in this field and then click **New** to complete the new status row. See "Site Statuses and Milestones" on page 31.
Sub-Status	(read-only) Automatically populated when you complete the **Status** field.
Status Comment	
Status Date	
Time Zone	Select the site's time zone in the drop-down list.
Interest Pack Sent	(read-only) Automatically populated when each milestone is recorded. See "Tracking Site Milestones" on page 35.
Reg Pack Sent	
Contract Sent	(read-only) Automatically populated with information entered on the site's **Contracts** tab by the protocol's SSU representative.
Contract Executed	

Field	Guidelines
Reg Complete	(read-only) Automatically populated when each milestone is recorded. See "Tracking Site Milestones" on page 35.
IP Sent	
Starter Box Sent	
Activated for Enrollment	(read-only) Shows the date that is entered into the **Completed** field for the **Activated for Enrollment** milestone on the **Milestones** view tab.
Comments	Enter comments about the site, up to a maximum of 1,500 characters.
# Enrolled	(read-only) Automatically populated with the number of enrolled subjects for the site. This field only appears in the site's list view.

2. Completing the PI's Contact Record

When you complete Step 1 of the site creation process (see "1. Defining the Site Associations" on page 11), you select the PI, but you do not define the PI's contact information, such as address and phone numbers. The PI contact record must be completed by filling in this information as it relates to the PI's association to the site.

1   Click the **Site Contact** view tab for the site.

Fields for the PI's record appear.

2   Use the following table as a guideline for completing the PI's record.

Field	Guidelines
Address Line 1	**1** Click the selection icon in this field to open the **Pick Address** window. A list of addresses associated to the *global* contact record appears. **2** Select the correct address, and then click **OK**. **Note**: If the correct address is not listed in the **Pick Address** window, click **Cancel** and then submit a change request to add the new address (see "Adding or Updating Contact Information" on page 63).
Preferred Communication	Select the best way to communicate with the PI from the drop-down list.
E-Mail	**1** Click the selection icon in this field to open the **Pick Email** window. **2** Do one of the following: ♦ If the correct email address is listed, select it, and then click **Select**. **Or** ♦ If the correct email address is *not* listed, click the plus sign button, complete the email information form, click **OK**, and then click **Select**.
EDC Access Needed	Select the checkbox to indicate that the PI needs access to the clinical electronic data capture (EDC) system.
EDC Training	**1** Click the selection icon in this field. The Pick EDC Training window appears. **2** Click the plus sign button. **3** Select the EDC system from the **EDC Training** drop-down list. **4** In the **EDC Training Date** field, enter the date that the training occurred. **5** Click **Pick**.

Field	Guidelines
EDC Training Date	(read-only) Automatically populated when you complete the **EDC Training** field.
Start Date	Enter the date that the PI's association with the site became effective. The default value is today's date.
End Date	If necessary, enter the date that the PI's association with the site is no longer valid. **Warning**: Do not add a future end date to a record. Records with end dates will not appear in search lists throughout the CTMS.
Bio/CV/ML	Contains a hyperlink to the contact's BioSketch, CV, and/or Medical License located in a DCRI network folder. This hyperlink is added by the DCRI Service Desk.

Associating the PI's Phone/Fax/Pager

1 On the **Site Contact** view tab, select the PI.

2 Scroll to the bottom of the **Site Contact** view tab to see the **Phones** applet, a sub-view attached to the **Site Contact** view.

Phones				＋ 🗑
Type	Number	Ext:	Manual Dialing flag	Location

3 Click the plus sign (＋).

The Add Phones dialog window appears, listing numbers currently associated to the PI's global contact record.

Add Phones

＋ 🔍 | Type × ∨ |

Type	Number	Ext:	Start Date	E
Fax	205-555-2223		7/3/2007	
Pager	205-555-0997		7/3/2007	
Phone	205-555-9000		7/3/2007	
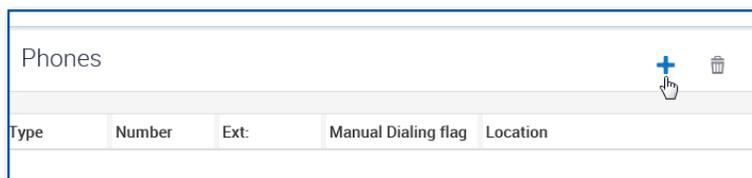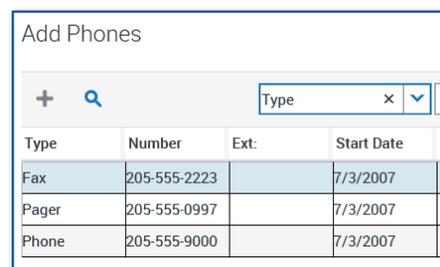
4 Select the primary phone/fax/pager number. To select more than one number, hold down the **Ctrl** key while clicking on the correct records.

> **NOTE**: If the correct number is not listed in the **Add Phones** window, click **Cancel** and then submit a change request to add the new number. (See "Adding or Updating Account Information" on page 67.)

5 Click **Add**.

The numbers appear on the Phones applet.

Changing a Site's Principal Investigator

Because the PI is recorded in the main site record, and not just in the **Site Contact** view tab, changes must be reflected in both areas.

1 Click the **Site Management** screen tab.

2 Query for the site.

3 In the site record, click the selection icon in the **PI Last Name** field.

The Pick Contacts dialog appears.

4 Query for and select the new PI's contact record.

5 Click OK.

6 Click the **Site Contact** view tab for the site.
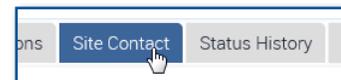
7 Refresh the page so all fields are updated.

On the Site Contact view tab, the *new* PI record replaces the old PI record. This is because the old PI is viewed as an "inactive" record now.

8 To view both PI records, select **All** from the drop-down list to the right of the search box.

The *new* PI record shows today's date in the **Start Date** field, and the *old* PI record shows today's date in the **End Date** field.

ry Specialt	Start Date	End Date	Bio
esiology	11/22/2016		
	4/15/2009	11/22/2016	

9 If necessary, change the **Start Date** field for the *new* PI, and the **End Date** field for the *old* PI to properly reflect the date that the transition occurred.

10 Complete the empty fields (Address, Preferred Communication, EDC Access/EDC Training, E-Mail, Phones) for the new PI record.

> **NOTE**: If you do not need to maintain the old PI's record for this site, send a CTMS Request (CTMSR) form to the DCRI Service Desk (*dcriservicedesk@dm.duke.edu*) requesting that the record be deleted from the list of site contacts. See "Appendix A: CTMS Request Form" on page 75.

3. Associating Additional Contacts to a Site

Use this procedure to associate additional contacts, such as the study coordinator, to a site.

1 Go to the **Site Management** screen.

2 Locate the site by running a query on the **Site** # field. (See "Querying the Site" on page 10.)

3 Scroll down to click the **Site Contact** view tab.
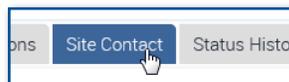
By default, only *active* site contacts (records that do not have a date in the **End Date** field) display. To view *all* site contacts, select **All** from the drop-down list.

4 If necessary, query for the site contact to make sure that it does not already appear in the list of site contacts for the site.

5 On the **Site Contact** view tab, click the plus sign (**+**).

A new, blank record appears in the list.

6 Use the following table as a guideline for completing the new record.

* indicates a required field

Field	Guidelines
Role*	Select the contact's role at the site from the drop-down list.

Last Name*	**1** Click the selection icon in this field.
	The Pick Contacts window appears.
	
	2 Locate the name of the site contact, using the query options at the top of the window.
	
	Tip: For best results, query for the contact's name by clicking **Query** (🔍), and then enter the first few letters of the **Last Name** and the first letter of the **First Name**, along with the **Prov/State** field.
	
	3 Do one of the following:
	♦ If the correct name is listed, select the contact, and then click OK .
	Or
	♦ If the correct name is *not* listed:
	
	   a Click the plus sign (**+**).
	
	   b Enter the contact's name in the **Last/First/ Middle Name** fields.
	
	   c In the **Address Line 1** field, click the selection icon to view a list of all addresses in the CTMS database. Query for and select an existing address, or click the plus sign to enter a new one, and then click OK .
	
	   d In the **Primary Phone** field, click the selection icon to open the **Contact Phone Numbers** window, click the plus sign to add the new phone number, and then click OK .
	
	   e In the **Primary Fax** field, click the selection icon to open the **Contact Phone Numbers** window, click the plus sign to add the new fax number, and then click OK .
	
