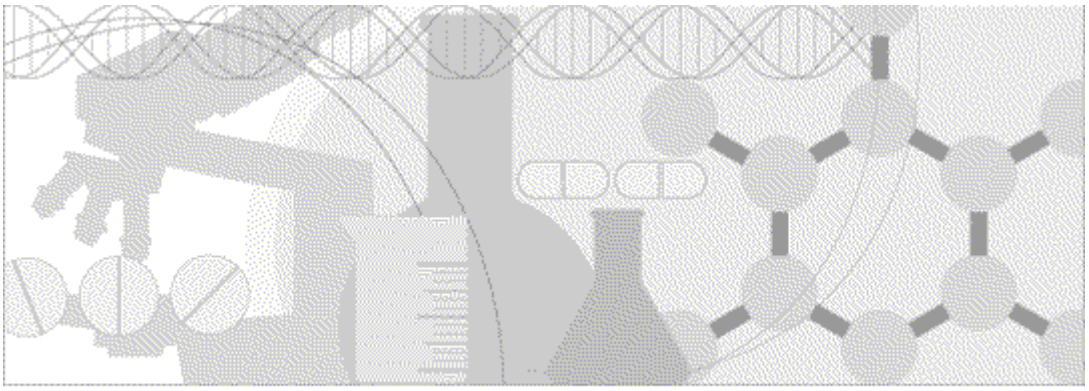
PDF Quick Reference

Oracle® Health Sciences InForm CRF Submit Release 3.1.2



ORACLE

Part Number: E40031-01

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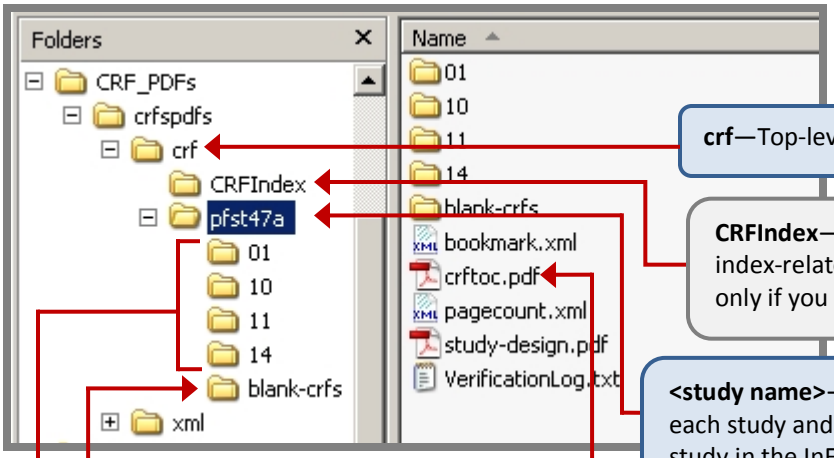
PDFs and Adobe® Reader®

The *PDF Quick Reference* provides an overview of the Portable Document Format (PDF) files generated by the CRF Submit software and instructions for viewing PDFs.

The CRF Submit application is used to format and generate study PDFs. You must have Adobe Reader installed on your computer to open and view PDFs. Oracle recommends that you use Adobe Reader version 9.0 or higher to view PDFs. For more information and a free download, visit the Adobe website (www.adobe.com).

PDF file structure

PDFs and the associated files have a predefined folder hierarchy. The following example uses the CRF Submit default settings for generating a PDF. The study name is pfst47a. A table of contents was generated and the PDFs were generated as one file per CRB.



crf—Top-level folder in the hierarchy.

CRFIndex—A folder that contains index-related files. This folder exists only if you generated an index.

<study name>—A folder is created for each study and given the name of the study in the InForm application.

Table of contents—The <study name> folder contains a table of contents file (called **crftoc.pdf**) for the study. This file provides a top-level organization of the sites, and subjects included in the PDFs related to the study. It also links to the directory location for each file associated with the PDFs.

blank-crfs—A subfolder that contains a set of form templates that do not contain any data.

site-specific folders—There is one subfolder that contains site-specific data for each site that was selected for PDF generation. The name of this folder is the Site Name in the InForm study.

- If you generate PDFs as one file **per CRB** (per subject) the site-specific folder contains the subject PDFs. One PDF is created per subject.
- If you generate PDFs as one file **per Visit**, the site-specific folder contains one subfolder for each subject. One PDF is created per visit per subject.

Opening a PDF

When PDF generation is complete, you can open the PDF file in Adobe Reader.

- In **Windows Explorer**, locate the table of contents file (**crftoc.pdf**) and double click the file.

