

Quick Reference Card: Clinical Site Monitoring: Issue Resolution (CRS)

Q How do I access the Issue Resolution screen to find issues that have been reported by DAID?

- 1 On the top menu bar, point to **Site Monitoring > Open > Issue Resolution**. The **Issue Resolution** screen opens to display all issues that have been entered by DAIDS; **OR**

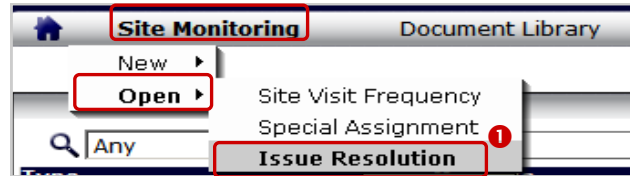


Figure 1: Top Menu Bar

- 2 Locate a count of issues waiting on the CRSs response in the **Issue Resolution** Web Part's **Site** column.
- 3 Click the **Visit Dates** link in the **Issue Resolution** Web Part (accessible from the CSM Home screen).

Visit Quarter	Visit Dates	Site ID	Report ed	# of Issues		Resolv ed	By SA
				DAIDS	Site		
4Q 2007	03-Dec-2007 to 06-Dec-2007	5401	1	0	1	0	0

Figure 2: Issue Resolution (IR) Web Part

Q How do I respond to issues entered by DAIDS?

- 1 Select an issue that has an action indicator “!” by clicking the checkbox or Issue Number. Selecting the checkbox on the Site Name or Quarter and Visit Dates row will auto-select all issues below. The Edit pane opens to the right.

Issue No	Assignment	Issue	Issue Desc...	Corrective...	Resolutio...	Comments	Status
<input type="checkbox"/>	6901 - Bronx-Lebanon Hosp. IMPAACT CRS						Tc
<input type="checkbox"/>	3Q 2008 - V1 29-Sep-2008 to 03-Oct-2008						Tc
<input checked="" type="checkbox"/>	IR - 00153	Regulatory File Re...	Other				In Resolutio...

Figure 3: IR Screen



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Q How do I respond to issues entered by DAIDS (Continued)?

- 2 In the **Corrective Action** field, enter the actions you plan to implement or are currently using to minimize and prevent the issue that has been entered by DAIDS from occurring in the future.
- 3 In the **Resolution Comments** field, enter details regarding how the identified issue was fixed or addressed.
- 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.

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"/>

Figure 4: Edit Pane - Enter Response



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Q How do I save and send issues for a site visit?

To save issues BEFORE sending to DAIDS:

- 1 Click the **Save** button in the Edit Pane.

To send issues to DAIDS:

- 2 Send an individual issue by clicking the **Send** button in the Edit Pane.

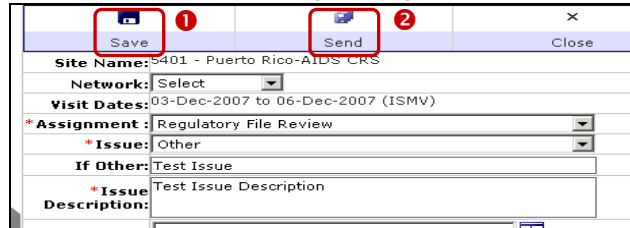


Figure 5: Edit Pane - Save /Send an Issue

OR

- 3 Send multiple issues reported for a site by selecting the checkboxes for the desired issues. Selecting the checkbox on the Site Name or Quarter and Visit Dates row will auto-select all issues below.

- 4 Click the **Send All** button.

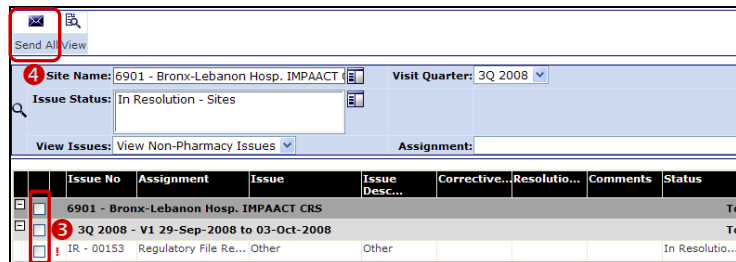


Figure 6: Edit Pane - Send Multiple Issues

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Q How do I know if an issue has been resolved by DAIDS?

- 1 Locate a count of issues that have been marked Resolved by DAIDS in the **Issue Resolution** Web Part's **Resolved** column.

- 2 Locate a count of issues that have been marked **To be Resolved by Special Assignment** in the **Issue Resolution** Web Part's **By SA** column. These issues will be resolved through a special assignment by the CSM contractor at the next site visit.

- 3 Click the **Visit Dates** link to open the **Issue Resolution** screen and view additional details about each issue.

Visit Quarter	Visit Dates	Site ID	# of Issues				
			Report ed	In Resolution DAIDS	Site	Resolv ed	By SA
1Q 2008	03-Mar-2008 to 06-Mar-2008	601	1	1	0	0	0
1Q 2008	25-Feb-2008 to 28-Feb-2008	2401	1	1	0	0	0

Figure 7: IR Web Part - Site Responses

Still Have Questions?
 Submit a Help Ticket Online:
 Point to Help on the top right menu bar;
 Click DAIDS-ES Support.

Email: DAIDS-ESSupport@NIAID.NIH.gov
 Phone: 1-866-DES-1605 (866-337-1605)
 Fax: 1-866-DES-1606 (866-337-1606)

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