

DAIDS Clinical Site Monitoring (CSM) System Reference Guide for Sites



Under DAIDS contract number N01-AI-30060, which is entitled "DAIDS Enterprise Information Management System" (DAIDS-ES), this document was prepared for:

Division of Acquired Immunodeficiency Syndrome (DAIDS)
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Clinical Site Monitoring Reference Guide for Sites

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Introduction to Clinical Site Monitoring (CSM)

What Is Clinical Site Monitoring?

The Clinical Site Monitoring (CSM) application maintains clinical site monitoring information for DAIDS (Division of Acquired Immunodeficiency Syndrome) world-wide studies. The focus of the application is to standardize findings, visit reports, and issues and corresponding responses across networks and non-networks.

The Clinical Site Monitoring application provides the following key Clinical Site Monitoring information:

- Site visit plan (projected visit) and site monitoring calendar (actual visit),
- Scheduling activities and monitoring assessments,
- Audit trails,
- Visit findings and conclusions version history, and
- Correspondence tracking between DAIDS and sites.

Various user roles are implemented within the CSM application. Not all tasks may be performed by all users. Please refer to the section, “CSM User Roles Matrix,” on page 18 for specifics on the privileges of the various user types.

What Can I Do with Clinical Site Monitoring?

The CSM system enables DAIDS staff and collaborators to enhance and improve the scheduling, conduct, and reporting of information relating to clinical site monitoring visits. CSM provides tools to identify and track monitoring visit schedules and assignment requests. These tools also assist with the resolution of issues identified during site monitoring visits.

Who Is Clinical Site Monitoring Intended for?

The system is intended for the DAIDS staff and collaborators involved in monitoring DAIDS clinical trials.

How Can I Access Clinical Site Monitoring?

Users who have a NIH account will be able to access CSM from the DAIDS Portal (<http://daidsportal.niaid.nih.gov>) directly from their browser upon logging into their system, as it utilizes single sign-on technology.

Users who have a NIH network and e-mail user ID and password, but are accessing the portal outside of the DAIDS or NIAID offices may use CITRIX to access the DAIDS Portal remotely.

Users who do not have access to the DAIDS Portal through a NIH account, but have been granted access outside NIH can access Clinical Site Monitoring through the following link: <https://daidses.niaid.nih.gov/DeltaFlyer>





Terms You Should Know

Terms You Should Know	
TERM	DEFINITION
Visit Frequency	Identifies the number of times an interim site monitoring visit will be performed within a year.
Special Assignments	Assignments that are requested by the DAIDS Staff in order to follow-up on issues/trends identified during site monitoring visits. These are addressed by the monitoring contractor in addition to the assignments performed during routine site monitoring visits.
Pre-Visit Letter (PVL)	Letter sent to the site informing them of the upcoming site monitoring visit.
Announced Site Visit Work Order (AWOL)	Includes all announced assignments that the monitor will be performing during a scheduled site visit.
Full Site Visit Work Order	Includes all assignments that the monitor will be performing during a scheduled site visit.
Web Parts	Web Parts are the basic building blocks of a portal. Each Web Part is a customizable component that consists of a title bar, a frame, and content. Since Web Parts are considered modular units of information, they are created in a standardized way that allows for flexibility and variety in use.
Document Library	Collection of all available site monitoring documents and other associated protocol documents, i.e., Report Templates and Guidelines, Quarterly Reports, Quarterly Assignments, etc.

Clinical Site Monitoring Support

Obtaining Support

To report a problem, make a suggestion or request regarding CSM, contact DAIDS-ES Support directly by telephone, fax, or e-mail. Live assistance is available 8:30 A.M. to 5:30 P.M. U.S. Eastern Time, Monday through Friday (excluding US holidays). You may also submit a ticket request from within CSM through a DAIDS-ES Support Web page. Once you contact DAIDS-ES Support, you will receive a confirmation e-mail with a unique ticket number.

① Contact Information for the DAIDS-ES Support Desk

Phone: (1) (866) 337-1605 (toll free USA), or (1) (240) 499-2239 (Outside USA)

Fax: (1) (866) 337-1606 (toll free USA), or (1) (301) 948-2242 (Outside USA)

E-mail: DAIDS-ESSupport@niaid.nih.gov

② Submit a Problem or Suggestion/Request or View My Ticket Status from within CSM

To Submit from CSM

1. From within the application, go to the top right navigation bar and then point to Help.

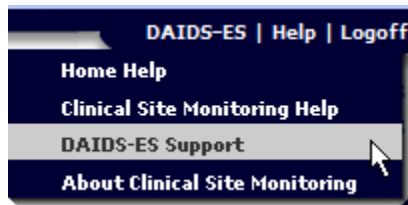


Figure 1: DAIDS-ES Support option

2. Click **DAIDS-ES Support** from the drop-down list. DAIDS-ES Support Submission Web page displays.

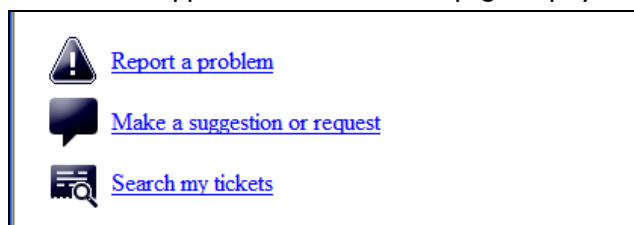


Figure 2: DAIDS-ES Support Submission Web page

To Report a Problem or Make a Suggestion

1. Click one of the following links:
 - **Report a problem**
 - **Make a suggestion or request**The DAIDS-ES Support Submission form displays.

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Report a problem

*Application: *Phone:

*Problem Type: *E-mail:

Severity: Normal High Immediate

E-mail Receipt: Yes No

*Problem Description:

Attach File:

Figure 3: DAIDS-ES Support Submission form

2. Enter the required information into the submission form.
3. Click **Submit**.

An e-mail is sent that confirms your submission and gives you a ticket number for future reference.

To View My Ticket Status

1. From within the application, go to the top right navigation bar and then point to Help.
2. Click **DAIDS-ES Support** from the drop-down list.
DAIDS-ES Support Submission Web page displays.
3. Click **Search my tickets**.
The Search my tickets submission form displays.

Search my tickets (Quick)

Type of Search: Quick Advanced

Ticket ID: Customer's Name:

Ticket Status: Application:

Ticket ID	Customer's Name	Ticket Type	Sugg/Prob Type	Application	Status	Severity	Submitted Date
40076	Andrea Allin	Problem	Logon Problem	Clinical Site Monitoring	Closed	Immediate	5/21/2008 3:16:08 PM

Figure 4: Search my tickets submission form

4. Locate the ticket from the list of your submitted tickets currently in the database.
Tip: Use the Quick Search option to locate the ticket.
5. View the current status of the selected ticket, ask for further assistance, or submit comments and requests.

③ Access the online help system

From the top right navigation bar, point to **Help**, and then click one of the following:

- **[Page] Help**

Opens Help to the full CSM Help with the topic associated with the page in your current view. This is a full text version of the Help function that includes access to the Table of Contents (TOC), Index, Search, and Glossary features.

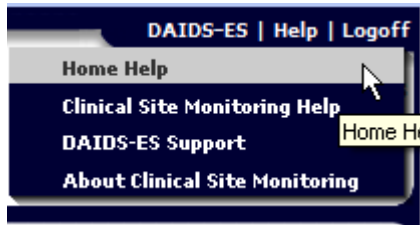


Figure 5: [Page] Help option

- **CSM Help**

Opens Help to the full CSM Help with the **Welcome** page in view.

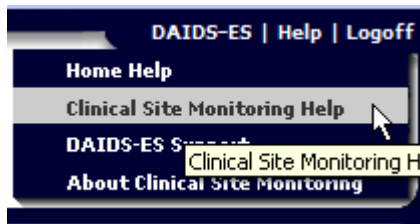


Figure 6: Clinical Site Monitoring Help option

Using Common Functions


Common functions enable you to use and move quickly through the pages. This section provides information on the common navigation functions and page elements throughout the application.

Using Lists of Values (LOV)

An LOV displays items that form a long list from which you select a value for a field. Usually, an LOV is used when the list is too long to display in a drop-down list. Although there are LOV fields where you can select multiple values at a time (check boxes), most require only one value (option button). Also, some LOVs provide search functions to help you find the value you need faster than scrolling through the list.

Within an LOV dialog box, you can search for a value, select an item, or add additional search criteria.

