July 2014

CTMS Site Monitoring

User Reference Guide

Duke Clinical Research Institute

ittd IT Training & Documentation

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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 Monitoring Overview

Site visit scheduling, tracking, and reporting can be performed in DCRI's Clinical Trial Management System (CTMS). Monitors can record their activities during the course of a clinical trial and track the following items:

- Planned and actual site visits that comply with a clinical trial's monitoring plan.
- Subject forms that are reviewed during a site visit or in-house at the DCRI.
- Issues and protocol deviations identified during a site visit or at any other time during the course of the clinical trial, including the resolution of those issues.

CTMS integration enables you to create custom Confirmation and Follow-Up letters as well as Trip Reports that pull together the information you track.

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Protocol-Specific Options

Before a new protocol is entered into the CTMS, a Protocol Setup meeting occurs to identify protocol-specific requirements and settings, including options that might influence how you enter site visit data. Please refer to your protocol's Data Entry Guideline (DEG) document to determine how data should be entered into the CTMS for your protocol.

Other protocol-specific options include:

- Blinding/unblinding field requirement.
- Whether or not to use the CTMS Trip Report tool.
- Custom checklist activities.
- Custom Confirmation and Follow-Up letters.

Site Visits: How Often?

Optionally, protocol-wide monitoring intervals can be configured during protocol setup by submitting a CTMS Request (CTMSR) form by email to the DCRI Service Desk (dcriservicedesk@dm.duke.edu).

Your requested interval appears on all sites in the protocol, but you can override this setting on a per-site basis by changing the following fields in the site record:

Field	Guidelines
Monitoring Interval Override	Enter a number that is the interval of the unit of measure you specify in the **Monitoring Interval Unit Override** field. For example, enter *2* (for two days, two weeks, two months, or two years).
Monitoring Interval Unit Override	From the drop-down list, select the unit of measure (*Days*, *Weeks*, *Months*, *Years*) to go with the interval you entered in the **Monitoring Interval Override** field.
Monitoring Interval Override Reason	From the drop-down list, select the reason for the override.

Site Visit Process Flow

The following flow charts represent the steps to properly record a site visit and create a Trip Report. You will find detailed instructions in the remaining sections of this guide.

Before the Site Visit

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During/After the Site Visit

Marking Subjects to be Monitored

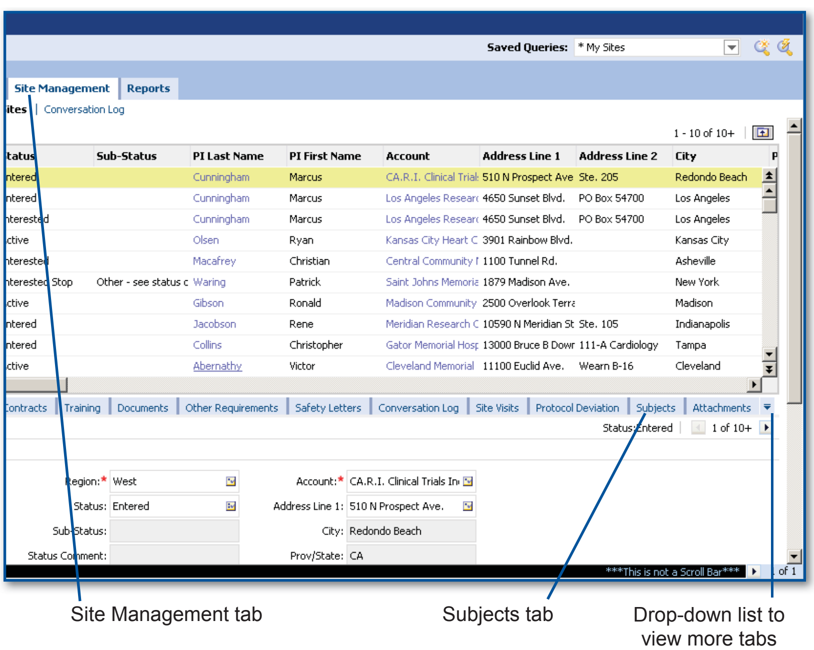
Depending on the Monitoring Plan for your protocol, a percentage of subjects enrolled at a site will need to be monitored (source verification of subject forms). In the CTMS, all enrolled subjects are listed in subject-related views. You can indicate which subjects you intend to monitor by following the process below.

Warning: If your trial uses an Interactive Voice Response System (IVRS) to automatically pull enrollment information into the CTMS, do NOT use the **New** button in the **Subjects** view to add a new subject record. There can be a 48-hour delay from the time subject information is received from the IVRS to when it appears in the CTMS.

Notes

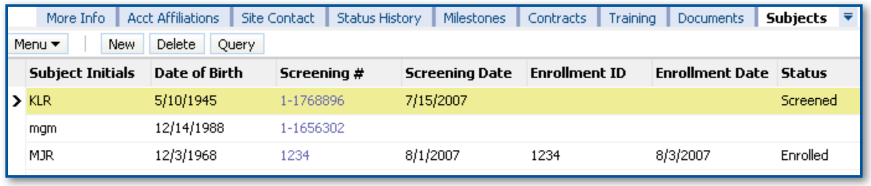
Marking Subjects

1. Go to the **Site Management** screen.
2. Locate the site by running a query on the **Site #** field. (See "Query Basics" in IT Training's *CTMS Fundamentals* user reference guide.)
3. Select the site by clicking to the left of the site record.
4. Select **Subjects**. If this tab does not show, click the drop-down list to the right of all view tabs at the bottom of the window.



NOTES

5 If necessary, query for the subject under the **Subjects** view tab.



WARNING: Do not attempt to add subjects manually until you determine whether subjects are automatically or manually added to the CTMS for your protocol.

6 To mark a subject record for monitoring, click in the subject's **To Be Monitored** field.

7 Check the box to flag the subject for monitoring.

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

Documenting a Site Visit

Site visit scheduling, tracking, and reporting can be performed in the CTMS. Monitors can record their activities during the course of a clinical trial, and track the following items:

- Planned and actual site visits that comply with the protocol's monitoring plan.
- Subject forms that are reviewed during a site visit or in-house at the DCRI.
- Issues and protocol deviations identified during a site visit or at any other time during the course of the clinical trial, including the resolution of those issues.

There are two steps involved with documenting a site visit:

Step 1: Create a site visit record (discussed in this section).

Step 2: Create a Trip Report (see "Trip Reporting" on page 27).

CTMS integration enables you to create custom Confirmation and Follow-Up letters (see "Creating a Follow-Up Letter" on page 54), as well as Trip Reports, which automatically incorporate the data that you have entered.

Site visits can consist of site selections, site initiations, periodic monitoring, site close-outs, and unscheduled visits. This section covers how to record site visit data, including fields that you can populate before, during, and after a site visit.

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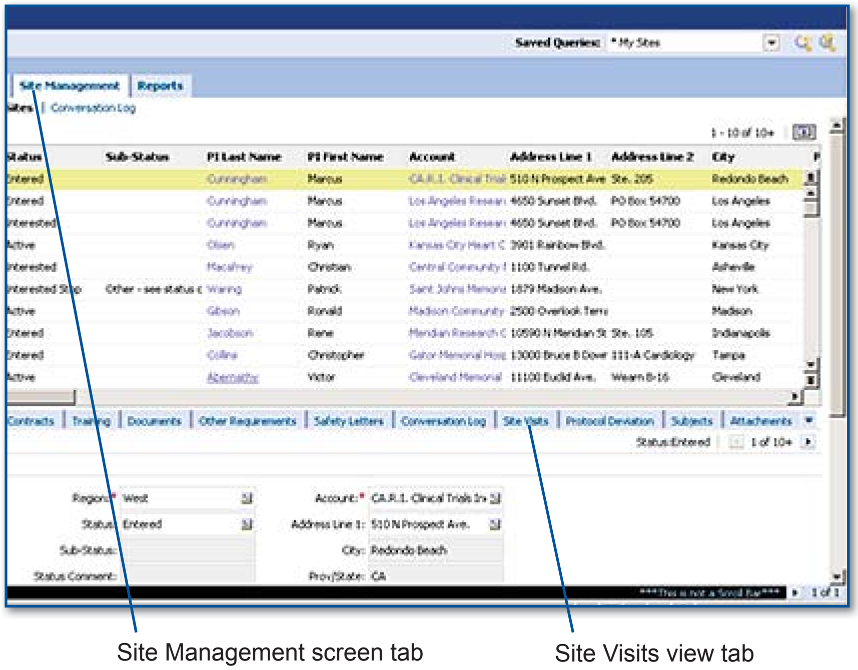
Creating a Site Visit Record

1. Click the **Site Management** screen tab.
2. Locate the site by running a query on the **Site #** field. (See “Query Basics” in IT Training’s *CTMS Fundamentals* user reference guide.)
3. Select the site by clicking to the left of the site record.
4. Click the **Site Visits** view tab at the bottom of the window.



The Site Visits applet opens. An applet is an area that performs a separate function in the Siebel application.

5. On the **Site Visits** view applet, do one of the following:
   - ♦ Click the **New** button to start a new row.

     OR

   - ♦ Click the **Query** button to locate and edit an existing visit record.
6. Use the following table as a guideline for completing the row.

*** Indicates a required field**

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Field	Guidelines
Visit Name	Enter a descriptive name for the visit that will appear on the Trip Report. **Note:** Refer to your protocol's Data Entry Guideline (DEG) or clinical monitoring plan to determine the naming convention for your site visits. For example, the **Visit Name** could be the site name concatenated with the visit type: *30-Day* or *Visit1*.
Visit Type*	Select the appropriate value from the drop-down list to identify the type of visit that is being scheduled. **Note:** After moving off of this field (or pressing **Ctrl**+**S** to save the entry), the entry becomes a hyperlink connected to the Trip Report for the visit (only for protocols using DCRI's trip reporting service).
Unblinded?*	If applicable, use the drop-down list to specify whether this visit was performed by a blinded or unblinded clinical research associate (CRA). *Blinded* CRAs can only view records marked blinded. *Unblinded* CRAs can view all records. **Note:** For most protocols, this field is read-only.
Planned Visit Start	Enter the estimated date that the visit will be performed.
Planned Visit Completion	Enter the estimated date that the visit will be completed.

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Field	Guidelines
Actual Visit Start	Enter the date that the visit actually occurred.
Actual Visit Completion	Enter the date that the visit actually ended.
Visit Status	Automatically displays the current status of the visit, based on whether a date appears in the **Planned Visit Completion (***Planned*), **Actual Visit Completion** (*Done*), or **Visit Cancelled (***Cancelled***)** field. The default value is *Planned*. The process for using this field is trial-specific. Some trial teams edit an existing record; others delete the old record and add a new one. For visits with *Site Selection* in the **Visit Type** field, the following statuses appear in the **Visit Status** drop-down list: ♦ **Not Required - Waiver** should be used when DCRI does not have documentation that the site has had an on-site monitoring visit in the last 24 months, but the sponsor waives the requirement for the site selection visit. Selecting this status changes the **Trip Report Status** field’s value from *Not Started* to *Not Required*. ♦ **Not Required - Exemption** should be used when DCRI has documentation that the site has had an on-site monitoring visit in the last 24 months, so it is exempt from the requirement for an on-site site selection visit. Selecting this status changes the **Trip Report Status** field’s value from *Not Started* to *Not Required*. (continued on next page)

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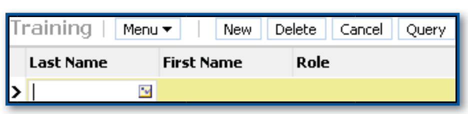
Field	Guidelines
(continued)	**Note:** When a *Not Required* status is selected, all other fields in the site visit record are locked from editing.
Trip Report Status	Automatically populated from the Trip Report's **Report Status** field.
Visit Mechanism	Select the type of visit from the drop-down list. The default value is *On-site*.
Co-Monitoring Visit	If the visit will be performed by more than one CRA, select **Yes** from the drop-down list. The default value is *No*.
Training Visit	If the visit will be used to train one or more CRAs, select **Yes** from the drop-down list. The default value is *No*. To record trainer/trainee names and roles: 1 Select **Yes** from the **Training Visit** drop-down list. 2 Save the record by pressing **Ctrl**+**S**. 3 Scroll down to the **Training** area of the window.  4 Click **New**. 5 In the **Last Name** field, click the selection icon to select the other CRA's name. 6 In the **Role** field, select the CRA's training role. 7 Save the record by pressing **Ctrl**+**S**. **Note**: Training role information is not recorded on the printed PDF copy of the Trip Report.

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Field	Guidelines
Assigned To	To assign the visit to another CTMS user (the default value is your user name): 1 Click the selection icon in the field. 2 Query for and select the name of the person from the **Available** list. 3 Click **Add** to add the name to the **Selected** list. 4 Check the **Primary** checkbox to indicate the person who is responsible for completing the site visit record. 5 *(optional)* Remove the original name from the **Selected** list by selecting it and clicking **Remove**. 6 Click **OK**.
Loop Visit Name	Enter a name to identify that the visit is part of a combined trip to other sites. For example, enter **East Coast Loop**.
Loop Sequence	Enter a number that represents the sequence of the visit in a particular loop. For example, enter **2** to represent the second visit completed in the loop.
Planned Patients Monitored	Enter the number of subjects that are estimated to be monitored on the site visit.
Actual Patients Monitored	Enter the number of subjects that were actually monitored on the site visit.
Travel Time	Enter the number of hours that you travelled. Numbers are rounded to the nearest tenth. For example, entering *5.25* rounds to *5.3* hours.
Time On Site	Enter the number of hours that you were on site. Numbers are rounded to the nearest tenth. For example, entering *5.25* rounds to *5.3* hours..

Field	Guidelines
Planning/Reporting Time	Enter the number of hours that you spent planning for and documenting the site visit. Numbers are rounded to the nearest tenth. For example, entering *5.25* rounds to *5.3* hours.
Confirmation Letter Sent Date	Enter the date that the Confirmation Letter for the visit was sent to the site.
Follow-Up Letter Sent Date	Enter the date that the Follow-Up Letter for the visit was sent to the site.
Comments	Enter any comments related to the visit, up to a maximum of 255 characters.
Trip Report Completed	Enter the date that the Trip Report was completed. **Note:** The process for using this field can be trial-specific. Typically, this date represents when all documentation is complete for the visit and Trip Report.
Visit Cancelled	If applicable, enter the date the visit was cancelled. **Note**: Selecting *Cancelled* from the **Visit Status** field automatically populates this field with the current date.
Submit To Last Name	Automatically populated from the Trip Report's **Submitted To** field.
Submit To First Name	Automatically populated from the Trip Report's **Submitted To** field.
Submitted By Last Name	Automatically populated from the Trip Report's **Submitted By** field.
Submitted By First Name	Automatically populated from the Trip Report's **Submitted By** field.