	(continued on the next page)

Field	Guidelines
(continued)	**f** In the **Primary Email** field, click the selection icon to open the **Contact Email Addresses** window, click the plus sign to add the new email address, and then click `OK`.
	g Click `OK` to close the **Pick Contacts** window.
	The new contact information is submitted to the DCRI Service Desk for verification, and the Site Contacts view tab reappears.
	Selection of a name automatically populates the **First Name** and **Primary Specialty** fields.
Office/Dept	(read-only) Automatically populated after an address is selected in the **Address Line 1** field.
Address Line 1	**1** Click the selection icon in this field. The Pick Address window appears, listing all addresses associated to the *global* contact record.
	2 Select the correct address, and then click `OK`. **Note**: If the correct address is not listed in the **Pick Address** window, click **Cancel**, and then submit a change request to add the new address (see "Adding or Updating Contact Information" on page 63).
Preferred Communication	Select the best way to communicate with the contact from the drop-down list.
EDC Access Needed	Check the box to indicate that the contact needs access to the clinical electronic data capture (EDC) system.
EDC Training	**1** Click the selection icon in this field to open the **Pick EDC Training** window.
	2 Click the plus sign (**+**).
	3 Select the EDC system from the **EDC Training** drop-down list.
	4 In the **EDC Training Date** field, enter the date that the training occurred.
	5 Click **Pick**.

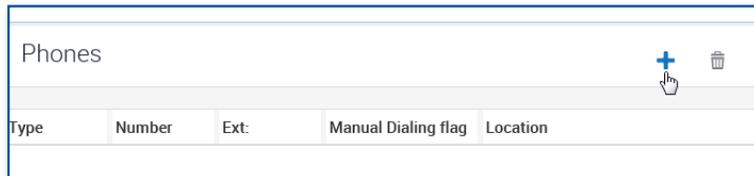| Field	Guidelines
EDC Training Date	(read-only) Automatically populated when you complete the **EDC Training** field.
Primary Specialty	Automatically populated when you select a name in the **Last Name** field.
E-Mail	**1** Click the selection icon in this field. The Pick Email window appears. **2** Do one of the following: ♦ If the correct email address is listed, select it, and then click **Select**. **Or** ♦ If the correct email address is not listed, click **Cancel**, and then submit a change request to add the email address to the contact's global contact record. (See "Requesting Changes to Global Contact & Account Information" on page 63).
Start Date	Enter the date that the contact's association with the site became effective. The default value is today's date.
End Date	If necessary, enter the date that the contact's association with the site is no longer valid. **Warning**: Do not add a future end date to a record. Records with end dates will not appear in search lists throughout the CTMS.
Bio/CV/ML	Contains a hyperlink to the contact's BioSketch, CV, and/or Medical License located in a DCRI network folder. This hyperlink is added by the DCRI Service Desk.

7 Save the record by pressing **Ctrl**+**S**.

TIP: If the same person has multiple roles, copy the record (**Ctrl+B**) and change the role. You may have to edit some other fields as well.

Associating the Contact's Phone/Fax

1   On the **Site Contact** view tab, select the contact.

2   Scroll to the bottom of the **Site Contact** view tab to see the **Phones** applet, a sub-view attached to the **Site Contact** view.

Phones				+ 🗑
Type	Number	Ext:	Manual Dialing flag	Location

3   Click the plus sign (**+**).

The Add Phones dialog window appears, listing numbers currently associated to the PI's global contact record.

Add Phones

	+ 🔍	Type	× ⌄	
Type	Number	Ext:	Start Date	E...
Fax	205-555-2223		7/3/2007	
Pager	205-555-0997		7/3/2007	
Phone	205-555-9000		7/3/2007	
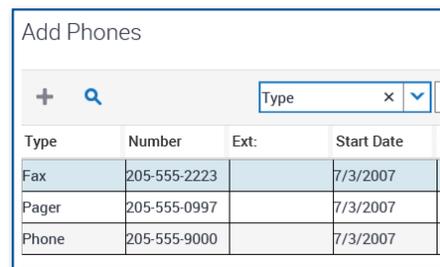
> **NOTE**: If the correct number is not listed in the **Add Phones** window, click **Cancel** and then submit a change request to add the new number. (See "Adding or Updating Contact Information" on page 63.)

4   Click **Add**.

The numbers appear in the Phones applet. Checkmarks indicate the primary numbers for the site contact.

4. Associating Additional Accounts to a Site

Use this procedure to associate an additional account, such as an Institutional Review Board (IRB) or lab, to a site.

> **NOTE**: All protocols are required to track IRB information for all sites at an *Interested* or *Active* status.

1   Go to the **Site Management** screen.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Scroll down to click the **Acct Affiliations** view tab at the bottom of the window.

...re Info	Acct Affiliations	Site Contact

4 If necessary, query for the account to make sure that it does not already appear in the list of accounts for this site.

5 On the **Acct Affiliations** view tab, plus sign (**+**).

A new blank record appears.

6 Use the following table as a guideline for completing the new record.

Field	Guidelines

Account Name	**1** Click the selection icon in this field.
	The Pick Account window appears.
	
	2 Locate the account, using the query options at the top of the window.
	Tip: For best results, query on the **City**, **Prov/State**, and **Account Name** fields (enter the first few letters of the account name to best narrow your search).
	
	3 Do one of the following:
	♦ If the correct account is listed, select it, and then click OK .
	    Or
	♦ If the correct account is *not* listed:
	    a Click the plus sign (**+**).
	    a Complete the new row.
	    b Click OK .
	The new account information is submitted to the DCRI Service Desk for verification, and the Acct Affiliations view tab reappears.
	
	Selection of an account name automatically populates the Status, Sub-Status, Account Type, Account Class, and Parent Account Name fields.

Account Role	From the drop-down list, select an option to designate the role for the account's affiliation to the site.

Field	Guidelines
Start Date	Enter the date that the account association began for the site affiliation. The default value is today's date.
End Date	If necessary, enter the date that the account association ended for the site affiliation. **Warning**: Do not add a *future* end date to a record. Records with end dates will not appear in search lists throughout the CTMS.
Office/Dept	(read-only) Automatically populated when an address is selected in the **Address Line 1** field.
Address Line 1	**1** Click the selection icon in this field. The Pick Address window appears. **2** Select the correct address for the contact's affiliation to the site. **Note**: If the correct address is not listed in the **Pick Address** window, click **Cancel** and then submit a change request to add the new address (see "Adding or Updating Contact Information" on page 63). **3** Click OK . Selection of an address automatically populates the Office/Dept, Address Line 1, Address Line 2, Address Line 3, City, Prov/State, Postal Code, and Country fields.
Parent Account Name	(read-only) Automatically populated when an account is selected in the **Account Name** field.

7 Save the record by pressing **Ctrl**+**S**.

Viewing Protocol Experience for an Account

Protocol experience for accounts that are affiliated on a site's **Acct Affiliations** view tab can also be found on the main **Accounts** screen's **Protocol Experience** view tab.

For example, the image below shows the **Acct Affiliations** tab for a site, viewed from the **Site Management** screen tab, showing *Iowa General Hospital* as the *CT Facility*. To find out where else this account appears in CTMS, complete the steps below.

1 Click the **Accounts** screen tab.

A listing of accounts appears.

2 Highlight a particular account.

3 Scroll down to click the Protocol Experience view tab.

A list appears of all records in CTMS that include this account.

5. Verifying Activity Plans

An activity plan is a pre-defined protocol-specific list of required activities—milestones, documents, and training—that, when applied to a site, will pre-populate the appropriate activity view tab.

Activity plans are defined by Project Leaders and entered into the CTMS by a CTMS Administrator when a project begins. Projects can have more than one activity plan to track different types of activities, but care must be taken in selecting Activity Plans: only the DCRI Service Desk can delete or replace them.

Adding an *Additional* Activity Plan

> **WARNING**: If there is only one activity plan for a protocol, it will be automatically applied to all new sites for that protocol. However, if there are *multiple* activity plans for a protocol, they must be applied manually to each new site. Be careful: once you apply an Activity Plan, you cannot change it to a different one (the existing plan must first be deleted by the Service Desk).

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Click the **Activity Plans** view tab at the bottom of the window. If you do not see the **Activity Plans** tab, click the drop-down arrow at the right side of the view tabs to select it.

