



# Oracle® RDC OnSite

## Research Coordinator Training

Medtronic Clinical Research Institute



# Training Requirements

- RDC system training is designed and conducted for access to OnSite.
- Additional RDC training will be provided on a per study basis by designated sponsor personnel as needed.
- Previous RDC training cannot be substituted and/or extended to other personnel on sponsor's behalf.
- Trainees must complete all applicable sections.
- Once all required training has been completed, training documentation and user account information will be provided by sponsor.



# Agenda

## Key Topics:

- Login Process
- System Overview
- Data Entry
- Discrepancy Management
- eSignatures
- Reports



## Reference: Definitions

- **RDC:** Remote Data Capture, which is a synonym for EDC, or Electronic Data Capture. RDC OnSite is Oracle's version of an EDC system.
- **Casebook:** The set of CRFs to be collected at various visits for each patient. Also known as a Data Collection Instrument (DCI) Book.
- **Discrepancy:** CRF data that have been flagged as being suspect (illogical, inconsistent, or implausible). Discrepancies can be univariate (single-field) or multivariate (multi-field). Discrepancies may be auto-generated by the system or manually created by a user.
- **Verify:** RDC terminology meaning "*to monitor*". Verified means monitored, i.e. source document verified.



# Login Process

# Site Login Process:



- Use Internet Explorer and enter the following URL: <https://onsite.medtronic.com> (Bookmark this site)
- Click the **Change password** link
- Enter your User ID and click **Next**

The login screen has a dark blue background. At the top left, the word "Login" is written in a large, white, sans-serif font. Below it, in a smaller white font, is the text "Onsite Clinical Remote Data Capture". There are two input fields: the first is labeled "Username:" and the second is labeled "Password:". Below the password field is a small, underlined link that says "Change password". At the bottom center, there is a blue button with the word "LOGIN" in white, uppercase letters.

The screen has a dark blue header with the text "Medtronic Secured Access" in white. Below the header, the text "Forgotten Password?" is displayed in a large, white, sans-serif font. Underneath, it says "Please help us identify who you are." in a smaller white font. There is a label "Enter your userid:" followed by a white input field. At the bottom, there are two yellow buttons: "Next" and "Cancel". The background of the screen shows a close-up of a keyboard with the "Enter" key highlighted.

# Site Login Process:



- The system will send you a new, temporary password via email from [helpdesk@medtronic.com](mailto:helpdesk@medtronic.com) or [rs.gbs-isaccountadmin@medtronic.com](mailto:rs.gbs-isaccountadmin@medtronic.com) (depending on geography)
  - If your email address changes contact sponsor
- Click on the **Return to login screen**

# Site Login Process:

- Enter your Username and temporary password
- Enter the temporary password in current password field
- Enter a new password in the new password and again in confirm new password fields
- Click **Change Password**
- Click **Continue** on the next screen
- Close Internet Explorer and open a new Internet Explorer window
- Log into RDC with the new password

A screenshot of a web login page. The background is dark blue with a subtle pattern of white stars. At the top, the word "Login" is written in white, with "Onsite Clinical Remote Data Capture" in a smaller font below it. There are two input fields: "Username:" and "Password:". Below the password field is a link that says "Change password". At the bottom center is a blue button with the word "LOGIN" in white capital letters.A screenshot of a web page titled "Medtronic Secured Access". The main heading is "Password Change Request" with the instruction "Please change your current password before continuing." Below this are three input fields: "Current Password", "New Password", and "Confirm New Password". At the bottom are two buttons: "Change Password" (yellow) and "Cancel" (white with a yellow border). On the right side, there is a close-up image of a keyboard key labeled "Enter". At the bottom of the page, there is a small copyright notice "© Medtronic, Inc." and a footer note "Please do NOT bookmark this page."