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Field	Guidelines
Submitted Date	Automatically populated when the Trip Report's **Report Status** field shows *Submitted*.
Approved Date	Automatically populated when the Trip Report's **Report Status** field shows *Approved*.
Expense Report Submitted	Enter the date that the expense report for the visit was submitted to the project lead.
Exp Rpt Submit By FN	Automatically populated when a name is selected in the **Exp Rpt Submit By LN** field.
Exp Rpt Submit By LN	Click the selection icon to select your name (or the name of the person submitting the expense report).
Exp Rpt Appr By FN	Automatically populated when a name is selected in the **Exp Rpt Appr By LN** field.
Exp Rpt Appr By LN	Click the selection icon to select the name of the person who approved the expense report.
Expense Report Approved	Enter the date that the expense report for the visit was approved.
Trip Report Sent to Sponsor Date	Automatically populated when the Trip Report's **Report Status** field shows *Sent to Sponsor*.

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

Completing Fields After Trip Report Approval

NOTES

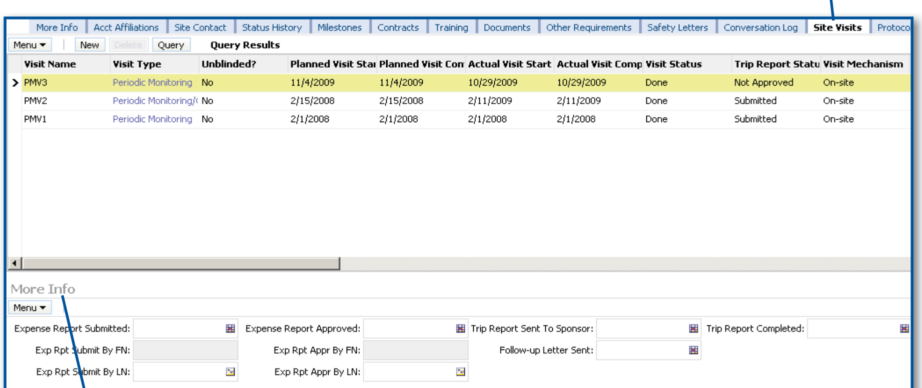
When the Trip Report is approved (see “Trip Report Approval Process” on page 61), all fields in the Trip Report and Site Visit Record are locked from editing. The following fields are made available on the **More Info** applet below the site visit record, so that you can complete them even after the Trip Report is approved, since these events generally occur after approval:

- Expense Report Submitted
- Exp Rpt Submit By FN
- Exp Rpt Submit By LN
- Exp Rpt Appr By FN
- Exp Rpt Appr By LN
- Expense Report Approved
- Trip Report Sent to Sponsor
- Follow-Up Letter Sent
- Trip Report Completed

Adding Data to Fields After Trip Report Approval

1. On the **Site Visits** view tab, select the site visit by clicking to the left of the record.
2. Scroll down to the **More Info** applet at the bottom of the window.

Site Visits view tab



More Info applet

3. Use the following table as a guideline for completing the fields.

NOTES

* Indicates a required field

Field	Guidelines
Expense Report Submitted	Enter the date that the expense report for the visit was submitted to the Lead CRA or Project Lead.
Exp Rpt Submit By FN	Automatically populated when a name is selected in the **Exp Rpt Submit By LN** field.
Exp Rpt Submit By LN	Click the selection icon to select your name (or the name of the person submitting the expense report).
Expense Report Approved	Enter the date that the expense report for the visit was approved.
Exp Rpt Appr By FN	Automatically populated when a name is selected in the **Exp Rpt Appr By LN** field.
Exp Rpt Appr By LN	Click the selection icon to select the name of the person who approved the expense report.
Trip Report Sent to Sponsor	If applicable, enter the date that the Trip Report was sent to the sponsor.
Follow-Up Letter Sent	Enter the date that the Follow-Up Letter for the visit was sent to the site.
Trip Report Completed	Enter the date that the Trip Report was completed. **Note:** The process for using this field can be trial-specific. Typically, this date represents when all documentation is complete for the visit and Trip Report.

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

Viewing the Trip Report Status History

NOTES

The **Trip Report Status History** applet that appears at the bottom of both the **Site Visits** screen tab (at the top of the window) and the **Site Visits** view tab (available on the **Site Management** screen tab) shows status changes that were made to the Trip Report.

Trip Report - Status History | Menu ▾ | Query

Employee Login	Operation	Field	Old Value	New Value	Date
SI001EEE	Modify	DCRI Submitted By Last Name		CRA	12/4/2007 10:16:01 AM
SI001EEE	Modify	Trip Report Status	Not Started	In Progress	12/4/2007 10:16:01 AM
SI001EEE	Modify	DCRI Submit To Last Name		CRA Mgr	12/4/2007 10:17:05 AM
SI001EEE	Modify	Trip Report Status	In Progress	Submitted	12/4/2007 10:17:16 AM
SI001EEE	Modify	DCRI Submitted Date		12/04/2007	12/4/2007 10:17:16 AM

The applet's read-only fields are explained in the table below.

Field	Description
Employee Login	Who made the update.
Operation	The action that was taken.
Field	The field that was updated.
Old Value	The value that was in the field prior to the update.
New Value	The new value that is now in the field.
Date	The date that the update occurred.

TRIP REPORTING

A *Trip Report* is populated before, during, and after a site visit, containing data that is collected by CRAs. The CTMS supports electronic signature technology, enabling submission and approval of Trip Reports to be done electronically.

Trip Reports can contain the following information:

- Type of visit
- *Submitted by* and *approval* information
- Site visit attendees
- Site visit checklist items
- Site visit follow-up items
- Informed Consent Form (ICF) monitoring information
- Case Report Form (CRF) monitoring information
- Protocol deviations
- Site visit attachments
- Site visit observations and comments

TIP: Although you cannot save “versions” of your electronic Trip Report, you can save a PDF copy at any time to capture the most current updates. See “Viewing and Creating a PDF Trip Report” on page 66.

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Notes

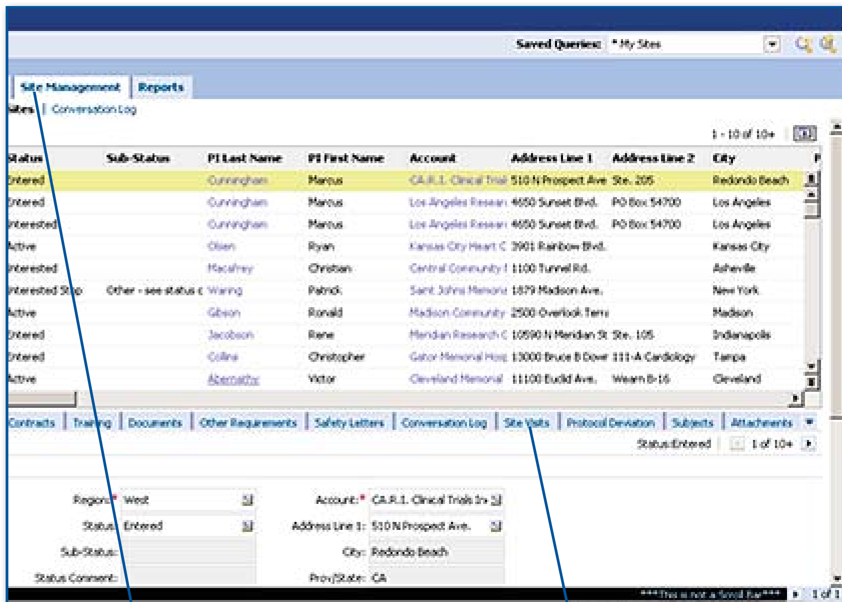
Starting a New Trip Report

When a site visit has been scheduled, the Trip Report can be started to help you prepare for the visit. Specifically, the **Report Template** should be selected, which automatically changes the **Report Status** to *In Progress* and populates the **Checklist Activities** tab.

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

2 Locate the site by running a query on the **Site #** field. (See “Query Basics” in IT Training’s *CTMS Fundamentals* user reference guide.)

3 Select the site by clicking to the left of the site record.



Site Management screen tab

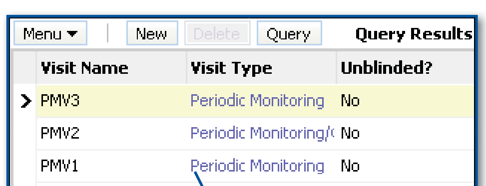
Site Visits view tab

4 Click the **Site Visits** view tab at the bottom of the window.

5 If necessary, query for the visit in the **Site Visits** view tab.

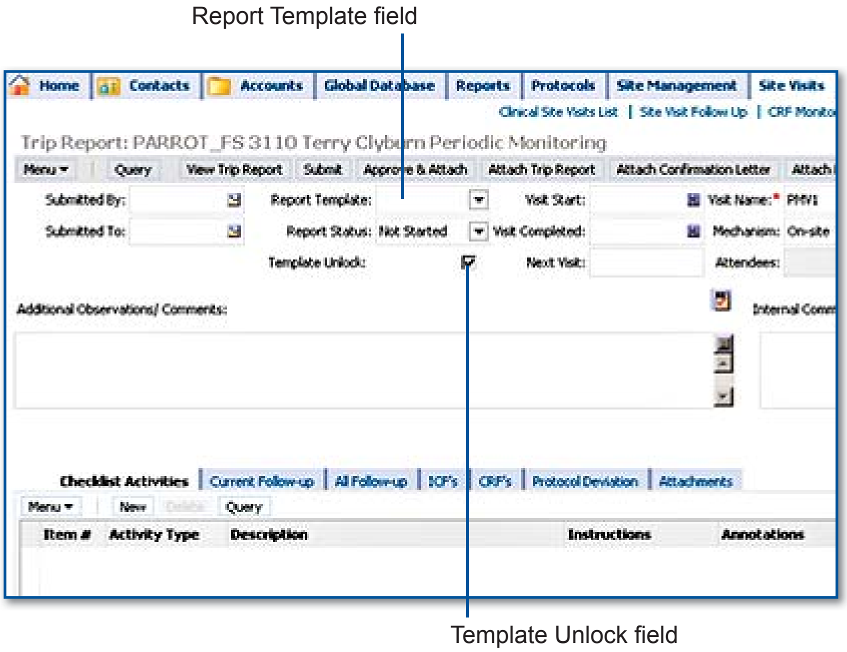
If the query does not return any records, you must enter the site visit prior to completing this procedure. See “Documenting a Site Visit” on page 15.

6 Click the blue hyperlink in the **Visit Type** field.



Visit Type hyperlink

The Trip Report detail window appears.



7 Click the **Report Template** drop-down arrow to select a template.

The following occurs:

- The **Report Template** field becomes read-only.
- The **Report Status** field is populated with the value *In Progress*.
- The **Template Unlock** field is unchecked.
- The **Checklist Activities** tab is populated with checklist items to be addressed during the site visit.

WARNING: If applicable, protocol-specific templates will be listed first in the **Report Template** drop-down list. Use protocol-specific templates unless otherwise instructed. Refer to your protocol's DEG or clinical monitoring plan to determine which template to use.

8 Press **Ctrl**+**S** to save the record.

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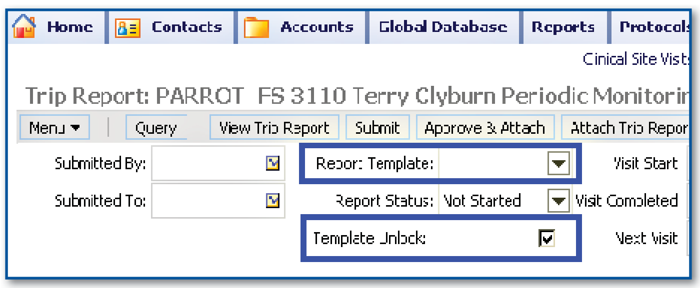
Changing the Report Template

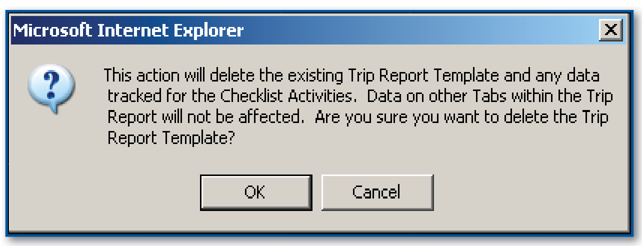
By default, when a Report Template is selected, the selection immediately becomes read-only to prevent accidental changes of the template after data has been added to the **Checklist Activities** tab. The **Template Unlock** checkbox enables you to unlock the **Report Template** field and change the template when needed. Both the **Report Template** and **Template Unlock** fields are read-only for Trip Reports with a **Report Status** of *Submitted*, *Approved*, or *Sent to Sponsor*.

WARNING: When you change a Report Template, all previously entered data on the **Checklist Activities** tab will be deleted and replaced with the checklist associated with the new template. Data on all other tabs in the **Trip Report** window will not be affected if you change the Report Template.



1 Select **Template Unlock**, and then step off the field to save the selection.

The following message appears:



2 Do one of the following:

- Click **OK** if you want to replace the checklist and any previously entered data with the new template's checklist. You can now click the **Report Template** drop-down arrow to select a new template.

  Or

- Click **Cancel**. No changes will be made.

Creating a Confirmation Letter

Notes

You can create Confirmation Letters in the **Trip Report** window, using a built-in template tool. This tool pulls data from your site visit record and Trip Report to populate the letter with information specific to your visit. Letters are saved in Microsoft Word format, enabling you to save them to another file location, print and mail or fax them, or attach them to an email message.

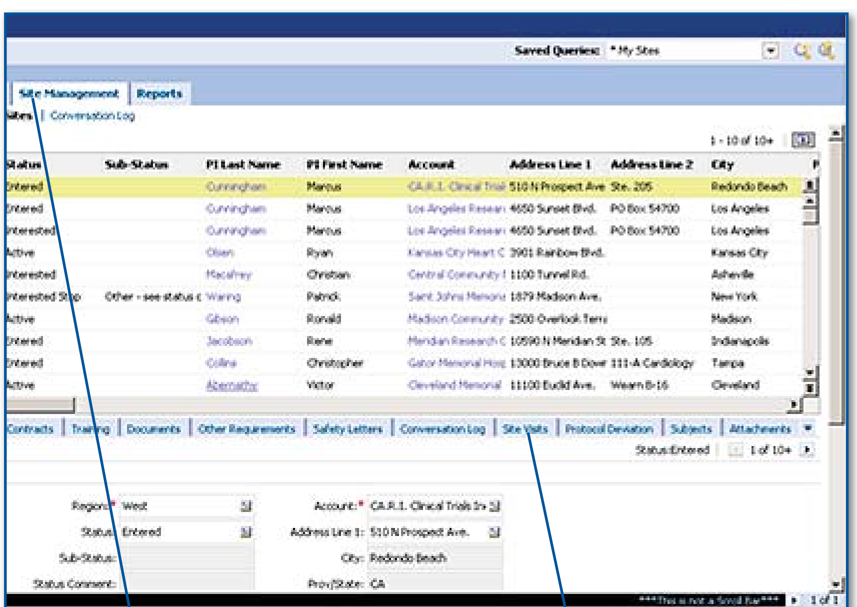
Note: Standard, site-visit-type-specific letter templates are automatically created when following the letter generation procedures below. Protocol-specific, site-visit-type-specific letter templates can be accommodated. Requests should be submitted on a CTMS Request (CTMSR) form by email to the DCRI Service Desk (*dcriservicedesk@dm.duke.edu*).