Conversation Log
Site Visits
Issue Log
Protocol Deviation
Subjects
Attachments
Internal Personnel
Activity Plans

4   If the activity plan is *not* already listed on the **Activity Plans** view tab:

a   Click the plus sign (+).
A new, blank row appears.

b   Use the following table as a guideline when completing the new row.

Field	Guidelines
Planned Start	Defaults to today's date. Do not change this date.
Template	Select the activity plan that is being applied, from the drop-down list.

Field	Guidelines
Description	Automatically populated when you select an activity plan in the **Template** field. You can enter additional text in this field to further define the activity plan.

c Save the record by pressing **Ctrl**+**S**.

> **WARNING**: If you have just added a new site, there can be a slight delay before the activity plan is automatically applied.

5 To view all of the site-required activities to be tracked, scroll down to the **Activities** view applet.

Activity	Activity Type	Description	Status	Comments
Document	FDA 1572	1572	Unscheduled	
Document	CV	Sub-I CV	Unscheduled	
Document	Financial Disclosure	PI FDF	Unscheduled	
Document	Confidentiality Agreement	Secrecy Agreement	Unscheduled	

> **NOTE**: You may have to refresh your view to see new activities that were added to each view tab as a result of applying the activity plan.

Deleting an Activity Plan

To remove an activity plan record, submit a CTMS Request (CTMSR) to the DCRI Service Desk (dcriservicedesk@dm.duke.edu).

SITE STATUSES AND MILESTONES

S ite statuses and milestones reflect a site's progress at any given point during a project. Maintained over the course of the project, a site's status and milestone history provides metrics that enable the DCRI to review a site's overall performance during a project, especially when considering sites for participation in future projects.

You are responsible for carefully maintaining site status and milestone history over the course of a project, to provide an accurate picture of a site's overall performance. This section is designed to give you the information that you will need to ensure that you are tracking statuses and milestones properly.

Introducing Site Statuses

When you add a site to the CTMS, the site's default status is *Entered*. Thereafter, you must manually apply statuses.

While in each site status, the site can also achieve one or more *milestones*. Milestones are specific events that a site achieves as it progresses from one status to the next.

The most current status appears in the site's **Status** field, and the corresponding **Status Date** field reflects the effective date of that site status.

You can also view a status history by clicking on the **Status History** view tab for that site.
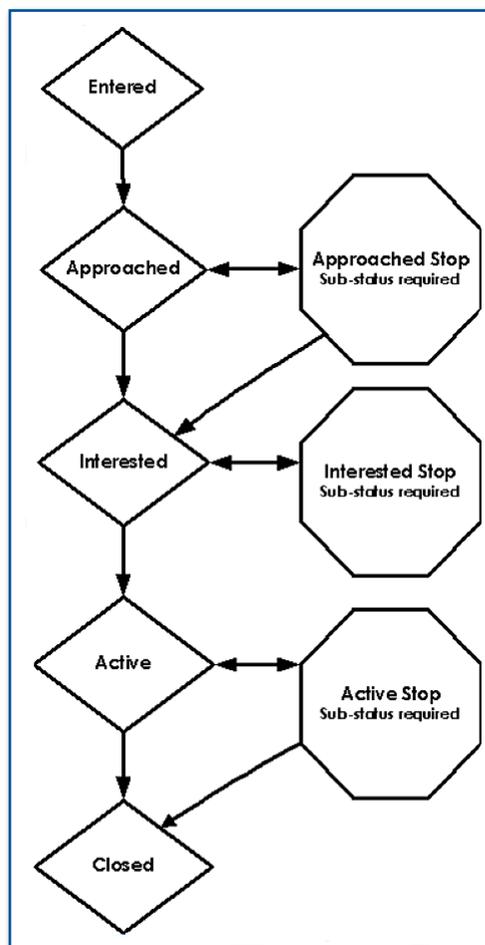
The following table defines the site statuses.

Site Status	Definition
Entered	The site has been added to the CTMS (default site status).
Approached	Communication has been established with the site via written or oral correspondence.
Approached Stop	The site will not participate in the project for one of the following reasons: ♦ Unable to contact the site for reasons in the **Comments** field. ♦ The site decided not to participate. ♦ Competing trial. ♦ DCRI decided not to use the site. ♦ Other reasons indicated in the **Comments** field. **Note**: *Stop* statuses require a sub-status. Select the appropriate reason from the **Sub-Status** field.
Interested	The site has confirmed interest in the project.
Interested Stop	The site will not participate in the project for one of the following reasons: ♦ The site decided not to participate. ♦ The site is unresponsive. ♦ DCRI decided not to use the site. ♦ The IRB did not approve. ♦ Regulatory compliance issues. ♦ Contract issues. ♦ Competing trial. ♦ Other reasons indicated in the **Comments** field. Note: *Stop* statuses require a sub-status. Select the appropriate reason from the **Sub-Status** field.

Site Status	Definition
Active	The site has received the investigational product and has achieved the appropriate milestone(s). For example, the *contract executed* and *regulatory complete* milestones were achieved. The site remains in this status throughout enrollment and follow-up.
Active Stop	The site's participation in the project stopped prematurely for one of the following reasons: - Regulatory compliance issues. - Safety issues. - IRB-related issues. - The site is unresponsive. - The investigational product is not available. - The site decided not to participate. - Other reasons indicated in the **Comments** field. **Note**: *Stop* statuses require a sub-status. Select the appropriate reason from the **Sub-Status** field.
Closed	The close-out process is complete, all data forms have been received, and all queries have been completed.

NOTE: A warning appears if a new site status date is later than any existing status date and is not marked as *current* or if a new site status date (marked as *current*) is prior to any existing status date.

Changing Site Statuses

Change a site's status after all prerequisites have been met. You can verify this by reviewing the activities on the **Milestones**, **Training**, **Documents**, and **Other Requirements** view tabs.
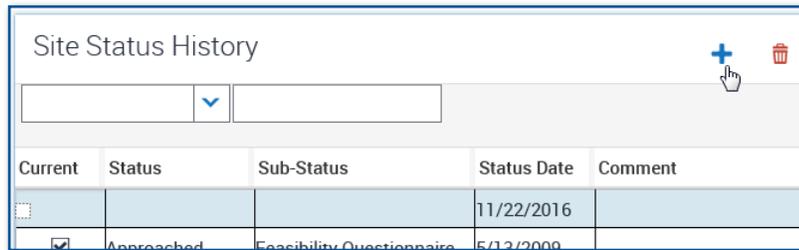
1 Go to the **Site Management** screen.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Scroll down to click the **Status History** view tab.

| s | Site Contact | Status History | Milestones |

4 Click the plus sign (**+**).

A new, blank row appears.

| Site Status History | | | **+** | 🗑 |

Current	Status	Sub-Status	Status Date	Comment
☐			11/22/2016	
☑	Approached	Feasibility Questionnaire	5/13/2009	

> ⚠ **WARNING**: Delete a status record only if it was entered in error. Since the **Status** field becomes read-only after creating the record, always create a new status record to properly reflect the status history for a site.

5 Use the following table as a guideline to complete the new row.

* indicates a required field

Field	Guidelines
Current	Select the checkbox to designate the most up-to-date status (the default when you enter the first status record). The record marked as "current" displays on the **Site** screen.
Status*	Select a status from the drop-down list.
Sub-Status*	If applicable, select a **Sub-Status** from the drop-down list. If a *Stop* status was selected in the **Status** field, this field is required.

Field	Guidelines
Status Date	Enter the date that the new status became effective. The default value is today's date.
Comment	If needed, enter comments relating to the status record.

6 Save the new status record by pressing **Ctrl**+**S**.

> **NOTE**: Selecting the *Active Stop* or *Closed* status in the **Status** field triggers a reminder to complete the **Enrollment Complete** milestone.

Tracking Site Milestones

Record a milestone after all prerequisites have been met. Milestones typically used to gather metrics appear on the main site form and are automatically populated when a milestone is recorded. Applicable protocols have the ability to communicate with vendors by email when a site is ready to receive supplies (see "Communicating with Vendors" on page 37).

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Click the **Milestones** view tab.

| Status History | Milestones | Contracts |

If an activity plan has been applied to the site (see "5. Verifying Activity Plans" on page 29), a list of milestones appears on the **Milestones** view tab.