# Login Process: Password Rules

- The password cannot be the same as the User ID (Username)
- Passwords are **case sensitive**
- The **first character** in a Password **must** be an **alpha** character
- Passwords **cannot** start with a numeric value or a punctuation mark
- Passwords must be **at least 7** and **no more** than 15 characters in length
- Passwords must contain **at least one numeric** character
- Passwords must contain **at least one uppercase** character
- Passwords must contain **at least one lowercase** character
- Passwords may **not** contain any of the following special characters:
  - ! @ % ^ & \* ( ) - + = { } [ ] | \ : ; " ' < > , . ? / ~ ` # \$ \_
- A password cannot be reused until the password has been changed at least 10 times
- The system may reject passwords that are too similar (e.g., if you change Coffee1 to Coffee2)



# Login Process: Password Reminders

- If your login fails 3 consecutive times due to the entry of an incorrect password, the system will lock your account
  - ❖ Wait 10-15 minutes and try to login again
  - ❖ If you are still unable to login, contact Medtronic
- **Passwords expire after 6 months for external users.**
  - ❖ The system will notify the user when they log in that a password is going to expire soon, or if it has expired
- Research Coordinators and Investigators each receive their own accounts
- Do NOT share your password with anyone as it is equivalent to your electronic signature
- Do NOT use another person's account to log in



# System Overview

# System Overview: Global Links

The screenshot displays the ORACLE RDC Onsite interface. At the top, there is a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports'. The user is logged in as 'User1 Flex(CRA Role, LSHP2X17)' with a last refresh time of '09-11-2009 08:22:32'. The current study and site are 'FLEXSTUDY1' and '001'. A 'Logout Help' button is highlighted in a red box in the top right corner. The main content area is divided into several sections: 'News' (No Records Found), 'Activities' (links for CRFs, verification, and comments), 'Links' (links to Yahoo, Google, MSN, Expedia, Mapquest, and Dynamic Link Study/Site/User), and 'Patient Selection List'. The 'Patient Selection List' section includes a 'Patient Search' form with fields for Range, Show (set to All), and Reference, and a table of patients. A blue overlay box titled 'Global Links' is positioned over the 'Patient Search' area, containing a list of links.

**Global Links**

- **Logout:** Ends the RDC session
- **Help:** General RDC help system, not specific to the study protocol

Select	Reference	Patient Number	Last Modified	Casebook
<input type="checkbox"/>		11		STUDYBOOK1
<input type="checkbox"/>		12		STUDYBOOK1
<input type="checkbox"/>		13		STUDYBOOK1
<input type="checkbox"/>		14		STUDYBOOK1
<input type="checkbox"/>		15		STUDYBOOK1
<input type="checkbox"/>		16		STUDYBOOK1

# System Overview: Tabs

The screenshot displays the ORACLE RDC Onsite web application. At the top, there is a navigation bar with tabs for Home, Casebooks, Review, and Reports. A box highlights these tabs, with an arrow pointing to a callout box. The callout box, titled "Tabs", lists the functions of each tab: Home (main screen for patient selection), Casebooks (data entry), Review (data review), and Reports (report generation). Below the navigation bar, the user is logged in as "User1 Flex(CRA role, LSHP2X17)" and the system shows the study and site as "FLEXSTUDY1" and "001". The main content area includes a "Patient Selection List" with a search form and a table of patients.

**ORACLE<sup>®</sup> RDC Onsite** Logout Help

Home Casebooks Review Reports

Logged in as User1 Flex(CRA role, LSHP2X17); Last Refresh 09-11-2009 08:22:32

Study and Site FLEXSTUDY1 001

[Study and Site Summary](#)

**News**  
No Records Found

**Activities**  
[Show all CRFs \(QC\) for Site 001](#)  
[Review non-blank CRFs ready for initial verification](#)  
[Review Investigator comments](#)

**Links**  
[Yahoo](#)  
[Google](#)  
[MSN](#)  
[Expedia](#)  
[Mapquest](#)  
[Dynamic Link Study](#)  
[Dynamic Link Site](#)  
[Dynamic Link User](#)