Tip: Instead of manually signing the letters, CTMS offers an optional electronic signature feature that is 21 CFR Part 11 compliant. For this capability to work, you must request electronic signature configuration for your protocol's letters in a CTMSR sent to the DCRI Service Desk.

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

2 Locate the site by running a query on the **Site #** field. (See "Query Basics" in IT Training's *CTMS Fundamentals* user reference guide.)

3 Select the site by clicking to the left of the site record.



Site Management screen tab

Site Visits view tab

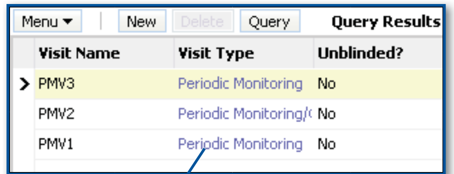
NOTES

4 Click the **Site Visits** view tab at the bottom of the window.

5 If necessary, query for the visit on the **Site Visits** view tab.

If the query does not return any records, you must enter the site visit prior to completing this procedure. See “Documenting a Site Visit” on page 15.

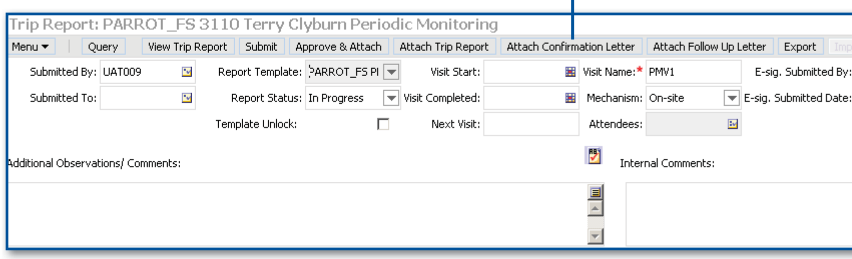
6 Click the blue hyperlink in the **Visit Type** field.



Visit Type hyperlink

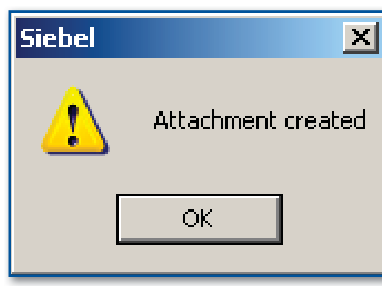
The Trip Report detail window appears.

Attach Confirmation Letter button



7 Click **Attach Confirmation Letter**.

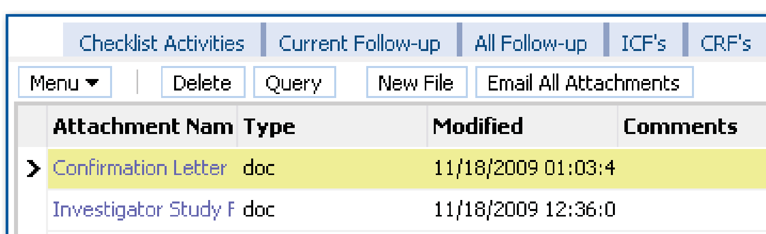
After a brief pause, the confirmation window to the right appears, telling you that the Confirmation Letter has been added to your Attachments tab.



8 Click **OK**.

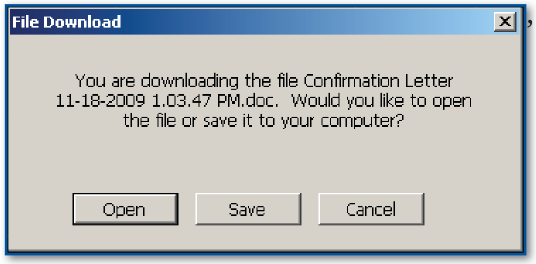
9 Click the **Attachments** tab.

The new Confirmation Letter appears at the top of the list.



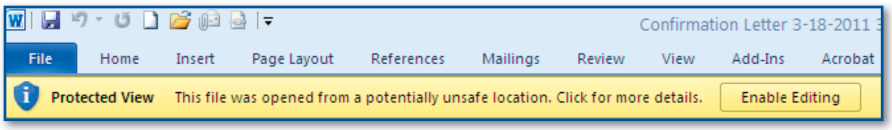
10 Click the **Confirmation Letter** hyperlink.

A message appears, enabling you to open the file or save it to another location.



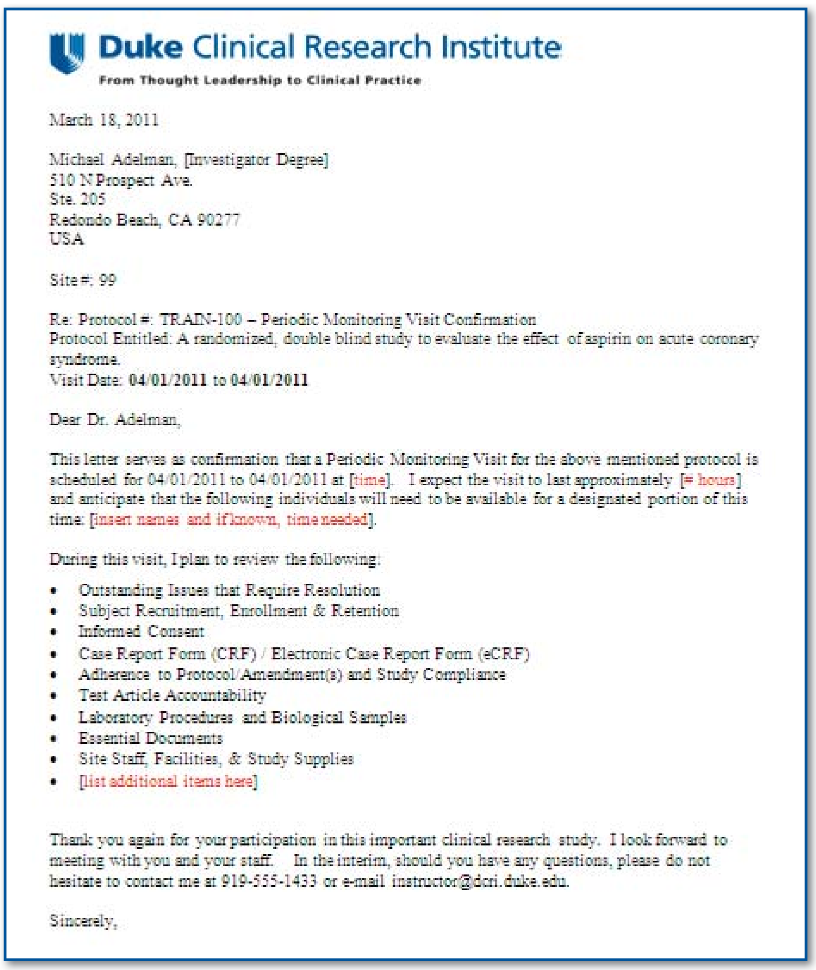
11 Click **Open**.

The letter opens in Microsoft Word in Protected View mode.



12 To edit the file, click **Enable Editing** at the top of the Word window.

13 Review and edit the letter as needed.



Duke Clinical Research Institute

From Thought Leadership to Clinical Practice

March 18, 2011

Michael Adelman, [Investigator Degree]
510 N Prospect Ave.
Ste. 205
Redondo Beach, CA 90277
USA

Site #: 99

Re: Protocol #: TRAIN-100 – Periodic Monitoring Visit Confirmation
Protocol Entitled: A randomized, double blind study to evaluate the effect of aspirin on acute coronary syndrome.
Visit Date: **04/01/2011** to **04/01/2011**

Dear Dr. Adelman,

This letter serves as confirmation that a Periodic Monitoring Visit for the above mentioned protocol is scheduled for 04/01/2011 to 04/01/2011 at [time]. I expect the visit to last approximately [# hours] and anticipate that the following individuals will need to be available for a designated portion of this time: [insert names and if known, time needed].

During this visit, I plan to review the following:

- Outstanding Issues that Require Resolution
- Subject Recruitment, Enrollment & Retention
- Informed Consent
- Case Report Form (CRF) / Electronic Case Report Form (eCRF)
- Adherence to Protocol/Amendment(s) and Study Compliance
- Test Article Accountability
- Laboratory Procedures and Biological Samples
- Essential Documents
- Site Staff, Facilities, & Study Supplies
- [list additional items here]

Thank you again for your participation in this important clinical research study. I look forward to meeting with you and your staff. In the interim, should you have any questions, please do not hesitate to contact me at 919-555-1433 or e-mail instructor@dcri.duke.edu.

Sincerely,

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NOTE: If the letter's signature block includes the line pointed out below, then electronic signatures are enabled for this letter.

Sincerely,

Mary Monitor
Clinical Research Associate
Duke Clinical Research Institute
DCRIElectronicSignaturePlaceHolder-DONOTDELETE

Important! Do not edit or delete this text.

14 To print the letter, select **File>Print**.

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

WARNING: You can no longer save a Word document directly to the CTMS if you 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, following steps 15 and 16.

16 To add the file back into the Trip Report, click **New File** on the **Attachments** tab, locate the file, and then click **Open**.

17 If electronic signatures have been enabled for the letter, then do the following:

- **a** On the **Attachments** tab, save the record by pressing **Ctrl + S**.

  WARNING: If you forget to press Ctrl + S, changes you saved in Word are lost.

- **b** On the **Attachments** tab, highlight the letter by clicking to the left of the record.
- **c** Click Sign.

  An Electronic Signature window appears.
- **d** Enter your DCRI network password, and then click **OK**. A confirmation window appears.
- **e** Click **OK**.

  On the **Attachments** tab, a new PDF version of the letter appears with the text *Authored and Electronically Signed by [your name][DD MMM YYYY][HH:MM][AM/PM]* in the signature area of the letter.

  NOTE: To see the new PDF attachment, you may need to refresh your screen.

TIP: The default name for the PDF is rather long. You can change this title by aiming to the right of the default name and clicking a blank area of the **Title** field, and then entering a new name for the PDF file.

f Check your Data Entry Guidelines (DEG) for instructions on whether or not to delete the original Word version of the letter.

TIP: To send the letter via email, go to the **Attachments** tab, click to the left of the letter to highlight it, and then select **File**>**Send Email**.

Completing the Trip Report

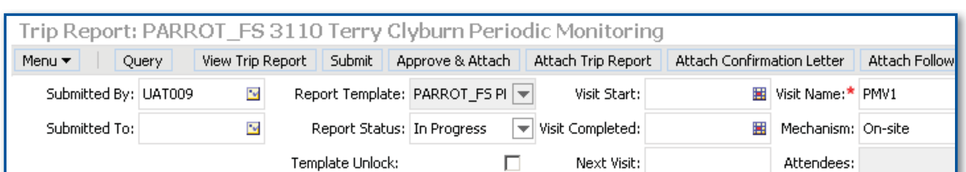
Once a Trip Report has been started, you can return to it as often as needed to complete additional fields, add new data, and attach documents—*until* the Trip Report is approved. To open an existing Trip Report, follow steps 1–6 of “Starting a New Trip Report” on page 28.

This section covers the various pieces of the **Trip Report** window:

- Form fields (see next)
- Checklist activities (page 39)
- Follow-up activities (page 42)
- ICF tracking (page 45)
- CRF tracking (page 47)
- Protocol deviations (page 49)
- Attachments (page 51)

Form Fields

The fields in the upper portion of the **Trip Report** window pertain to the site visit and determine the type of Trip Report you are completing. The header at the top of the window displays the site number, principal investigator, and visit type for the report.



Upper left portion of Trip Report, showing some of the form fields

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Use the following table as a guideline to complete the form fields.

Field	Guidelines
Submitted By	When submitting a Trip Report for approval, click the selection icon in this field to open the **Pick Internal Personnel** window. Select your name from the list, and then click the **Pick** button. See “Trip Report Approval Process” on page 61.
Submitted To	When submitting a Trip Report for approval, select the name to which the report is being submitted. See “Trip Report Approval Process” on page 61.
Report Template	Select a Trip Report template from the drop-down list. This step populates the **Checklist Activities** tab. See “Starting a New Trip Report” on page 28. If you would like to change the template, see “Changing the Report Template” on page 30.
Report Status	Populated with the appropriate status when the following actions occur: ♦ *Not Required*. (For SSV visits) Appears when the site visit’s **Visit Status** is *Not Required*. ♦ *Not Started*. Default status indicating that a template has not yet been selected in the **Report Template** field. ♦ *In Progress*. Appears when the CRA selects a template in the **Report Template** field. ♦ *Submitted*. Appears when the CRA submits the Trip Report for approval. ♦ *Sent to Sponsor*. Selected by the team member designated to send the Trip Report to the sponsor (typically the Lead CRA). ♦ *Recall*. Can be selected by the CRA after the Trip Report has been submitted for approval, allowing the CRA to edit the Trip Report. ♦ *Not Approved*. Selected by the Trip Report approver (typically the Lead CRA) to indicate that the Trip Report requires further editing by the CRA. ♦ *Approved*. Appears when the Trip Report approver (typically the Lead CRA) clicks the **Approve & Attach** button. See “Trip Report Approval Process” on page 61.

Field	Guidelines
Template Unlock	Check the box to unlock the **Report Template** drop-down list. See “Changing the Report Template” on page 30.
Visit Start	Automatically populated from the site visit record’s **Actual Start Date** field.
Visit Completed	Automatically populated from the site visit record’s **Actual Completion Date** field.
Next Visit	Enter the next date that you plan to visit the site. If this field is populated, it will show on the Trip Report. If this field is not populated, the words *Next Visit* will not appear on the printed Trip Report.
Visit Name	Automatically populated from the site visit record’s **Visit Name** field.
Mechanism	(read-only) Automatically populated from the site visit record’s **Visit Mechanism** field.
Attendees	To select the attendees who participated in the visit: 1 Click the selection icon in this field. 2 Query a name in the left side of the window. **Note:** By default, the list shows only site (“affiliated”) personnel. To view a list of all CTMS contacts, click **All Contacts**. 3 Click **Add** to add the name to the right side of the window. 4 Click the **Attending Role** drop-down arrow to select the attendee’s role. 5 If needed, repeat steps 2–4 to add other attendees. 6 Click **OK**. **Note:** Contacts with a date in the **End Date** field can still be selected as an attendee for the visit.