or

1 Open **Adobe Reader**.

2 Select **File** > **Open**.

3 Browse to the location where the table of contents file (**crftoc.pdf**) is stored.

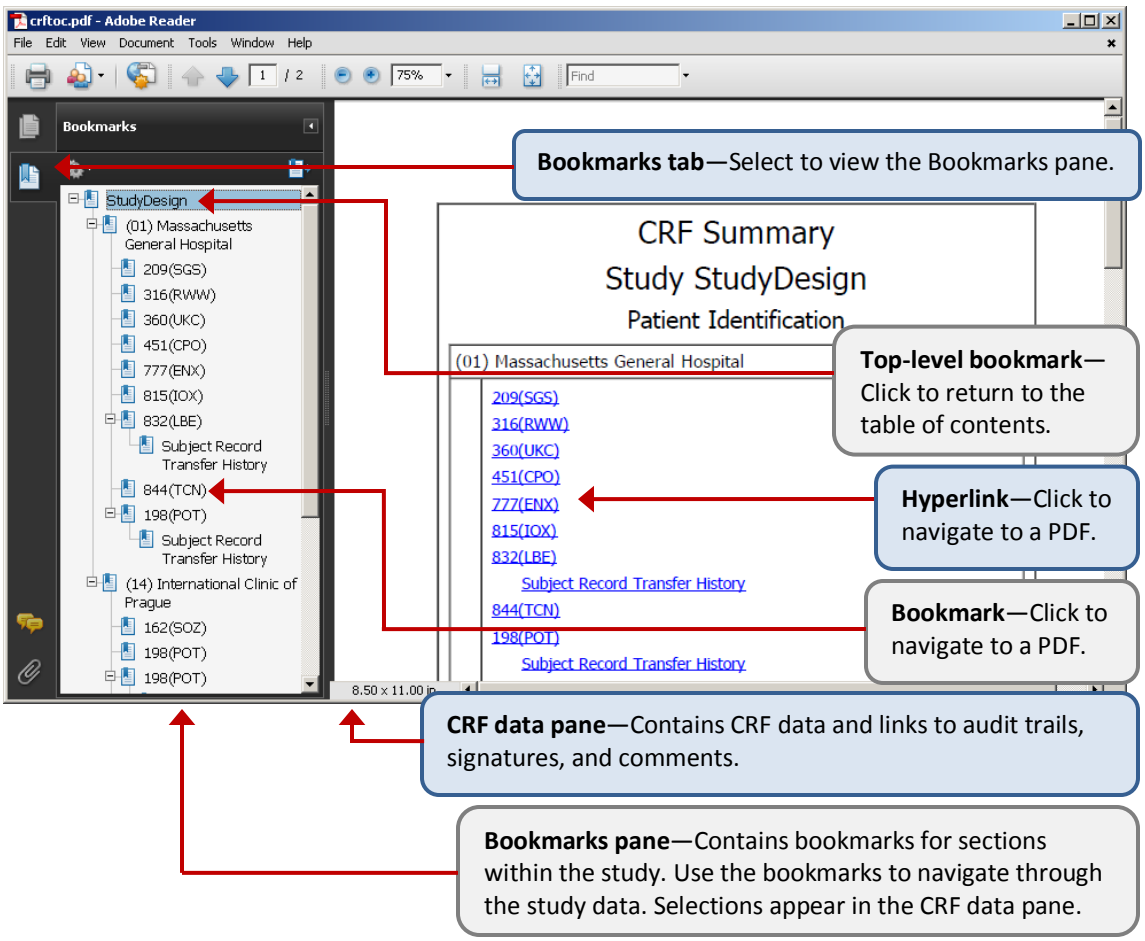
4 Select **crftoc.pdf** and click **Open**.

Printing a PDF

Navigate to a PDF file and do one of the following:

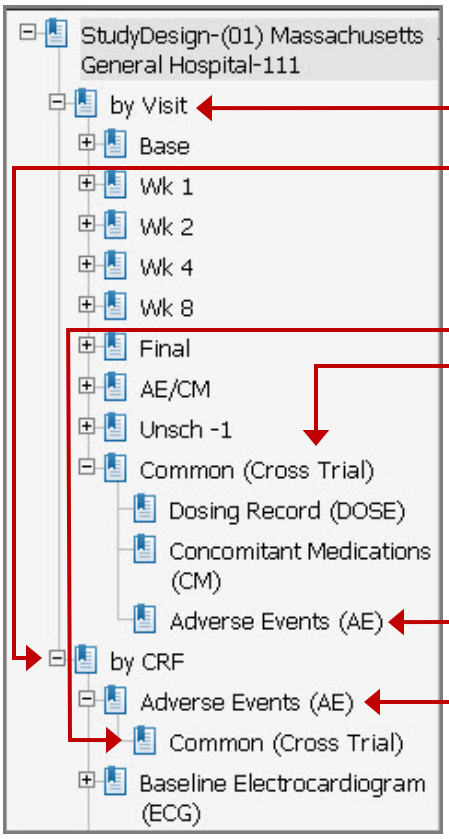
- Open the PDF and select **File** > **Print**.
- Open the PDF and press **Ctrl+P**.
- Right click the PDF and select **Print**.

PDF navigation



Viewing PDFs

Reviewing subject data and adverse events



1. Use the **+** nodes to expand the bookmarks to view the **by Visit** or **by CRF** nodes.
2. Continue to select **+** nodes to expand the list of visits or CRFs. Then select the CRF you want to view.

   The CRF appears in the right pane.

Common Cross Trial links—Forms that are included in more than one place across a study are grouped under the Common (Cross Trial) bookmark.

