Duke Clinical Research Institute Quick Reference Card

Data Surveillance Log

The Data Surveillance Log (DSL) allows you to track protocol-level data surveillance items, with the option to "push" a record to one or more of the protocol's sites. The record(s) will then appear on the each of the selected site's Issue Log tab, as well as on the protocol's Data Surveillance tab.

Recording a Data Surveillance Record

- 1 Click the **Protocols** screen tab.
- **2** Highlight the protocol record.
- **3** Click the **Data Surveillance** view tab. Any previously-recorded issues are displayed, sorted by the Date Identified field.



- Click New.
- **5** Use the following table when completing the new record.

Field	Guidelines
DSL Type	Select a type from the drop-down list. This field maps to the Type field on the site's Issue Log tab.
Date Identified	Defaults to today's date. Enter the date that the issue was identified. This field maps to the Date Identified field on the site's Issue Log tab.
Project Activity Description	Enter the description of the issue, up to a maximum of 1,500 characters.
Findings	Enter issue findings, up to a maximum of 1,500 characters.
Action Description	Enter action information, up to a maximum of 1,500 characters. This field maps to the Description field on the site's Issue Log tab.
Resolved	Defaults to <i>Open</i> . When the issue is resolved, select <i>Done</i> from the dropdown list.
Completed Date	Defaults to <i>blank</i> . Enter the date that the issue was resolved.
Resolution / Action Comments	Enter resolution information, up to a maximum of 1,500 characters.

Pushing a Data Surveillance Issue to Sites

- 1 On the **Data Surveillance** tab, highlight the record that you want to push to sites.
- 2 In the **Sites** applet at the bottom of the window, click **New**.



- **3** Highlight the sites to which you want to push the issue. Select multiple sites, by holding the Ctrl key while selecting site records.
- 4 Click OK.



Note: If needed, you can delete site records by clicking the **Delete** button. Once the data surveillance records have been pushed to sites, you cannot delete site records from this list.

Push To Site 5 Click **Push to Sites** (above DSL records). The site's **Site** # field becomes a hyperlink that you can click to view the site's **Issue Log**. The record will appear on each of the selected site's Issue Log view tab, regardless of the site's status.



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Understanding the DSL's Sites View Tab

Site records listed here are read-only. When records are entered and modified at the site level, they will also display here.

Field	Description
Site #	Site number to which DSL records will be or have been pushed. The field becomes a hyperlink after a DSL record is pushed to the site. Click the hyperlink to view the site's Issue Log .
Issue Status	Before the DSL record is pushed to the site, this field is blank. After the DSL record is pushed to the site, this field displays the Status from the site's Issue Log .
Completed Date	Before the DSL record is pushed to the site, this field is blank. After the DSL record is pushed to the site, this field displays the Completed Date from the site's Issue Log .
Resolution / Action Comments	Before the DSL record is pushed to the site, this field is blank. After the DSL record is pushed to the site, this field displays the Resolution / Action Comments from the site's Issue Log .
PI Name	Displays the site's Principal Investigator . This column is hidden by default on the Sites list, but shows on the pop-up applet when selecting sites to which DSL records will be pushed.
Site Name	Displays the site's Account Name . This column is hidden by default on the Sites list, but shows on the pop-up applet when selecting sites to which DSL records will be pushed.
Region	Displays the site's Region . This column is hidden by default on the Sites list, but shows on the pop-up applet when selecting sites to which DSL records will be pushed.

Updating an Existing DSL Site Record

Changes made to the **DSL Type**, **Action Description**, or **Date Identified** fields can be pushed to the associated sites.

- 1 Update the fields on the DSL record, as needed.
- Click Push to Sites.

The matching fields will now be updated on each of the site's Issue Log tab. All other fields on the existing Issue Log record will remain unchanged.

Adding Sites to an Existing DSL Record

- 1 On the **Data Surveillance** tab, highlight the record that you want to push to sites.
- 2 In the **Sites** applet at the bottom of the window, click **New**.
- **3** Highlight the sites to which you want to push the issue. Select multiple sites, by holding the Ctrl key while selecting site records.
- 4 Click OK.

Note: If needed, you can delete site records by clicking the **Delete** button. Once the data surveillance records have been pushed to sites, you cannot delete site records from this list.

5 Click **Push to Sites** (above the DSL records list). The site's **Site** # field becomes a hyperlink that you can click to view the site's **Issue Log**. The record will appear on each of the selected site's **Issue Log** view tab, regardless of the site's status.

Deleting a DSL Record

To delete a DSL record, submit a CTMS Request (CTMSR) to the DCRI Service Desk (dcriservicedesk@dm.duke.edu), requesting record deletion.

Note: Deleting a DSL record also deletes associated site records and Issue Log records.

Deleting a Site Record from the DSL Sites View Tab

- Before a DSL record is pushed to the site, the Issue Status field is blank, and you can delete the site record by highlighting the record and then clicking Delete.
- After a DSL record is pushed to the site, the **Issue Status** field is populated with the status Open or Done, and you cannot delete the record. Submit a CTMSR to the DCRI Service Desk (dcriservicedesk@dm.duke.edu) to request record deletion.

Note: Deleting a DSL record also deletes associated site records and Issue Log records.



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DSL Considerations

- Records on the DSL cannot be copied (including records listed on the **Sites** view tab).
- Protocol deviations cannot be added to the DSL. They should be added on the site's **Protocol Deviations** tab.
- As a business rule, you should wait until all sites have resolved the issue before marking a DSL record as Done.
- No site field feeds back to the DSL record. Site-level fields feed back to the Site record on the DSL.

Understanding DSL-Related Fields on the Site's Issue Log

For details about using the site's **Issue Log**, see the *CTMS Site Management User Reference Guide*. The list below defines how DSL fields map to the site's **Issue Log** when a DSL record is pushed to a site.

Field	Guidelines
Type	Displays the DSL record's DSL Type
Description	Displays the DSL record's Action Description
Date Identified	Display's the DSL record's Date Identified
Method	Displays <i>DSL</i> or <i>Remote</i> , to indicate where the record was created.

Getting Help

If you have questions or comments about the content of this Quick Reference Card (QRC), please email IT Training. If you experience any technical problems working with CTMS Data Surveillance Log that you are unable to resolve, email the DCRI Service Desk or, for time-sensitive issues, call them at 919.668.8916. A ticket will be forwarded to a CTMS support representative.