To Search for a Value

1. Click  next to the field, as shown in Figure 7 below.

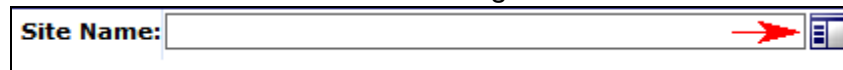
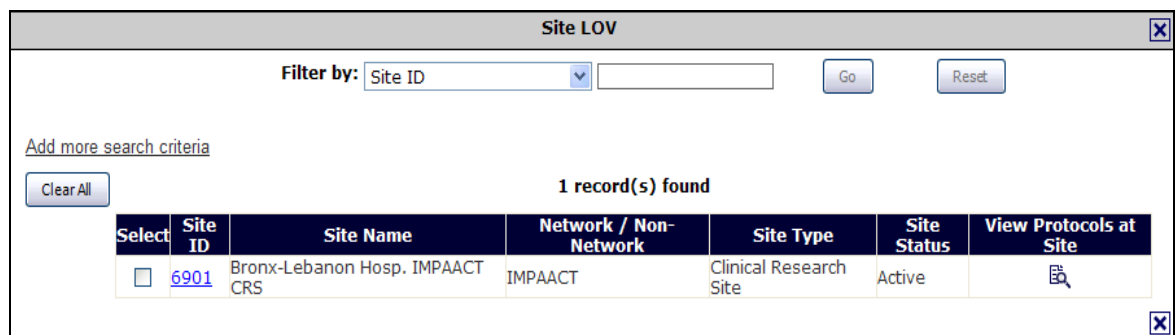


Figure 7: Example LOV

2. The List of Values displays in a dialog box.





Select	Site ID	Site Name	Network / Non-Network	Site Type	Site Status	View Protocols at Site
<input type="checkbox"/>	6901	Bronx-Lebanon Hosp. IMPAACT CRS	IMPAACT	Clinical Research Site	Active	

Figure 8: LOV dialog box

3. Click the **Filter by**  and select an option to filter by. The value selected further refines the LOV results. *Example:* Site ID.
4. Type the specific value you are searching for in the text box next to the **Filter by** field.
5. *Optional:* Click **Add more search criteria**. An additional drop-down list and text box displays in the LOV dialog box for you to filter your search. Refer to the section below "To Add Additional Search Criteria" for more details on using this feature.
6. Click **Go**. The search results display only those LOV results that match your search criteria.

To Add Additional Search Criteria

1. Click the **Add additional search criteria** link, as shown in Figure 8 on page 9.
2. Additional search options display in the LOV so you can further narrow your search.

Note: The Add additional search criteria link becomes the **Remove additional search criteria** link once selected.

To Select an Item

- Whether you use the search function or not, do one of the following to select an item in an LOV (as shown in Figure 8 on page 9):
 - Select an option of the value needed.
 - Select a check box of the value(s) needed.
- Click **Close**.
The selected items display in the page field.

Using Wildcards (%)

Use the wildcard feature to shorten search queries and return more results. Within the DAIDS-ES applications, in all text boxes on any search page, you can use the percent sign (%) as a wildcard for searching.

To Use a Wildcard in Searches

- Ending in a particular set of characters:** Insert the wildcard to the left of the characters.
For example: Type **%lon** to find last names ending with *lon*.
- Beginning with a particular set of characters:** Insert the wildcard to the right of the characters.
For example: Type **wo%** to find institution names beginning with *wo*.

The screenshot shows a search window titled "Site LOV". The "Filter by:" dropdown is set to "Site Name" and the search text is "Bro%". There are "Go" and "Reset" buttons. Below the search area, there is a "Clear All" button and a message "1 record(s) found". A table displays the search results:

Select	Site ID	Site Name	Network / Non-Network	Site Type	Site Status	View Protocols at Site
<input type="checkbox"/>	6901	Bronx-Lebanon Hosp. IMPAACT CRS	IMPAACT	Clinical Research Site	Active	

Figure 9: Wildcard Search Example

- Middle characters of the record:** Insert a wildcard on both sides of the characters.
For example: Type **%health%** to find all records with the word *health* somewhere in the record.

Navigating

The following sections describe what the navigation features are and how to use them within a page and within data grids.

Using Navigation Bars and Links

Use the navigation menu bars and menu page links to navigate between the different pages of the application.

Navigating within a Datagrid

Datagrids and LOVs display information that is specific to individual functions within the application. For example, search results and various types of records display in datagrids. These datagrids have many "pages" associated with them through which you can navigate. The DAIDS-ES application's default displays 10 rows per page.

Site LOV

Filter by: Site ID

Add more search criteria

911 record(s) found

Select	Site ID	Network / Non-Network	Site Name	Site Type	Site Status	View Protocols at Site
<input type="checkbox"/>	1108	ACTG	AIDS Community Health Ctr. ACTG CRS	Clinical Research Site	Active	
<input type="checkbox"/>	11301	ACTG, HPTN, HVTN	Asociacion Civil Impacta Salud y Educacion - Miraflores, CRS	Clinical Research Site	Active	
<input type="checkbox"/>	11302	ACTG, HPTN	Investigaciones Médicas en Salud - INMENSA. Lince CRS	Clinical Research Site	Active	
<input type="checkbox"/>	103	ACTG	Beth Israel Deaconess Med. Ctr., ACTG CRS	Clinical Research Site	Active	
<input type="checkbox"/>	2851	ACTG	Beth Israel Med. Ctr., ACTU	Clinical Research Site	Phase Out	
<input type="checkbox"/>	104	ACTG	BMC ACTG CRS	Clinical Research Site	Active	
<input type="checkbox"/>	30007	HVTN	Brigham and Women's Hosp. CRS	Clinical Research Site	Active	
<input type="checkbox"/>	2501	ACTG, MTN	Case CRS	Clinical Research Site	Active	
<input type="checkbox"/>	11501	ACTG	Chiang Mai Univ. ACTG CRS	Clinical Research Site	Active	
<input type="checkbox"/>	2705	Network	Cook County Hosp. CORE Ctr.	Clinical Research Site		

1

Figure 10: Datagrid Sample

You can navigate within tables and/or LOVs throughout the DAIDS-ES applications as follows:



Move forward one page.



Move back one page.



Move forward to last datagrid page.



Move back to first datagrid page.



Drop-down list that lists the number of pages within the datagrid. You can select the page number from the drop-down list to display a specific page (sometimes faster than using the forward button).



Sort column contents in alphanumeric order. Either up or down arrow may be present. Hover over the column heading to activate the arrow icon.

Using Page Elements

These common elements enable you to move quickly through the pages to select or type values for fields and understand at a glance the function of each element, such as buttons.

Using Fields

















The following are the field types used within DAIDS-ES applications and a description of each, which also provides instructions on how to use the field. Also listed are the attributes associated with a field that provide you online guidance in completing/filling in a field correctly.

- A square box that appears beside an option that acts as check box. Select the check box to place a check mark in the box. Clear the check box to remove the check mark.
- An option button selects one option from a group of mutually exclusive options. Common term: radio button.
- Text Area A multiline rectangular box in which you can type text, such as comments or description. A counter control tracks how many characters you are typing.
- * (Asterisk) Displays next to a required field.
- ! (Exclamation point) An indicator that the value you entered or selected is incorrect. Correct the entry or click **Save** to view the error message.























ToolTip — A pop-up ToolTip appears when you position the mouse cursor over a field. A ToolTip displays for approximately three seconds and provides the definition or other pertinent information for the field or column label. ToolTips can also display information for links and pop-ups.

Using Buttons and Icons

The following are the buttons and icons used within DAIDS-ES applications and a description of what the button or icon does.

- | | |
|---|--|
|  Returns to application Home page. |  Closes the dialog box. |
|  Selects from a list of values dialog box. |  Moves to previous record. |
|  Selects a value from a drop-down list. |  Moves to next record. |
|  Adds a date (month, date, and year). |  Clears the record. |
|  Opens a Report page. |  Submits a record. |
|  Displays a record for review. |  Saves the data. |
|  Displays in Microsoft® Excel format. |  Deletes the record. |
|  Displays in PDF format. |  Allows frequency to be reviewed. |

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	Displays Work Order Checklist.		Indicates that user acknowledged and reviewed the documents.
	Displays record history.		Projected visit status.
	Mails a record.		Planned visit status.
	Indicates that notification has been sent.		Completed visit status.
	Displays Record Review Tool.		Waived visit status.
	Deletes a record.		Cancel visit status.
	Invokes help.		Waiver requested visit status.
	Adds a record.		Rescheduled visit status.
	Deletes a record.		Confirmed site visit.
	Uploads a file.		Cancellation requested.
	Prints the page or file.		Closes the Edit Pane.

Using Calendars


Calendar fields in the DAIDS-ES applications provide you a pop-up calendar from which to choose the day, month, and year.

Note: If a Calendar field is present, you cannot type a date into the field.





Figure 11: Pop-up Calendar

To Select a Date from a Calendar Field

1. Click  to open the **Calendar** dialog box.

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2. Click  or  in the **Month** and **Year** fields to increase or decrease the month and year values until the correct calendar displays.
3. You may also click and select the month and year values from the list.
4. Click directly on any day of the selected calendar view.
5. The **Calendar** dialog box closes and the date you selected populates the **Date** field.

