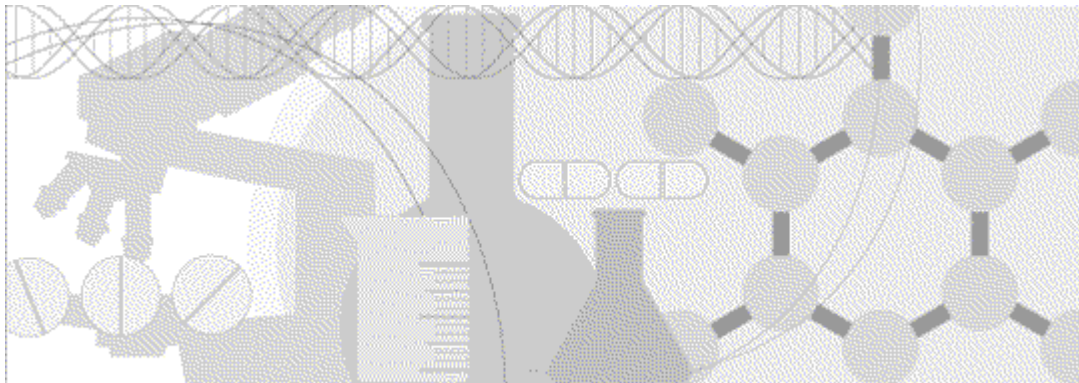


PDF Quick Reference

Oracle[®] Health Sciences InForm CRF Submit
Release 3.1.2



ORACLE

Contents

PDFs and Adobe® Reader®	1
PDF file structure.....	1
Opening a PDF.....	2
Printing a PDF.....	2
PDF navigation.....	2
Viewing PDFs	3
Reviewing subject data and adverse events.....	3
Viewing blank forms.....	4
Viewing repeating forms.....	5
Viewing comments.....	6
Viewing signature history.....	7
Viewing audit trail information.....	8
Viewing linked blank forms.....	9
Viewing the security settings for the PDF.....	10
Viewing the Document Information Title field.....	11
Finding Subject Record Transfer History in the table of contents.....	12
InForm™ data and PDF output	13
Deleted items.....	13
Images in the Protocol Guide and Study Help.....	13
Page orientation.....	13
Table headers.....	13
The InForm date/time control labels.....	14