**Patient Selection List**

**Patient Search**

Range   
Show All  
Reference

**Patients**

Select Patients and... Op

[Select All](#) | [Select None](#)

Select	Reference			
<input type="checkbox"/>			11	STUDYBOOK1
<input type="checkbox"/>			12	STUDYBOOK1
<input type="checkbox"/>			13	STUDYBOOK1
<input type="checkbox"/>			14	STUDYBOOK1
<input type="checkbox"/>			15	STUDYBOOK1

# System Overview: Study and Site Selection

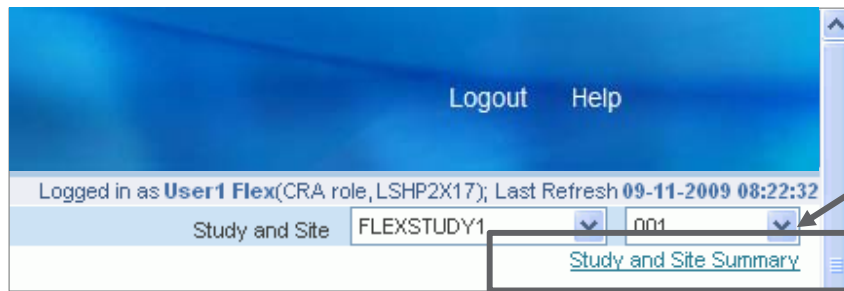
The screenshot displays the ORACLE RDC Onsite web application. The top navigation bar includes 'Home', 'Casebooks', 'Review', and 'Reports'. The user is logged in as 'User1 Flex(CRA role, LSHP2X17)' with a last refresh time of '09-11-2009 08:22:32'. The 'Study and Site' section shows two dropdown menus: the first is set to 'FLEXSTUDY1' and the second to '001'. A 'Study and Site Summary' link is visible below the second dropdown. The main content area is titled 'Patient Selection List' and shows 'No Records Found'. Below this is a 'Patient Search' section with two dropdown menus and 'Clear' and 'Go' buttons. A blue callout box with white text explains the selection process. The bottom of the page shows a table with columns for checkboxes, icons, and patient IDs (13, 14, 15) associated with 'STUDYBOOK1'.

**Study and Site selection**

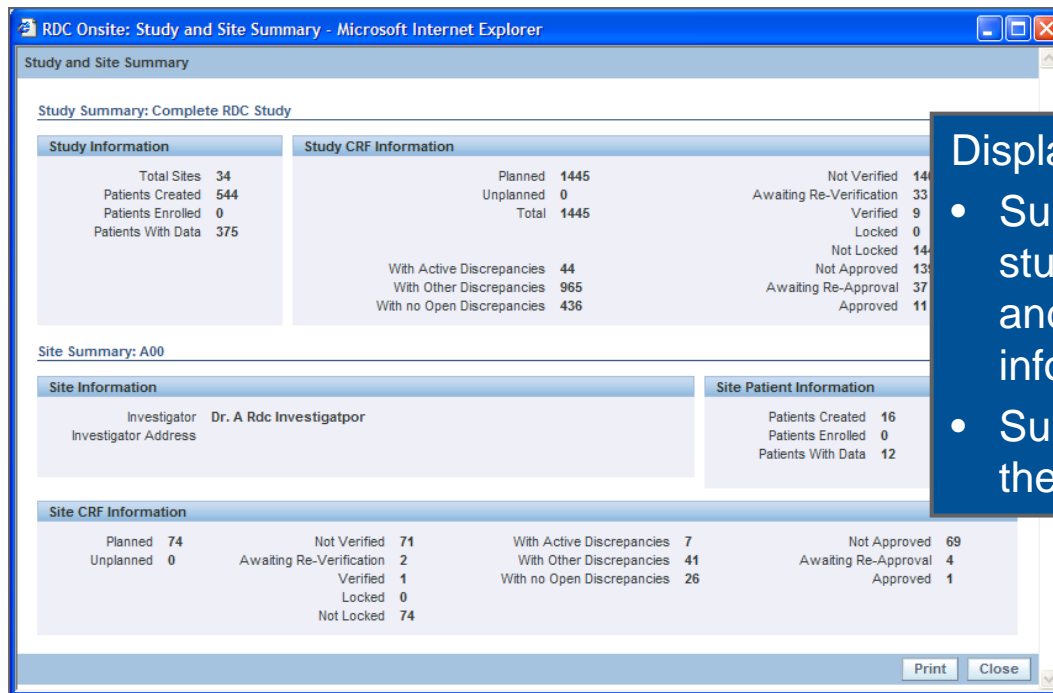
- The first dropdown lists studies you have access to
- The second dropdown lists investigational sites you have access to
- After selecting study and site, the system automatically updates the patient list