Adverse events—Generally found in Common (Cross Trial) forms. Depending on the setup of the study, you can usually navigate to adverse event data from the bookmark pane by doing one of the following:

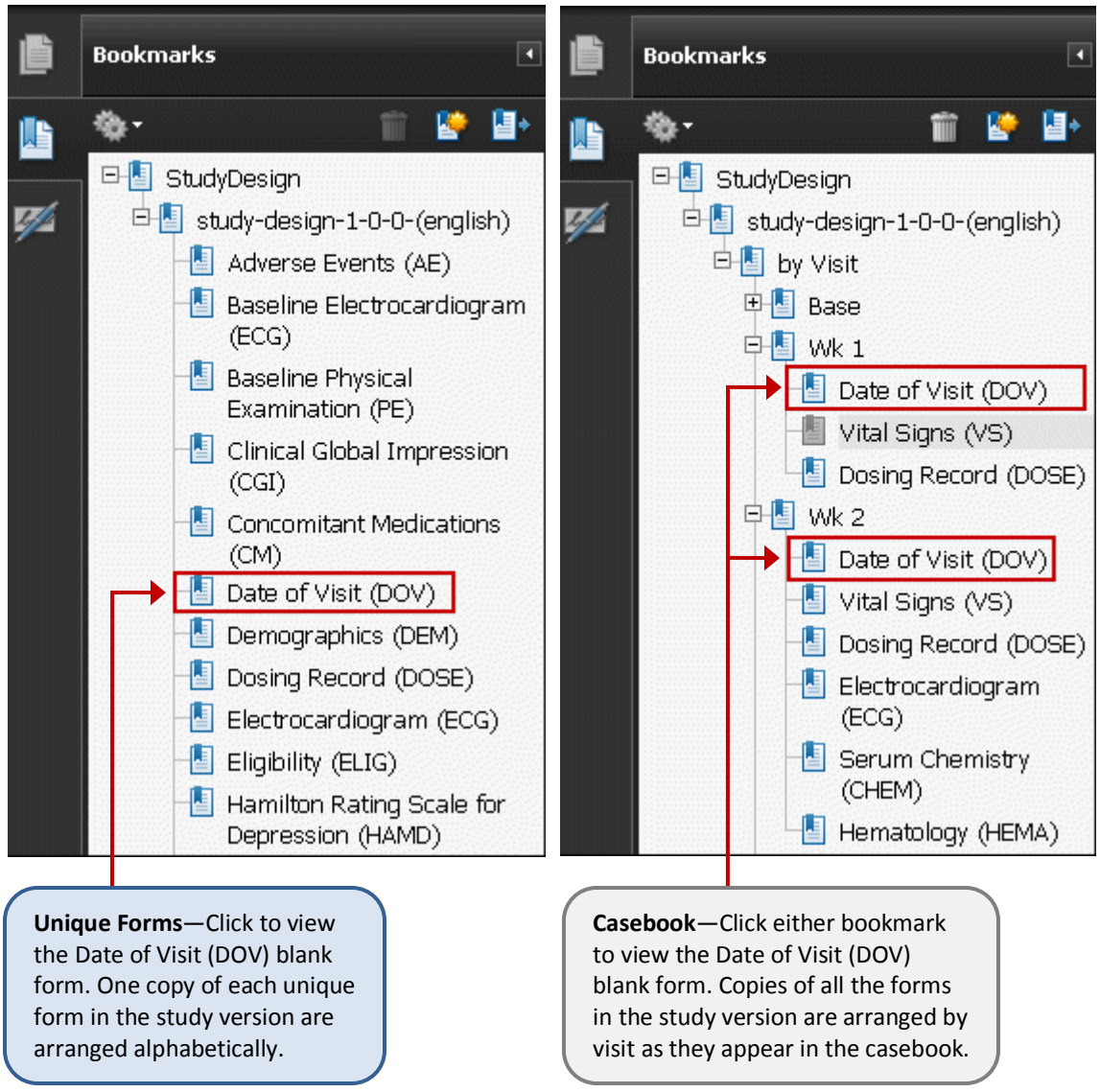
- Expand nodes **by Visit** > **Common (Cross Trial)** > **Adverse Events (AE)**.
- Expand nodes **by CRF** > **Adverse Events (AE)**.

Viewing blank forms

Blank forms are generated in one of the following balnk form formats:

- Unique Forms
- Casebook

The following example compares the bookmarks of both formats.

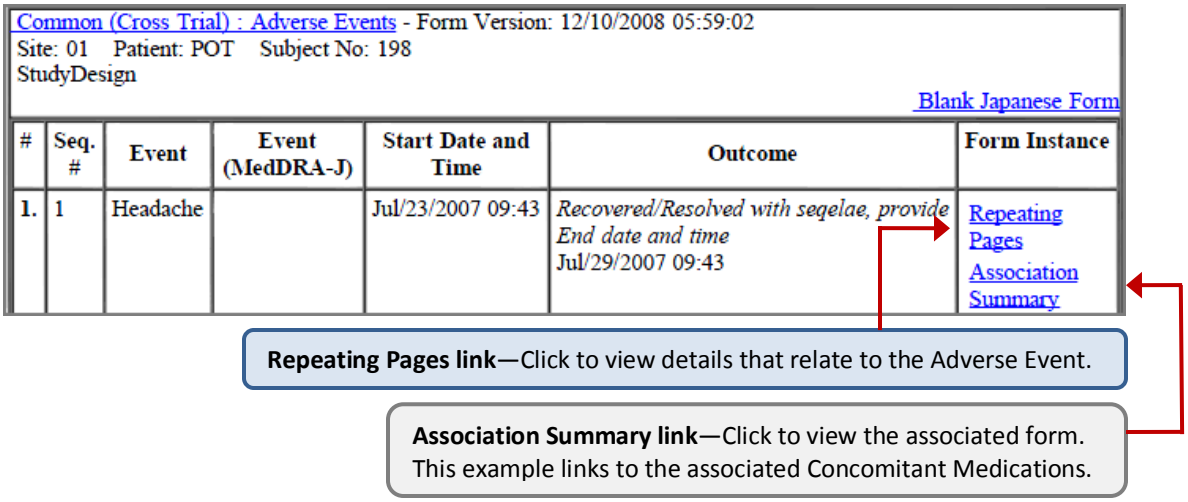


Unique Forms—Click to view the Date of Visit (DOV) blank form. One copy of each unique form in the study version are arranged alphabetically.