Site Milestone   +

| Drug IP | Device IP | Starter Box | Reg Pack | | | |

Template	Milestone	Description	Planned	Completed	Comments
☞	IRB Submission	IRB Submission			
☞	Interest Letter/Form/Pack	Interest Letter/Form/Pack		3/2/2009	flkajsl;kgjal;sc
☞	Reg Pack Sent	Reg Pack Sent		3/17/2009	kjgl;kj;,zvm./x
☞	Starter Box Sent	Starter Box Sent			

NOTE: A flag (🏳) in the **Template** column indicates an item from the activity plan. These rows cannot be deleted. Milestones that you add *in addition* to the template milestones can be deleted by clicking the trash button (🗑).

4   Do one of the following:

♦   If the milestone is listed, complete the row for the milestone by filling in the **Completed** and **Comments** fields.

Or

♦   If the milestone is not listed, click the plus sign (➕) in the **Milestones** view tab.

WARNING: Milestones to be tracked for your protocol should already be listed as a result of applying the activity plan (see "5. Verifying Activity Plans" on page 29). If a milestone is not listed, contact your project lead to determine whether the new milestone should be added to the template, and then applied to all sites within the protocol.

5   Use the following table as a guideline when completing the new row.

| Field	Guidelines
Template	(read-only) Flags in the **Template** column indicate items from the activity plan.
Milestone	If entering a new record, select the milestone from the drop-down list.
Description	If entering a new record, enter a *brief* description of the milestone.
Planned	Enter the date that the milestone is planned to occur.
Completed	Enter the date when the milestone was achieved. Future dates are not allowed.
Comments	Enter comments related to the milestone.
Completed By	(read-only) Automatically populated with your user ID.

6   Save the record by pressing **Ctrl**+**S**.

The milestone is recorded and the date is automatically populated in the site form.
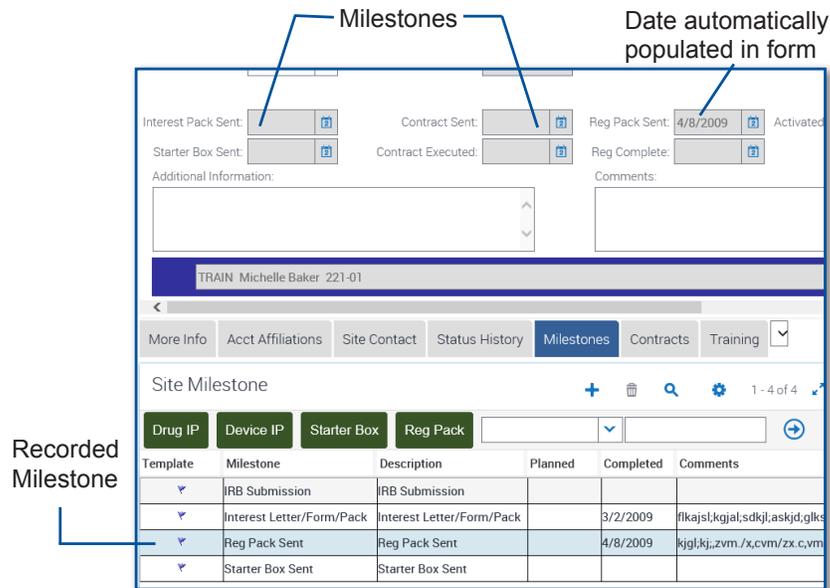
Communicating with Vendors

The CTMS enables you to communicate with vendors by email when a site is ready to receive various supplies. To set up this automated tool for applicable protocols, required information is collected by the DCRI Service Desk at protocol setup or provided by a CTMSR after the protocol is configured.
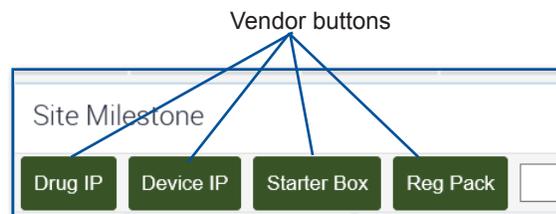
Prerequisites Required

There are prerequisites at the site level that must be in place for the vendor communication process to work correctly.

♦   **Drug IP** or **Device IP**

◊   Site contact with the **Role** of *IP Shipment Contact* with an associated address.

◊   Milestone of **Investigational Product Sent** or **Device Sent** in the activity plan.

♦ **Starter Box**

   ◊ Site contact with the **Role** of *Study Coordinator* with an associated address.

   ◊ Milestone of **Starter Box** in the activity plan.

♦ **Reg Pack**

   ◊ Site contact with the **Role** of *Study Coordinator* with an associated address.

   ◊ Milestone of **Reg Pack Sent** in the activity plan.

Sending an Email Notification to a Vendor

1 Click the site's **Milestones** view tab.

2 Click the appropriate button above the list of milestones.

A confirmation message appears.

3 Click **OK**.

Email notification is sent to the vendor, and the affiliated milestone's **Completed** field is updated with today's date. You are copied on the email for documentation of the request.

Adding Milestones to the Activity Plan

If milestones will be tracked at more than one site within a protocol, they should be listed on the appropriate Activity Plan. To add milestones to an Activity Plan, submit a CTMS Request Form (see "Appendix A: CTMS Request Form" on page 75).

TRACKING SITE DOCUMENTS

The CTMS enables you to track documents sent to and collected from sites. When an activity plan is applied to a site (see "5. Verifying Activity Plans" on page 29), all specified documents are pre-populated on the **Documents** view tab to provide easier tracking. However, you might have to add the same document multiple times. For example, you record CVs, Medical Licenses, and Financial Disclosures for multiple site personnel.

> **NOTE**: A flag (🏳) in the **Template** column indicates an item from the Activity Plan. This row cannot be deleted. Documents that you enter *in addition* to the template documents can be deleted by clicking the 🗑 button.

Tracking a Site Document

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Documents** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
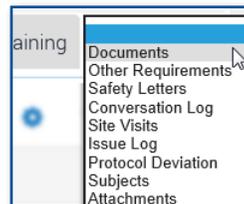
The Document Tracking listing appears.

Template	Document	Document Description	Status	Version Da
🏳	CV	PI CV		
🏳	CV	Sub-I CV		
🏳	Confidentiality Agreement	Secrecy Agreement	Approved by Sponsor	2/1/2011
🏳	FDA 1572	1572		

5 If the document is listed, complete the record by filling in the appropriate fields (see the field guidelines on the next page).

6 If the document is *not* listed, do one of the following:

♦ To add a document that is *not* listed on your site's Activity Plan, click the plus sign (**+**), select the new document, and then complete the record by filling in the appropriate fields.

Or

♦ To add a duplicate copy of a document that is listed on your site's Activity Plan, highlight the record and then press **Ctrl** + **B** to create a copy. Complete the record by filling in the appropriate fields.

7 Use the following table as a guideline when completing the row.

> **NOTE**: To capture information about all types of documents, there are more columns/fields than apply to any specific document. Only complete the fields that are appropriate for the document you are recording.

Field	Guidelines
Template	A flag in the **Template** column indicates an item from the activity plan.
Document	Select the document from the drop-down list.
Document Description	If necessary, enter a description of the document. **Note**: Text in this field automatically becomes a hyperlink to the **Attachments** view tab, where you can attach documents or related files. For more information, see "Adding Site Attachments" on page 51.
Status	**1** Click the selection icon in this field to open the **Document Tracking History** window. **2** Click the plus sign (**+**). **3** Select the checkbox in the **Current** field to indicate that this is the most current status for the document. **4** Select the document status from the **Status** drop-down list. **5** In the **Status Date** field, enter the date when the new status occurred. Future dates are not allowed. **6** If necessary, enter comments regarding this document in the **Comments** field. **7** Click **OK**.

Field	Guidelines
Version Date	If applicable, enter the document's version date. Refer to your protocol's DEG to determine the appropriate version date of a document. Future dates are not allowed.
Expiration Date	If applicable, enter the date that the document expires or is no longer valid. For example, an IRB Approval Letter is usually only valid for one year. Refer to your protocol's DEG to determine the appropriate expiration date of a document.
Last Name	If applicable, follow the steps below to select a person related to the document. For example, select the name of the person for whom a CV is recorded.
	1 Click the selection icon in this field to open the **Pick Site Contact** window (lists the names of people from the **Site Contact** view tab).
	2 Select the name.
	3 Click **Pick**. Selection of a name automatically populates the **First Name** and **Role** fields
Sent Date	(read-only) Automatically populated when you complete the status field for the document.
Received Date	
Approval Date	
Source Verified Date	Enter the date that the document was source verified at the site.
Doc In House	Check the box to indicate that the document is located at DCRI.
Doc On Site	Check the box to indicate that the document is located at the site.