Study	Site	Patient ID	Study Book
FLEXSTUDY1	001	13	STUDYBOOK1
FLEXSTUDY1	001	14	STUDYBOOK1
FLEXSTUDY1	001	15	STUDYBOOK1

# System Overview: Study and Site Summary



Clicking **Study and Site Summary** opens a display window



Display window:

- Summarizes all sites in the study the user can access and high level study information
- Summarizes information in the selected site

# System Overview: Sections

**News:** Can be used to share study specific information such as study milestones

**Activities:** Displays links to tasks specific to the user role such as discrepancy review, CRFs ready for initial verification, CRFs ready for initial approval, or Investigator Comments

**Links:** Displays external links specific to the study such as an electronic diary website



# System Overview: Sections

**ORACLE** RDC Onsite

Logout Help

Home Casebooks Review Reports

Logged in as User1 Flex(CRA role, LSHP2X17); Last Refresh 09-11-2009 08:22:32

Study and Site FLEXSTUDY1 001

[Study and Site Summary](#)

**News**  
No Records Found

**Activities**  
[Show all CRFs \(QC\) for Site 001](#)  
[Review non-blank CRFs ready for initial verification](#)  
[Review Investigator comments](#)

**Links**  
[Yahoo](#)  
[Google](#)  
[MSN](#)  
[Expedia](#)  
[Mapquest](#)  
[Dynamic Link Study](#)  
[Dynamic Link Site](#)  
[Dynamic Link User](#)

**Patient Selection List**

**Patient Search**

Range   
Show All  
Reference

**Patients**

Select Patients and... Open

Select All | Select None

Select	Reference
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	

• **Activities:** Use the **Review Non-blank CRFs...** links with caution – Pre-filters are set with only some forms selected

For example: *Review non-blank CRFs ready for initial approval* contains CRFs with no discrepancies and are verified.

The Review tab at the top left of the page can be used in place of these links to ensure all forms of interest are included in the filter.

# System Overview: List of Patients

**ORACLE** RDC Onsite

Home Casebooks Review Reports

Logged in as User1 Flex(CR Study and S

Discrep

**News**  
No Records Found

**Activities**  
[Show all CRFs \(QC\) for Site 001](#)  
[Review non-blank CRFs ready for initial verification](#)  
[Review Investigator comments](#)

**Links**  
[Yahoo](#)  
[Google](#)  
[MSN](#)  
[Expedia](#)  
[Mapquest](#)  
[Dynamic Link Study](#)  
[Dynamic Link Site](#)  
[Dynamic Link User](#)

**Patient Selection List**

**Patient Search**

Range  -

Show All

Reference

**Patients**

Select Patients and... Open Patient Casebooks

Select All | Select None

Select	Reference	Patient Number	Last Modified	Casebook
<input type="checkbox"/>		11		STUDYBOOK1
<input type="checkbox"/>		12		STUDYBOOK1
<input type="checkbox"/>		13		STUDYBOOK1
<input type="checkbox"/>		14		STUDYBOOK1
<input type="checkbox"/>		15		STUDYBOOK1
<input type="checkbox"/>		16		STUDYBOOK1