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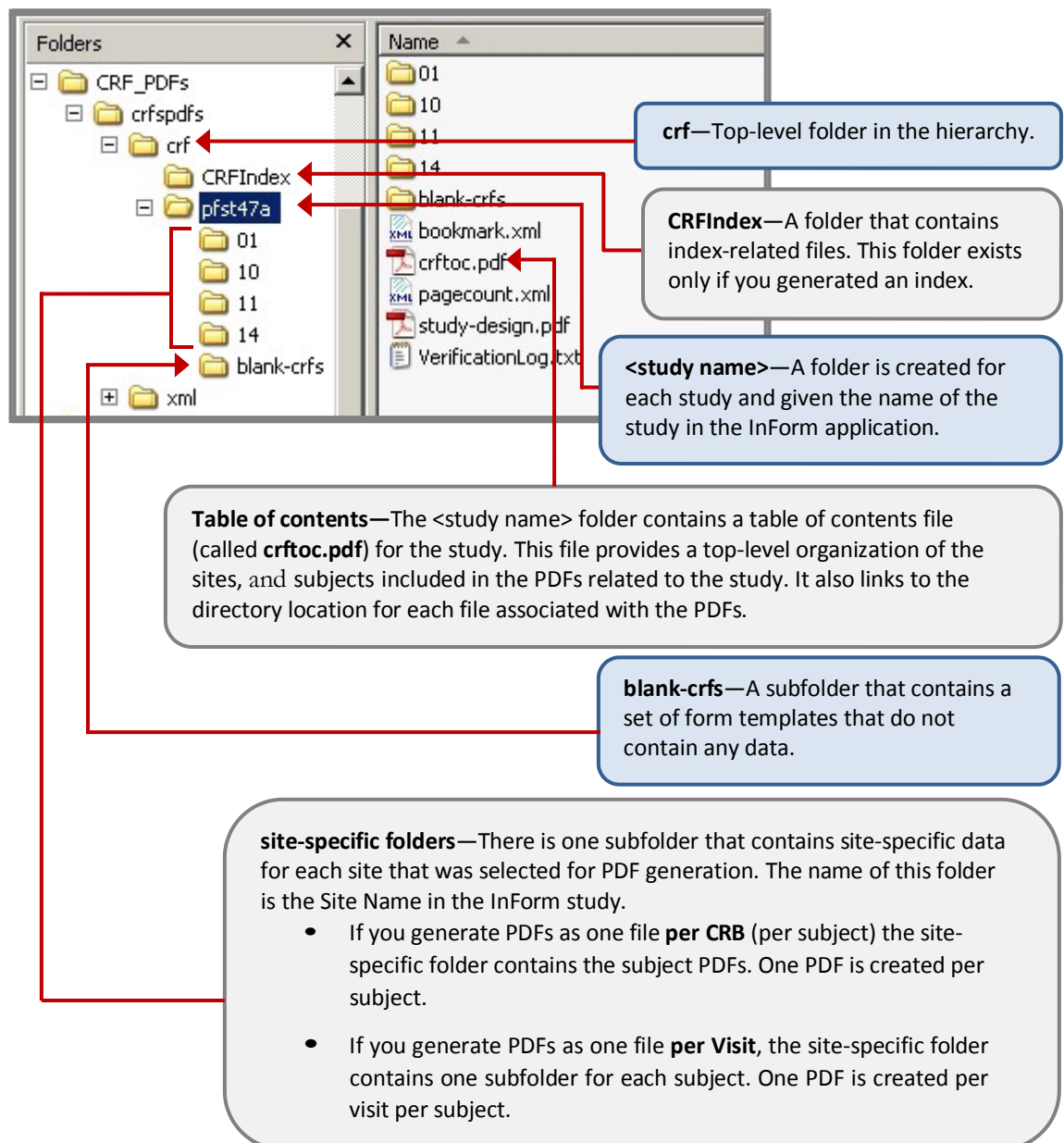
PDFs and Adobe® Reader®

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.