Casebook—Click either bookmark to view the Date of Visit (DOV) blank form. Copies of all the forms in the study version are arranged by visit as they appear in the casebook.

Viewing repeating forms

Repeating forms are organized in an item-detail relationship. The initial view displayed is a summary page. The summary page is for navigational purposes only, and shows only the data for the first key itemsets in a single table. Subsequent pages contain the details of each form.



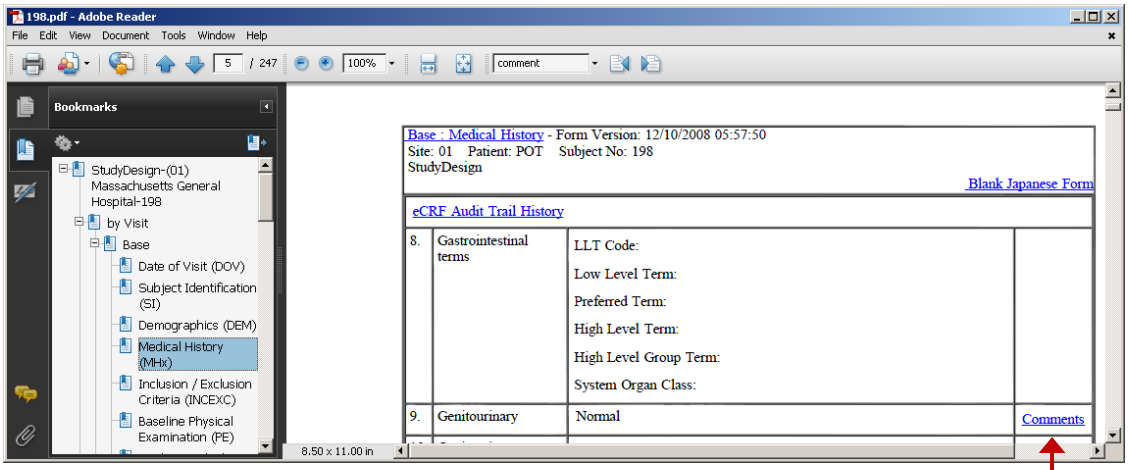
Common (Cross Trial) : Adverse Events - Form Version: 12/10/2008 05:59:02
Site: 01 Patient: POT Subject No: 198
StudyDesign

Blank Japanese Form

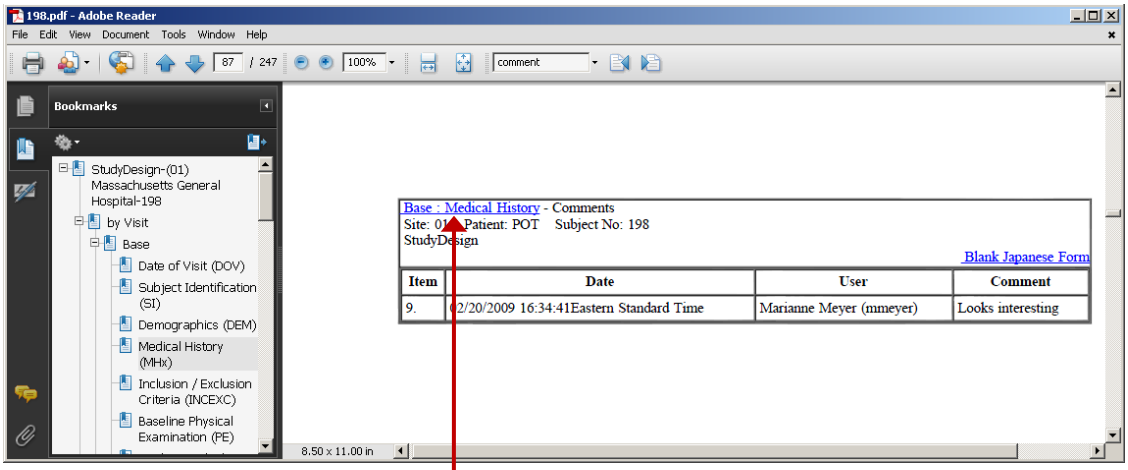
#	Seq. #	Event	Event (MedDRA-J)	Start Date and Time	Outcome	Form Instance
1.	1	Headache		Jul/23/2007 09:43	*Recovered/Resolved with seqelae, provide End date and time* Jul/29/2007 09:43	Repeating Pages Association Summary

Viewing comments

Comments appear on a form if an item has comments associated with it.



Comments—Click to go to the comments section, which directly follows the form and is shown below.