## List of Patients

- **Patient Search:** Expand to search for patients with specific criteria
- **Patients:** Lists all patients assigned to the site, unless filtered using the Patient Search criteria

# System Overview: Patient Summary

Click on a patient icon to display a patient summary





Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	X1		
<input type="checkbox"/>	X2		
<input type="checkbox"/>	X3		
<input type="checkbox"/>	X4		
<input type="checkbox"/>	X5		
<input type="checkbox"/>	X6		
<input type="checkbox"/>	X7		
<input type="checkbox"/>	X8		
<input type="checkbox"/>	X9		
<input type="checkbox"/>	X10		

RDC Onsite: Patient Summary [T] - Windows Internet Explorer

Patient Summary : X1

Patient Information	Discrepancies	CRFs
Patient <b>X1</b> Birthdate <b>1960-09-01</b> Gender <b>Male</b> Age <b>51</b> Site <b>394425</b> Latest Update <b>09-Feb-2012</b>	Active <b>17</b> Other <b>178</b> Closed <b>1</b> Total <b>196</b>	With Active Discrepancies <b>8</b> With Other Discrepancies <b>13</b> With no Open Discrepancies <b>19</b> Total <b>40</b> Earliest Entry <b>23-Oct-2007</b> Latest Entry <b>09-Feb-2012</b>
CRFs Status	Visits	
Not Verified <b>40</b> Awaiting Re-Verification <b>0</b> Verified <b>0</b> Not Approved <b>40</b> Awaiting Re-Approval <b>0</b> Approved <b>0</b>	First <b>Enrollment 01-Dec-2007</b> Latest <b>Eq - Retired 01-Jan-2011</b> Next <b>null null</b>	

## Icon Descriptions:

-  Patient has no discrepancies
-  Patient has at least 1 **active** discrepancy, i.e. for the user role logged in
-  Patient has **other** discrepancies, i.e. for another user role
-  No data entered for patient



# Data Entry

# Data Entry: Patient Selection

Start data entry on a new patient or add a new CRF for an existing patient.

**Patients**

Select Patients and... Open Patient Casebooks

Select All | Select None

Select		Patient Number	Last Modified	Casebook
<input checked="" type="checkbox"/>				RDC_BOOK1
<input checked="" type="checkbox"/>				RDC_BOOK1
<input checked="" type="checkbox"/>				RDC_BOOK1
<input checked="" type="checkbox"/>				RDC_BOOK1
<input checked="" type="checkbox"/>		0205	09-Sep-2008 13:41:43	RDC_BOOK1
<input checked="" type="checkbox"/>		0206	09-Sep-2008 13:41:43	RDC_BOOK1
<input checked="" type="checkbox"/>		0207	09-Sep-2008 13:41:43	RDC_BOOK1
<input type="checkbox"/>		0208	09-Sep-2008 13:41:43	RDC_BOOK1
<input type="checkbox"/>		0209	09-Sep-2008 13:41:43	RDC_BOOK1
<input type="checkbox"/>		0210		RDC_BOOK1

Select Patients and... Open Patient Casebooks

**1. Select patient(s) whose data will be viewed, entered or updated**

**2. Select Open Patient Casebooks**

**3. Click Go**

# Data Entry: Casebook Spreadsheet

Casebook Spreadsheet

Patients: Previous 1-7 of 7 Next

Casebook View: RDC\_BOOK1

Visit: VISIT1

Select Patients and... Generate Patient Data Report Go Add Visit Page

Select All | Select None

**Each column is a CRF**

**Visit Selection**






Select	Patient	DEM	Test	AE	VISIT1
<input type="checkbox"/>	0201	1	2		
<input type="checkbox"/>	0202	1	2	2 U1	
<input type="checkbox"/>	0203	1	2		
<input type="checkbox"/>	0204	1	2		
<input type="checkbox"/>	0205	1	2		
<input type="checkbox"/>	0206	1	2		
<input type="checkbox"/>	0207	1	2		