Opening a PDF

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

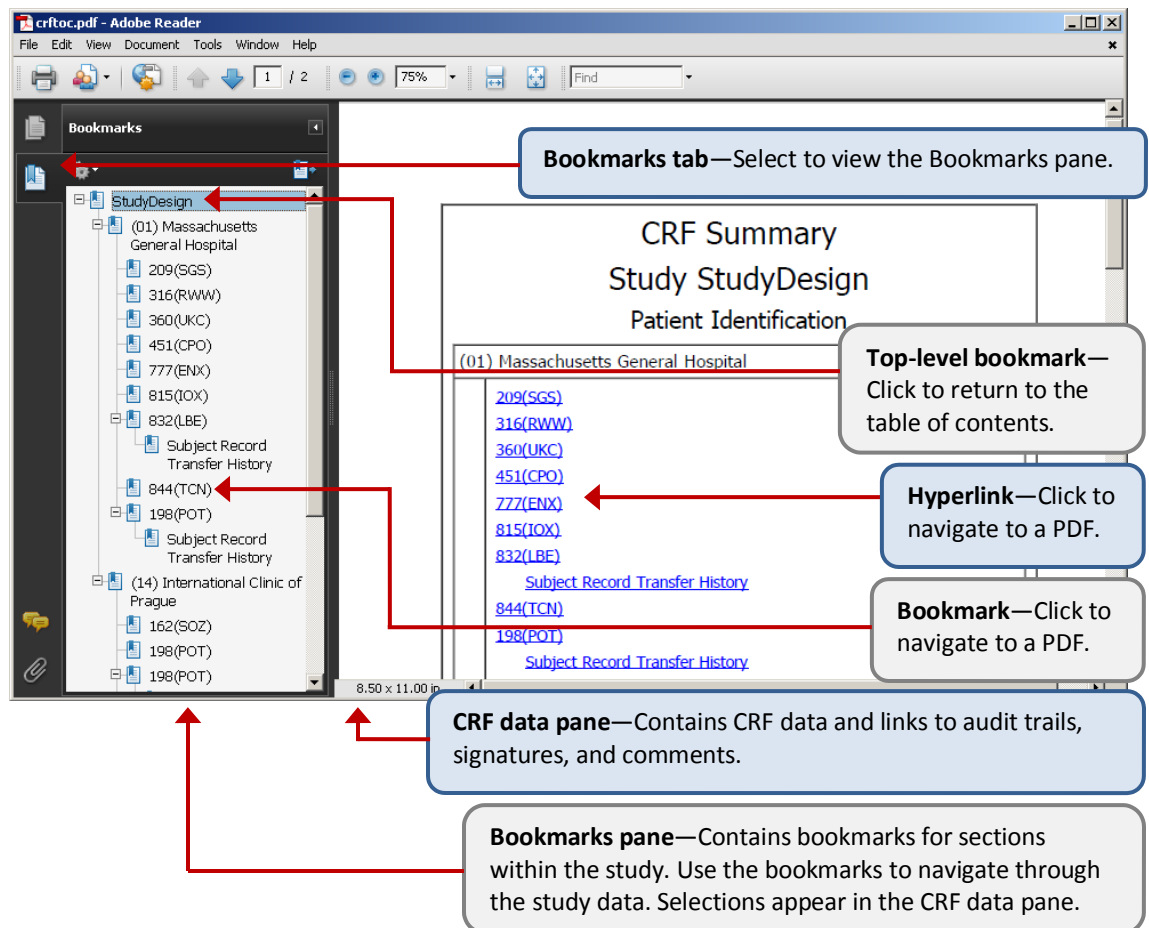
- In **Windows Explorer**, locate the table of contents file (**crftoc.pdf**) and double click the file.
- or
- 1 Open **Adobe Reader**.
 - 2 Select **File > Open**.
 - 3 Browse to the location where the table of contents file (**crftoc.pdf**) is stored.
 - 4 Select **crftoc.pdf** and click **Open**.

Printing a PDF

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

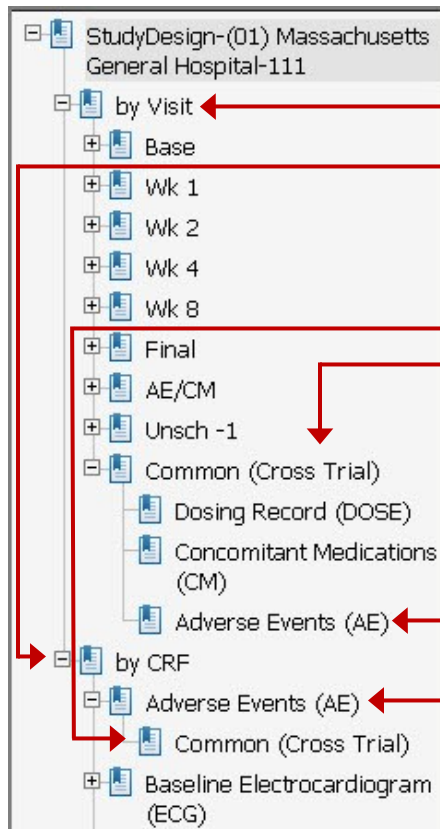
- Open the PDF and select **File > Print**.
- Open the PDF and press **Ctrl+P**.
- Right click the PDF and select **Print**.

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:

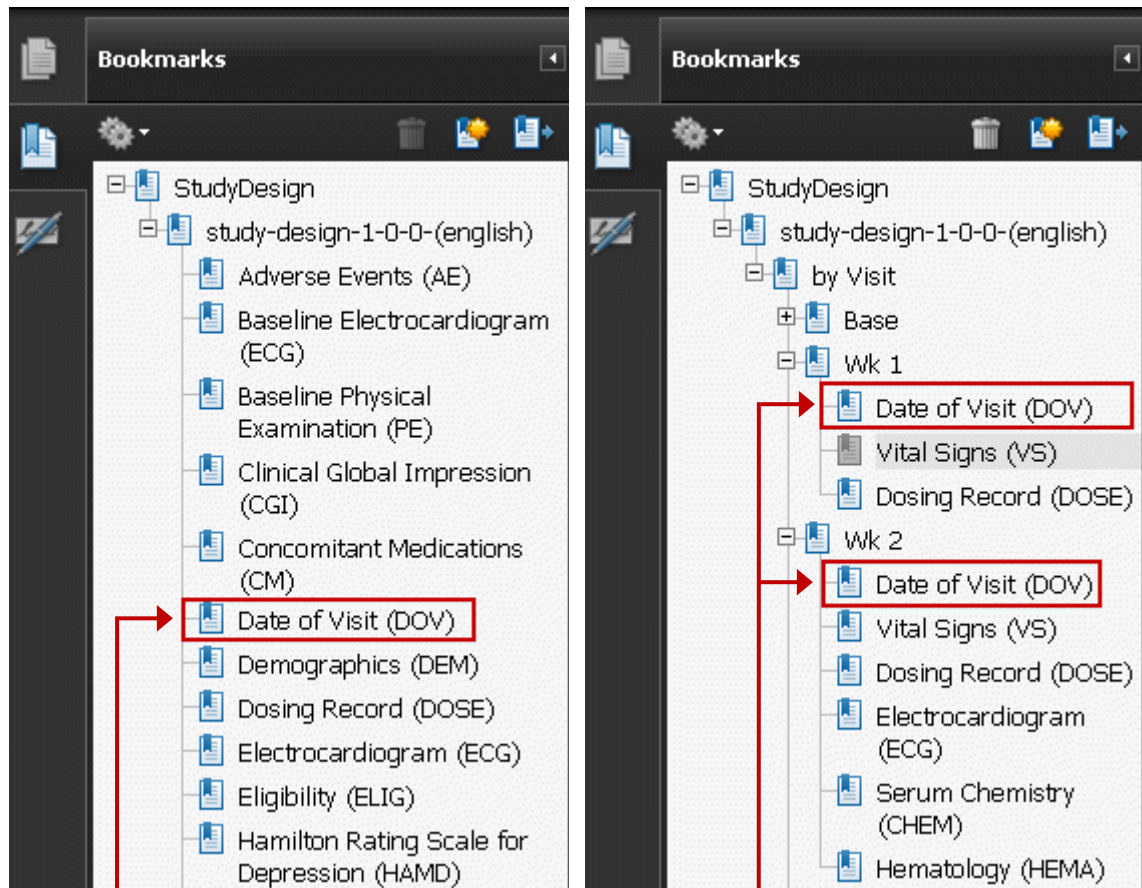
- Expand nodes **by Visit** > **Common (Cross Trial)** > **Adverse Events (AE)**.
- Expand nodes **by CRF** > **Adverse Events (AE)**.

Viewing blank forms

Blank forms are generated in one of the following blank 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.

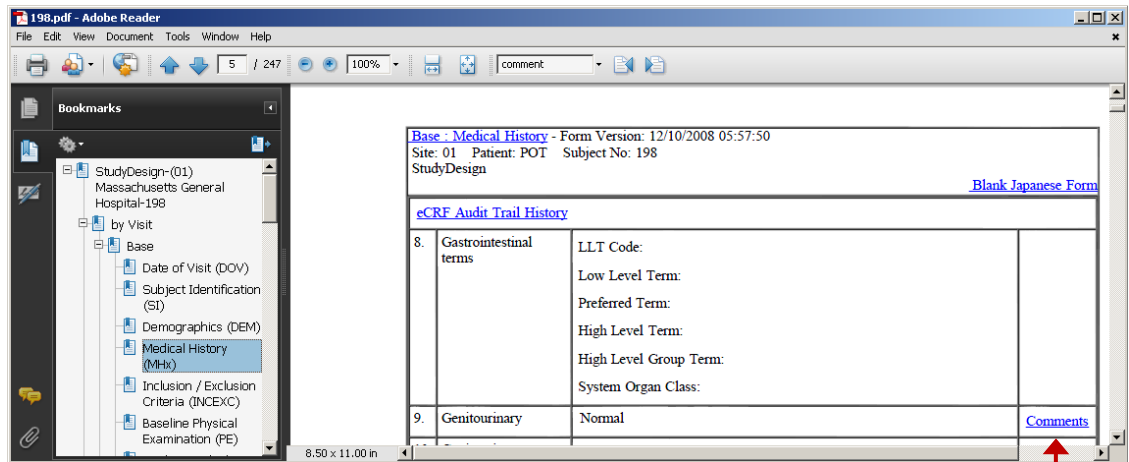
Common (Cross Trial) : Adverse Events - Form Version: 12/10/2008 05:59:02						
Site: 01 Patient: POT Subject No: 198						
StudyDesign						
Blank Japanese Form						
#	Seq. #	Event	Event (MedDRA-J)	Start Date and Time	Outcome	Form Instance
1.	1	Headache		Jul/23/2007 09:43	Recovered/Resolved with sequelae, provide End date and time Jul/29/2007 09:43	Repeating Pages Association Summary