Field	Guidelines
Comments	Enter comments relating to the document. **Note**: For documents related to the IRB or lab, record the IRB or lab name in this field.
Bio/CV/ML	Contains a hyperlink to the contact's BioSketch, CV, and/or Medical License located in a DCRI network folder. This hyperlink is added by the DCRI Service Desk.

8   Save the record by pressing **Ctrl**+**S**.

> **TIP**: To quickly duplicate a record, highlight the record and then press **Ctrl** + **B** on your keyboard. The document's Template flag, Name, and Description will be copied to the new record. (This method is the only way to add a document that is listed on the site's Activity Plan.)

Viewing a Document's Status History

To review the history of a document, select the document from the list and then scroll down to the **Status History** view applet at the bottom of the window.

Adding Documents to the Activity Plan

If documents will be tracked at more than one site within a protocol, they should be listed on the appropriate Activity Plan. To add documents to an Activity Plan, submit a CTMS Request Form (see "Appendix A: CTMS Request Form" on page 75).

TRACKING TRAINING AND EDUCATION

Use the **Training** view tab to track training and meetings for site personnel. When an activity plan is applied to a site (see "5. Verifying Activity Plans" on page 29), all specified training activities are pre-populated on the **Training** view tab to provide easier tracking. However, you might have to add the same activities multiple times. For example, you might need to record Human Research Training for multiple site personnel.
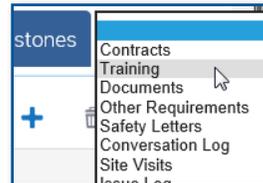
> **NOTE**: A flag (🏳) in the **Template** column indicates an item from the Activity Plan. This row cannot be deleted. Training activities that you enter *in addition* to the template activities can be deleted by clicking the 🗑 button.

Tracking Training Activity

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Select the site.

4   Click the **Training** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.

5   If the training activity is listed, complete the record by filling in the appropriate fields (see the field guidelines on the next page).

6 If the training activity is *not* listed, do one of the following:

♦ To add a training activity that is *not* listed on your site's Activity Plan, click the plus sign (**+**), select the new training activity, and then complete the record by filling in the appropriate fields.

Or

♦ To add a duplicate copy of a training activity that is listed on your site's Activity Plan, highlight the record and then press **Ctrl + B** to create a copy. Complete the record by filling in the appropriate fields.

7 Use the following table as a guideline when completing the row.

Field	Guidelines
Template	A flag in the **Template** column indicates an item from the activity plan.
Training	Select the activity from the drop-down list.
Description	If necessary, enter a description of the activity.
Last Name	**1** Click the selection icon in this field. The Pick Site Contact window appears, listing the names of people from the Site Contact view tab. **2** Select the name. **3** Click **Pick**. Selection of a name automatically populates the First Name and Role fields.
Status	Select a status from the drop-down list. The default value is *Unscheduled*. **Note**: There is no status history for "training" activities.
Status Date	Enter the date that the new status occurred. The default value is today's date.

Field	Guidelines
Expiration Date	Enter the date when the training activity expires.
Doc In House	Check the box to indicate that documentation regarding the training activity is located at the DCRI.
Doc On Site	Check the box to indicate that documentation regarding the training activity is located at the site.
Comments	Enter comments relating to the activity.
Completed By	(read-only) Automatically populated with your user ID.

8 Save the record by pressing **Ctrl**+**S**.

TIP: To quickly duplicate a record, highlight the record and then press **Ctrl** + **B** on your keyboard. The training activity's Template flag, Name, and Description will be copied to the new record. (This method is the only way to add a training activity that is listed on the site's Activity Plan.)

Adding Training Activities to the Activity Plan

If training activities will be tracked at more than one site within a protocol, they should be listed on the appropriate Activity Plan. To add training activities to an Activity Plan, submit a CTMS Request Form (see "Appendix A: CTMS Request Form" on page 75).

TRACKING OTHER REQUIREMENTS

Use the **Other Requirements** view tab to track additional site activities or site qualifications for your protocol. When an activity plan is applied to a site (see "5. Verifying Activity Plans" on page 29), all specified activities that do not qualify as a milestone, document, training activity, or safety letter are pre-populated on the **Other Requirements** view tab to provide easier tracking. However, you might have to add the same activities multiple times for multiple site personnel.

> **NOTE**: A flag (🚩) in the **Template** column indicates an item from the Activity Plan. This row cannot be deleted. Training activities that you enter *in addition* to the template activities can be deleted by clicking the 🗑 button.

Tracking Other Activities or Qualifications

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Other Requirements** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
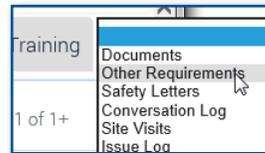
The Site Other Requirements listing appears.
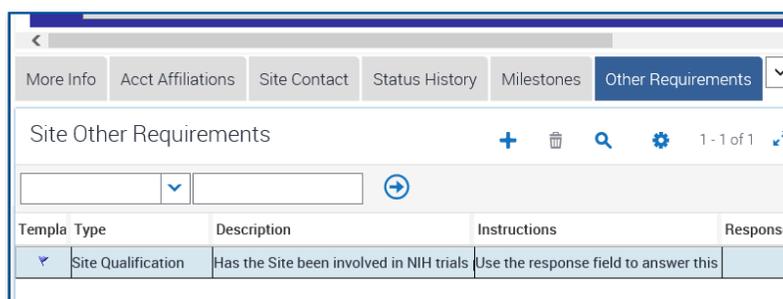
5 Do one of the following:

♦ If the activity is listed, complete the row for the activity by filling in the appropriate fields (see field guidelines on the next page).

Or

♦ If the activity is *not* listed or you need to add the same activity again, click the plus sign (➕) on the **Other Requirements** view tab.

6 Use the following table as a guideline when completing the row.

Field	Guidelines
Template	A flag in the **Template** column indicates an item from the activity plan.
Type	Select the activity type from the drop-down list.
Description	If necessary, enter a description of the activity.
Instructions	(read-only) Based on the activity plan template, tells which fields to complete (**Response**, **Quantity**, or **Date**) for the activity.
Annotations	(read-only) Contains additional instructions for completing the record.
Last Name	**1** Click the selection icon in this field. The Pick Site Contact window appears, listing the names of people from the Site Contact view tab. **2** Select the name. **3** Click **Pick**. Selection of a name automatically populates the First Name and Role fields.
Response	For activity items that require a response, such as *Yes* or *No*, select the option from the drop-down list.
Quantity	If applicable, enter the quantity for the activity.
Date	Enter the date that the activity was addressed.
Comments	Enter comments relating to the activity.
Completed By	(read-only) Automatically populated with your user ID.

7 Save the record by pressing **Ctrl**+**S**.

TIP: To quickly duplicate a record, highlight the record and then press **Ctrl** + **B** on your keyboard.

Adding Other Requirements to the Activity Plan

If other requirements will be tracked at more than one site within a protocol, they should be listed on the appropriate Activity Plan. To add other requirements to an Activity Plan, submit a CTMS Request Form (see "Appendix A: CTMS Request Form" on page 75).

TRACKING SAFETY LETTERS

Use the **Safety Letters** view tab to track trial and site safety letters. When an activity plan is applied to a site (see "5. Verifying Activity Plans" on page 29), all specified trial safety letters are pre-populated on the **Safety Letters** view tab to provide easier tracking.
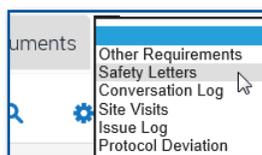
> **NOTE**: A flag (🚩) in the **Template** column indicates an item from the Activity Plan. This row cannot be deleted. Training activities that you enter *in addition* to the template activities can be deleted by clicking the 🗑 button.

Tracking Letters

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Safety Letters** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.

The Site Safety Letter listing appears.

Template	Type	Description	Case Number	Sequence	Version	Sent to Site	Submitted to I	Submission Letter Rece	IRB
🚩	Protocol Safety L...	GI Bleed			9/6/2006	3/12/2009			

5 Do one of the following:

♦ For a *trial* safety letter, complete the record by filling in the appropriate fields (see the field guidelines on the next page).

   Or

♦ For a *site* safety letter, click the plus sign (➕) on the **Safety Letters** view tab. Then complete the record by filling in the appropriate fields.

6 Use the following table as a guideline when completing the row.

* indicates field is pre-populated for *trial* safety letters

Field	Guidelines
Template*	(read-only) A flag in the **Template** column indicates an item from the activity plan.

