The ISF (Investigator Study File) tab within the CTMS trip report window allows you to record ISF documents, training events, and safety letters. This Quick Reference Card (QRC) outlines the features of the ISF tab.

General

- There will no longer be, by default, an *Investigator Study File Inventory* document on the trip report's **Attachments** tab.
- The **ISF** tab appears in the trip report window and is pre-populated from the site's Activity Plan with ISF-related documents, training events, and safety letters as determined by the protocol team. New ISF records that are added to a trip report's **ISF** tab are rolled forward to the next trip report, creating a running log of ISF records per site.

  Note: The ISF tab is only active for protocol teams that have opted to use this feature. If you have any questions, please email the DCRI Service Desk (dcriservicedesk@dm.duke.edu).

- CTMS will be configured (via request to the DCRI Service Desk) per protocol to display documents, training events, and/or safety letters in the following locations:
  - Only on the site's **Documents**, **Training**, and/or **Safety Letters** tab(s).
  - Only on the trip report's **ISF** tab.
  - On both the site tabs and trip report's **ISF** tab.

Recording a Document on the Trip Report's ISF Tab

IMPORTANT! On the trip report's **ISF** tab, use the **Copy** button or the **Ctrl+B** keystroke combination to copy an ISF document. Only the **Document Name** and **Description** will be copied to the new record.
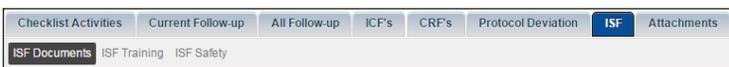
1. Click the trip report's **ISF** tab.
   By default, the **ISF Documents** list is displayed.
2. Click to the left of the record to highlight the document.
3. Scroll down to the **Action** area, and then click **New**.

4. Use the following table as a guideline for completing the *action* record:

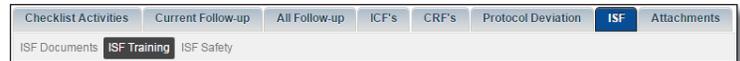| Field	Guidelines
Action	Select *Retrieved* or *Reviewed* from the drop-down list, as appropriate. You can create two separate records to record both actions.
Visit Date	(read-only) Automatically populated with the date from the site visit's **Actual Visit Start** field.
Comments	Enter comments regarding the action (255 character maximum).

5. Press **Ctrl+S** to save the record.
6. Scroll back up to the document record.
7. Use the following table as a guideline for completing the *document* record.

Field	Guidelines
Current	(read-only) Box automatically checked after an action is recorded for this document (see steps 3-5 above).
Document Name	(read-only) Displays the name of the document.
Document Description	(read-only) Displays the description of the document.
Version Date	If applicable, enter the version date of the document
Expiration Date	If applicable, enter the expiration date of the document.
First Name	(read-only) Automatically populated when you select a name in the **Last Name** field.

Field	Guidelines
Last Name	If applicable, click the selection icon to add the name of the person to whom the document refers.
Role	(read-only) Automatically populated when you select a name in the **Last Name** field.
Comments	Enter comments regarding the document (255 character maximum).
Doc On Site	Check the box to indicate that the document is located at the site.
Doc In House	(read-only) If checked, indicates that the document is located at DCRI (populated from the site's **Documents** tab).
RVWD this Visit	(read-only) Automatically checked after the *Reviewed* action is recorded for this document (see steps 3-5, above).
RTRV this Visit	(read-only) Automatically checked after the *Retrieved* action is recorded for this document (see steps 3-5, above).
Last RVWD Date	(read-only) Automatically populated with the date in the site visit's **Actual Visit Start** date field after the *Reviewed* action is recorded for this document (see steps 3-5, above).

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

Recording a Training Event on the Trip Report's ISF Tab

IMPORTANT! On the trip report's **ISF** tab, use the **Copy** button or the **Ctrl**+**B** keystroke combination to copy an ISF training record. Only the **Training Name** and **Description** will be copied to the new record.