Repeating Pages link—Click to view details that relate to the Adverse Event.

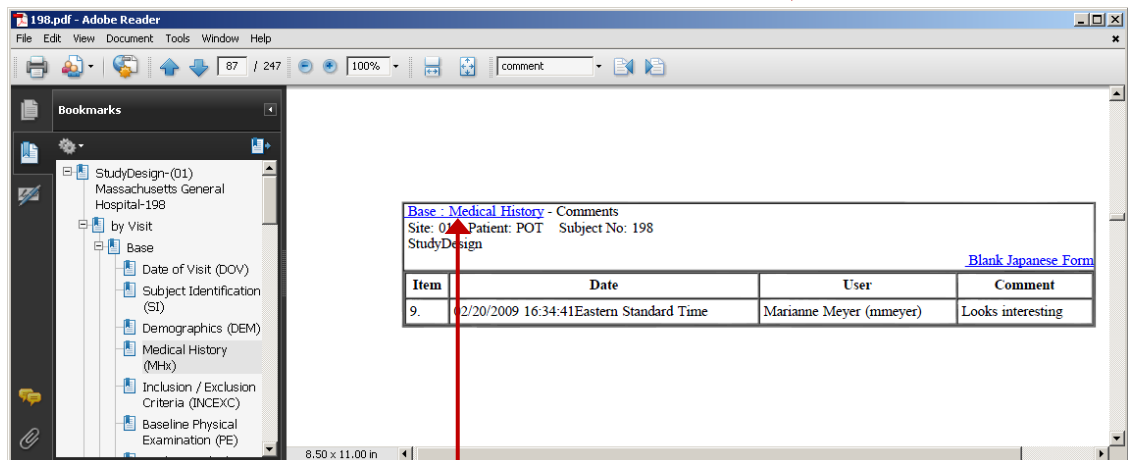
Association Summary link—Click to view the associated form. This example links to the associated Concomitant Medications.

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**.

The screenshot shows a form header with the following text: [Base : Vital Signs](#) - Form Version: 12/10/2008 05:57:13
Site: 01 Patient: POT Subject No: 198
StudyDesign

[Blank Japanese Form](#)