Field	Guidelines
Type*	(read-only) Shows the type of safety letter. The default value for new records is *Site Safety Letter*. **Note**: If you need to add another Trial Safety Letter, contact the DCRI Service Desk.
Description*	Enter a description of the event.
Case #*	Enter the case number for the letter.
Sequence*	If applicable, enter the sequence of the letter as related to other letters.
Version*	For new records, enter the letter's version date. This field is read-only for template records.
Sent to Site	Enter the date that the letter was sent to the site. This date may be pre-populated for *trial* safety letters.
Submitted to IRB	Enter the date that the letter was submitted to the IRB.
Submission Letter Received	Enter the date that DCRI received the letter that was sent to the IRB.
IRB Acknowledgment Received	Enter the date that the IRB acknowledged receiving the letter.
Sent to Sponsor	Enter the date that the letter was sent to the sponsor.
Doc In House	Select the checkbox to indicate that the safety letter is located at the DCRI.
Doc On Site	Check the box to indicate that the document is located at the site.
Comments	Enter comments relating to the letter.
Completed By	(read-only) Automatically populated with your user ID.

7 Save the record by pressing **Ctrl**+**S**.

Adding Trial Safety Letters to the Activity Plan

If trial safety letters will be tracked at more than one site within a protocol, they should be listed on the appropriate Activity Plan. To add trial safety letters to an Activity Plan, submit a CTMS Request Form (see "Appendix A: CTMS Request Form" on page 75).

ADDING SITE ATTACHMENTS

You can add attachments to a site that relate to a required site document, such as the principal investigator's CV, the 1572, or the IRB approval letter. You can also add attachments that are not required, such as driving directions to the facility or a link to the company's website.

> **WARNING**: An attachment with a large file size will cause the CTMS to perform slowly. Remove color graphics from documents and zip files to reduce the file size before attaching them in the CTMS.

Tracking a Site Document or Letter

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Select the site.

4   Click the **Attachments** view tab at the bottom of the window. If you do not see this tab, click the drop-down arrow to the right of the view tabs to select it.
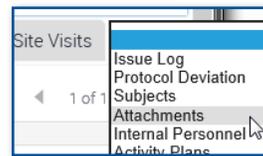
Attachments information appears.

5   If necessary, query for the attachment to make sure that it does not already appear in the list of attachments.

6   To add an attachment, do the following:

   a   Click **New File**.

b Find and select the file.

c Click **Open**.

7 To add a link to a website, do the following:

a Click **New URL**.

b Enter the complete ("absolute") website address in the URL field. For example, enter *http://www.trialsite.com*.

c Click **Add**.

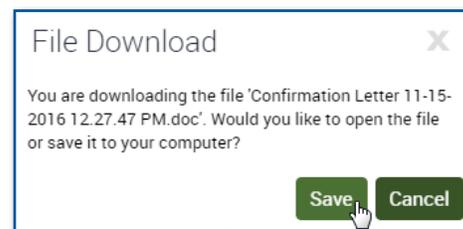**8** Save the record by pressing **Ctrl**+**S**.

> **NOTE**: Attachments in the CTMS are copies of the original files. Documents that were locked from editing before being attached in the CTMS are not locked in the CTMS. To help prevent editing, save documents as PDFs before attaching them in the CTMS.

Editing a Word Document from the Attachments Tab

Most users find they cannot save a Word document directly to the CTMS if they had opened that file from within the CTMS. The work-around is to first save the document to another location and then import it back into the CTMS by following the steps below.

1 In the **Attachment Name** column, click the link for the document.

A message appears.

File Download

You are downloading the file 'Confirmation Letter 11-15-2016 12.27.47 PM.doc'. Would you like to open the file or save it to your computer?

Save   Cancel

2 Click **Save**.

> **Internet Explorer**: An orange confirmation message appears across the bottom, prompting you to **Open** (recommended) or **Save** the file.
>
> **Firefox**: A confirmation message appears, prompting you to open with Word (recommended) or save the file.
>
> **Chrome**: The file appears in your Downloads folder and can be clicked at the bottom of the browser window to open.

The file opens in Microsoft Word.

3 Use Word features to review, edit, and print the document, as needed.

4 To save the letter, select **File>Save as** in Word, and then navigate to the location where you want to save the file (selecting file type **doc* or **docx*).

The Save As window appears.

**5** Save the file to an external location, such as a project folder.

6 To add the file back into the Trip Report:

a Click [🔗 New File] on the **Attachments** view tab.

b Navigate to and select the Word file you just saved, and then click **Open**.

The file appears in the list on the Attachments view tab.

7 If you saved the file with the same name and extension as the original file, you are asked (after saving or stepping off the record) if you want to replace the old file with the new one. Click **OK**.
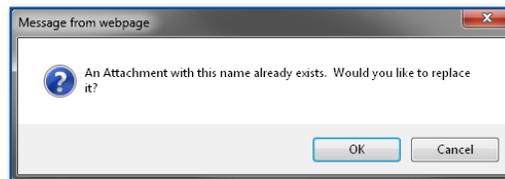
LOGGING CONVERSATIONS

Use the *Conversation Log* to capture required communications and other correspondence with the site. You can record activity types such as:

♦ Call—Inbound/Outbound

♦ Email—Inbound/Outbound

♦ Fax—Inbound/Outbound

♦ Letter—Inbound/Outbound

> **NOTE**: Only the person who created a Conversation Log entry (whose name appears in the **Owner First / Last Name** fields) can edit that record. For other users, all fields of the record are locked from editing.

Logging a Conversation

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Conversation Log** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
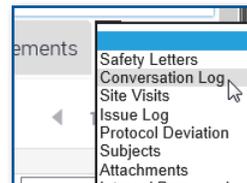
The Conversation Log listing appears.

Type	Unblinded?	Activity Date	Activity Time	Description	Keywords
Call - Inbound		6/18/2007		PI called to ask an important question.	Clinical Question
Call - Inbound		4/26/2007		PI called to ask about drug storage.	Informed Consent
Call - Inbound		4/18/2007		Called to ask something important.	Audit
Call - Outbound		4/4/2007		discuss AE	Enrollment

5 On the **Conversation Log** tab, click the plus sign (**+**).

A new, empty row appears.

6 Use the following table as a guideline to complete the new row.

TIP: Select a row and scroll down to enter data in the form displayed at the *bottom* of the window. Data entered in form fields is more visible and can be spell-checked. Use the navigation buttons to go to the next/previous conversation.

Conversation Log	+ 🗑 🔍 ⚙
Activity #: 1-4CXUY	Description:
Type▾	▾
Activity Date: 11/29/2016 📅	
Activity Time: 11:59 AM	
Keywords: 🔲	
Contact First Name:	

Bottom of Conversation Log view

Field	Guidelines
Activity #	(read-only) This is a CTMS system-generated unique identifier.
Type	In this required field, select the activity description from the drop-down list, for example, *Call - Inbound*. The default value is *Other*.
Activity Date	Enter the date that the activity occurred. Defaults to the current date.
Activity Time	Enter the time that the activity occurred. Defaults to the current time.
Description	Enter a detailed description of the activity. For example, for a Call - Inbound activity type, enter the conversation details in this field, up to a maximum of 4,000 characters.
	You can copy email text to this field by highlighting the email text, pressing **Ctrl + C** to copy it, clicking in the Conversation Log's **Description** field, and then pressing **Ctrl + V** to paste the text into the field.
	Warning! Be careful not to copy email headers and blank rows into the **Description** field, as they can take up a large amount of storage space.

Field	Guidelines
Keywords	Used primarily for Call activity types, this field assists in organizing and querying for data. **1** Click the selection icon to display the **Activity Keywords** applet. **2** Click the plus sign (**+**). **3** Click the **DCRI Keywords** drop-down arrow to select a keyword. **4** Repeat steps *2–3* to add additional keywords. **5** Click **OK**.
Contact First Name or **Contact Last Name**	**1** Click the selection icon in either of these fields to view a list of contacts currently affiliated with the site. **Note**: To view all contacts in the CTMS, click **All Contacts**. Click **Affiliated Contacts** to return to the list of site contacts. **2** Select the contact associated with the activity in the left pane. **3** Click **Add** to move the contact name to the right pane. **4** Select the appropriate option from the **Attending Role** drop-down list. **5** Click **OK**. **6** Repeat these steps to add additional contacts to the record.
Owner First Name and **Owner Last Name**	(read-only) Shows the first and last name of the person who created the conversation log entry.