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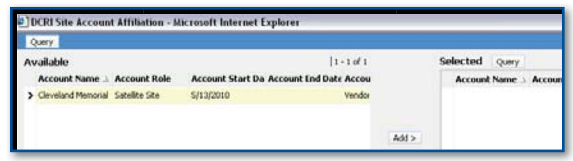
Field	Guidelines
Other Locations	To record other affiliated sites you attended while visiting the main site:  **1** Click the selection icon in the field. A DCRI Site Account Affiliation window appears. Accounts listed on the site's Acct Affiliations tab appear in the Available (left) box.  **2** Select an account that you visited while on this site visit, and then click **Add**. The site appears in Selected (right box). **3** Click **OK**. **Note:** If this field is populated, the accounts appear on the PDF copy of the Trip Report.
E-sig Submitted By **E-sig Submitted Date** **E-sig Approved By** **E-sig Approved Date**	Automatically populated during the Trip Report approval process. **Note:** *E-sig* (electronic signature) information appears in the current user's time zone in the Trip Report window. The PDF version of the Trip Report will always display e-sig information in Eastern Standard / Daylight Time (EST / EDT) time zone. See "Trip Report Approval Process" on page 61.
Additional Observations/ Comments	Use this field to capture additional comments about the trip. All users can enter comments in this field (maximum 16,000 characters). Comments entered in this field appear on the final printed Trip Report.
Internal Comments	Use this field to capture comments to and from the Trip Report approver. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field will not show on the final printed Trip Report. When the Trip Report is approved, the contents of this field are deleted.

Checklist Activities

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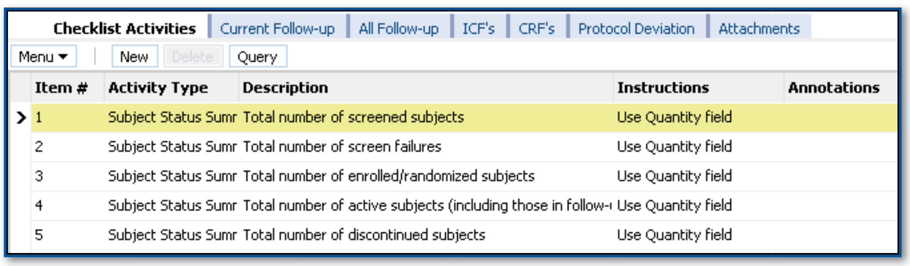
The **Checklist Activities** tab displays a list of questions and issues to be addressed during the site visit. The list of checklist activities is determined by the template that is selected in the **Report Template** field in the top portion of the **Trip Report** window.

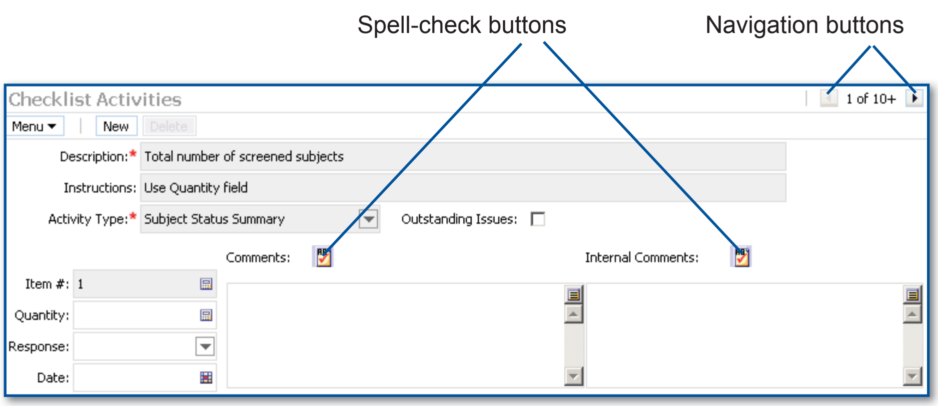
Answer each item by selecting an option from the appropriate column. (For example, you enter numbers in the **Quantity** column.) Depending on your protocol, you can also refer to the **Instructions** and **Annotations** fields to help you understand the proper way to answer specific questions.



Item #	Activity Type	Description	Instructions	Annotations
1	Subject Status Sumr	Total number of screened subjects	Use Quantity field	
2	Subject Status Sumr	Total number of screen failures	Use Quantity field	
3	Subject Status Sumr	Total number of enrolled/randomized subjects	Use Quantity field	
4	Subject Status Sumr	Total number of active subjects (including those in follow-ı	Use Quantity field	
5	Subject Status Sumr	Total number of discontinued subjects	Use Quantity field	

Upper portion of Checklist Activities tab

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



Lower portion of Checklist Activities tab

WARNING: You must turn off your pop-up blocker for the spell-check feature to work. See “Enabling CTMS Pop-Up Windows” in Appendix A of IT Training’s *CTMS Fundamentals* user reference guide.

NOTES

1 On the **Checklist Activities** tab, do one of the following:

- To complete an existing checklist activity, select the activity by clicking to the left of the record.

  Or

- To add a new checklist activity, click the **New** button.

2 Use the following table as a guideline to complete the record.

* indicates field is pre-populated for template activities

Field	Guidelines
Item # *	During protocol setup, this field can be pre-populated with a numbering sequence for each activity. Pre-populated ("template") item numbers cannot be modified. If new activities are added to the list, you cannot duplicate an item number.
Activity Type *	Select a category for the checklist item from the drop-down list.
Description *	Enter the question or issue that needs to be addressed at the site, up to a maximum of 256 characters.
Instructions *	(read-only) Based on the protocol, this field shows instructions for how to answer the question. For example, *Use the Response field to answer this question*.
Annotations *	(read-only) Based on the protocol, this field shows additional instructions for how to answer the question. For example, this field provides additional steps to take if the answer in the **Response** field is *Yes*.
Quantity	For checklist items that require a number answer, enter the quantity in this field. **Note**: Only one answer can be entered in the **Quantity**, **Response**, or **Date** field. When a value is entered in one field, the other two are locked from editing. Clearing the field opens all three fields for editing.

Field	Guidelines
Response	For checklist items that require a response, such as **Yes** or **No**, select the option from the drop-down list. See the **Note** in the **Quantity** field guidelines.
Date	For checklist items that require a date answer, enter the date in this field. See the **Note** in the **Quantity** field guidelines.
Comments	Use this field to capture additional comments about the checklist activity. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field appear on the final printed Trip Report. **Note:** Use **Ctrl**+**X** to cut comments from another source and **Ctrl**+**V** to paste them into the **Comments** field.
Internal Comments	Use this field to capture manager comments about the checklist activity, as well as CRA responses to manager comments. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field will not show on the final printed Trip Report. When the Trip Report is approved, the contents of this field are deleted.
Created By	(read-only) Displays the current user ID.
Outstanding Issues	Check the box to indicate that there is an outstanding issue with the checklist item. **Note:** Checking the box does not automatically add a new entry in the **Current Follow-Up Items** tab.

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

TIP: To create a new checklist activity, click **New**.

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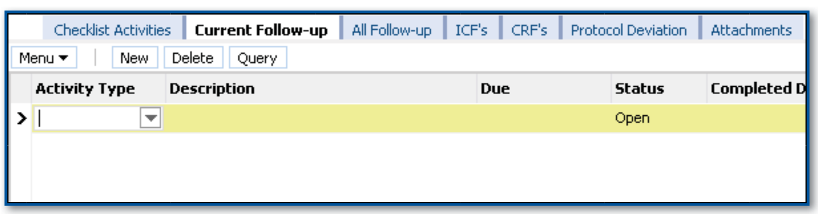
Follow-Up Activities

There are two follow-up activity tabs.

- **Current Follow-up**. Shows all follow-up activities for this visit only. You can add new records and edit records in this view.
- **All Follow-up**. Shows all follow-up activities for this visit, plus the following:
  - Follow-up activities from previous site visits that still have a **Status** of *Open*.
  - Previous site visit follow-up activities that were closed (Status is *Done*) after the previous site visit's **Actual Completion Date**.

  All activities listed on the **All Follow-up** tab appear on the printed Trip Report. In this view you cannot add new records; however, you can edit existing records.

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



Top portion of Current Follow-up tab

► Complete Follow-up Activities with the Current Follow-up Tab

1. Click the **Current Follow-up** tab.
2. If no additional follow-up activities need to be added to the existing list, skip to step 4 of this procedure.
3. If there are additional follow-up activities that need to be added, click the **New** button on the **Current Follow-up** tab.
4. Use the following table as a guideline to complete the new row or to fill in data for an existing follow-up activity.

* indicates a required field

Field	Guidelines
Activity Type*	Select an option from the drop-down list to identify the follow-up activity.
Description	Describe the follow-up activity that needs to be addressed at the site (maximum 4,000 characters).
Due	Enter the date that the follow-up activity should be completed. The default value is blank.
Status	Select the appropriate option from the drop-down list. The default value is *Open*.
Completed Date	Enter the date that the follow-up activity ended.
Resolution/Action Comments	Enter comments regarding the resolution of the follow-up activity (maximum 4,000 characters).
Assigned To:	Follow-up activities only appear in your list if your user ID is listed in the **Assigned To** field (the default). The name listed in the **SM Last Name** field on the site record is the default "primary" contact. To assign the follow-up activity to another person, follow these steps: 1 Click the selection icon in the field. 2 Select the person's name from the **Available** list. 3 Click **Add** to add the person's name to the **Selected** list. 4 Check the **Primary** checkbox to indicate the person that will be responsible for completing the activity. 5 Click **OK**. **Note:** The new person's name does not appear until you exit and return to the window.

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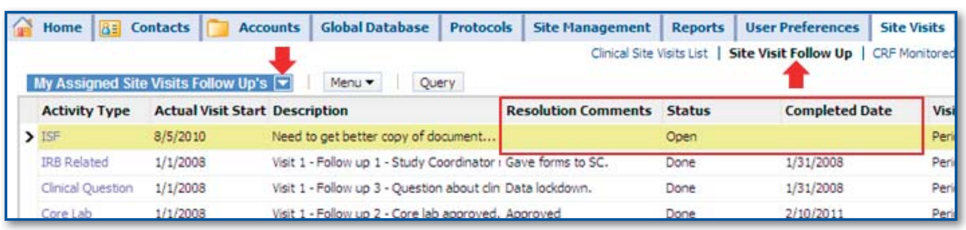
Field	Guidelines
Created By	(read-only) Displays the current user ID.
Show on Follow-Up Letter	Checked by default. Uncheck the box to remove the follow-up item from the Follow-Up Letter. See “Creating a Follow-Up Letter” on page 54.
Internal Comments	Use this field to capture comments to and from the Trip Report approver. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field will not show on the final printed Trip Report. When the Trip Report is approved, the contents of this field are deleted.

► Complete Follow-up Activities from the Site Visits Screen Tab

Alternately, you can close follow-up items by using the **Site Visits** screen tab (click the **Site Visit Follow Up** link). The fields that can be edited at this level include **Resolution Comments**, **Status**, and **Completed Date**. Use this method to close follow-up items after a Trip Report has been approved, or when a future site visit and Trip Report have not yet been entered for the site.



1 From the **Site Visits** screen tab (at the top of the window), click **Site Visit Follow Up**.

2 Query for the appropriate site visit.

3 Edit the follow-up record at the list level (do not drill into the site first).

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

NOTE: To view and/or edit records that are assigned to someone else, select *All My Sites* from the blue drop-down list at the top left of the window.

NOTES

ICF Tracking

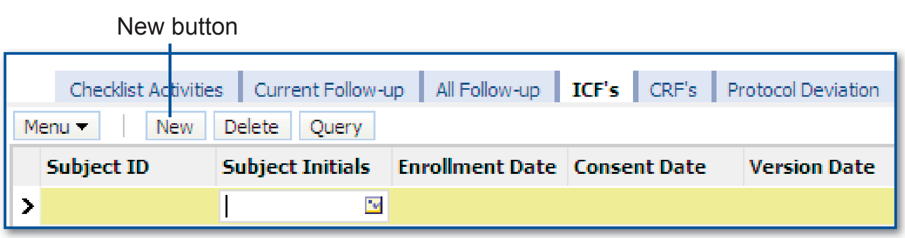
If your protocol is tracking subject Informed Consent Forms (ICFs) during site visits, click the **ICF’s** tab to record the information. Before the Trip Report is approved, you can use the **Delete** button to remove ICF records entered in error.

NOTE: Because some protocols are set up to automatically import enrollment data into the CTMS, there can be as much as a 48-hour delay before enrollment data appears in the CTMS.

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

1 Click the **ICF’s** tab, then click the **New** button.

A new row appears.



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

* indicates a required field

Field	Guidelines
Subject ID	(read-only) After the record is saved, shows the protocol-specific number automatically assigned to the subject. Typically, this is the site number concatenated with a sequence number.
Subject Initials*	**1** Click the selection icon in this field. **2** Select the subject by clicking to the left of the record. **3** Click **OK**. (continued on next page)

NOTES

Field	Guidelines
(continued)	**Notes:** ♦ If you do not see a subject record, contact your clinical administrator. There can be up to a 48-hour delay from the time subject information is received from the IVRS to when it appears in the CTMS. ♦ Subject initials do not appear on the printed Trip Report.
Enrollment Date	(read-only) Shows the date that the subject was enrolled.
Consent Date	Enter the date that the consent occurred.
Version Date	Enter the version date of the ICF. Refer to your protocol's DEG or clinical monitoring plan to determine what date to put in this field.
Type	Select the ICF type from the drop-down list.
Source Document Verified	Check the box to indicate that the source documents for the ICF have been verified.
Source Document Verified Date	Enter the date that the ICF for the subject was verified.
Comments	Enter comments pertaining to the ICF record (maximum 4,000 characters).
Internal Comments	Use this field to capture comments to and from the Trip Report approver. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field do not show on the final printed Trip Report. When the Trip Report is approved, the contents of this field are deleted.

3 Press **Ctrl**+**S** to save the record.

4 Repeat steps 1-3 as needed to record additional ICF data.

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

CRF Tracking

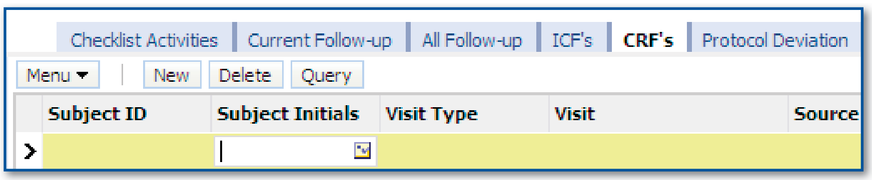
If your protocol is tracking subject Case Report Forms (CRF) during site visits, click the **CRF's** tab.

NOTE: Because some protocols are set up to automatically import enrollment data into the CTMS, there can be as much as a 48-hour delay before enrollment data appears in the CTMS.

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

1 Click the **CRF's** tab, and then click the **New** button.

A new row appears.



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

* indicates a required field

Field	Guidelines
Subject ID	(read-only) After the record is saved, shows the protocol-specific number automatically assigned to the subject. Typically, this is the site number concatenated with a sequence number.
Subject Initials*	1 Click the selection icon in this field. 2 Select the subject by clicking to the left of the record. 3 Click **OK**. **Notes:** ♦ If you do not see a subject record, contact your clinical administrator. There can be up to a 48-hour delay from the time subject information is received from the IVRS to when it appears in the CTMS. ♦ Subject initials do not appear on the printed Trip Report.