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

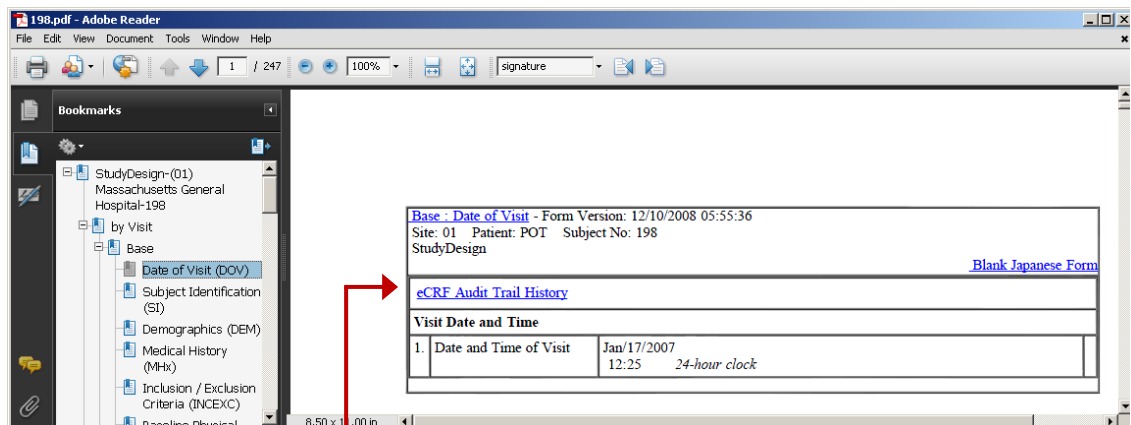
- Investigator Sigs
- CRA Sigs

Name	Signature Meaning	Date	Type	Action

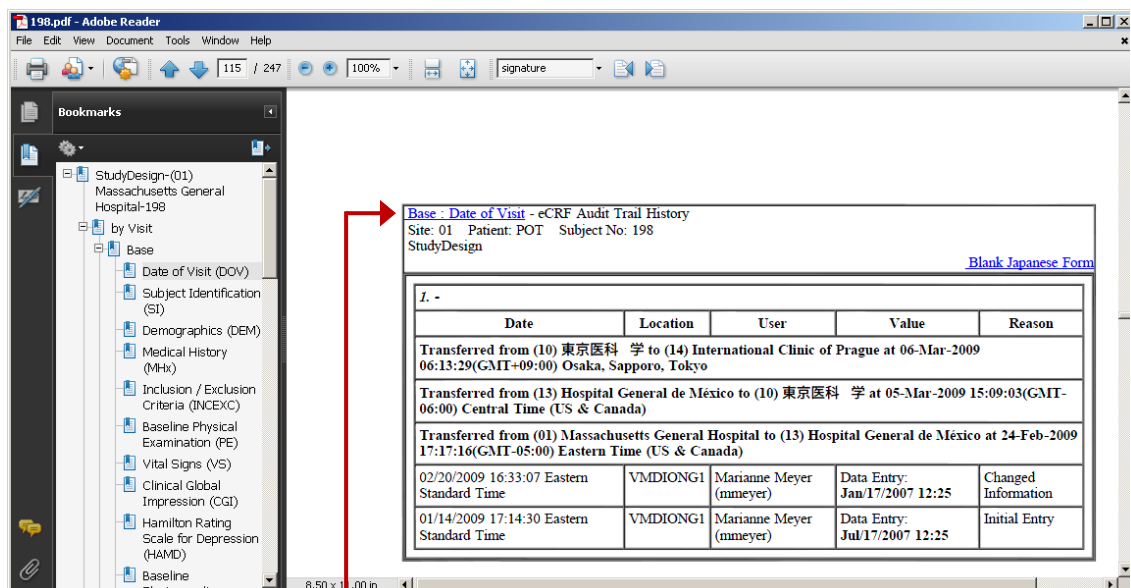
Signature information—Located in the audit trail at the bottom of each form that requires a signature.

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

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.

The screenshot shows Adobe Reader displaying a PDF form. The form has a header section with Japanese text: "Základní - Datum Návštěvy - フォームバージョン: 2008-12-10 15:55" and "施設: 14 症例: SOZ 症例番号: StudyDesign". Below this is a table with the heading "Navštivte Datum a čas" and one row containing "Datum a čas návštěvy", "7 /17/2007", and "12:25 24時間表示". A blue link "スペイン語のblankフォーム" is visible. A bookmarks pane on the left shows a tree structure with "StudyDesign-(14) International Clinic of Prague-162" and sub-items "ビジットごと" and "CRFごと".

Header labels—Appear in the Japanese submission language.

Link to blank form—Appears in the Japanese submission language. Click to open the corresponding blank page shown below.

Form labels and data—Labels appear in Czech. Information entered at the Czech site appears in the language in which it was entered into the InForm application.