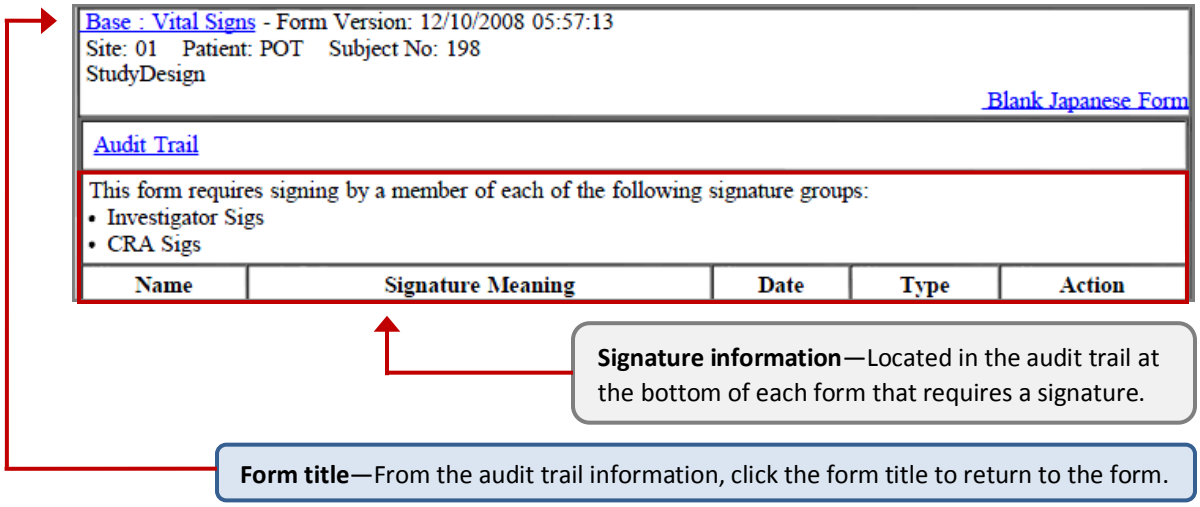
Form title—From the comments section, click the form title to return to the form.

Viewing signature history

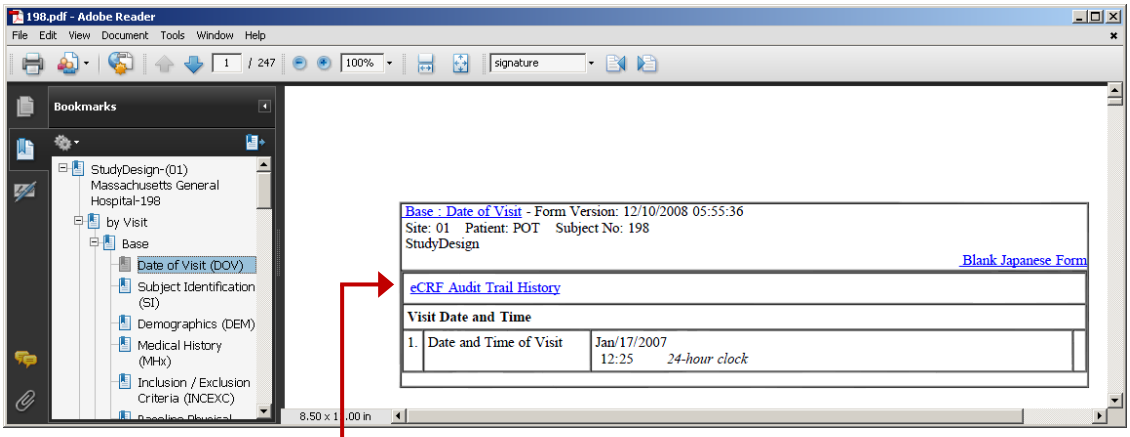
1 Do one of the following:

- Select **Edit** > **Find**.
- Select **Edit** > **Search**.

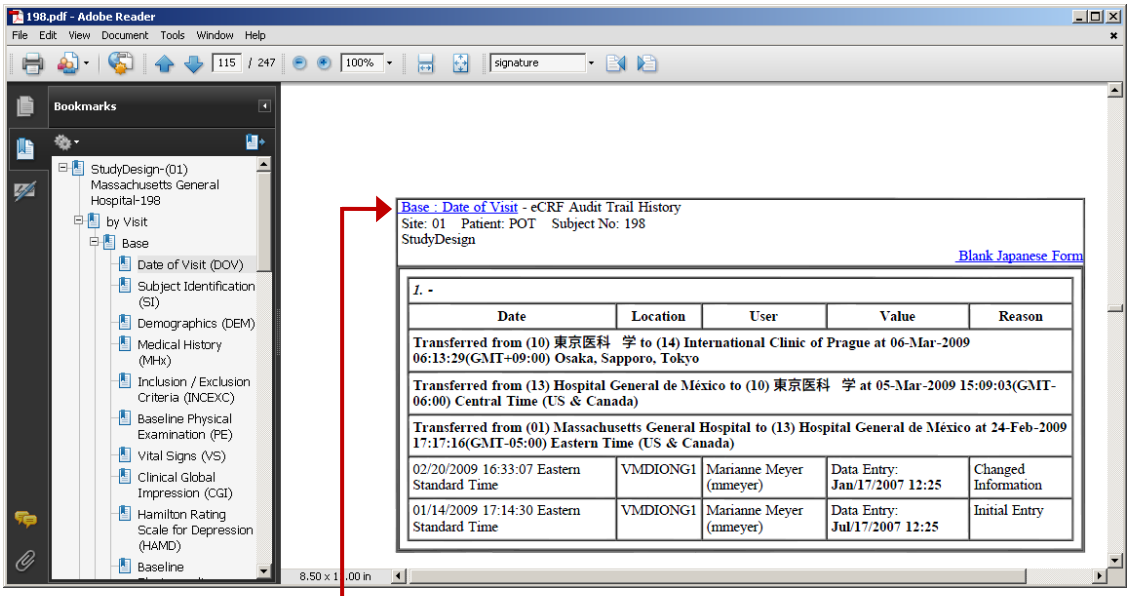
2 Search for the word **signature**.