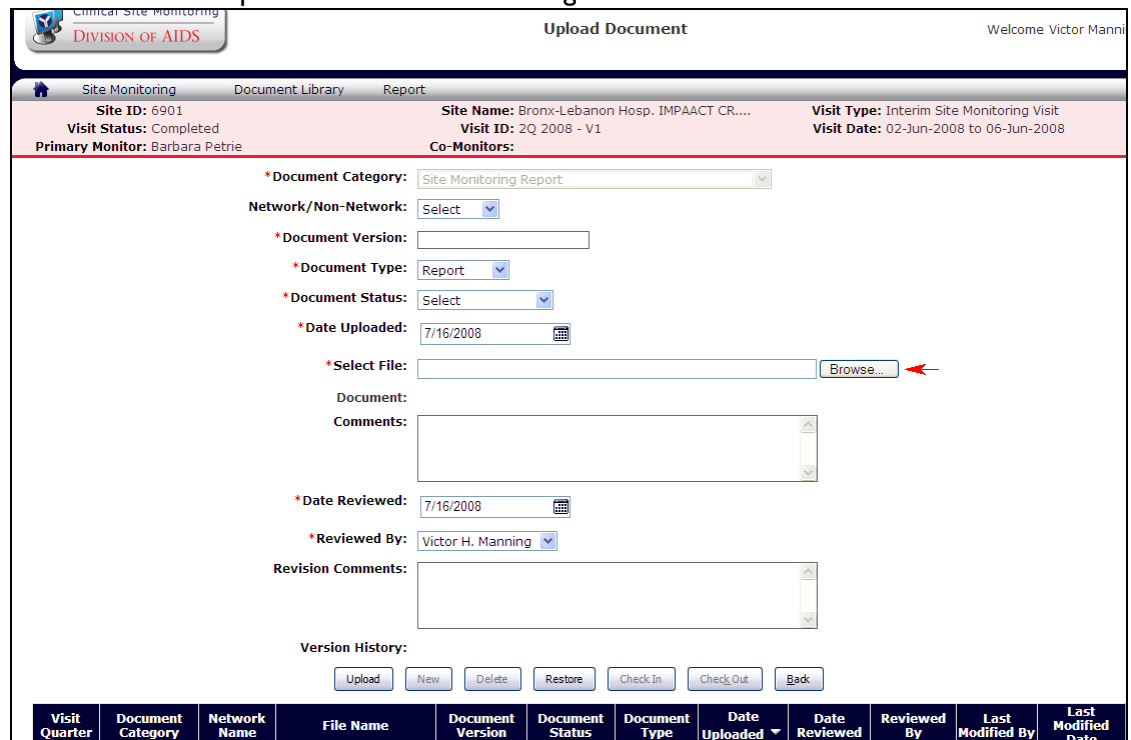
Note: You must select a day of the month to close the **Calendar** dialog box.

Uploading a File


In many instances, a DAIDS-ES application may request documents, pictures, and/or other types of files for you to upload into the application, such as a protocol document.

To Upload a File

1. Click **Browse** to open the **Choose File** dialog box.



The screenshot shows the 'Upload Document' screen in the DAIDS-ES application. The page header includes 'Clinical Site Monitoring' and 'DIVISION OF AIDS'. The user is logged in as 'Victor Manning'. The page contains a form for uploading a document, with the following fields and controls:

- Document Category:** Site Monitoring Report (dropdown)
- Network/Non-Network:** Select (dropdown)
- Document Version:** (text input)
- Document Type:** Report (dropdown)
- Document Status:** Select (dropdown)
- Date Uploaded:** 7/16/2008 (calendar icon)
- Select File:** (text input) **Browse...** (button) 
- Document:** (text input)
- Comments:** (text area)
- Date Reviewed:** 7/16/2008 (calendar icon)
- Reviewed By:** Victor H. Manning (dropdown)
- Revision Comments:** (text area)
- Version History:** (text area)

At the bottom of the form, there are buttons for 'Upload', 'New', 'Delete', 'Restore', 'Check In', 'Check Out', and 'Back'. Below the form is a table with the following columns: Visit Quarter, Document Category, Network Name, File Name, Document Version, Document Status, Document Type, Date Uploaded, Date Reviewed, Reviewed By, Last Modified By, and Last Modified Date.

Figure 12: Browse button (Upload Document screen)

2. Select a folder from the **Look in:** drop-down list.

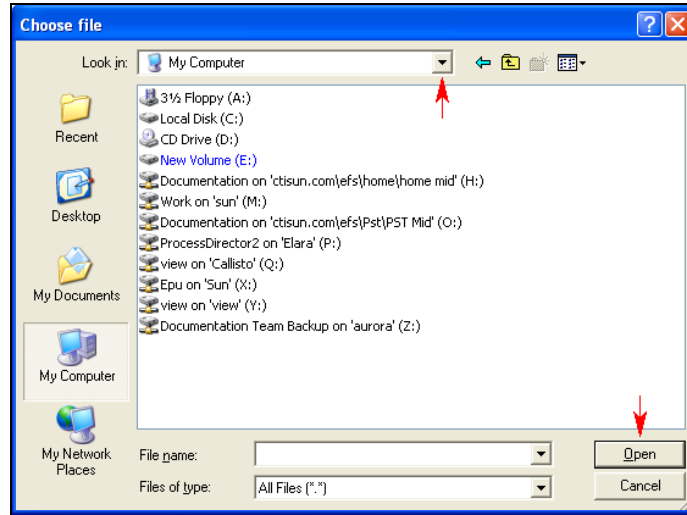





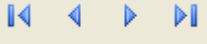
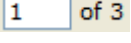
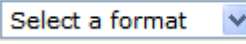
Figure 13: Choose File Dialog Box

3. Select a file from the open pane view to display in the lower **File Name** field.
4. Click **Open** to upload the file.

Using Reports

Site Visit Summary								
Visit ID	Visit Dates	Visit Quarter	Site ID	Site Name	Visit Type	Primary Monitor	Co-monitoring Visit	No. Of Co-monitors
Number of Records: 118								





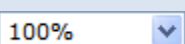
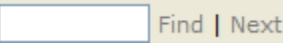
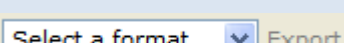





Figure 14: Report Sample

- Columns sort in ascending (A, B, C or 1, 2, 3) or descending (C, B, A or 3, 2, 1) order by clicking the column heading  to activate the ascending  or descending  arrow icon.
- Search results can be quickly viewed by clicking page controls  to move forward or backward, or selecting a page from the page counter  that displays at the top.
- Above the Search results, select **Acrobat (PDF) file** from the drop-down list  **Export** and click **Export** to export the results of the search to PDF format.


To Navigate within a Report Table

Report tables display information that is specific to the types of reports you are viewing. These tables may span many pages.

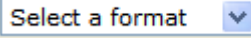

The following table describes the different ways you can navigate within report tables:

Navigating within a Report Table	
BUTTON	DESCRIPTION
	Move forward one page.
	Move back one page.
	Move forward to last report page.
	Move back to first report page.
	Click the drop-down arrow to change the way you view the page. Note: You may need to select Page Width or a size smaller than 100% to view all columns of a page.
	Type text in the text box and click Find to locate the text in the report. Click Next to move to the next occurrence of the text.
	Click the drop-down arrow to view the report in another format (e.g., TIFF file, Acrobat PDF file, Web archive, or Excel).
	Refreshes the information on the page.
	Prints the page or file.
	Click to activate the ascending  or descending  arrow icon and sort in ascending or descending order.

To Print a Report

To print a report, click the Print button  while viewing the report.

Alternatively, you can view the report in PDF view and then print it. To do this, perform the following steps:

1. Select **Acrobat (PDF) file** from the drop-down list   and click **Export** to export the results of the search to PDF format.
2. When prompted, select **Open** to open the PDF.
3. From the File menu, click **Print**.

To Export Report Data

1. Above the Search results, select **Excel** from the drop-down list

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Select a format and click **Export** to export the results of the search to a Microsoft® Excel spreadsheet. The **File Download** dialog box opens.

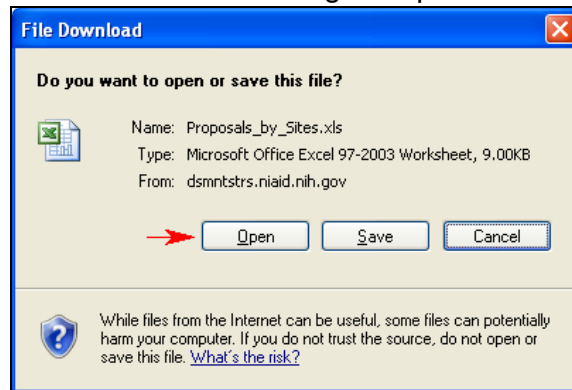


Figure 15: File Download Dialog Box

2. Click **Open** to view the results in an Excel spreadsheet. (You can also click **Save** to save the results to a file location to view later.) The data is exported and opens in MS Excel.
3. *Optional:* Print, Search, Save and other types of actions can be taken in MS Excel (outside of CSM) to manipulate the data.
4. Select **File > Exit** from the menu to close MS Excel and return to the DAIDS-ES application.

To Search within a Report

Type text in the text box Find | Next and click **Find** to locate the text in the report. Click **Next** to move to the next occurrence of the text.