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Field	Guidelines
Visit Type	Select an option from the drop-down list to describe the CRF visit.
Visit	Enter the visit name (maximum 150 characters), based on your protocol's work instructions for naming conventions. For example, enter 30-day.
Source Verified	Check the box to indicate that the source documents for the CRF have been verified.
Source Document Verified Date	Enter the date that the source documents were verified.
Retrieved	If applicable, check the box to indicate that the CRF pages were retrieved from the site by the Monitor.
Retrieved Date	If applicable, enter the date that the CRF pages were retrieved.
Page #	If applicable, enter the page numbers of the pages that were retrieved. Alternatively, for Electronic Data Capture (EDC) trials, enter screen reference information (maximum 60 characters). For example, enter **1-50**.
Comments	Enter comments related to the CRF record (maximum 4,000 characters).
Internal Comments	Use this field to capture comments to and from the Trip Report approver. All users can enter comments in this field (maximum 4,000 characters). Comments entered in this field will not show on the final printed Trip Report. When the Trip Report is approved, the contents of this field are deleted.

3. Press **Ctrl**+**S** to save the record.
4. Repeat steps 1-3 as needed to record additional CRF data.

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

NOTES

Protocol Deviations

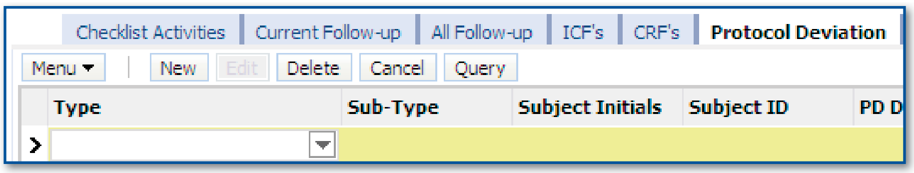
Use the **Protocol Deviation** tab to record both subject-related and site-related deviations that have occurred at the site.

▶ To record a protocol deviation

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

1 Click the **Protocol Deviation** tab, then click the **New** button.

A new row appears.



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

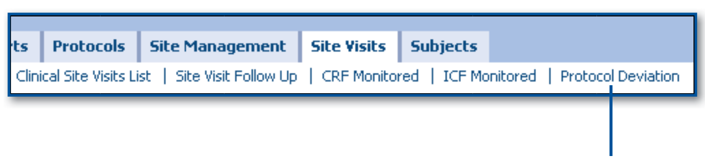
Field	Guidelines
Type	Select the type of protocol deviation from the drop-down list.
Sub-Type	Select either **Site** or **Subject** from the drop-down list to further specify the deviation.
Subject Initials	If the **Sub-Type** is *Subject*, click the selection icon in this field to select the subject to whom the deviation relates. If the **Sub-Type** is *Site*, this field is read-only.
Subject ID	(read-only) After the record is saved, shows the protocol-specific number automatically assigned to the subject. Typically, this is the site number concatenated with a sequence number.
PD Date	Enter the date that the deviation occurred.

NOTES

Field	Guidelines
PD Description	Enter a description of the deviation.
Action Description	If applicable, describe the action that was taken to address the deviation.
Follow-Up Required	Check the box to indicate that there is a follow-up item for this deviation. **Note:** Checking the box creates a new entry on the **Current Follow-up** tab. The follow-up activity's **Description** field is populated with the following: ♦ If the **Subtype** is *Subject*, includes the word "Subject," Subject Initials, Subject ID, PD Date, and Action Description. ♦ If the **Subtype** is *Site*, includes the word "Site," the PD Date, and Action Description.

▶ To view all protocol deviations for your protocol

1. Click the **Protocol Deviation** hyperlink at the top of the **Site Visits** screen tab.



Protocol Deviation Link

2. Do one of the following:
   - Click the blue hyperlink in the **Type** field to go to the **Protocol Deviation** tab on the Trip Report for that deviation.

     Or

   - Click the blue hyperlink in the **Follow-Up** field to go to the **Current Follow-Up** tab in the Trip Report for that deviation.

NOTES

Attachments

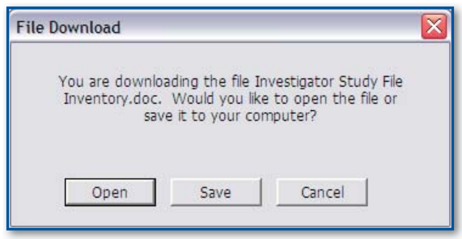
Before the Trip Report is approved, you can attach documents, including the a PDF copy of the Trip Report itself, to the electronic Trip Report. The names of the attachments appear on the printed report (if the **Show on Trip Report** checkbox is selected).

The *Investigator Study File Inventory* (Reg Doc Checklist) is pre-attached to the **Attachments** tab. View a sample in “Appendix B: Attachments” on page 77.

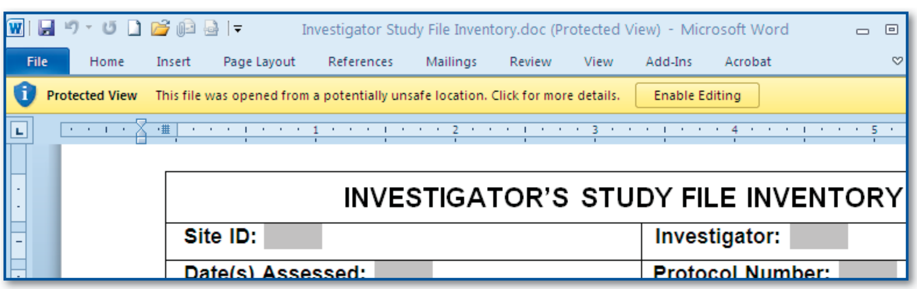
▶ To complete the Investigator Study File Inventory document

1 Click the *Investigator Study File Inventory* blue hyperlink.

Note: If the window shown at right appears, click **Open** to open the file or **Save** to save it to another location.



The file opens in Microsoft Word in Protected View mode.



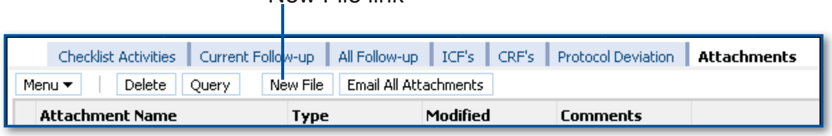
2 To edit the file, click **Enable Editing** at the top of the Word window.

3 Complete the appropriate entries, and then click **File>Save As** to save the file to an external location. This method can be used to keep a “running log” of Investigator Study File related information.

▶ To attach a document

1 Click the **Attachments** tab, and then click **New File**.

New File link



NOTES

2 Select the file that you want to attach.

3 Click **Open**.

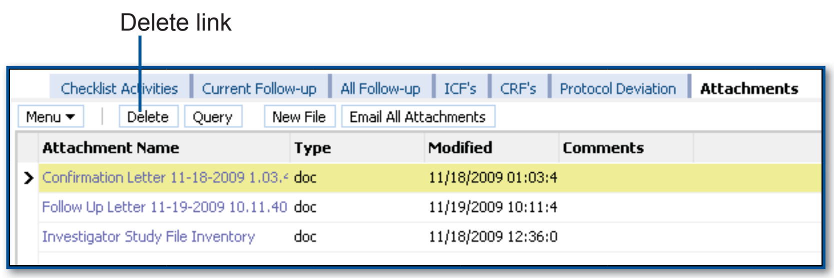
4 In the **Comments** field, enter additional comments about the attachment, (maximum 4,000 characters).

5 In the **Show on Trip Report** field, select the checkbox to show the attachment name in the list of attachments on the printed Trip Report.

▶ To delete a document

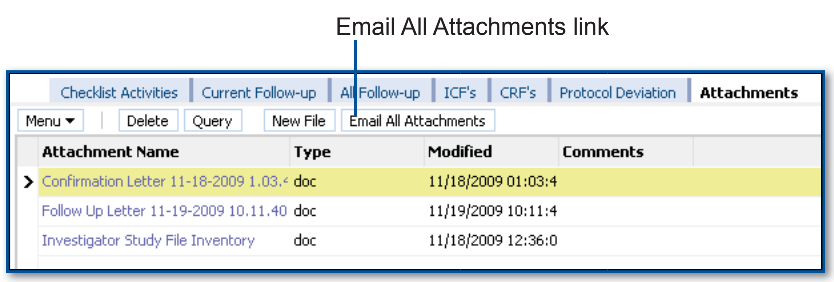
1 Select the attachment row that you want to delete.

2 Click **Delete**.



▶ To email all attachments

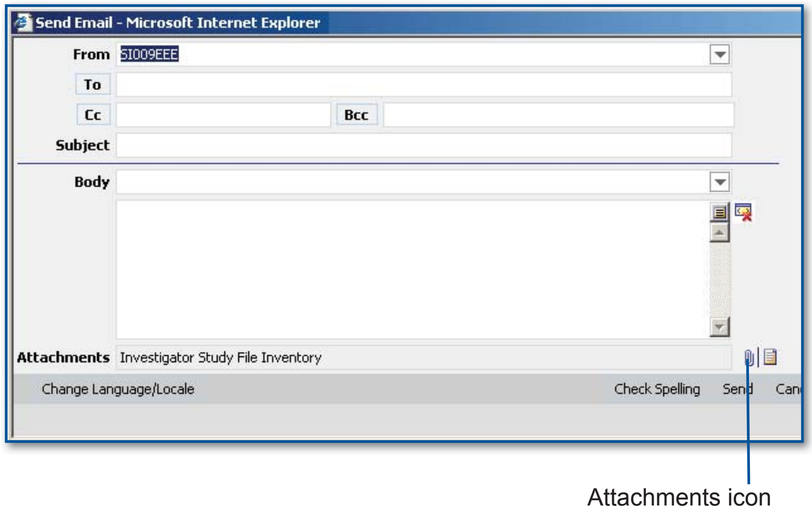
1 On the **Attachments** tab, click **Email All Attachments**.



The CTMS Send Email window appears. All attachments on the Attachments tab list are automatically attached to the message.

NOTES

2 Click the **Attachments** icon to view a list of the attachments that will be included on the email.



3 If necessary, delete or add files using the **Delete** and **New File** buttons at the top of the window.

4 Attachments that are deleted from the email **Attachments** list will still appear on the Trip Report **Attachments** tab.

5 Click **OK** to return to the **Send Email** window.

6 Address the email message by doing one of the following:

- Enter the email address in the **To** field.

Or

- Click the **To** button and select a contact from the CTMS global database.

7 Enter a subject in the **Subject** field.

8 Enter a message in area under the **Body** field.

9 Click **Send**.

NOTE: Because the **From** field is automatically populated with your user name, messages sent using this method appear to be from you. However, note that there will be no record of the sent message in your Microsoft Outlook **Sent** folder.

NOTES

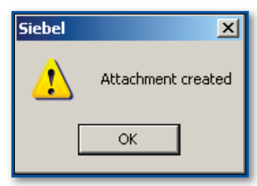
Creating a Follow-Up Letter

Follow-Up Letters can be created in the **Trip Report** window, using a built-in template tool. This tool pulls data from your site visit record and Trip Report to populate the letter with information specific to your visit. Letters are saved in Microsoft Word format, enabling you to save them to another file location, print and mail or fax them, or attach them to an email message.

NOTE: Standard, site-visit-type-specific letter templates are automatically created when following the letter generation procedures below. Protocol-specific, site-visit-type-specific letter templates can be accommodated. Requests should be submitted on a CTMS Request (CTMSR) form by email to the DCRI Service Desk (*dcriservicedesk@dm.duke.edu*).

TIP: Instead of manually signing the letters, CTMS offers an optional electronic signature feature that is 21 CFR Part 11 compliant. For this capability to work, you must request electronic signature configuration for your protocol's letters in a CTMSR sent to the DCRI Service Desk.

1 In the **Trip Report** window, click **Attach Follow Up Letter**.

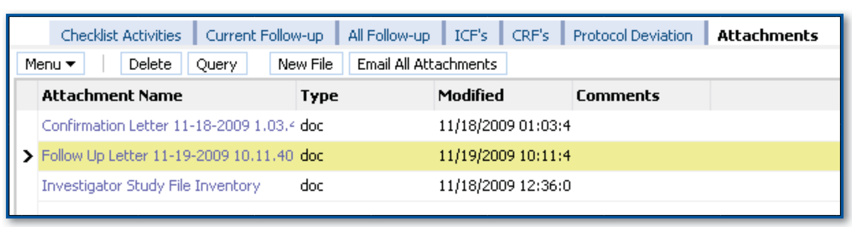


After a pause, a confirmation window appears, telling you that the Follow-Up Letter has been added to your **Attachments** tab.

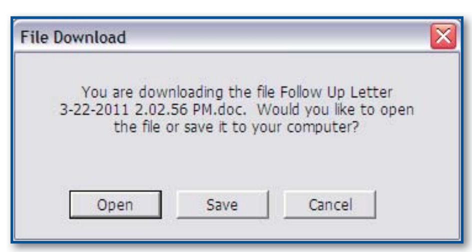
2 Click **OK**.

3 Click the **Attachments** tab.

The new Follow-Up Letter appears in the list.

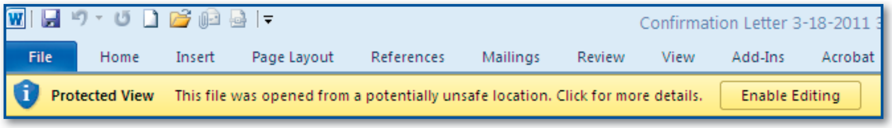


4 Click the **Follow Up Letter** hyperlink.



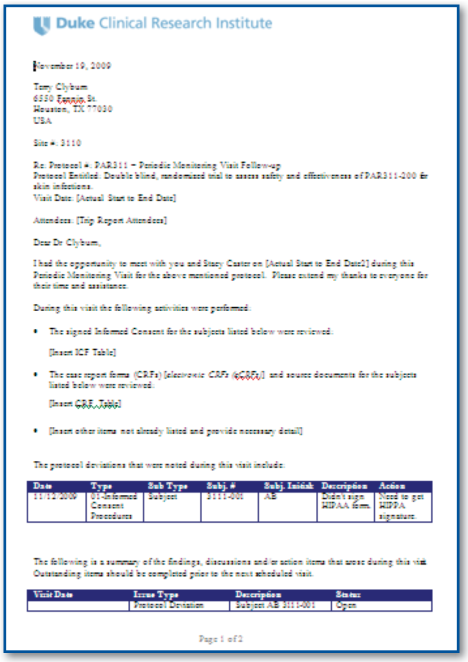
Note: If the window shown right appears, click **Open** to open the file or **Save** to save it to another location.

The letter opens in Microsoft Word in Protected View mode.



5 To edit the file, click **Enable Editing** at the top of the Word window.

6 Review and edit the letter as needed.



Duke Clinical Research Institute

November 19, 2009

Terry Clyburn
6550 Fannin St.
Houston, TX 77030
USA

Site #: 3110

Re: Protocol #: PAR311 – Periodic Monitoring Visit Follow-up
Protocol Entitled: Double blind, randomized trial to assess safety and effectiveness of PAR311-200 for skin infections.
Visit Date: [Actual Start to End Date]

Attendees: [Trip Report Attendees]

Dear Dr Clyburn,

I had the opportunity to meet with you and Stacy Carter on [Actual Start to End Date2] during this Periodic Monitoring Visit for the above mentioned protocol. Please extend my thanks to everyone for their time and assistance.