**Each cell contains a unique CRF for that particular patient in the selected visit**



**Each row is a patient and their CRFs**

# Data Entry: CRF Icon Descriptions

## CRF Entry Status

-  Available for entry
-  Marked blank
-  Entry started (Saved Incomplete)
-  Entry complete (Saved Complete – no discrepancies)
-  Batch loaded data

## Discrepancy Status

-  Active (at least 1 discrepancy for the user role logged-in)
-  Other (all discrepancies are for a different user role)

## Approval and Verification Status

-  Verified
-  Requires re-verification
-  Approved
-  Requires re-approval

*Multiple statuses may be displayed. For example, a CRF can show a discrepancy, require re-approval and re-verification.*



# Data Entry: Entering a New CRF

Casebook Spreadsheet

Patients: (A) Previous 1-7 of 7 Next (V) Casebook View: RDC\_BOOK1 (v) Visit

Select Patients and... Generate Patient Data Report (v) Go Add Visit Page Add Other Page

Select All | Select None

Select	Patient	DEM	Test	AE	VISIT1		
<input type="checkbox"/>	0201	1	2				
<input type="checkbox"/>	0202	1	2				
<input type="checkbox"/>	0203	1	2				
<input type="checkbox"/>	0204	1	2				
<input type="checkbox"/>	0205	1	2				
<input type="checkbox"/>	0206	1	2				
<input type="checkbox"/>	0207	1	2				

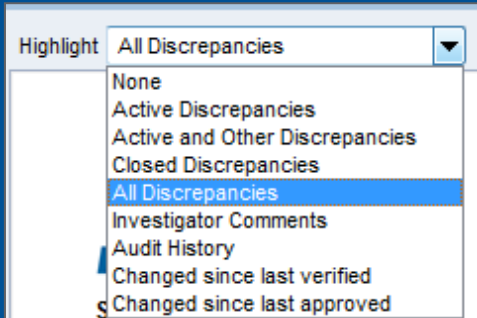
- An icon with a blank page and green arrow means a CRF is available for data entry
- Click the icon to begin data entry, or click any other icon to edit an existing CRF



# Data Entry: Data Entry Window

The screenshot displays the Medtronic Data Entry Window. At the top, a **Toolbar** contains various icons for navigation and editing. The main content area is titled **DEMOGRAPHICS** and includes the Medtronic logo, **Subject ID: X1**, **Doc. No:**, and **Visit Date:**. The form is divided into sections: **1. DEMOGRAPHICS**, **1.1 Date of Birth:** (with a date input field), **1.2 Gender:** (radio buttons for Male and Female), **1.3 Ethnicity:** (radio buttons for Hispanic or Latino, Not Hispanic or Latino, and Subject Refused), and **1.4 Race: (check all that apply; you must check at least one)** (checkboxes for American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Other, specify: [text field], and Subject Refused). A **CRF Entry** label is overlaid on the form. At the bottom left, an **Audit History Pane** shows a table with columns: **Date**, **Changed From**, **Changed To**, **By**, **Reason**, **Comment**, and **Details**. The table is currently empty. On the right side, a **Discrepancy Navigator Pane** is visible, featuring a **Show** dropdown menu set to **All Discrepancies**, a **List** section, a **Details** section with **Related Values** and **History** buttons, and an **Action** dropdown menu with a **Go** button.