CSM User Roles Matrix

Role

The DAIDS-ES system recognizes the "Role" and associated sites of each user when you first log on to the system and organizes the information displayed in the Home and Search pages accordingly.

The following Roles are available in the application:

CSM User Roles		
USER ROLE	DEFINITION	FUNCTIONS/TASKS
CTU User	Responsible for viewing reports and issues for their CRS in the system for overseeing monitoring activities at their sites	<ol style="list-style-type: none"> 1. Receive Email Notifications of Pre-Visit Letter and Site Monitoring Reports 2. View alerts 3. View site visit documents 4. View issue resolution 5. View templates
CRS User	Responsible for performing non-pharmacy site monitoring tasks in CSM	<ol style="list-style-type: none"> 1. Receive Email Notifications of Pre-Visit Letter and Site Monitoring Reports 2. View alerts 3. Acknowledge site visit reports 4. Perform Issue Resolution 5. View site visit documents 6. Access templates
Pharmacy User	Responsible for performing pharmacy-related site monitoring tasks in CSM	<ol style="list-style-type: none"> 1. Receive Email Notifications of Pre-Visit Letter and Site Monitoring Reports 2. View alerts 3. Perform Issue Resolution 4. View site visit documents 5. View Site Visit Summary report 6. Access templates
ICC User	Responsible for performing site monitoring tasks in CSM (for INSIGHT CRS's only)	<ol style="list-style-type: none"> 1. Receive Email Notifications of Pre-Visit Letter and Site Monitoring Reports 2. View alerts 3. View site visit documents

Section 4

CSM User Roles		
USER ROLE	DEFINITION	FUNCTIONS/TASKS
		<ol style="list-style-type: none">4. Perform issue resolution5. Access templates
DMC User	Responsible for viewing site monitoring data in CSM (for INSIGHT CRS's only)	<ol style="list-style-type: none">1. View alerts2. View site visit documents3. View issue resolution4. Access templates