During this visit the following activities were performed:

- The signed Informed Consent for the subjects listed below were reviewed:

  [Insert ICF Table]

- The case report forms (CRFs) [*electronic CRFs (eCRFs)*] and source documents for the subjects listed below were reviewed:

  [Insert CRF Table]

- [Insert other items not already listed and provide necessary detail]

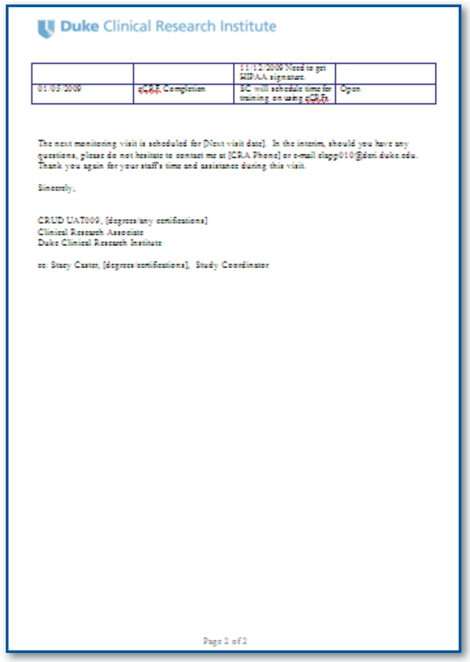
The protocol deviations that were noted during this visit include:

Date	Type	Sub Type	Subj. #	Subj. Initials	Description	Action
11/12/2009	01-Informed Consent Procedures	Subject	3111-001	AB	Didn't sign HIPAA form.	Need to get HIPPA signature.

The following is a summary of the findings, discussions and/or action items that arose during this visit. Outstanding items should be completed prior to the next scheduled visit.

Visit Date	Issue Type	Description	Status
	Protocol Deviation	Subject AB 3111-001	Open

Page 1 of 2



Duke Clinical Research Institute

		11/12/2009 Need to get HIPAA signature.	
01/05/2009	eCRF Completion	SC will schedule time for training on using eCRFs.	Open

The next monitoring visit is scheduled for [Next visit date]. In the interim, should you have any questions, please do not hesitate to contact me at [CRA Phone] or e-mail clapp010@dcri.duke.edu. Thank you again for your staff's time and assistance during this visit.

Sincerely,

CRUD UAT009, [degrees/any certifications]
Clinical Research Associate
Duke Clinical Research Institute

cc: Stacy Carter, [degrees/certifications], Study Coordinator

Page 2 of 2

Sample Follow-Up Letter

NOTE: If the letter's signature block includes the line pointed out below, then electronic signatures are enabled for this letter.

Sincerely,

Mary Monitor
Clinical Research Associate
Duke Clinical Research Institute
DCRIElectronicSignaturePlaceHolder-DONOTDELETE

Important! Do not edit or delete this text.

7 To print the letter, select **File>Print**.

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

NOTES

NOTES

WARNING: You can no longer save a Word document directly to the CTMS if you 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, following steps 8 and 9.

9 To add the file back into the Trip Report, click **New File** on the **Attachments** tab, locate the file, and then click **Open**

10 If electronic signatures have been enabled for the letter, then do the following:

a In CTMS, on the **Attachments** tab, save the record by pressing **Ctrl + S**.

WARNING: If you forget to press Ctrl + S, changes you saved in Word are lost.

b On the **Attachments** tab, highlight the letter by clicking to the left of the record.

c Click Sign.

An Electronic Signature window appears.

d Enter your DCRI network password, and then click **OK**. A confirmation window appears.

e Click **OK**.

On the **Attachments** tab, a new PDF version of the letter appears with the text *Authored and Electronically Signed by [your name][DD MMM YYYY][HH:MM][AM/PM]* in the signature area of the letter.

NOTE: To see the new PDF attachment, you may need to refresh your screen.

TIP: The default name for the PDF is rather long. You can change this title by aiming to the right of the default name and clicking a blank area of the **Title** field, and then entering a new name for the PDF file.

f Check your Data Entry Guidelines (DEG) for instructions on whether or not to delete the original Word version of the letter.

TIP: To send the letter via email, go to the **Attachments** tab, click to the left of the letter to highlight it, and then select **File**>**Send Email**.

Working with the Offline Trip Report

NOTES

The CTMS Trip Report can be exported to Microsoft Excel, where you can enter site visit data while working offline. The data can then be imported back into the CTMS Trip Report.

Key Points for Exporting

- The export function can *only be performed once* per Trip Report. In special situations, you can request that the DCRI Service Desk reset the function (email *dcriservicedesk@dm.duke.edu*).
- *Before* exporting data:
  - Select a template from the **Report Template** field.
  - Verify that the **Report Status** is *In Progress*.
  - For manual enrollment, complete all subject records.
- All CTMS Trip Reports are saved to **C:\CTMS\Trip_Reports**. If the folder does not already exist, the CTMS creates it for you.
- Exporting makes all CTMS Trip Report fields *read-only* until the data is imported again.

Exporting a CTMS Trip Report to Excel

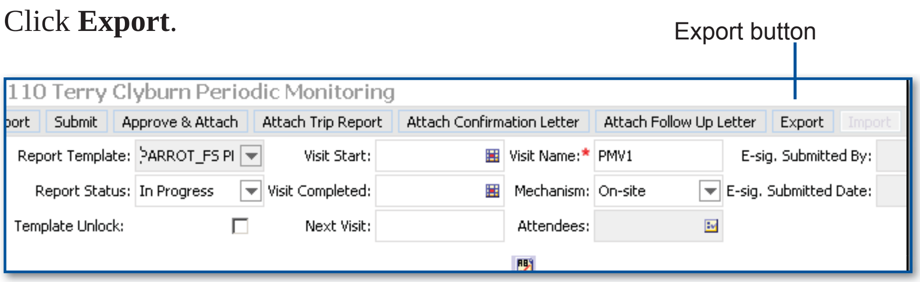
WARNING: The fields might not appear to be read-only immediately after exporting. However, refreshing the screen by clicking the **Execute Query** button applies the read-only formatting. Any edits made after exporting will be overwritten during the import process.

1 Select a template from the **Report Template** field.

2 Verify that the **Report Status** field displays *In Progress*.

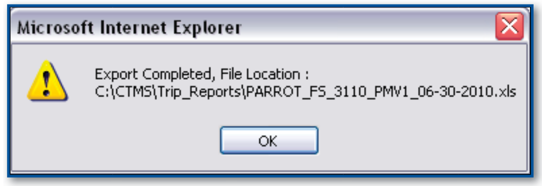
3 *Required for manual enrollment only:* Ensure that all subject records have been completed.

4 Click **Export**.



NOTES

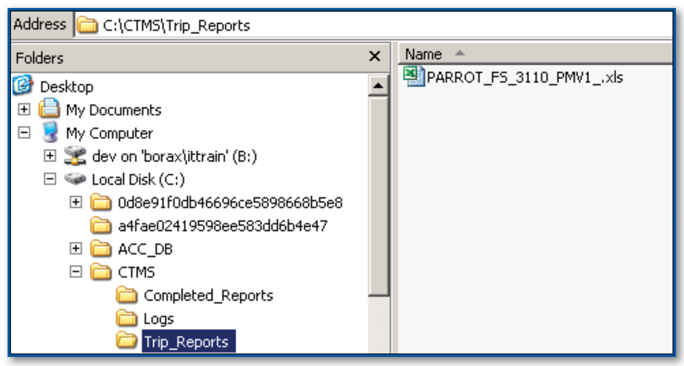
After a brief pause, the following export confirmation message appears, including the name and location of the new Excel file.



Note the name and location of the file for future reference. The file name uses the format of **Protocol_Site #_Visit Name_Planned Visit Completion Date**.

5 Click **OK**.

The new Excel Trip Report file appears in the location indicated in the export confirmation message.



Entering Data into the Exported Trip Report

1 Navigate to the location indicated in the export confirmation message.

2 Open the appropriate Excel file.

Note: The Excel tabs correspond to tabs in the CTMS Trip Report. The **Subjects** tab populates pick-lists for the **ICFs**, **CRFs**, and **Protocol Deviation** tabs.

3 Click the appropriate tab and enter data into applicable fields. Refer to the Excel file's **Information** tab for guidelines about populating the fields.

4 Save and close the Excel file.

NOTES

WARNING: Save the file back to the **C:\CTMS\Trip_Reports** folder. Do not change the name of the file or convert it to Microsoft Excel 2010 (*.xlsx) format. You cannot import data back into the CTMS unless the Excel file is in this folder with the original name and file extension.

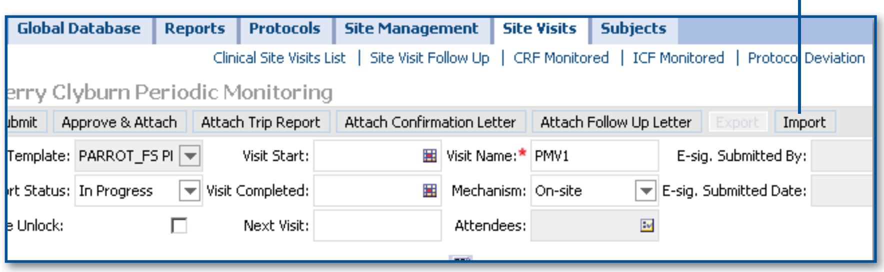
Key Points for Importing

- The import function can only be performed *once* per Trip Report.
- Save the Excel file in the same location (**C:\CTMS\Trip_Reports**). Do not change the name of the file.
- Before importing, save and close the Excel file.
- After the data is imported into the CTMS, the Excel file is automatically moved to **C:\CTMS\Completed_Reports**.

Importing a Trip Report from Excel Back to the CTMS

1. Save and close the Excel file.
2. In the **CTMS Trip Report** window, click **Import**.

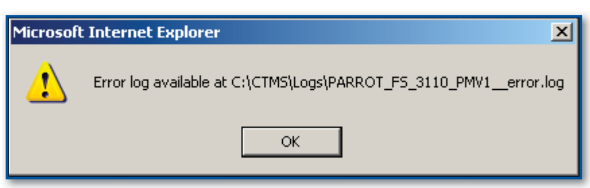
Import button



3. Do one of the following:
   - If an ICF error message appears during the import process:

     a. Click **OK**.

        A new message appears indicating the location of a log file with error details.



     b. Write down the location of the log file, and then click **OK**.

        The error message closes.

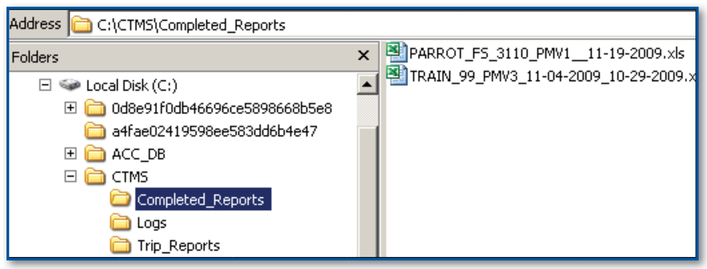
     c. Email DCRI Service Desk (*dcriservicedesk@dm.duke.edu*) for assistance.

NOTES

- If the **Import Completed** confirmation message appears, click **OK**.

After a successful import:

- Each tab of the CTMS Trip Report populates with data from the corresponding tab name in the Excel file.
- All **CTMS Trip Report** fields are editable.
- The Excel file moves to **C:\CTMS\Completed_Reports**. Files in this folder are automatically deleted after 60 days.



WARNING: Always take time to verify that your data was imported properly. The CTMS does not always give an error message when importing data that was entered incorrectly.

Trip Report Approval Process

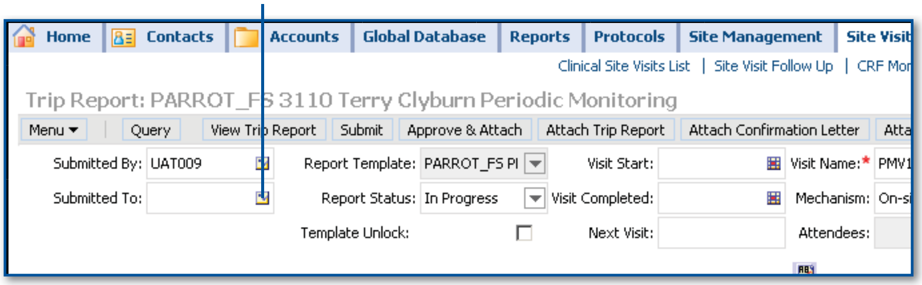
NOTES

After completing a Trip Report, the CRA submits it for approval. The Trip Report approver must then approve the Trip Report before it can be submitted to the sponsor. The CTMS uses electronic signature technology for the Trip Report approval process.

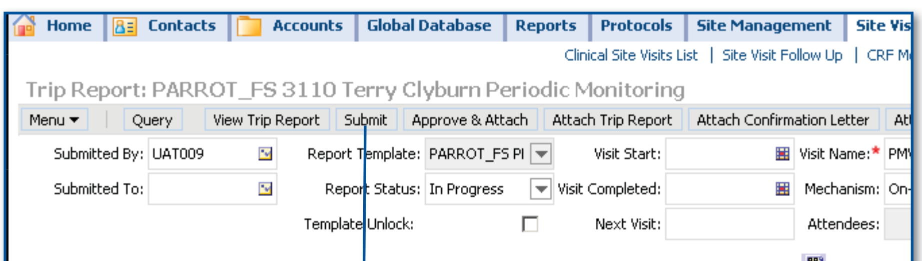
Submitting a Trip Report for Approval

1. On the **Trip Report** window, click the selection icon in the **Submitted To** field.

Selection icon in the Submitted To field



2. Query for and select the Trip Report approver’s name.
3. Click **Pick**.
4. Verify that *In Progress* appears in the **Report Status** field.
5. Click **Submit**.



Submit button

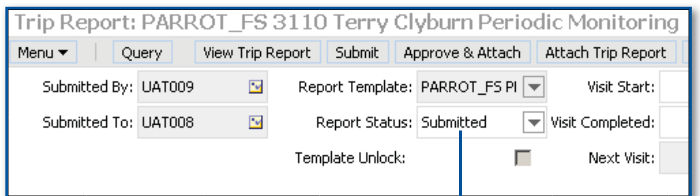
NOTES

The **Sign Submittal** window appears so that you can electronically sign your submission.

6 Enter your DCRI network **Password**.

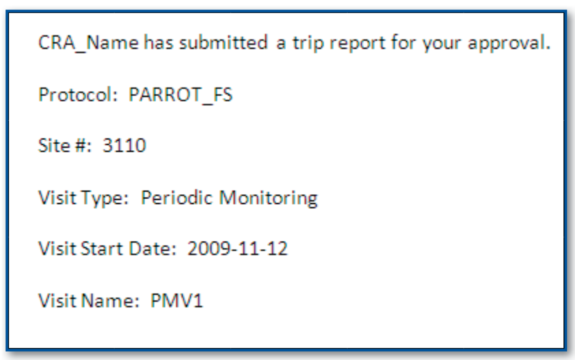
7 Click **OK**.