# Data Entry: Toolbar

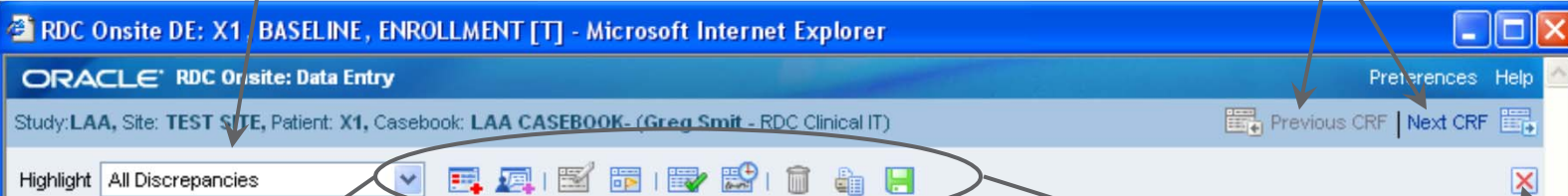


Highlight All Discrepancies

- None
- Active Discrepancies
- Active and Other Discrepancies
- Closed Discrepancies
- All Discrepancies
- Investigator Comments
- Audit History
- Changed since last verified
- Changed since last approved

Dropdown to control the highlighting of data entry fields

Next and Previous CRFs in the Visit



RDC Onsite DE: X1 BASELINE, ENROLLMENT [T] - Microsoft Internet Explorer

ORACLE RDC Onsite: Data Entry

Study: LAA, Site: TEST SITE, Patient: X1, Casebook: LAA CASEBOOK - (Greg Smit - RDC Clinical IT)

Highlight All Discrepancies

Previous CRF | Next CRF

Close CRF



A detailed view of the toolbar icons, including: Add Discrepancy, Add Investigator Comment, Delete Row, Blank Flag Tool, Verify, Approve, Delete CRF, Print, and Save.

Add Discrepancy

Delete Row

Verify

Delete CRF

Save

Add Investigator Comment

Blank Flag Tool

Approve

Print

# Data Entry: Entering Data

**1. DEMOGRAPHICS**

1.1 Patient Initials: \_\_\_\_\_ (first two)

1.2 Date of Birth:

1.3 Gender:  Male  
 Female

1.4 Ethnicity:  Hispanic or Latino  
 Not Hispanic or Latino  
 Subject Refused

1.5 Race: (check all that apply; you must check at least one)

American Indian or Alaska Native     White

Asian     Other, specify

Black or African American     Subject Refused

Native Hawaiian or Other Pacific Islander

**Header**

Doc. No: \_\_\_\_\_

**Body - Data entered here**

**Date fields** - enter directly or click calendar icon (DD-MMM-YYYY)  
 T: enters today's date  
 Y: enters yesterday's date  
 If a date is unknown, consult study specific training or study team member

**List of Values with drop down list** - identified by the magnifying glass icon

**List of Values with Radio Button** - click on choice or tab and press space bar (select only one)

**List of Values with Checkboxes** - click the choice or tab and press space bar (check all that apply)



# Data Entry: Investigator Comments

- Use this feature when you want to add a comment to a specific data field in the CRF
  - These are reviewed by the sponsor but not responded to  
Example: “Medication start date may be off by a couple days”
- **Do not enter any subject data as an Investigator Comment**

# Data Entry: Adding Investigator Comments

1. Click on the field that will receive the comment.

2. Click the Investigator Comment icon in the toolbar.

3. In the popup window, enter the comment and click **OK**.

The screenshot shows the ORACLE RDC Onsite Data Entry application interface. The main window displays a data entry form for a study named 'LAA' at a 'TEST SITE' for patient '02'. The form includes a question: '11. Is the subject currently taking an antiplatelet?'. The 'Yes' option is selected, and the user has entered '02-APR-2008' as the start date for Aspirin. A toolbar at the top of the form contains several icons, including one for adding an investigator comment. A popup window titled 'Add Investigator Comment' is open, showing the text 'Medication start date may be off by a couple days' in the comment field. The 'OK' button is highlighted.

# Data Entry: Viewing/Editing Investigator Comments

In the Highlight dropdown, select **Investigator Comments**.