Site Monitoring Work Flow

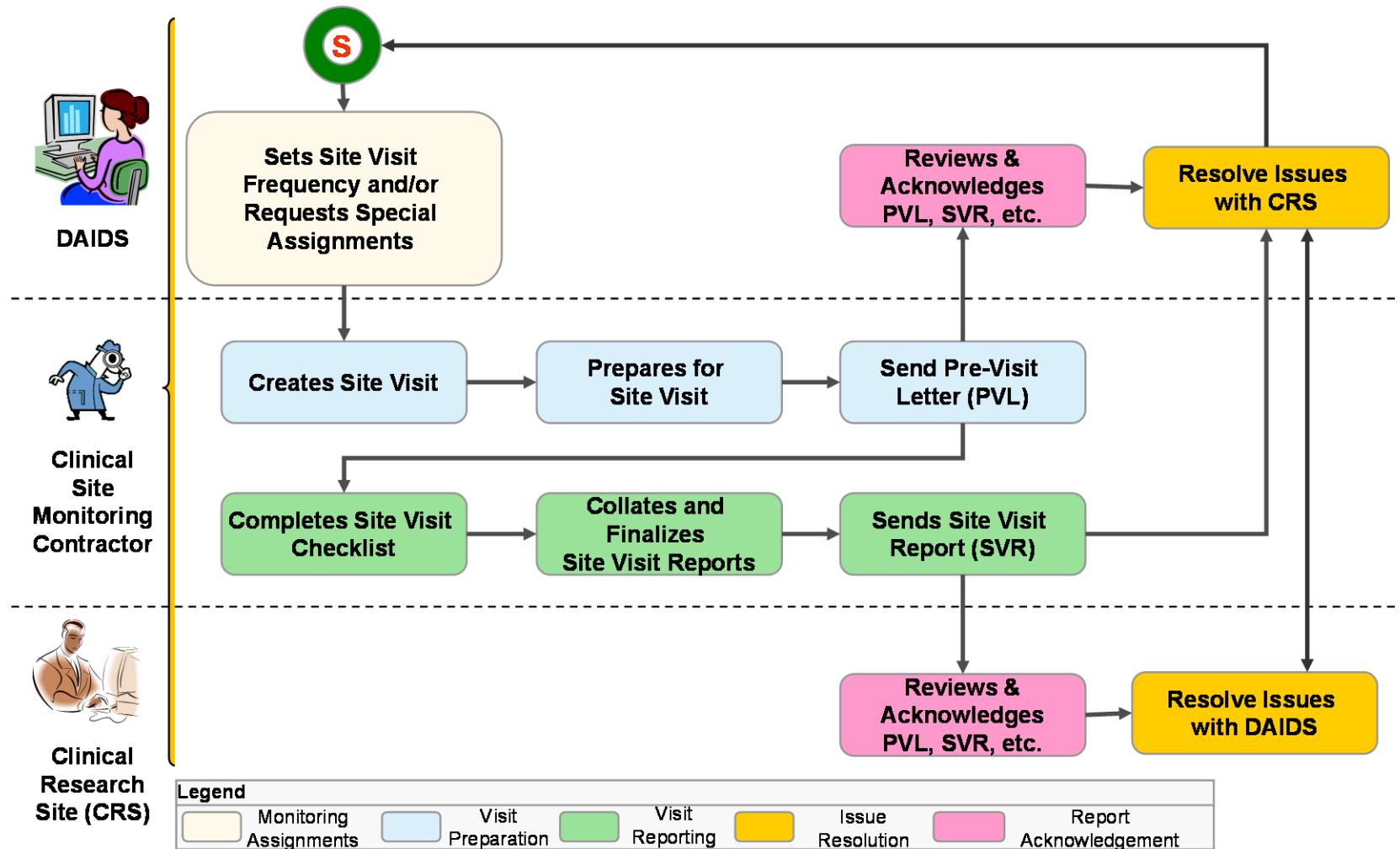


Figure 16: Clinical Site Monitoring Work Flow Diagram

DAIDS CSM Work Flow

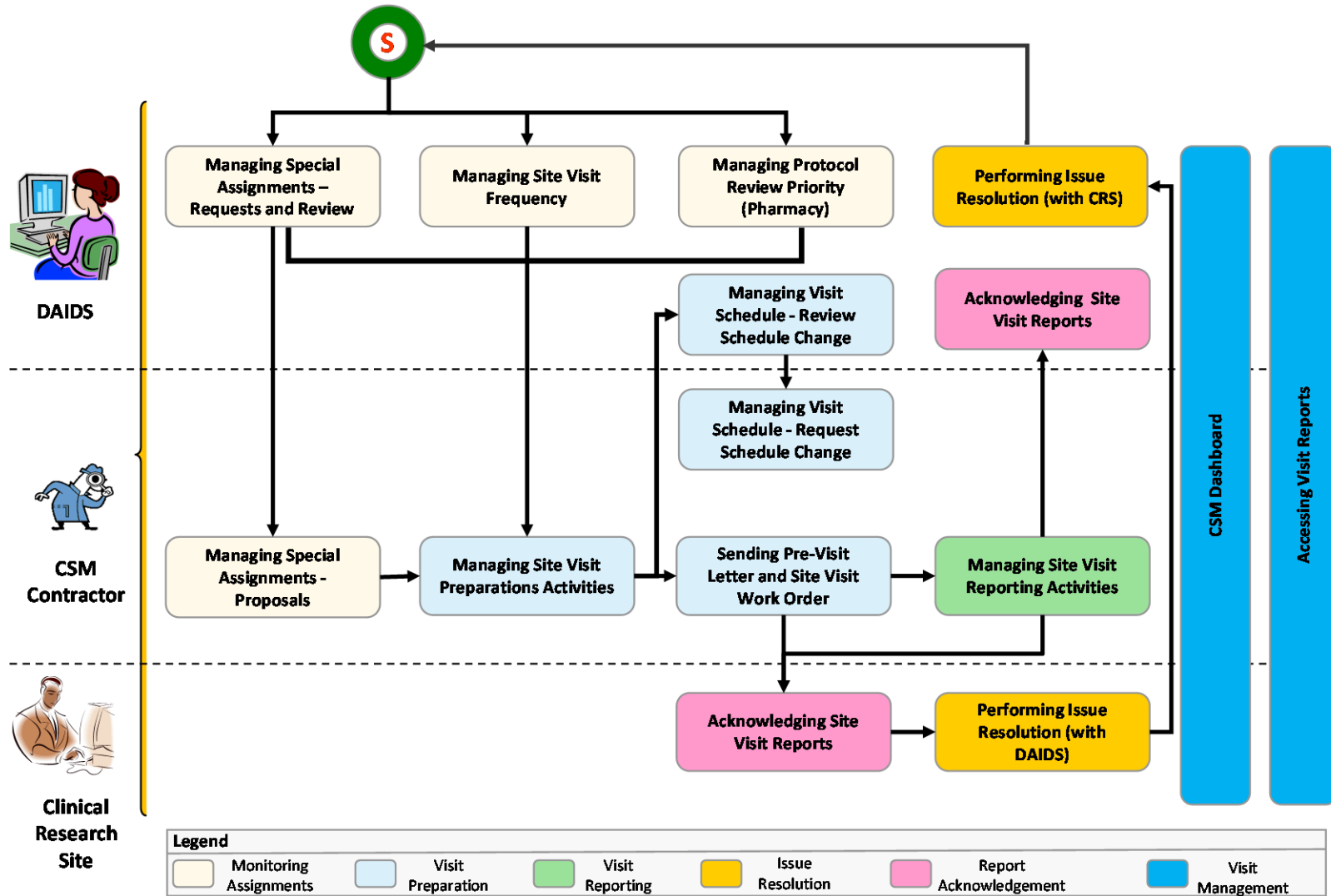


Figure 17: Clinical Site Monitor Process Flow Diagram



CSM Dashboard: Site Staff Members

Alerts Web Part

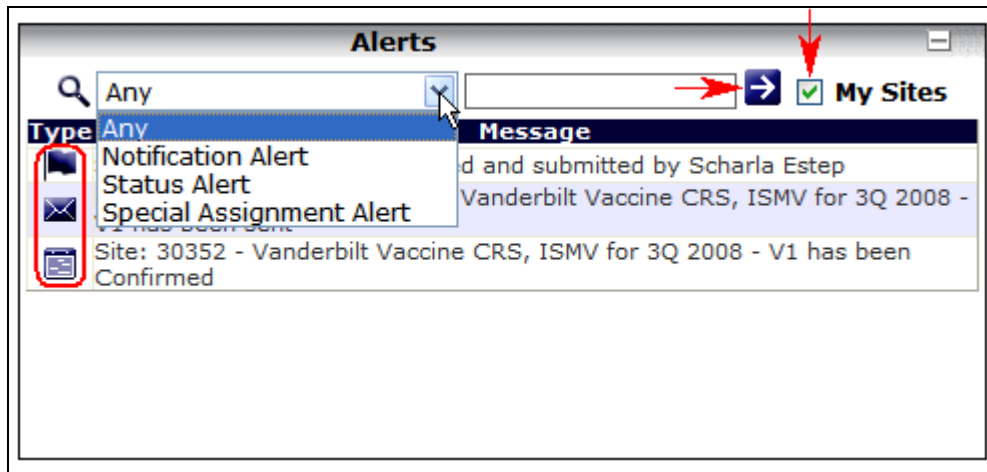


Figure 18: Alerts Web Part

What information is provided?

Displays the following types of alerts based on role of the logged in user:

- **Notification Alerts** – Notifies the user of the availability of a report in the system (e.g., Final Pre-Visit Letter, Site Monitoring Report, Site Initiation Report and Site Closeout Report).
- **Status Alerts** – Notifies the user of any visit status changes in the system (e.g. “Projected” → “Planned” → “Confirmed” → “Completed”, etc.).

Key Features

- Displays alerts based on user roles.
- Icons are used to distinguish the different types of alerts.
- Provides “My Site” option to filter the display of alerts for sites assigned to the logged in user.


When would you use this?

- **Notification Alerts** – To trigger report acknowledgement activities.
- **Status Alerts** – To trigger scheduling activities.

What triggers the data in this Web Part?

- **Notification and Status Alerts** - Visit preparation and reporting activities performed by CSM contractor.

Procedure to search for alerts matching specific criteria

1. Select an alert type from the drop-down list (as shown in Figure 18 on page 22) and enter search criteria.
2. Click the  to display search results.

Note: The **My Sites** check box defaults to selected for some user roles and cannot be cleared.

Alerts Information	
FIELD	DESCRIPTION
Type	Displays different types of alerts the logged in user can search alerts on, as described in the “ What information is provided? ” section.
Message	Displays alert message associated with the type of alert.

Site Visit Reporting Acknowledgement

Visit Quarter	Visit Type	Visit Dates	Site ID	Documents	# of Days Pending
Q 2008 - 1	ISMV	26-May-2008 to 30-May-2008	31458	Site Monitoring Report	2
Q 2008 - 1	ISMV	02-Jun-2008 to 06-Jun-2008	6901	Site Monitoring Report	8
Q 2008 - 1	ISMV	09-Jun-2008 to 12-Jun-2008	CIP 11405	Site Monitoring Report	8

Figure 19: Site Visit Reporting Acknowledgement Web Part

What information is provided?

Displays the following documents that are available for acknowledgement for a specific site visit:

- **Site Initiation Report** – Sent by monitoring contractor as a deliverable out of a Site Initiation Visit.
- **Site Monitoring Report** – Sent by monitoring contractor as a deliverable out of an Interim Site Monitoring Visit or Special Assignment Visit.
- **Site Closeout Report** – Sent by monitoring contractor as a deliverable out of a Site Closeout Visit.

Note for Site Pharmacist: The SMR / SCR / SIR links will be removed as soon as the last PAB report is acknowledged.

Key Features

- Provides access to acknowledge review of site visit reports.
- Color indicators are used to show documents that have been waiting on acknowledgment for an extended period of time or that have been successfully acknowledged by DAIDS.

When would you use this?

To acknowledge review of the site visit report submitted by the CSM contractor.

What triggers the data in this Web Part?

Email notification sent through CSM by the CSM Contractor.

Procedure to search specific reports for acknowledgement

1. Select a search category (as shown in the field information below) and enter search criteria.
2. Click the to display the search results.

Note: The **My Sites** check box defaults to selected for some user roles and cannot be cleared.

3. *Optional:* Click a *Visit Dates* link to review and acknowledge site visit reports.

Note: Only the CRS users (specifically the CRS Site Leader or CRS Clinical/Site Coordinator) have the option to click on the Visit Dates link to review and acknowledge site visit reports.

Site Visit Reporting Acknowledgement Information	
FIELD	DESCRIPTION
Acknowledgement indicator	Indicates if the report has been acknowledged or not by displaying an open v/s closed envelope.
Visit Quarter	Displays visit quarter for which the site visit document needs to be acknowledged.
Visit Type	Displays the visit type for which the site visit document needs to be acknowledged.
Visit Dates	Displays the visit start date and end date for which the site visit document needs to be acknowledged.
Site ID	Displays the Site ID for which the site visit document needs to be acknowledged.
Documents	Displays the type of document that needs to be acknowledged.
No. of Days Pending	<p>Displays the number of days the site visit document has not been acknowledged. The counter starts the day the report is sent and stops the day the report is acknowledged.</p> <p>A green tick mark is displayed next to the number as soon as the report is acknowledged.</p>

Issue Resolution

Visit Quarter	Visit Dates	Site ID	# of Issues				
			Report ed	In Resolution DAIDS	In Resolution Site	Resolv ed	By SA
1Q 2008	25-Feb-2008 to 29-Feb-2008	2301	2	0	2	0	0

Figure 20: Issue Resolution Web Part

What information is provided?

Displays the issues that have been entered in the system that are in the following workflow statuses:

- **In Resolution (DAIDS)** – Site has submitted the corrective action plan and/or resolution comments to DAIDS.
- **In Resolution (Site)** – DAIDS has submitted issues to site.
- **Resolved** – DAIDS has marked issues as resolved.
- **To Be Resolved By SA** – DAIDS has marked issues as to be resolved by special assignment.

Key Features

- Provides access to view and update issue resolution correspondence.
- Displays the number of issues per site visit grouped by resolution status.
- Provides number of issues waiting on response by DAIDS or Site.

When would you use this?


To view issue activity requiring action from Sites, depending upon different issue statuses:

- **In Resolution (DAIDS)** – Indicates that DAIDS needs to review the corrective action plan and/or resolution comments submitted by Site.
- **In Resolution (Site)** – Indicates that Site needs to review list of issues and submit corrective action and/or resolution comments to DAIDS.
- **Resolved** – Indicates that no further action is required by DAIDS and Site.
- **To Be Resolved By SA** – Indicates that no further action is required by DAIDS.

What triggers the data in this Web Part?

Issue Resolution activities performed by DAIDS and Sites, based upon existing workflow and corresponding issue resolution statuses.

Procedure to search issue resolution metrics for a specific quarter or site

1. Select a search category (as shown in the field information below) and enter search criteria.
2. Click the  to display the search results.

Note: The **My Sites** check box defaults to selected for some user roles and cannot be cleared.

3. *Optional:* Click a Visit Dates link to view or manage an issue resolution.

Note: All Site User Roles have access to view issues for their sites by clicking on the Visit Dates link, but only the CRS users (specifically the CRS Site Leader or CRS Clinical/Site Coordinator), Pharmacy Users (Pharmacist of Record) and ICC Users have the option to click on the Visit Dates link to review and respond to issue.

Issue Resolution Information	
FIELD	DESCRIPTION
Visit Quarter	Displays visit quarter of the site visit for which the issue metrics are provided.
Visit Dates	Displays the visit start date and end date for the site visit for which the issue metrics are provided.
Site ID	Displays the Site ID of the site visit for which the issue metrics are provided.
# of Issue Reported	Displays the total number of issues that have been reported for a given site visit.
# of Issues In Resolution DAIDS	Displays the total number of issues waiting review by DAIDS.
# of Issues In Resolution Sites	Displays the total number of issues awaiting corrective action plan and/or resolution comments by Site.
# of Issues Resolved	Displays the total number of issues that have been marked as resolved by DAIDS.
# of Issues By SA	Displays the total number of issues that have been marked as to be resolved by special assignment by DAIDS.