The status automatically changes to *Submitted* in the **Report Status** field.



Report Status changes to *Submitted*

8 An automatic email alert notification is sent to the Trip Report approver, stating that there is a Trip Report waiting for approval.



CRA_Name has submitted a trip report for your approval.

Protocol: PARROT_FS

Site #: 3110

Visit Type: Periodic Monitoring

Visit Start Date: 2009-11-12

Visit Name: PMV1

Example of email message to Trip Report approver

Approving a Trip Report

Only users set up with approval permission in the CTMS can approve a Trip Report.

NOTE: If the Trip Report is *Approved* or *Not Approved* by someone other than the person it was originally submitted to, the **Submitted To** field changes to the new approver's name and email notifications properly reflect the new approver's name.

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

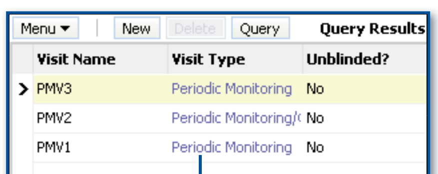
2 Locate the site by running a query on the **Site #** field. (See "Query Basics" in IT Training's *CTMS Fundamentals* user reference guide.)

3 Select the site containing the Trip Report that you want to approve by clicking to the left of the site record.

4 Click the **Site Visits** view tab at the bottom of the window.

5 If necessary, query for the correct visit on the **Site Visits** tab.

6 Click the blue hyperlink date in the **Visit Type** field.



Visit Type hyperlink

The **Trip Report** detail window appears.

7 Do one of the following:

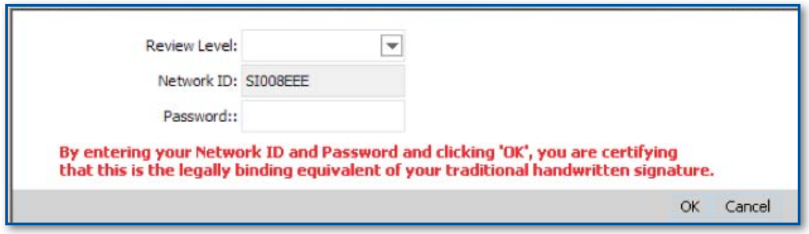
- If no changes are required, proceed to step *8*.
- If changes are required, complete the next procedure, "Returning a Trip Report to the CRA for Editing" on page 65.

8 Click **Approve & Attach**.

The **Sign Approval** window appears so that you can electronically sign your approval.

NOTES

NOTES



9 (*optional, per protocol*) Click the **Review Level** drop-down arrow to select a number (*1*, *2*, or *3*) to indicate the protocol-defined review level.

> **NOTE**: *Trip Report Review Levels* are defined per protocol (in the Data Entry Guideline document), to indicate, for example, the level of effort required by the Lead CRA (trip report approver) to review a CRA's trip report submission for approval. The field defaults to blank and only displays on the trip report PDF (under the e-signature area) if you select a level number.

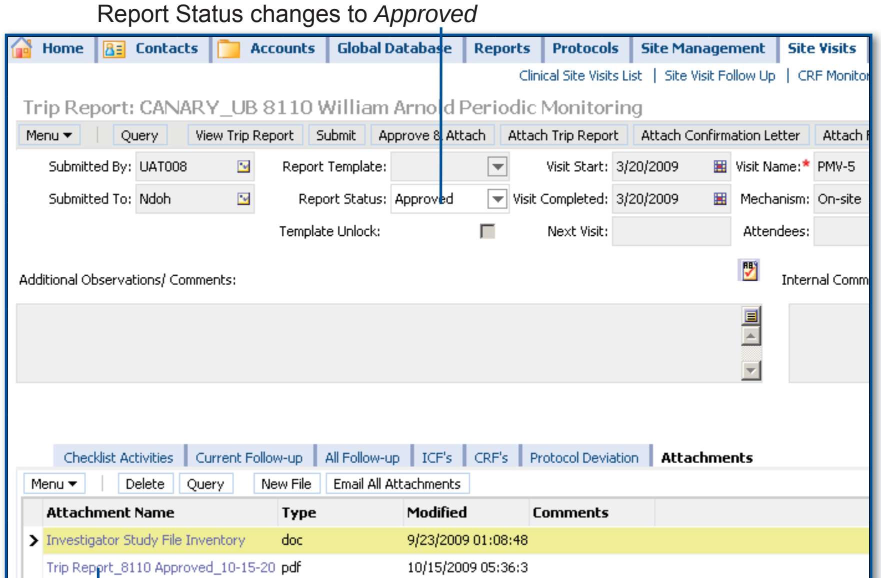
10 Enter your DCRI network **Password**.

11 Click **OK**.

The following automatically occurs:

- The **Trip Report Status** field changes to *Approved*.
- An email alert notification is sent to the CRA (the name that is in the **Submitted By** field), stating that the Trip Report has been approved.
- The approved PDF version of the Trip Report is attached to the **Attachments** tab.

Report Status changes to *Approved*



Approved PDF appears in **Attachments** tab

Notes

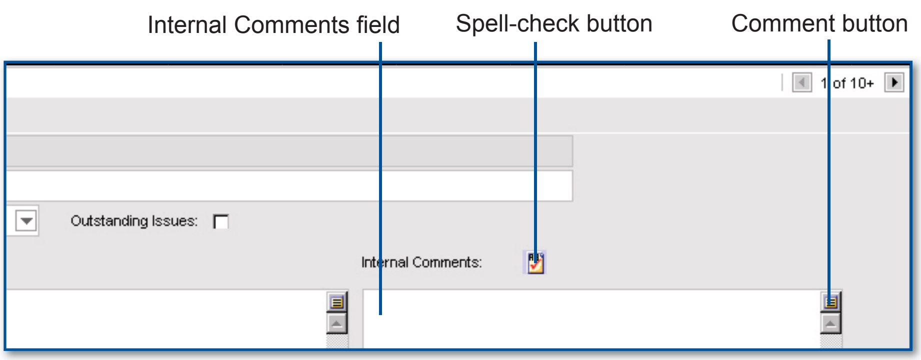
Note: To edit an approved Trip Report, the status must first be changed back to *Submitted*. The CTMS Administrator must configure your login to have approval responsibility in the CTMS before you can change the status of an approved report.

Returning a Trip Report to the CRA for Editing

1 Follow steps 1–6 of the “Approving a Trip Report” on page 63.

2 Enter general comments in the **Internal Comments** fields on the **Trip Report** form applet in the upper portion of the window, and in the **Internal Comments** fields located on each of the **Trip Report** tabs, as needed.

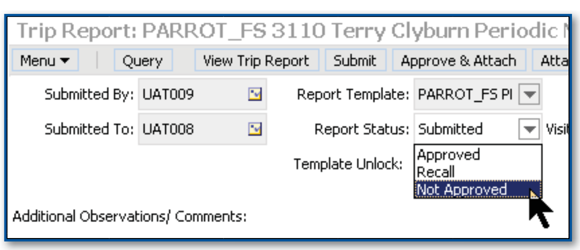
- Click the **Comment** button to view a larger window.
- Click the **Spell-Check** button to check the spelling of your comments.



Lower portion of Checklist Activities tab

Note: All users can edit the **Internal Comments** fields to accommodate dialog between Trip Report approvers and CRAs. Text from these fields will not show on the printed Trip Report and will be permanently removed from the audit trail when the Trip Report is approved.

3 In the **Trip Report** form applet in the upper portion of the window, click the **Trip Report Status** drop-down arrow to select **Not Approved**.



NOTES

4 Press **Ctrl+S** to save the record.

5 An automatic email alert notification is sent to the CRA (whose name is in the **Submitted By** field), stating that the Trip Report has not been approved.

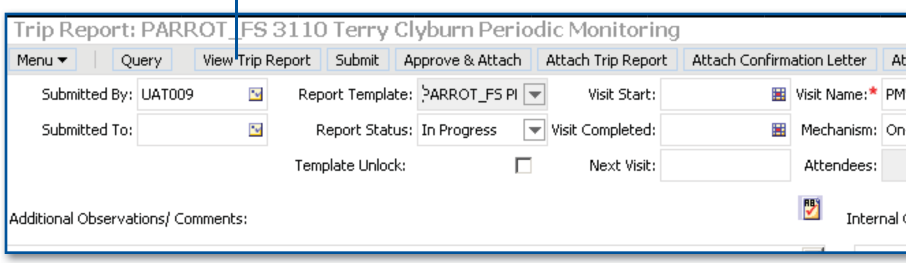
Viewing and Creating a PDF Trip Report

At any time, you can view the PDF version of the Trip Report by following the procedure below. You can also create a PDF version of the Trip Report to attach to the Trip Report's **Attachments** tab or save outside of the CTMS.

Viewing the PDF Trip Report

1 On the **Trip Report** window, click **View Trip Report**.

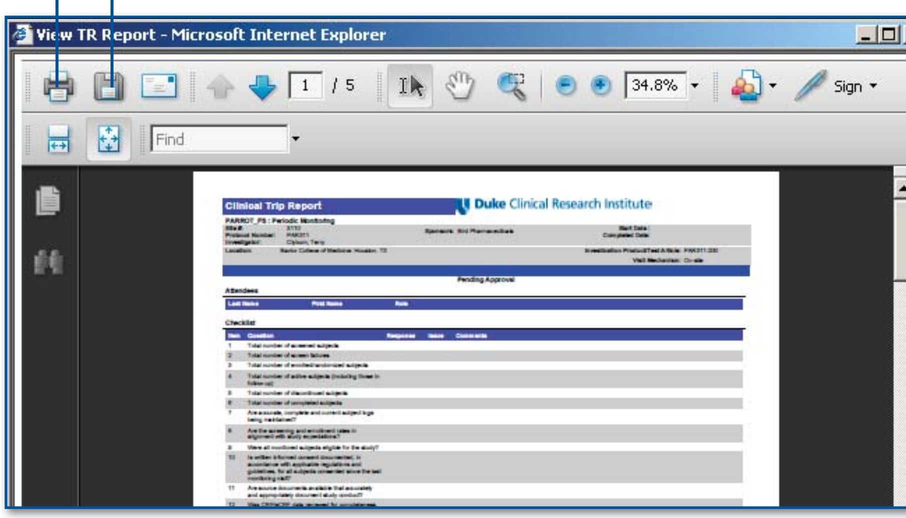
View Trip Report button



The PDF file opens in an Adobe Acrobat viewer window.

Print button

Save button



Notes

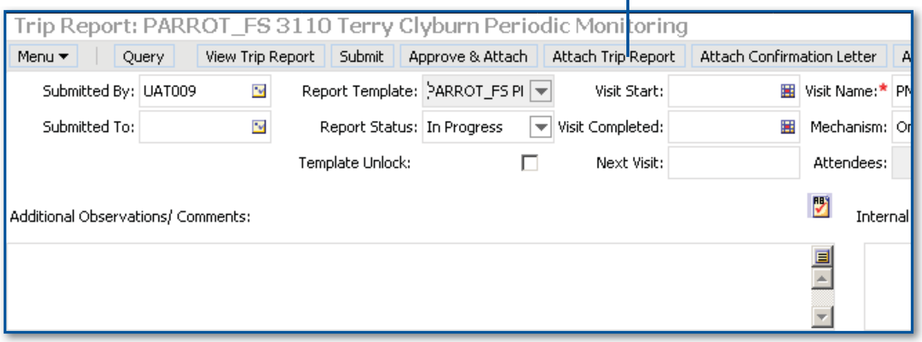
2 Click the **Print** button to send the file to a printer.

3 Click the **Save** button to save the file to a folder outside of the CTMS.

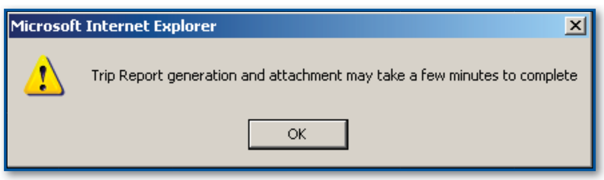
Creating a PDF version of the Trip Report

1 In the **Trip Report** window, click **Attach Trip Report**.

Attach Trip Report button

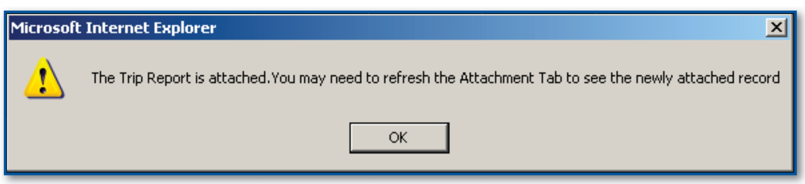


The following message appears.



2 Click **OK**.

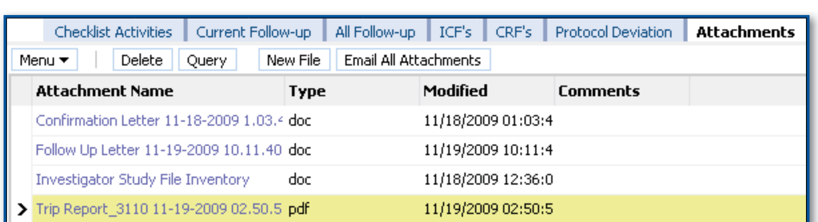
After a brief pause, the following message appears.



3 Click **OK**.

4 Click the **Attachments** tab.

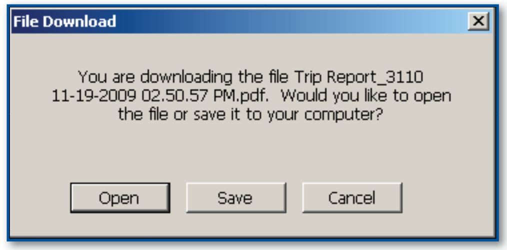
The new Trip Report entry appears in the list.