Checklist Activities	Current Follow-up	All Follow-up	ICF's	CRF's	Protocol Deviation	**ISF**	Attachments

ISF Documents   **ISF Training**   ISF Safety

1   On the trip report's **ISF** tab, click the **ISF Training** link

2   Click to the left of the record to highlight the training record.

3   Scroll down to the **Action** area, and then click **New**.

Action	Menu ▼	New	Delete	Query		No Records	
Action		Visit Date		Comments			

4   Use the following table as a guideline for completing the *action* record:

Field	Guidelines
Action	Select *Retrieved* or *Reviewed* from the drop-down list, as appropriate. You can create two separate records to record both actions.
Visit Date	(read-only) Automatically populated with the date from the site visit's **Actual Visit Start** field.
Comments	Enter comments regarding the action (255 character maximum).

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

6   Scroll back up to the training record.

7 Use the following table as a guideline for completing the *training* record.
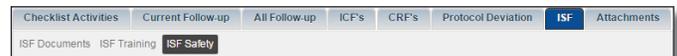
Field	Guidelines
Current	(read-only) Box automatically checked after an action is recorded for this training event (see steps 3-5 above).
Training	(read-only) Displays the name of the training event.
Description	(read-only) Displays the description of the training event.
First Name	(read-only) Automatically populated when you select a name in the **Last Name** field.
Last Name	If applicable, click the selection icon to add the name of the person to whom the training event refers.
Role	(read-only) Automatically populated when you select a name in the **Last Name** field.
Comments	Enter comments about the training event (255 character maximum).
Status	Select the appropriate status from the drop-down list.
Status Date	Enter the date that corresponds to the status.
Expiration Date	If applicable, enter the expiration date of the training event.
Doc On Site	Check the box to indicate that the training documentation is located at the site.
Doc In House	(read-only) If checked, indicates that the training documentation is located at DCRI (populated from the site's **Training** tab).

Field	Guidelines
RVWD this Visit	(read-only) Automatically checked after the *Reviewed* action is recorded for this training event (see steps 3-5, above).
RTRV this Visit	(read-only) Automatically checked after the *Retrieved* action is recorded for this training event (see steps 3-5, above).
Last RVWD Date	(read-only) Automatically populated with the date in the site visit's **Actual Visit Start** date field after the *Reviewed* action is recorded for this training event (see steps 3-5, above).

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

Recording a Safety Letter on the Trip Report's ISF Tab

If the protocol team opted to display safety letters on the trip report's **ISF** tab, *trial* safety letters from the site's Activity Plan appear on the ISF tab. Record actions for these letters, using the steps below.

Checklist Activities	Current Follow-up	All Follow-up	ICF's	CRF's	Protocol Deviation	**ISF**	Attachments

ISF Documents   ISF Training   ISF Safety

1 On the trip report's **ISF** tab, click the **ISF Safety** link

2 Click to the left of the record to highlight the safety letter record.

3 Scroll down to the **Action** area, and then click **New**.

Action	Menu ▾	New	Delete	Query	🔍		No Records	🔁
Action		Visit Date		Comments				

4 Use the following table as a guideline for completing the *action* record:

Field	Guidelines
Action	Select *Retrieved* or *Reviewed* from the drop-down list, as appropriate. You can create two separate records to record both actions.
Visit Date	(read-only) Automatically populated with the date from the site visit's **Actual Visit Start** field.
Comments	Enter comments regarding the action (255 character maximum).

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

6 Scroll back up to the safety letter record.

7 Use the following table as a guideline for completing the *safety letter* record.

Field	Guidelines
Current	(read-only) Box automatically checked after an action is recorded for this safety letter (see steps 3-5 above).
Description	(read-only) Displays the description of the letter.
Case #	(read-only) Displays the case number for the letter.
Sequence	(read-only) Displays the sequence of the letter as related to other letters.
Version	(read-only) Displays the letter's version date.
Comments	Enter comments about the safety letter (255 character maximum).
Submitted to IRB	Enter the date that the letter was submitted to the IRB.

Field	Guidelines
Submission Letter Received	Enter the date that DCRI received the letter that was sent to the IRB.
IRB Acknowledgement Received	Enter the date that the IRB acknowledged receiving the letter.
Doc On Site	Check the box to indicate that the safety letter is located at the site.
Doc In House	(read-only) If checked, indicates that the safety letter is located at DCRI (populated from the site's **Safety Letters** tab).
RVWD this Visit	(read-only) Automatically checked after the *Reviewed* action is recorded for this safety letter (see steps 3-5, above).
RTRV this Visit	(read-only) Automatically checked after the *Retrieved* action is recorded for this safety letter (see steps 3-5, above).
Last RVWD Date	(read-only) Automatically populated with the date in the site visit's **Actual Visit Start** date field after the *Reviewed* action is recorded for this safety letter (see steps 3-5, above).