Viewing audit trail information



eCRF Audit Trail History link—Click to view the audit trail summary for an entire form.



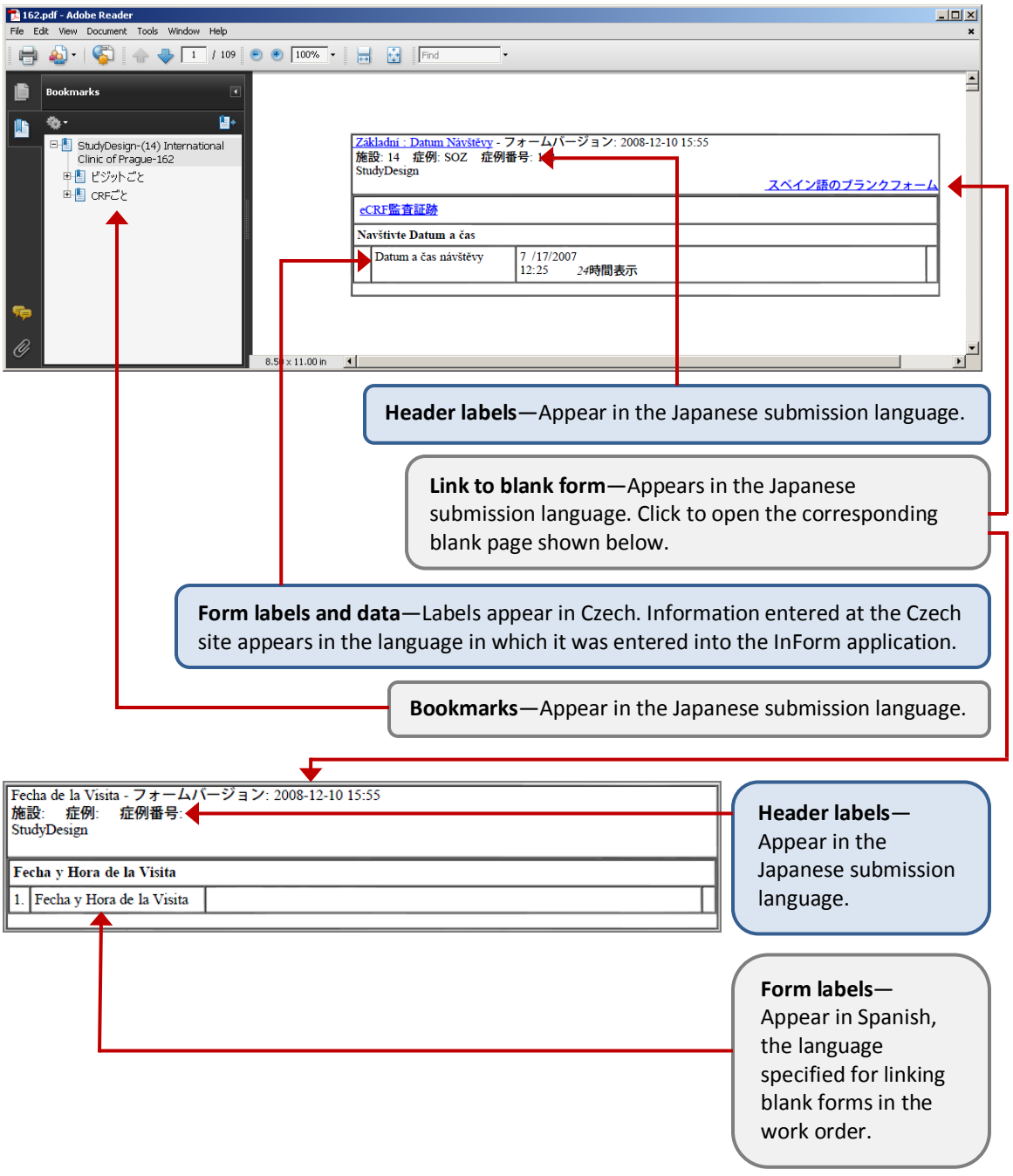
Form title—From the audit trail information, click the form title to return to the form.

Viewing linked blank forms

If blank forms were generated for a multilingual study, each page in the PDF file has a link to a corresponding blank page in the language that was specified when the work order was created was created.

In the following example:

- The submission language is Japanese.
- The form was created with Czech labels and data was entered at a Czech site.
- The form links to a Spanish blank form.