Note: Pharmacy and Non-Pharmacy Issues will be maintained and tracked separately.

- Pharmacy issues correspondence will take place between DAIDS Pharmacist and Pharmacist of Record, and
- Non-Pharmacy Issue correspondence will take place between DAIDS POs and CRS Site Leader and/or Clinical/Site Coordinator.

Working with Issue Resolution Emails

What information is provided?

Sends Issue Resolution email alerts indicating whether issues are pending or closed or no issues exist for a site visit.

Key Features

- “Pending Issues” email notification is sent to the Site Leader, DAIDS PO, Site Pharmacist, DAIDS Pharmacist, CRPMC Pharmacist and the DAIDS Pharmacy manager on weekly basis providing information on pending issues.
- “Closed Issues” email notification is sent to the Site Leader and DAIDS PO when all issues are resolved.
- “No Issues” email notification is sent to the Site Leader and DAIDS PO when there are no issues found in site visit.

When would you use this?

These emails can be used as an aid to monitor the issue resolution activities.

What triggers the emails?

Pending Issues – This email alert is sent from the CSM application automatically on weekly basis. Currently the email is set to be sent on every Monday.

Closed Issues – This email is sent out when the last issue on a site visit is resolved.

No Issues – This email is sent out when the user marks that there are no issues for the site visit in the Site Visit Report Acknowledgement screen.

From: DAIDS CSM Notification System [mailto:DAIDSCSMNotification@niaid.nih.gov]
Sent: Wednesday, November 19, 2008 12:23 PM
To: flex@jhmi.edu;imp@jhmi.edu
Subject: DAIDS Clinical Site Monitoring Notification – No Issues

From OCSO's perspective no issues require resolution within the following site visit report and the report is closed. Your PoR should resolve any pharmacy related issues directly with DAIDS PAB.

201 - Johns Hopkins Adult AIDS CRS [1Q 2008 - V1 (18-Feb-2008 to 21-Feb-2008)]

Sincerely,

Sue A Welsch
E-mail: swelsch@niaid.nih.gov
Phone: 1-301-402-2295

Figure 21: Issue Resolution Email

Acknowledging Reports

Viewing E-mail Notifications

Clinical Research Site Leader, Clinical/Site Coordinator, Pharmacist of Record (if any pharmacy assignments exist in the site visit), CTU PI, CTU Coordinator, ICC users will receive email notifications generated from the system notifying them of the availability of pre-visit letters and site visit reports. DMC users will receive email notifications generated from the system notifying them of the availability of final site visit reports in the system.

The receipt of this email in your mailbox initiates the report acknowledgement and issue resolution process at DAIDS.

What information is provided?

- Quick link to access the report acknowledgement screen as well as instructions to acknowledge review of the site monitoring report.
- Quick link to access the site visit documents in order to view all relevant documents associated with the site visit.

Key Features

- Report acknowledgement screen and site visit documents can be accessed by clicking the URL inserted in the email.
- Integrated with Master Contact to populate the email address of all the email recipients.

Note: Thus a change in the contact information has implications for this process. Please assure that any change of personnel contact information, such as e-mail address, phone number, or fax number, is communicated to the DAIDS-ES.

From:	DAIDSCSMNotificationSystem@niaid.nih.gov	Sent:	Fri 9/19/2008 5:13
To:	spb@tsa.ucsf.edu; susan.buchbinder@sfdph.org; swelsch@niaid.nih.gov; twagner@sfdph.org		
Cc:			
Subject:	30305 - San Francisco Vaccine and Prevention CRS, 3Q 2008 - V1 (02-Sep-2008 to 05-Sep-2008) Interim Site Monitoring Visit - Site Monitoring Report Notification		

The Site Monitoring Report is ready for your review and can be accessed by clicking the URL [here](#) (for DAIDS users) or [here](#) (for Non-DAIDS users). In order to assure proper distribution of these documents and ensure effective follow-up of the visit findings, review is required by the

- **DAIDS POs** for non-pharmacy section of the report;
- **CRS Site Leader** or **CRS Clinical/Site Coordinator** for the non-pharmacy section of the report;
- **Site Pharmacist of Record** for pharmacy section of the report and
- **DAIDS Pharmacist** or **CRPMC Pharmacist** for pharmacy section of the report

Upon clicking the URL, you will be re-directed to the "Report Acknowledgement" screen where you will be required to perform the following tasks:

1. Review the Site Monitoring Report by clicking on the document.
2. Acknowledge successful **review** of the Site Monitoring Report by clicking on the corresponding checkbox and then clicking Save.

Please note that for any network specific correspondence requiring sharing of these reports, please access these by clicking the URL [here](#) (for DAIDS users) and [here](#) (for Non-DAIDS users). This URL can also be used to access the relevant report templates.

Thank you,
 Andrea Bennett (Monitoring Manager)
 Phone: 1 (910) 772-6846
 Fax: 1 (919) 654-8938
 Email: Andrea.Bennett@wilm.ppd.com

The information referenced herein is confidential and may contain sensitive information that is legally privileged. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices.

Figure 22: Site Monitoring Report Email Snippet

When would you receive this email?

- **Pre-Visit Letter Email Notification** – Upon site visit confirmation.
- **Site Monitoring Report Email Notification** – Upon report finalization on or before the report due date (based upon existing reporting timelines).

Who receives this email?

- **To:** CRS Site Leader, CRS Clinical/Site Coordinator, DAIDS POs by default and Site Pharmacist of Record, DAIDS Pharmacist and CRPMC Pharmacist, if there are any pharmacy assignments associated to the site visit.
- **Cc:** CTU PI, CTU Coordinator, ICC User, DMC User, CSM Contractor (Managers, Monitors and PAs).

To Acknowledge a Document

When would you use this?

To view the pre-visit letter and site visit report and acknowledge receipt/review of the reports respectively.

Key Features

- Acknowledgement of a pre-visit letter and site visit report is tracked within the system and can be printed for filing purposes.

Who is responsible for this?

- CRS Site Leader, Clinical/Site Coordinator, DAIDS POs for non-pharmacy sections of the report.
- Site Pharmacist of Record, DAIDS Pharmacists and/or CRPMC Pharmacists for pharmacy sections of the report.

Procedure to acknowledge reports

1. Click on the first URL in the **Site Monitoring Report** email notification OR from the CSM Dashboard (i.e. Home Page), click on the **Site Visit Date** corresponding the Site Monitoring Document you wish to acknowledge. The Report Acknowledgement page displays.

Document	Acknowledgement Date	Comments	Acknowledgement By	Acknowledgement Type	Acknowledge
302008V1-30007-AWO.pdf	08/14/2008		Lizanne Noble	Review	<input checked="" type="checkbox"/>
302008V1-30007-PVL.pdf	08/11/2008		Lizanne Noble	Review	<input checked="" type="checkbox"/>
302008V1-30007-Site_Monitoring_Report.xls	10/16/2008	update by gln	Lindsey Baden	Review	<input checked="" type="checkbox"/>

Figure 23: Report Acknowledgements

Section 11

2. Click on the **Site Monitoring Document** link to review the document.
3. After reviewing the document, complete the report acknowledgement fields (as shown in the field information below).

Note: Click **Restore** at anytime prior to clicking **Save** to restore the pre-populated fields on this page. Click **Back to Home** to return to the Home Page.

4. Click **Save**.
A message appears indicating that the update was successful.

Note: The name of the user logged in will be automatically populated in the "Acknowledgement By" field.

Site Visit Report Acknowledgement Information

FIELD	DESCRIPTION
Acknowledgement Date	Provides option to select the date the report was acknowledged. Date is automatically populated if no date is selected.
Comments	Provides option to document comments associated with the review of site monitoring report.
Acknowledge	Provides option to acknowledge review of site monitoring report.

Site Visit Reporting Acknowledgements Web Part

Acknowledgement information once entered in the system will now be visible in the Site visit Reporting Acknowledgement Web Part. To view additional information on the Report Acknowledgements Web Part, see the section "Site Visit Reporting Acknowledgement " on page 24.

Performing Issue Resolution

Working with Issue Resolution

When would you report issues?

To follow-up on issues identified in the Site Visit Report.

Note: Reference the section “CSM Dashboard: Site Staff Members” || “Issue Resolution Web Part” for additional information.

Key Features

- Provides correspondence tracking during the issue resolution process.
- Provides a visual indicator to identify that the issue is waiting on response by either DAIDS or CRS.
- Issues can be entered at an assignment or protocol level.
- Multiple issues can be submitted at one time.
- Issue can be saved for future review prior to sending to DAIDS.
- Pharmacy and Non-Pharmacy Issues are maintained, tracked and closed separately.
- Issues are tracked throughout the correspondence process using the issue statuses listed below:

Issue Status Information		
ISSUE STATUS	DEFINITION	ACTION TO BE PERFORMED
Open	Issue has been created but not yet submitted.	DAIDS needs to send these issues to Site.
In Resolution	Issue is in the process of resolution between DAIDS and Sites.	Site needs to respond to DAIDS with a Corrective Action Plan and/or Resolution Comments OR DAIDS needs to respond back to the site or mark issues as resolved Note: This is based upon the “!” indicator provided on the screen.
Resolved	Issue has been marked as closed by DAIDS.	No action required by Site.
To Be Resolved By Special Assignment	Issue has been marked as resolved but DAIDS will request a special assignment as follow-up.	No action required by Site.