7 Save the record by pressing **Ctrl**+**S**.

NOTES

Viewing All Conversation Logs

To view a list of all conversation logs across all protocols:

1 At the top of the page, click the **Site Management** screen tab, and then click the **Conversation Log** screen link.

You view all conversation logs regardless of site/protocol.

2 To find specific logs:

a Click the **Query** button (🔍).

b Enter one or more words into a field, such as the **Keywords** field.

> **T**IP: You can use an asterisk (*) as a wildcard.

c Click the **Go** button (➡).

All entries that contain your keywords appear.

TRACKING ISSUES

Use the **Issue Log** view tab to track site-level issues outside of the trip report. By default, this tab displays site-related issues in descending order by the **Date Identified**.

Considerations When Using the Issues Log

♦ Unblinded follow-up items should *never* be entered on the **Issue Log** tab.

♦ **Issue Log** records cannot be copied.

♦ **Issue Log** records can be created without regard to the site's status.

♦ You cannot track protocol deviations on the **Issue Log** tab. An error message appears to remind you to enter records on the **Protocol Deviations** tab (see "Tracking Protocol Deviations" on page 61).

♦ To delete an **Issue Log** record, submit a CTMSR to the DCRI Service Desk, requesting record deletion.

♦ The **Site-Level Issue Log Report** captures all site-level issues.

Tracking Site-Level Issues

1 Go to the **Site Management** screen.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Issue Log** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
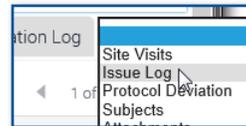
The Issue Log listing appears.
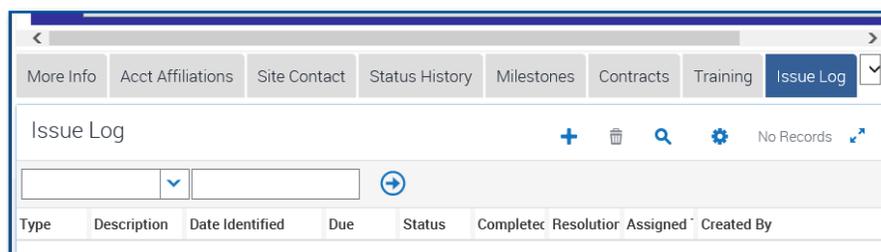
5 Do one of the following:

♦ If the activity is listed, complete the row for the activity by filling in the appropriate fields (see field guidelines on the next page).

Or

♦ If the activity is not listed or you need to add the same activity again, click the plus sign (**+**) on the **Issue Log** view tab.

6 Use the following table as a guideline when recording a new site-related issue outside of the trip report.

Field	Guidelines
Type	Select the issue type from the drop-down list.
Description	Enter the issue description, up to a maximum of 1,500 characters.
Date Identified	Defaults to today's date. Enter the date that the issue was identified. The system does not allow entry of a future date.
Due	Defaults to *blank*. You can enter a date that the issue is expected to be resolved/completed, if needed.
Status	Defaults to *Open*. When the issue is resolved, select *Done* from the drop-down list. If *Done* is selected, the **Completed Date** field will be automatically populated with today's date.
Completed Date	When the **Status** is changed to *Done*, this field is populated with today's date, but enables you to enter a previous date representing the date the issue was resolved. The system will not allow entry of a future date. Entering a date in this field will automatically change the **Status** to *Done*.
Resolution/Action Comments	Enter resolution/action comments, up to a maximum of 1,500 characters.
Assigned To	Defaults to the Site Manager as *Primary* (if the **Site Manager** field is populated on the site record), and the user ID of the person who entered the record. Click the selection icon in this field to assign the record to someone else.
Created By	(Read-only) Automatically populated with the user ID of the person who created the record.

7 Save the record by pressing **Ctrl**+**S**.

TRACKING PROTOCOL DEVIATIONS

Use the **Protocol Deviation** view tab to track site-level protocol deviations. This tab, available whether the protocol uses the CTMS trip report or not, contains both site-level and trip report-level protocol deviations.

Protocol deviations recorded on the trip report screen will also appear on the site-level **Protocol Deviation** tab.

Recording a Site-Level Protocol Deviation

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Select the site.

4   Click the **Protocol Deviation** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
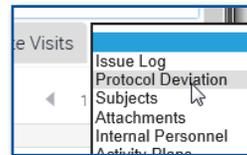
The Protocol Deviation listing appears.

Type	Sub-Type	Subject Initials	Subject ID	PD Date	PD Description	Action Description	Discovered	Entry Location
01-Infor…	Subject	REM	5511:LLK4…	2/22/2008	Signed wrong version	Have patient sign a new		Trip Report
10-Other…	Site			1/31/2008	PI didn't sign HIPPA F	No follow up done Proto		Trip Report

5   Do one of the following:

♦   If the activity is listed, complete the row for the activity by filling in the appropriate fields.

   Or

♦   If the activity is not listed, click the plus sign (**+**) on the **Protocol Deviation** view tab.

6   Do one of the following.

♦   For site-level entries, the **Discovered Date** defaults to today's date and can be edited.

♦ For trip report-level entries, the **Discovered Date** is the **Actual Visit Start** date, and this field cannot be edited on the site-level

ption	Discovered Date	Entry Location
sign a new ICF	11/20/2016	Trip Report
done Protocol d	12/12/2016	Trip Report

Protocol Deviations tab. The **Entry Location** field indicates where the record was entered.

7 Save the record by pressing **Ctrl+S**.

REQUESTING CHANGES TO GLOBAL CONTACT & ACCOUNT INFORMATION

CTMS Administrators in the DCRI Service Desk maintain the contact and account information you associate with your sites. When you add new contacts or accounts, that new information is verified by the CTMS Administrators (see "3. Associating Additional Contacts to a Site" on page 21, and "4. Associating Additional Accounts to a Site" on page 25).

To request *changes* to existing contact/account information (i.e., address, phone, or email data) or to add *new* data, use the procedures in this section.

Because the data in the CTMS is shared across projects, the DCRI Service Desk must verify your new entries and change requests to determine whether they will affect other projects. This protects the integrity of the data by minimizing inappropriate deletions or duplicate contact or account records.

Adding or Updating Contact Information

You can request additions and updates to contact information (e.g., address, phone, or email data) to the CTMS database by submitting a change request.

> **NOTE**: When a new site contact record is added, there is a 15-minute grace period in which you can make corrections to data without going through the change request process listed here. If it has been over 15 minutes since the record was added, follow the procedure in this section to request data additions and changes.

1 Click the **Site Management** screen tab.

2 Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3 Select the site.

4 Click the **Site Contact** view tab in the lower portion of the window.
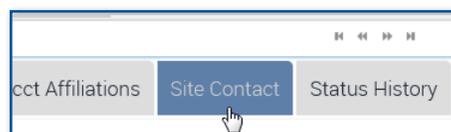
The Active Only listing appears.

5 If necessary, query for the site contact on the **Site Contact** view tab.

6 Click the blue hyperlink name in the **Last Name** field for the site contact.

The contact record appears on the **Contacts** screen tab.

7   **Important!** Click the **Change Request** button.

The Global Database screen tab appears (with Change Request fields).

8   Enter your edits, using the table below as a guideline.

NOTE: You can cancel your change request at any time by clicking the Cancel Request button on the right side of the window.

TIP: If you are requesting multiple changes, finish entering all changes *before* you click the **Submit Request** button.

To	Do This
Update or add general contact information	Complete the appropriate fields in the upper form area of the window, such as **Greeting**, **Degree**, or **Job Title**.
Update existing address information for the contact	**1** Click the **Address** tab in the lower portion of the window. **2** Select the address. **3** Click **Update Address**. **4** Complete the **Address Change Request** form. **5** Click **OK**.

To	Do This

Add new address information for the contact	**1** Click the **Address** tab in the lower portion of the window.
	
	2 Click the plus sign (**+**).
	
	3 Query for the address, using the street number and **Prov/State**, or part of the street name between asterisks and **Prov/State** fields. (For international addresses, search by entering the street number and **Country**.)
	
	4 Do one of the following:
	
	♦ If the address exists in the database:
	   a Select it.
	   b Click **OK**.
	
	   Or
	
	♦ If the address *does not* exist in the database:
	   a Click the plus sign (**+**).
	   b Complete the new row.