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

Note: To record an ISF *site* safety letter, on the **ISF** tab, click the **ISF Safety** link and then click **New**. Complete the record using the table above as a guideline (all fields will be editable, except fields related to the *action*). This will display as a site safety letter on the site's **Safety Letters** tab.

Creating an ISF Follow-Up Activity

Use the button at the top of the ISF tab to quickly create an ISF-related follow-up activity.

Note: The ISF-related follow-up feature is not linked to any particular ISF record, so you do not need to select a record before clicking the **Create Followup** button.
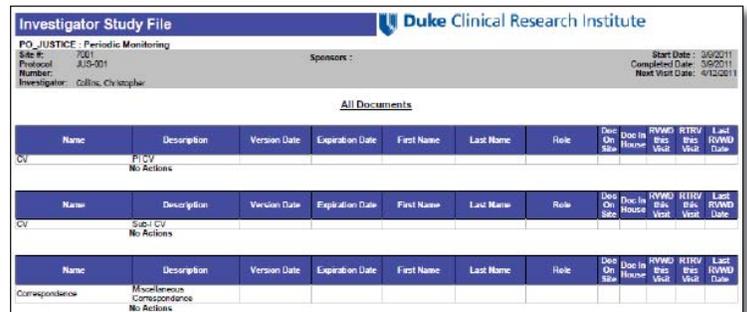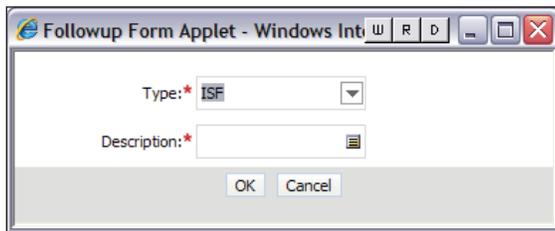

1 Click **Create Followup**.

2 Keep the default *ISF* option in the **Type** field.
3 Enter a follow-up description in the **Description** field.
4 Click **OK**.
5 Click the **Current Follow-Up** tab to view and edit the newly-created follow-up activity.

Viewing the ISF Report

The ISF Report can be viewed at any time. Protocol teams can configure the report (via request to the DCRI Service Desk) to include any combination of the following:

- Current Documents
- All Documents
- Both Current and All Documents
- Current Training
- All Training
- Both Current and All Training
- Current Safety
- All Safety
- Both Current and All Safety

The option also exists to exclude one or more categories. For example, you may want to track information about Safety Letters at the **ISF** level, but not want this category to show in the PDF copy of the ISF Report.

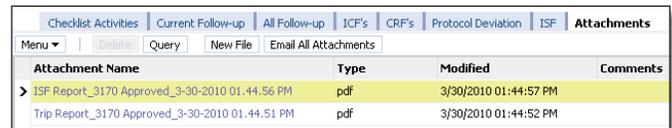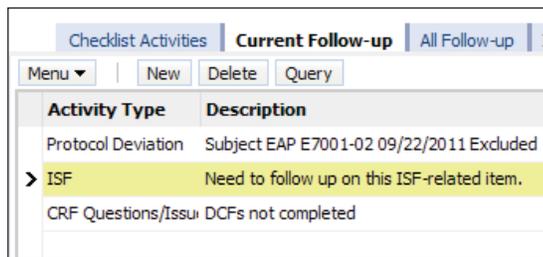At the top of the **ISF** tab, click **View ISF Report**.

The ISF Report appears in a separate window.

Note: When the trip report is *Approved*, an ISF Report is automatically generated and attached to the trip report's **Attachment's** tab.

Warning! Do not add or edit ISF records, or create ISF-related follow-up activities, on an *Approved* trip report (even though fields on the ISF tab remain editable). Instead, record ISF information on the next site visit's trip report.

Questions?

If you have any questions, please email the **DCRI Service Desk** (dcriservicedesk@dm.duke.edu).