Section 12

Note: Once all issues (Pharmacy and Non-Pharmacy) are either marked as resolved or to be resolved by special assignment, all issues reported for the site visit are marked as closed.

Who is responsible for creating and submitting issues?

- DAIDS Pharmacists or CRPMC Pharmacists can create and/or submit special issues for Pharmacy tasks.
- DAIDS Program Officers can create and/or submit special assignments for Non-Pharmacy tasks.
- Pharmacist of Record is responsible for submitting corrective action plan and/or resolution comments for Pharmacy Issues.
- CRS Site Leader or CRS Clinical/Site Coordinator or ICC User is responsible for submitting corrective action plan and/or resolution comments for Non-Pharmacy Issues.

Note: Only DAIDS Pharmacists or DAIDS Program Officers can mark issues a “Resolved” or “To Be Resolved By Special Assignment.”

Procedure to find issues

1. From the **Site Monitoring** menu option, point to **Open**, and click **Issue Resolution**. The Issue Resolution page displays.

The screenshot shows the 'Issue Resolution' page in the DAIDS Enterprise System. At the top, there's a navigation bar with 'Site Monitoring', 'Document Library', and 'Report'. Below that, there are search fields for 'Site Name' (6901 - Bronx-Lebanon Hosp. IMPAACT), 'Issue Status' (In Resolution - Sites), 'Visit Quarter' (3Q 2008), and 'View Issues' (View Non-Pharmacy Issues). There are also 'Go' and 'Clear' buttons. Below the search fields is a table of issues.

	Issue No	Assignment	Issue	Issue Desc...	Corrective...	Resolutio...	Comments	Status	Updated By	Updated Date
	6901 - Bronx-Lebanon Hosp. IMPAACT CRS								Total Issues:1	
	3Q 2008 - V1 29-Sep-2008 to 03-Oct-2008								Total Issues:1	
	IR - 00153	Regulatory File Re...	Other	Other				In Resolutio...	Sue Welsch	21-Nov-2008

Figure 24: Issue resolution Search fields

2. Enter the criteria in the search fields on the top of the page and click . The Issue Resolution page displays issues matching the search criteria.

Issue Resolution Search Fields Information

FIELD	DESCRIPTION
Site Name	Provides option for DAIDS to select the site.

Issue Resolution Search Fields Information

FIELD	DESCRIPTION
	Select the name from the List of Values. Access to CRS Profile Report and Protocols at Site Report is available from the list of values.
Visit Quarter	Provides option to select issues based upon visit quarter.
Issue Status	Provides option to select issues based upon issue status.
View Issues	Provides option to select the issue type.
Assignment Type	Provides option to select the Assignment type.

Issue Resolution Search Results Fields Information

FIELD	DESCRIPTION
Issue No	Displays the issue number created when creating issue.
Assignment	Displays the Assignment type entered when creating issue.
Issue	Displays the Issue entered when creating issue.
Issue Description	Displays the issue description entered when creating issue.
Corrective Action	Displays the corrective action entered when creating issue.
Resolution	Displays the resolution provided by sites / DAIDS
Comments	Displays the comments entered when creating the issue
Status	Displays the Issue status.
Updated By	Displays the user who last updated the issue record.


Issue Resolution Search Results Fields Information

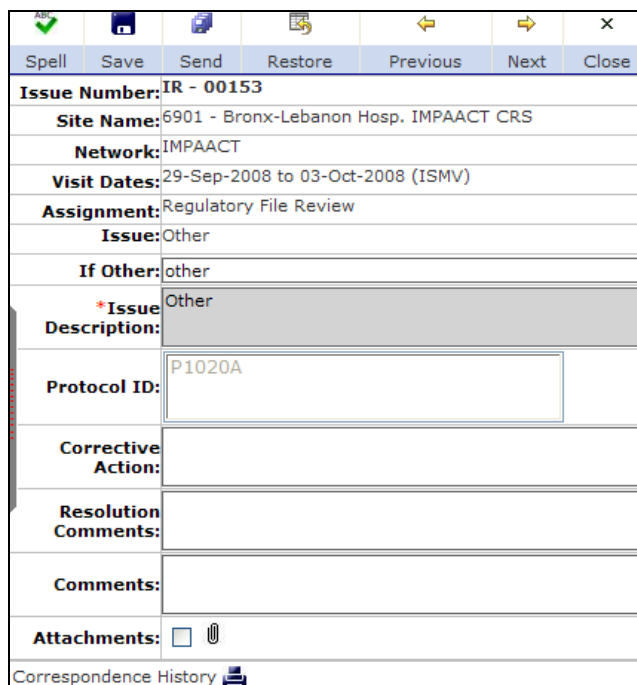
FIELD

DESCRIPTION

Updated Date:	Displays the date on which the issue was last updated.
----------------------	--

Procedure to modify issues

1. From the **Site Monitoring** menu option, point to **Open**, and click **Issue Resolutions**. The Issue Resolution page displays.
2. Enter the criteria in the search fields on the top of the page and click . The Issue Resolution page displays issues matching the search criteria.
3. Click in the Check Box corresponding to “!” to modify the associated issue.
4. A pane opens on the right side of the screen displaying the issue information.










FIELD	DESCRIPTION
Issue Number:	IR - 00153
Site Name:	6901 - Bronx-Lebanon Hosp. IMPAACT CRS
Network:	IMPAACT
Visit Dates:	29-Sep-2008 to 03-Oct-2008 (ISMV)
Assignment:	Regulatory File Review
Issue:	Other
If Other:	other
*Issue Description:	Other
Protocol ID:	P1020A
Corrective Action:	
Resolution Comments:	
Comments:	
Attachments:	<input type="checkbox"/> 
Correspondence History 	

Figure 25: Right pane displaying issue information



5. Modify the issue information in the edit pane.

Note: Click  at anytime prior to clicking  to clear the search fields.
6. Click  to save the issue.
A message appears indicating that the update was successful.
7. *Optional:* Click  to submit the issue to the site.
8. *Optional:* Click  to print the Comments History.

Procedure to respond to issues


1. Select an issue that has an action indicator “!” by clicking the checkbox or Issue Number. The Edit pane opens to the right.
2. In the **Corrective Action** field, enter details on the site’s long range goal that will ensure that the particular issue will not reoccur.
3. In the **Resolution Comments** field, enter details regarding the steps that the site will take to rectify the issue that has been entered by DAIDS.
4. In the **Comments** field, enter any additional details or clarification for DAIDS.
5. Click the paperclip icon to add attachments related to the issue. Select the checkbox to add multiple attachments to the issue.

Procedure to send issue responses to DAIDS

1. Save an issue prior to sending it to DAIDS by clicking the  button in the Edit Pane.
2. Send an individual issue by clicking the  button in the Edit Pane.
3. Send responses for all issues reported by DAIDS by selecting the checkbox on the Site Name row and click the **Send All** button on the top left of the toolbar. Send responses for all issues reported for visit date(s) by selecting the checkbox on the Quarter and Visit Date(s) row and click the **Send All** button as shown in Figure 24 on page 33.


Note: Issues once sent to DAIDS cannot be modified until DAIDS responds back to the issue response.

Procedure to view issue resolution report

1. From the **Site Monitoring** menu option, point to **Open**, and click **Issue Resolutions**. The Issue Resolution page displays.
2. Click  on the top left corner of the screen as shown in Figure 24 on page 33. A popup displays the Issue Resolution report.

ISSUE RESOLUTION										
Site ID: 30007			Site Name: Brigham and Womens Hosp. CRS							
Visit Quarter: 1Q 2008			Network/Non-Network: HVTN							
Visit Type: Interim Site Monitoring Visit										
Number of Records: 2										
Issue No	Assignment	Issue	Issue Description	Corrective Action	Resolution Comments	Comments	Status	Protocols	Updated By	Updated Date
Visit ID: 1Q 2008 - V1 03-MAR-2008 - 06-MAR-2008										
IR - 00089	Protocol Specific Investigational Drug Audit	Other	other			new issue	Resolved	HVTN 085, HVTN 070, HVTN 072	Scharla Estep	27-Jun-2008
Total Issue (s): 1										
Visit ID: 2Q 2008 - V2 27-JUN-2008 - 30-JUN-2008										
IR - 00088	Investigational Pharmacy Inventory And Storage Assessment	Other	other	cap can be updated by site	rc can be updated by site	new data need more data	In Resolution	HVTN 048, HVTN 049, HVTN 050	Scharla Estep	27-Jun-2008
Total Issue (s): 1										
Report Date: 16-Jul-2008 9:57:58 AM										1 of 2

Figure 26: Issue Resolution Report

3. *Optional:* Enter the criteria in the search fields on the top of the page and click  to further narrow down the search results to be displayed on the Issue Resolution report.