Bookmarks—Appear in the Japanese submission language.

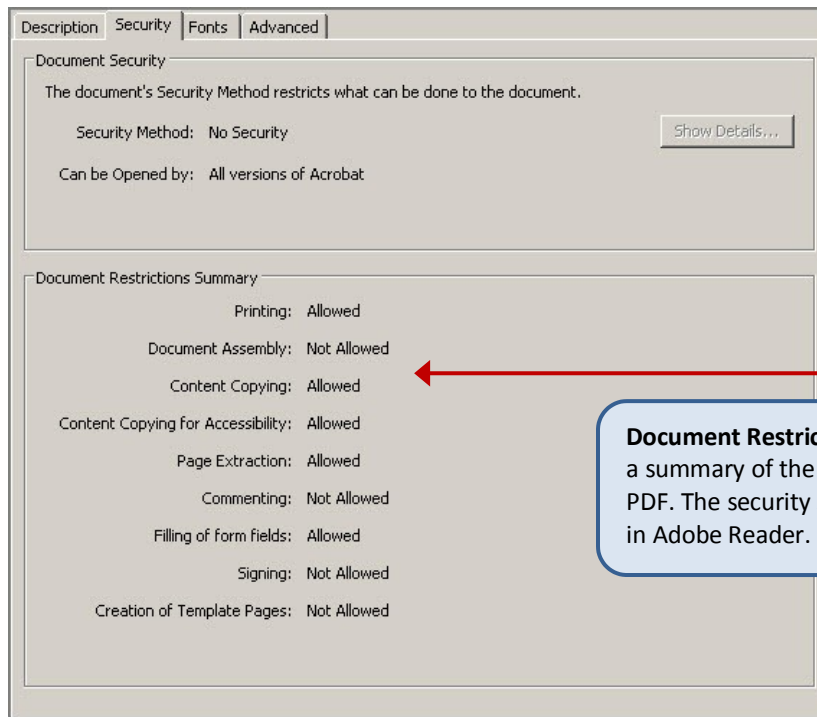
The linked blank form (Spanish) has a header section with Japanese text: "Fecha de la Visita - フォームバージョン: 2008-12-10 15:55" and "施設: 症例: 症例番号: StudyDesign". Below this is a table with the heading "Fecha y Hora de la Visita" and one row containing "1. Fecha y Hora de la Visita".

Header labels—Appear in the Japanese submission language.

Form labels—Appear in Spanish, the language specified for linking blank forms in the work order.

Viewing the security settings for the PDF

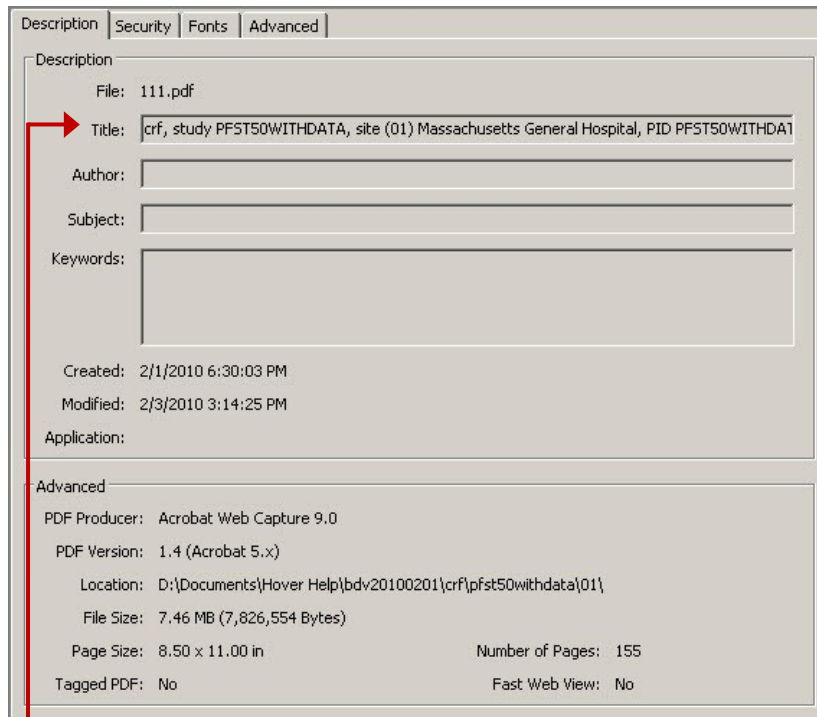
- 1 Open the PDF in Adobe Reader.
- 2 Select **File > Properties**.
The Document Properties window appears.
- 3 Select the **Security** tab.