Update existing phone information for the contact	**1** Click the **Phone** tab in the lower portion of the window. **2** Select the phone number. **3** Click **Update Phone**. **4** Complete the **Phone Change Request** form. **5** Click **OK**.
Add new phone information for the contact	**1** Click the **Phone** tab in the lower portion of the window. **2** Click **Add Phone**. **3** Complete the new row. **Note**: For international numbers, enter **+ Country Code - City Code - Remaining Number**. Example: +011-44-878789. The plus sign (+) indicates a non-US number.

To	Do This
Update existing email information for the contact	**1** Click the **Email** tab in the lower portion of the window. **2** Select the email address. **3** Click **Update Email**. **4** Complete the **Email Change Request** form. **5** Click **OK**.
Add new email information for the contact	**1** Click the **Email** tab in the lower portion of the window. **2** Click **Add Email**. **3** Complete the new row.

9 Enter comments in the **Comments** field to further clarify your request.

10 Click **Submit Request**.

Your request is submitted to the DCRI Service Desk for verification as the Site Contact view tab on the Site Management screen reappears. You now associate the new information to the site contact's record. See "3. Associating Additional Contacts to a Site" on page 21 for information on completing these fields. When your request has been processed, you will receive an email notification from the DCRI Service Desk.

Adding or Updating Account Information

At any time, you can request additions and updates to account information e.g., address or phone data) to the CTMS database by submitting a change request.

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Select the site.

4   Do one of the following:

♦   To work with the main site account, click the blue hyperlink in the **Account** field for the account (the hyperlink shows only in the list view, not in the form view).

> **Or**

♦   To work with *another* affiliated site account:

   a   Click the **Acct Affiliations** view tab at the bottom of the window

   b   Click the blue hyperlink in the **Account Name** field for the account.

The account record on the Accounts screen tab appears.

5   **Important!** Click the **Change Request** button.

The Global Database screen tab opens (with Change Request fields).

6 Enter your edits, using the table below as a guideline.

NOTE: You can cancel your change request at any time by clicking the **Cancel Request** button in the top right corner of the window.

TIP: If multiple changes are being requested, finish entering all changes *before* you click the **Submit Request** button.

To	Do This
Update or add general account information	Complete the appropriate fields in the upper form area of the window, such as **Account Name** or **Account Type**.
Update existing address information for the account	**1** Click the **Address** tab in the lower portion of the window. **2** Select the address. **3** Click **Update Address**. **4** Complete the **Address Change Request** form. **5** Click **OK**.

Add new address information for the account	**1** Click the **Address** tab.
	2 Click the plus sign (**+**).
	3 Query for the address, using the street number and **Prov/State** fields, or part of the street name between asterisks and **Prov/State** fields. (For international addresses, search by **Country**.)
	4 Do one of the following:
	♦ If the address exists in the database:
	  a Select it.
	  b Click **OK**.
	  c Enter a date in the **Start Date** field to indicate when the address became effective for the account.
	
	(continued on next page)

To	Do This

(continued)	**Or**
	♦ If the address *does not* exist in the database:
	  a Click the plus sign (**+**).
	  b Complete the new row.

Update existing phone information for the account	**1** Click the **Phone** tab in the lower portion of the window. **2** Select the phone number. **3** Click **Update Phone**. **4** Complete the **Phone Change Request** form. **5** Click **OK**.
Add new phone information for the account	**1** Click the **Phone** tab in the lower portion of the window. **2** Click **Add Phone**. **3** Complete the new row.

7 Enter comments in the **Comments** field to further clarify your request.

8 Click **Submit Request**.

Your request is submitted to the DCRI Service Desk for verification, as the Site Management screen reappears. When your request has been processed, you will receive an email notification from the Service Desk.

ENROLLING A SITE SUBJECT

S ite subjects are added to the CTMS for tracking throughout a clinical protocol. If your trial uses an interactive voice response system (IVRS) to automatically pull enrollment information into the CTMS, you do not need to manually enroll subjects.

> **WARNING**: There can be as much as a 48-hour delay from the time subject information is received from an IVRS to when it appears in the CTMS. If your trial uses an IVRS, do NOT use the **New** button in the **Subjects** view to add a new subject, as this will result in a duplicate entry.

Subject ID Configuration Options

The **Subject ID** field is system-generated and can be configured by the CTMS Administrators in the DCRI Service Desk to reflect any combination of the **Screening ID**, **Randomization ID**, and **Enrollment ID** (each ID can be unique). For new protocols, configuration is discussed during the Protocol Setup meeting. You can also submit a CTMSR to the DCRI Service Desk (*dcriservicedesk@dm.duke.edu*) to request configuration.

Example:

♦ Screening ID = 123-555

♦ Randomization ID = 1717

♦ Enrollment ID = 8888

The **Subject ID** can be configured in any of the following combinations:

All three IDs	123-555:1717:8888
Screening ID + Randomization ID	123-555:1717
Randomization ID + Enrollment ID	1717:8888
Enrollment ID + Screening ID:	8888:123-555

Manually Enrolling a New Subject

1   Click the **Site Management** screen tab.

2   Locate the site by running a query on the **Site #** field. (See "Querying the Site" on page 10.)

3   Select the site.

4   Click the **Subjects** view tab in the lower portion of the window. If this tab does not appear, click the drop-down arrow at the right end of the view tabs to select it.
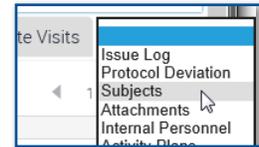
The Subjects listing appears.

5   To ensure that the subject has not already been added, follow the steps below to query for the subject:

a   On the **Subjects** view tab, click the **Query** button (🔍).

b   Enter the subject's initials in the **Subject Initials** field.

c   Click **Go**.

If no rows are returned, you can proceed with adding the subject.

6   On the **Subjects** view tab, click **New**.

The Subject Enrollment window appears.

7   Complete the subject record, using the following table as a guideline.

* indicates a required field

Field	Guidelines
Subject Initials*	Enter the subject's initials.
Date of Birth*	Enter the subject's date of birth (using the format MM/DD/YYYY). **Note**: If your protocol is not collecting date of birth information for subjects, enter **01/01/1880**.
Gender	Select the subject's gender from the drop-down list.
Screening ID*	Enter the subject's screening ID. **Note**: If your protocol is not screening subjects, this field will automatically be populated with the value in the **Enrollment ID** field.
Screen Date	If applicable, enter the date when the subject was screened.
Race	Select the subject's race from the drop-down list.
Enrollment ID*	Enter the subject's enrollment ID. **Note**: This field is required if the **Screening ID** field is blank.
Enrollment Date	Enter the date when the subject was enrolled.
Randomization ID	If applicable, enter the subject's randomization ID.

8 Click **Screen/Enroll**.

The new subject record appears, and the **Subject ID** field is automatically populated with the system-generated ID determined by your protocol team.

Subject ID	Subject Initials	Date of Birth	Screening ID	To Be Monitored	Sc
:enroll1234	JCR	1/26/1977	screen1234		1/
:enroll1385	ead	1/6/1997	screan9987	☑	1/

Editing a Subject Record

1 Click the blue hyperlink in the subject's **Screening ID** field.

The subject's global record appears.

2 Do any of the following:

♦ Click **Screen** or **Rescreen** to record screening information about the subject.

♦ Click **Enroll** to record enrollment information about the subject.

♦ Click the selection icon in the **Status** field to add new status information about the subject, such as a *Screen Failure*.

♦ Click the plus sign (**+**) in the **Visits** area at the bottom of the window to record visit information about the subject.

3 Save the record by pressing **Ctrl**+**S**.

4 To return to the site record, click the left-hand breadcrumb above the **Home** screen tab.

APPENDIX A: CTMS REQUEST FORM

Use the **CTMS Request** (CTMSR) form to request configuration or data changes to the CTMS.

1   Download the CTMSR form from the DCRI Intranet.

   a   Go to the CTMS Learning Center at:

   https://dcri.org/education-training/ctms-learning-center

   b   Under **Forms and Instructions**, click the **CTMSR: CTMS Request Form** link to open and download the document to any folder.

2   Complete the required fields on the form. Compile any supporting material in separate files.

3   Send email, with the form and supplemental files attached, to the Project Leader, Senior Lead CRA, or Lead CRA for approval.

   The approver will email back their approval (no signature is required).

4   Forward the email containing the Approver's approval, with form and supplemental files attached, to the DCRI Service Desk (dcriservicedesk@ dm.duke.edu).

   Your request will be tracked in the FootPrints system and handled by CTMS specialists at the Service Desk.