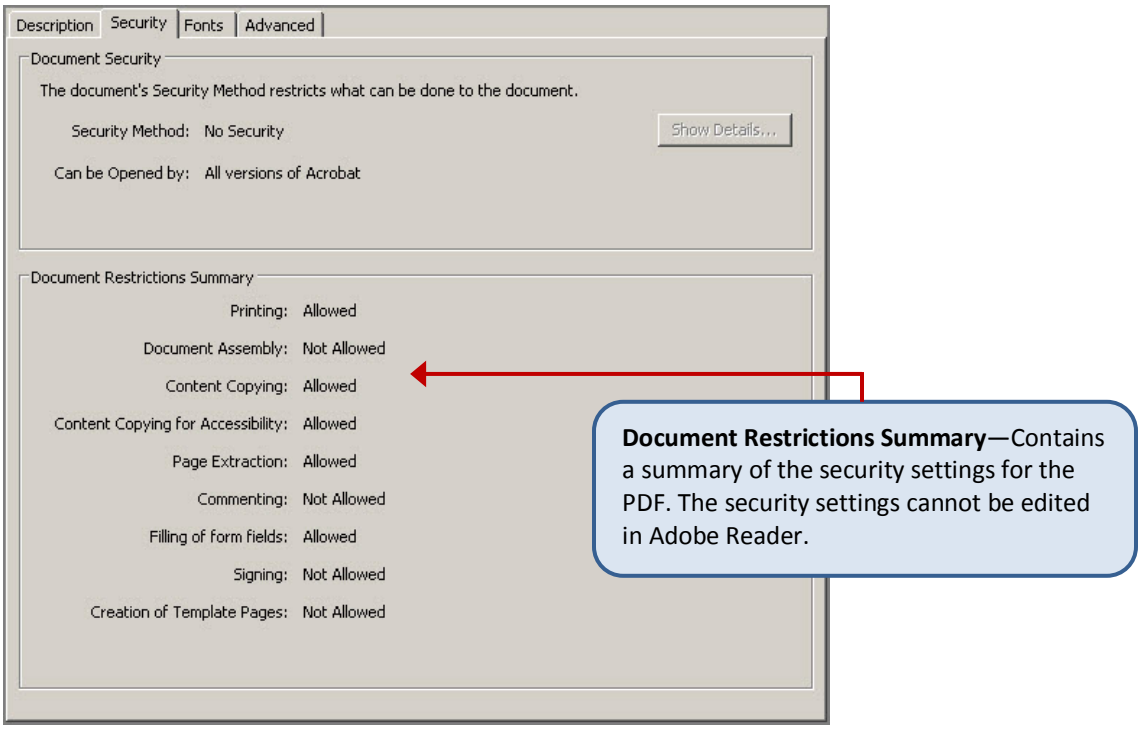
Viewing the security settings for the PDF

1 Open the PDF in Adobe Reader.

2 Select **File** > **Properties**.

The Document Properties window appears.

3 Select the **Security** tab.



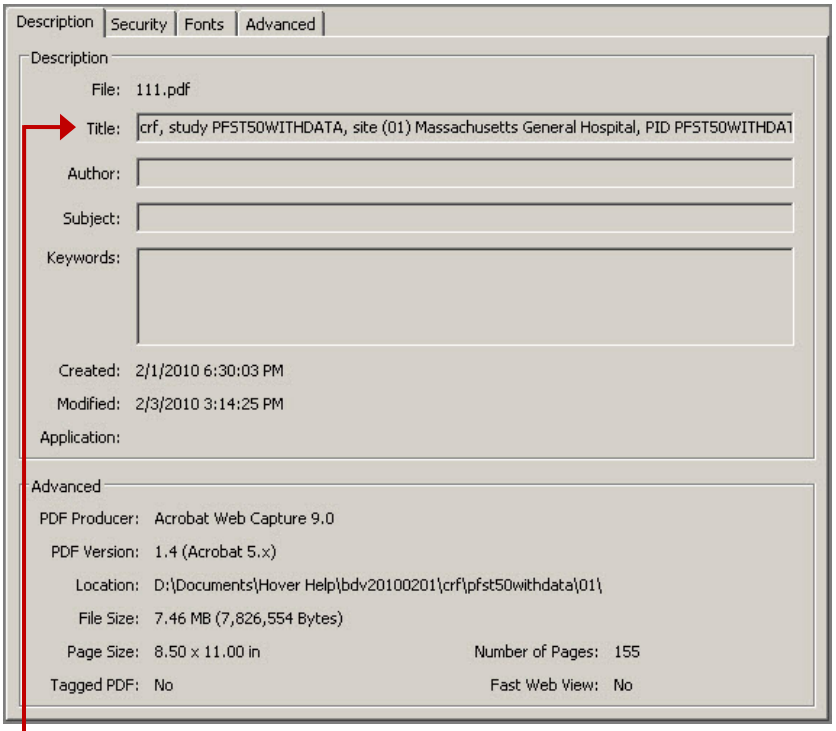
Viewing the Document Information Title field

1 Open the PDF in Adobe Reader.

2 Select **File** > **Properties**.

The Document Properties window appears.

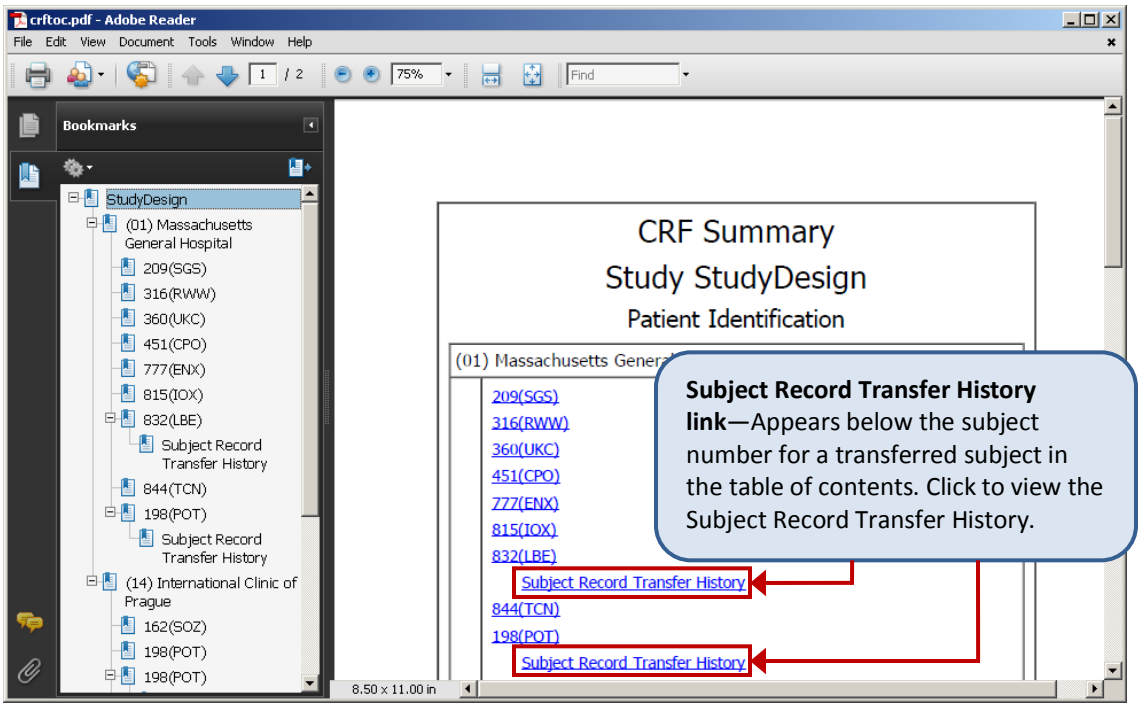
3 Select the **Description** tab.