Document Restrictions Summary—Contains a summary of the security settings for the PDF. The security settings cannot be edited in Adobe Reader.

Viewing the Document Information Title field

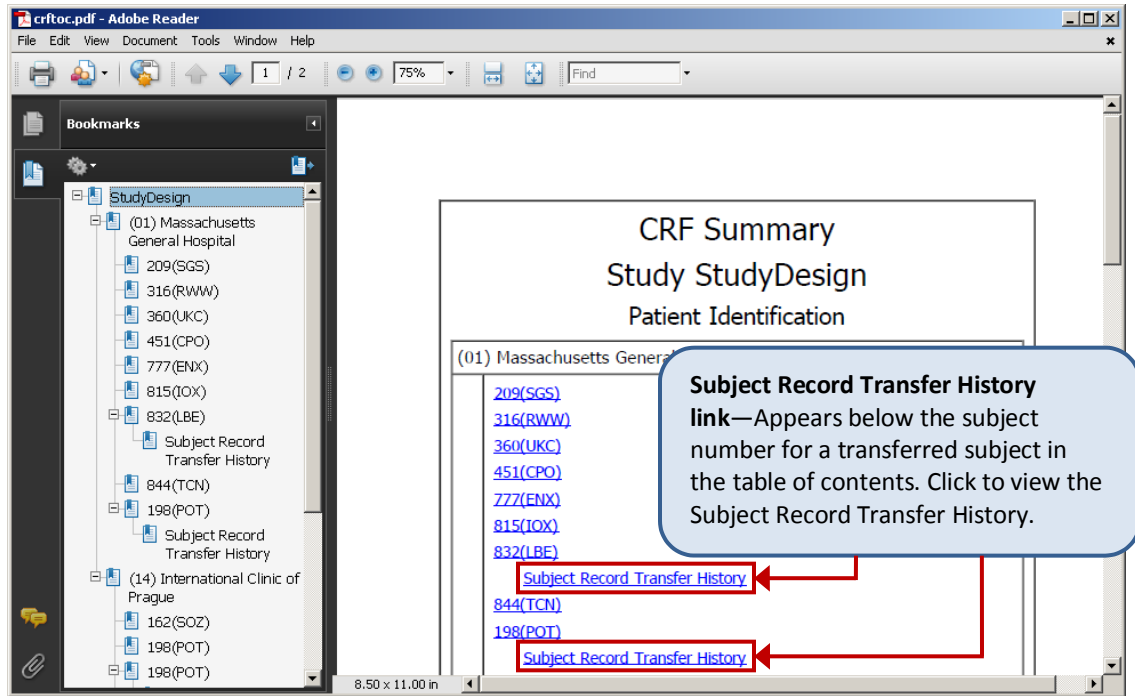
- 1 Open the PDF in Adobe Reader.
- 2 Select **File > Properties**.
The Document Properties window appears.
- 3 Select the **Description** tab.



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.



Subject Record Transfer History
 Final Site: 01 Final Patient: LBE Final Patient No: 832

<i>Transfer History</i>		
Date	Reason	User
06-Mar-2009 01:05:33(GMT+09:00) Osaka, Sapporo, Tokyo	Patient change of address	First Last (enen)
Originating Site	Originating Subject No	Originating Study Version
11	832	Study Design 1.0.0
Destination Site	Destination Subject No	Destination Study Version
01	832	Study Design 1.0.0

↑
Subject Record Transfer History—Includes subject data that is not filtered out by other CRF Submit functionality.

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 2-Dec-2006 Start	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.