Issue Resolution Web Part

Issue Resolution information once entered in the system will now be visible in the Issue Resolution Web Part. To view additional information on the Issue Resolution Web Part, see "Issue Resolution" on page 26.



Accessing Visit Reports

Site Visit Summary Report

What information is provided?

Displays site visit details for all site visits that have been confirmed and completed and allows the user to view all site visit report documents that have been submitted.

Key Features

- Report output can be filtered by entering filter criteria such as visit quarter.
- Columns displayed in the report can be customized.
- Site visits documents can be accessed by clicking the Site Visit ID link.
- Provides “My Site” option.

When would you use this report?

To view submitted site visit reports.

Who can view this report?

All DAIDS, Site and CSM contractor staff having access to the system can view this report.

Note: Site staff members have only access to reports for their site.

Procedure to Generate the Report

1. Click the **Report** menu option.
The Site Visit Summary page displays and the left pane is populated with report generation links.

Note: If the Site Visit Summary page is not displayed, click the Site Visit Summary link in the **Visit Reports** pane.

Figure 27: Site Visit Summary

Note: Use the Site Visit Summary page's **Customize** option to display the **Report Display Type** screen to add/remove additional columns from the report output. The Customize option also allows you to restore the default values to the report display options by clicking **Reset to Default** prior to clicking **Run Report**.

Figure s: Report Display Type

2. Complete as many of the search criteria as required (as shown in the field information below) to narrow the search results.
3. Click **Run Report**.
The Site Visit Summary Report page displays the visit information matching the selection criteria.

Visit ID	Visit Dates	Site ID	Site Name	Visit Type	Primary Monitor	Visit Status	Was Report Notification Sent?	Was Report Acknowledged By DAIDS PO?	Was Report Acknowledged By Site?	Were Pharmacy report(s) acknowledged by DAIDS Pharmacist
3Q 2008 - V1	29-Sep-2008 - 03-Oct-2008	6901	Bronx-Lebanon Hosp. IMPAACT CRS	Interim Site Monitoring Visit	Barbara Petrie	Completed	Yes	No	No	Not Applicable

Figure 28: Site Visit Summary Report

Procedure to view the report

Note: Refer to **Using Reports** section for tips on getting the most from this page.

Procedure to view the Site Visit Documents

1. To access the Site visit documents for a specific visit, select the **Visit ID** and click the hyperlink to navigate to **Site Visit Documents** screen.
2. To view a specific document, click the **File Name** and click the hyperlink.

Figure 29: Site Visit Documents

Site Visit Document Information

FIELD	DESCRIPTION
View Templates and Guidelines	Click this link to view the Templates and Guidelines.
Document Category	Displays the Site Visit Document category.
File Name	Displays the file name of the document.
Status	Displays the Site Visit Document status.
Date	Displays the Site Visit Document status date.

Accessing the Document Library

Working with Templates and Guidelines

What information is provided?

All report templates and guidelines that the CSM contractor currently uses in their routine monitoring visits are uploaded to the document library and can be accessed at any point in time from within the system.

Key Features

- Site users have only access to the PDF version of the templates.
- Templates and Guidelines for previous quarters can be pulled up at any point in time within the system.
- Version history is maintained of all documents uploaded into the system.

Who can view this?

Report Templates and Guidelines can be viewed by DAIDS, CRPMC and CSM Contractor Staff. Site users can only view Report Templates.

Procedure to view Templates and Guidelines

1. From the **Document Library** menu option, point to **View**, and then click **Templates and Guidelines**.
The Templates and Guidelines page displays with associated files listed in a table on the bottom of the page.

DAIDS-ES | Help | Logoff

Clinical Site Monitoring
DIVISION OF AIDS

View Templates and Guidelines

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Site Monitoring Document Library Report

*Visit Quarter: 4Q 2008

Document Category: Site Specific Investigational Pharmacy Assessment
Investigational Pharmacy Inventory And Storage Assessment
Protocol Specific Investigational Drug Audit
Regulatory File Review
Site Closeout Report
Site Initiation Investigational Pharmacy Assessment
Site Initiation Report
Site Monitoring Report
Site Operations Assessment
Record Review Tool

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Visit Quarter	Document Category	Network Name	File Name	Document Version	Document Status	Document Type
4Q 2008	Site Specific Investigational Pharmacy Assessment		VPRP_SSIPA_Template_408_V6.0_06Oct2008.pdf	6.0	Final	Template
4Q 2008	Site Specific Investigational Pharmacy Assessment		TRP_SSIPA_Template_408_V7.0_06Oct2008.pdf	7.0	Final	Template

Figure 30: View Templates and Guidelines

- Optional: Complete as many of the search criteria as possible (as shown in the field information below) to narrow the search results.
Note: Click **Clear** at anytime prior to clicking **Search** to restore the pre-populated fields on this page.
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Appendix: CSM Visit and Assignment Types

Visit Types in CSM	
FIELD	DESCRIPTION
Site Initiation Visit	Meeting before the start of a clinical trial to discuss the protocol and how it will be conducted.
Interim Site Monitoring Visit	Site visits that are conducted at pre-determined dates after patient enrollment has begun. The purpose of the interim visits is to meet with key study staff and review study operations. The primary topics include regulatory obligations, clinical operations assessments, and an audit of a randomly selected group of patient files. The visits should be completed within 1–3 days but may take longer depending on the number of patient file audits are required.
Site Closeout Visit	Monitoring visit that occurs at the end of a study to ensure appropriate completion of clinical trials, storage of clinical records, and disposition of investigational products.
Special Assignment Visit	Initiation visit conducted by the Clinical Site Monitor to ensure that both the facility and staff are able to carry out the study.

Assignment Types in CSM	
FIELD	DESCRIPTION
Site Initiation Assessment	Monitoring visit to assess the site's ability to conduct the study. This may include review of protocol, regulatory documents, Case Report Form, enrollment requirements, investigational drug, and responsibilities for conducting the clinical trial.
Site Initiation Investigational Pharmacy Assignment (SIIPA)	If investigational drugs are being used, the Clinical Site Monitor audits the pharmacies associated with the clinical research site that is conducting the study.
Record Review	Performed by Clinical Site Monitors to verify that all study data adhere to the protocol and its source documents. The number of records reviewed depends on the number of participants enrolled in the study.
Regulatory File	A regulatory file audit for each active protocol is to be completed each

Assignment Types in CSM	
FIELD	DESCRIPTION
Audit	quarter, to include initial Institutional Review Board (IRB)/Ethics Committee (EC) approval and continuing review approval (both local and U.S.), assurances, safety memos, protocol amendments, any other essential IRB communications, or essential regulatory documents as required by the DAIDS Essential Documents SOP.
Protocol Specific Investigational Drug Audit (PSIDA)	Usually conducted semi-annually depending on the individual site requirements, the Clinical Site Monitor performs an audit of each site pharmacy or drug management area for a sample of active protocols including, but not limited to, evaluation of: 1) the pharmacy's procedures to ensure that the treatment regimens are being dispensed in accordance with the protocol and DAIDS guidelines; 2) subject records, treatment assignment lists and accountability documents, to ensure that their confidentiality is maintained; and 3) the proper management of the study to ensure that procedures are being followed to prevent diversion of investigational drugs. This will include performing inventories of investigational agents physically present and reconciliation with accountability records.
Investigational Pharmacy Inventory and Storage Assessment (IPISA)	For sites using investigational drugs supplied by DAIDS, review of drug accountability and storage procedures is required under federal regulations and NIAID policy. During the onsite audit, a tour of the pharmacy/storage facility is conducted.
Operations Assessment (OPS)	Performed by the Clinical Site Monitor, the Operations Assessment includes: <ul style="list-style-type: none"> • Review of pharmaceutical products storage, files, and supply inventory. • General review of data collection operations. • Visit study laboratories and review QA and other activities. • Review of specimen storage and shipping. • Review of data entry operations.
Site Closeout Assessment	Visit performed by the Clinical Site Monitor to ensure appropriate completion of clinical trials, storage of clinical records, and disposition of investigational products.
Laboratory Specimen Verification	Audit performed by Clinical Site Monitor to ensure that laboratory specimens are correctly collected, processed, and shipped for analysis. This is important to assure that continuity of all techniques is maintained

Assignment Types in CSM	
FIELD	DESCRIPTION
	throughout the study duration, to minimize variability by clinic or by technician.
Pharmacy Special Assignment	Third party “for cause” on-site audits of pharmacies associated with the clinical research site.
Site Specific Investigational Pharmacy Audit (SSIPA)	<p>Audit performed by Clinical Site Monitor to ensure that:</p> <ul style="list-style-type: none"> • All protocol-specific documents are present and accessible only to the site pharmacist or his/her designee. • The investigational drug storage area is inspected. • All investigational drugs have been accounted for. • Study drugs are prepared and dispensed according to protocol.