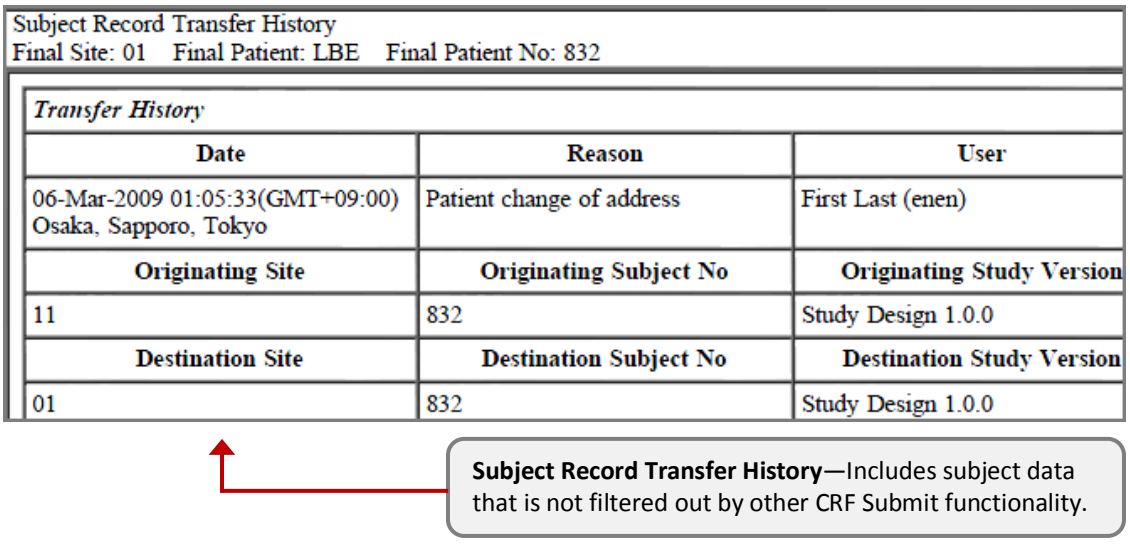


Document Information Title field—Generated only for forms that contain data. The title cannot be edited in Adobe Reader. Consists of:
crf, study <study name>, site <site mnemonic>, PID <study name>-<site mnemonic>-<subject number>

Finding Subject Record Transfer History in the table of contents

Links to the Subject Record Transfer History are in **crftoc.pdf**. The data for transferred subjects is included in the PDFs for every site in which the subject was associated, unless the Transferred Subjects in Current Site Only option was selected for a Custom PDF with Optional Blank Forms.





InForm data and PDF output

Deleted items

In the InForm application, items that are deleted appear with a strike-through. In the PDFs, deleted items are also crossed out, and the word **DELETED** appears in the Reason column.

6.a (Cont.)

Date	Location	User	Value	Reason
15/Jul/2010 15:20:47 (GMT-05:00) Eastern Time (US & Canada)	RDINFORMQ174	user (last) sys (first) (system)	Data Entry: **ID** **New Dose** ~~5 mg~~ **New Dose Start** ~~2/Dec/2006~~	Changed Information **(DELETED)**

Images in the Protocol Guide and Study Help

If the Protocol Guide and Study Help contain graphics, these images are not immediately visible in the PDF. In their place, the word **Image** appears as a link. When you click the **Image** link, if the URL for an image is accessible from the computer you are using, the image appears at the end of the PDF file.

If you want to archive or submit the images with the PDFs and the URL is not available, you must manually add the images to the archive or submission files.

Note: Forms with data do not contain images.

Page orientation

By default, output is printed in portrait orientation. The CRF Submit application automatically creates line-wraps in most text data. If the form data requires more space than the width of the page, the font is reduced up to 70% of the initial font size.

Table headers

When a table is displayed across more than one page, the table header appears on all additional pages. In rare instances, a table header might not appear on pages that contain unusually large amounts of form data.

If a single InForm item requires multiple pages of output, the table header does not repeat for pages after the first page.

The InForm date/time control labels

In the InForm application, each date/time control is labeled with the text **24-hour clock** to help the person performing data entry enter the correct times. The text does not appear during data review; however, it is displayed on the CRF Submit PDF file.