NOTES

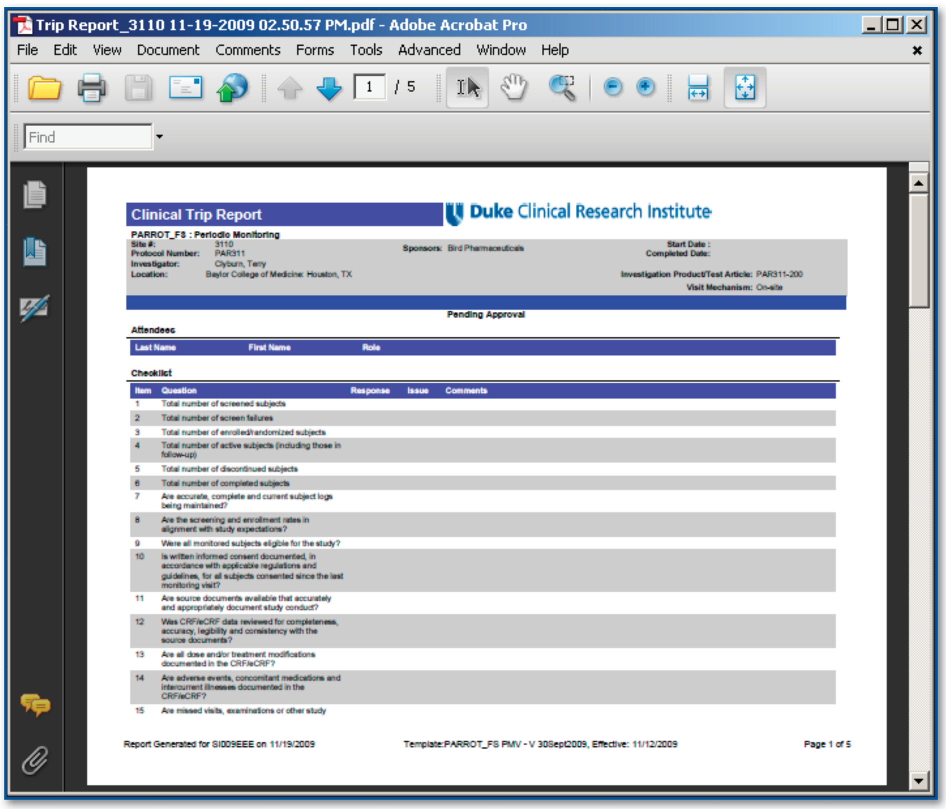
5 Click the **Trip Report** hyperlink.

The following window appears, enabling you to open the file or save it to another location.



6 Click **Open**.

The Trip Report opens in an Adobe Acrobat Reader window.



NOTE: Until the Trip Report is approved, you can delete attachments that are no longer needed.

Viewing Site Visit Metrics

The **Site Visits** screen tab can be used to look up site visit and Trip Report data without having to first drill into a specific site record.

Click the blue hyperlinks at the top of the **Site Visits** screen tab to change the list of records in your current view.

Hyperlink	Description
Clinical Site Visits List	Default view showing a list of site visits for all protocols to which you are assigned. Click the blue **Visit Type** hyperlink to open a site visit's **Trip Report**.
Site Visit Follow Up	Lists follow-up activities for all protocols to which you are assigned. Click the blue **Activity Type** hyperlink to drill into the Trip Report's **Current Follow-up** tab for a site visit.
CRF Monitored	Lists CRF records for all protocols to which you are assigned. Click the blue **Trip Report Type** hyperlink to drill into the Trip Report's **CRF's** tab for a site visit.
ICF Monitored	Lists ICF records for all protocols to which you are assigned. Click the blue **Trip Report Type** hyperlink to drill into the Trip Report's **ICF's** tab for a site visit.
Protocol Deviation	Lists protocol deviation records for all protocols to which you are assigned. Click the blue **Type** hyperlink to drill into the Trip Report's **Protocol Deviation** tab for a site visit.

Notes

Logging Conversations

Use the *Conversation Log* to capture required communication with the site, as well as other correspondence. This record can contain activity types such as:

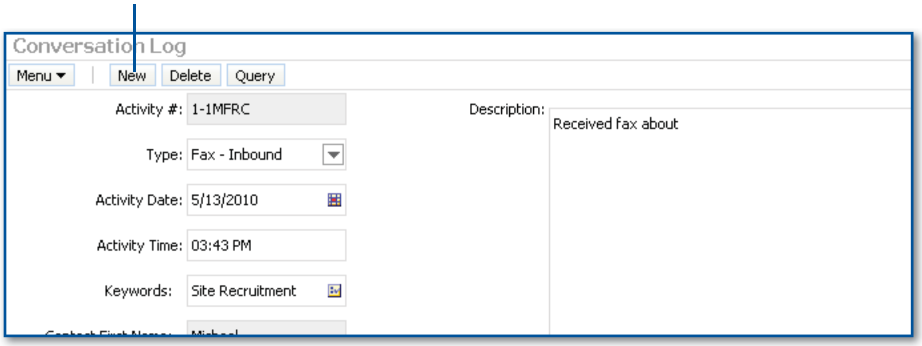
- Call—Inbound/Outbound
- Email—Inbound/Outbound
- Fax—Inbound/Outbound
- Letter—Inbound/Outbound

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 "Query Basics" in IT Training's *CTMS Fundamentals* user reference guide.)
3. Select the site by clicking to the left of the site record.
4. Click the **Conversation Log** view tab at the bottom of the window.
5. In the **Conversation Log** tab, click the **New** button.

New button



A new row appears.

Notes

NOTES

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.

Field	Guidelines
Activity #	(read-only) This is a CTMS system-generated unique identifier.
Type	Click the drop-down arrow to select the activity description (for example, **Call - Inbound**).The default value is *Other*.
Activity Date	Enter the date that the activity occurred.
Activity Time	Enter the time that the activity occurred.
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.

Notes

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 **New**. 3 Select a keyword from the **DCRI Keywords** drop-down list. 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 field to view a list of contacts currently affiliated with the site. **Note**: To view all contacts in the CTMS, click **All Contacts**. To return to the list of site contacts, click **Affiliated Contacts**. 2 In the left pane, select the contact associated with the activity. 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	(read-only) Shows the name of the person who created the conversation log entry.

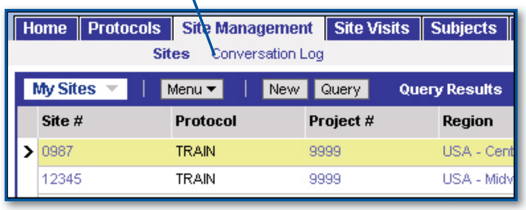
7 Save the record by pressing **Ctrl**+**S**.

NOTES

Viewing All Conversation Logs

You can view a list of *all* conversation logs by clicking the **Conversation Log** hyperlink at the top of the **Site Management** view tab.

Conversation Log hyperlink



All logs appear, regardless of site or protocol. To find specific conversation logs:

1 Click **Query**.

2 In the **Keywords** field, enter one or more words to narrow your search.

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

3 Click **Go**.

All logs appear that contain the keyword(s) you entered.

APPENDIX A: TRIP REPORT

NOTES

The following is an example of a Trip Report created in the CTMS. For detailed information, see “Trip Reporting” on page 27.

Clinical Trip Report — Duke Clinical Research Institute

CANARY_UB : Periodic Monitoring

Site #: 8150
Protocol Number: PRA-01
Investigator: Brown, Bradley
Location: Mount Sinai School of Medicine: New York, NY

Sponsors: Bird Pharmaceuticals

Start Date : 10/10/2009
Completed Date: 10/10/2009
Next Visit Date: next month
Investigation Product/Test Article: Pravachol
Visit Mechanism: On-site

Pending Approval

Attendees

Last Name	First Name	Role

Checklist

Item	Question	Response	Issue	Comments
1	Does the investigator anticipate using satellite sites or other off-site facilities? (If Yes, specify facility name, location, and relevant details)	Yes		test comments... test comments
2	Review IP Procedures	10/10/2009		test comments
3	Review Protocol	Yes		test
4	Were storage procedures for drug revived with PI and SC?	Yes		test - Yes it's open

Follow Up

Activity Type	Visit Date	Description	Status	Assigned To	Resolution	Completed Date
Clinical Question	10/10/2009	lots of questions lots and lots	Done	CRUD UAT009	lots of questions with no resolutions - open	10/20/2009
Clinical Question	5/1/2009	Pharmacist asked about overdose of test medication.	Open	Elaine Clapper	DCRI PI will contact pharmacist with answer to question	
GCP/ICH	6/4/2009	Test f/u item	Open	Angela Venetta		
IRB Related	10/10/2009	test in IRB related Materials	Open	CRUD UAT009	resolution testing should be done	
IRB Related	9/2/2009	Test F/U item	Open	Angela Venetta		
Regulatory Documentation	6/4/2009	Site to create Reg Binders	Open	Angela Venetta		
Study Supplies	7/5/2009	Storage Comments	Open	Angela Venetta		

Protocol Deviation

None

ICF

Report Generated for SI009EEE on 11/19/2009 — Template:Periodic Monitoring - PMV template, Effective: 6/3/2005 — Page 1

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Clinical Trip Report — Duke Clinical Research Institute

CANARY_UB : Periodic Monitoring

Site #: 8150
Protocol Number: PRA-01
Investigator: Brown, Bradley

Sponsors: Bird Pharmaceuticals

Start Date : 10/10/2009
Completed Date: 10/10/2009
Next Visit Date: next month

ICF

Subject ID	ICF Type	ICF Signature	Version Date	Source Doc Verified Date	Comments

CRF

Subject ID	Visit Type	Visit	Source Doc Verified Date	Retrieval Date	Page Number	Comments

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 10-20-2009 1.15.17 PM	31,033	doc	10/20/2009	

Additional Observations / Comments

field is open

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Appendix B: Attachments

The **Investigator Study File Inventory** (Reg Doc Checklist) automatically attaches to your Trip Report. See “Attachments” on page 51.

INVESTIGATOR'S STUDY FILE INVENTORY

Site ID:				Investigator:
Date(s) Assessed:				Protocol Number:
ESSENTIAL DOCUMENTS **YES = All versions of the following essential documents are present**	**Yes**	**No**	**N/A**	**Comments**
1. Signed Confidentiality agreement (or equivalent)	☐	☐	☐	Date of signature:
2. Certificate of Confidentiality	☐	☐	☐	Date of signature:
3. Curriculum Vitae (or biographical sketch) for Principal Investigator - Medical license (or equivalent)	☐	☐	☐	List Name(s):
4. Curriculum Vitae (or biographical sketch) for Sub-investigator(s) and/or other site personnel - Medical license (or equivalent)	☐	☐	☐	
5. Signed Investigator Statement (FDA 1572 or equivalent)	☐	☐	☐	Date of Signature:
6. Approved protocol and amendment(s) (including signed signature sheets) Protocol Version: Amendment(s):	☐	☐	☐	Date of Signature:
7. Investigator's Brochure/Instructions for Use (or equivalent product information)	☐	☐	☐	Version:
8. Conflict of Interest Statement or Disclosure Form (NIH/federally funded)	☐	☐	☐	Date of Signature:
9. Project Assurance Number (SPA/MPA/FWA)	☐	☐	☐	Number:
10. Financial Disclosure or certification of Clinical Investigator(s)	☐	☐	☐	Date of Signature:
11. Certificate of Investigator Meeting attendance or other proof of training	☐	☐	☐	
12. Human Subject Protection Training (NIH/federally funded)	☐	☐	☐	Date of Training:
13. IRB/IEC approvals for Protocol, ICF, advertisement (if applicable)	☐	☐	☐	
14. IRB/IEC correspondence between the site and the IRB	☐	☐	☐	
15. IRB/IEC membership roster (or project assurance number)	☐	☐	☐	
16. Blank Informed Consent Form (all versions) approved by the IRB/IEC	☐	☐	☐	Version Date:

DCRI Investigator Study File Inventory SM-F1-002, SM-F1-003 and SM-F1-004 SM-F3-002.01 Version Date: 15MAR 2005 Page 1 of 3

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INVESTIGATOR'S STUDY FILE INVENTORY

Site ID:				Investigator:
Date(s) Assessed:				Protocol Number:
ESSENTIAL DOCUMENTS **YES = All versions of the following essential documents are present**	**Yes**	**No**	**N/A**	**Comments**
17. Laboratory normal/reference ranges (all versions)	☐	☐	☐	Expiration date:
18. Laboratory certificates/supporting documents of licensure	☐	☐	☐	Expiration date:
19. Certificate of Registration/Order Forms (DEA Form 222/222)	☐	☐	☐	Expiration date:
20. Unblinding Procedures (for blinded trials)	☐	☐	☐	
21. Investigational Product Records (Shipping/Accountability/ Destruction)	☐	☐	☐	
22. Master Subject Log	☐	☐	☐	
23. Patient Screening Log	☐	☐	☐	
24. Biological Sample/Specimen Log	☐	☐	☐	
25. Site Personnel Authorization/Signature Log	☐	☐	☐	Date of last update:
26. Study communication (with DCRI, sponsor, laboratories, other involved institutions, etc.)	☐	☐	☐	
27. Site Visit Log	☐	☐	☐	
28. In-Service Materials	☐	☐	☐	
29. SAE documentation (copies of SAE reports, submission to IRB/IEC)	☐	☐	☐	
30. Audit documentation	☐	☐	☐	
31. Completed CRFs and documentation of corrections	☐	☐	☐	
Other Applicable regional or local requirements:	**Yes**	**No**	**N/A**	**Comments**
32. Patient Bill of Rights (California) Other: (Specify)	☐	☐	☐	
33. Massachusetts Controlled Substances Registration (MCSR)	☐	☐	☐	
34. HIPAA authorization document (US sites only)	☐	☐	☐	Approval Date:
35. Health Authorities: notification/approval (for non -US sites)	☐	☐	☐	Approval Date:

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Notes

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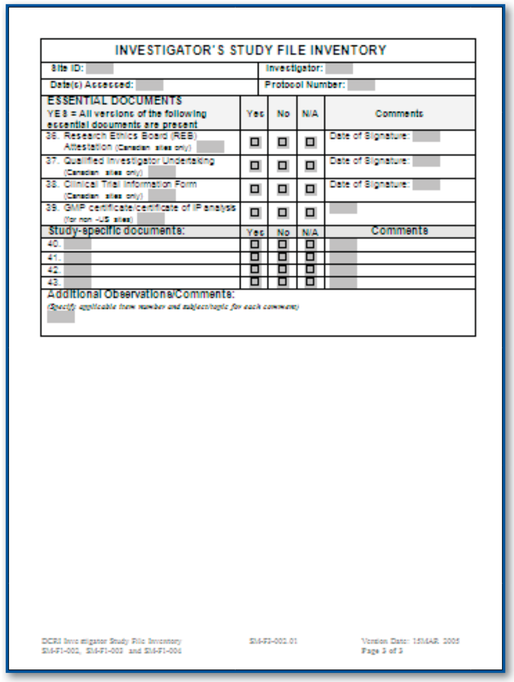

INVESTIGATOR'S STUDY FILE INVENTORY

Site ID:	Investigator:
Date(s) Assessed:	Protocol Number:

ESSENTIAL DOCUMENTS YES = All versions of the following essential documents are present	Yes	No	N/A	Comments
36. Research Ethics Board (REB) Attestation (Canadian sites only)	☐	☐	☐	Date of Signature:
37. Qualified Investigator Undertaking (Canadian sites only)	☐	☐	☐	Date of Signature:
38. Clinical Trial Information Form (Canadian sites only)	☐	☐	☐	Date of Signature:
39. GMP certificate/certificate of IP analysis (for non -US sites)	☐	☐	☐	
Study-specific documents:	Yes	No	N/A	Comments
40.	☐	☐	☐	
41.	☐	☐	☐	
42.	☐	☐	☐	
43.	☐	☐	☐	

Additional Observations/Comments:
(Specify applicable item number and subject/topic for each comment)

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