The screenshot shows the Oracle RDC Onsite Data Entry interface. The browser title is "RDC Onsite DE: X1, BASELINE, CRF 2: BASELINE [T] - Microsoft Internet Explorer". The application title is "ORACLE RDC Onsite: Data Entry". The study information is "Study: LAA, Site: TEST SITE, Patient: X1, Casebook: LAA CASEBOOK- (Greg Smit - RDC Clinical IT)". The "Highlight" dropdown menu is open, showing options: None, Active Discrepancies, Active and Other Discrepancies, Closed Discrepancies, All Discrepancies, **Investigator Comments** (highlighted), Audit History, Changed since last verified, and Changed since last approved. Below the dropdown, there are several text input fields. The first field contains "02-APR-2008" and is highlighted in purple. The second field contains "date: \_\_\_\_\_" and is also highlighted in purple. The third field contains "start date: \_\_\_\_\_" and is not highlighted. The text "(dd-mon-yyyy)" is shown next to each date field.

All fields with investigator comments will be highlighted in purple.

# Data Entry: Viewing/Editing Investigator Comments

Right-click the data field, and select **Investigator Comment**.

In the popup window, edit the comment and click **OK**, or view the comment and click **Cancel**.

# Data Entry: Viewing/Editing Investigator Comments

The investigator comment can also be viewed in the *Navigator* pane.

To view details, select desired data field from the available *List* section.

Details of selected comment will be displayed in the *Details* section below.

The screenshot displays the Oracle RDC Onsite Data Entry application. The main window title is "ORACLE RDC Onsite: Data Entry" and the subtitle is "Study: 0016TR, Site: 003, Patient: 16003001, Casebo". The "Highlight" dropdown menu is set to "Investigator Comments". The "Navigator" pane on the right is active, showing a "List" section with two items: "Screening Date" and "Inclusion Criteria Numbers". The "Details" section below the list shows the selected comment: "Investigator Comment: Subject will not be available for follow up visits between February and April. -MC". A "History" button is visible in the top right of the details section. The main data entry area shows a text field for "Inclusion Criteria Number(s)" with the value "4" entered. Below the text field, there is a bold instruction: "Investigator must approve this form in the study database". The footer of the application window contains the text "Copyright © 2000, 2007, Oracle. All rights reserved."



# Data Entry: Saving the CRF

The screenshot shows the ORACLE RDC Onsite Data Entry application interface. The main window displays the study information: "Study: LAA, Site: TEST SITE, Patient: X5, Casebook: LAA CASEBOOK- (Greg Smit - RDC Clinical IT)". The current CRF is titled "CRF 1: ENROLLMENT" and is for "Subject ID: X5". The Medtronic logo is visible in the top left. A toolbar at the top contains various icons, including a green floppy disk icon representing the "Save" function. A blue callout box with an arrow points to this icon, containing the text: "1. Click the **Save** icon in the toolbar." Below the main window, a "Save Complete?" dialog box is open. It contains the following text: "Prior to saving this CRF data, you may specify whether you wish to mark this data as being complete." There are two options: "Save Complete" (described as marking the CRF as complete) and "Save Incomplete" (described as saving the CRF as incomplete). At the bottom of the dialog are buttons for "Help", "Cancel", "Save Incomplete", and "Save Complete". A second blue callout box with an arrow points to the "Save Complete" button in the dialog, containing the text: "2. Click either: - **Save Complete** if all data have been entered - **Save Incomplete** if additional data will be entered later".



## Data Entry: Notes about Saving

- **Saving Complete** may cause additional discrepancies to display. These are multivariate discrepancies which validate across multiple data fields
- All changes made to data after **Saving Complete** will be maintained in the system's audit trail for further reference
- **Saving Incomplete** will not cause additional discrepancies to be created
- Changes made to data after **Saving Incomplete** will not be maintained in the system's audit trail until **Saving Complete** is selected
- **Save your work often!!! The system times out after 30 minutes of inactivity, and you will not be warned of a pending timeout!**

# Data Entry: Closing the CRF

RDC Onsite DE: X1, BASELINE, DEMOGRAPHICS [T] - Windows Internet Explorer

ORACLE RDC Onsite: Data Entry Preferences Help

Study: NEU\_ Previous CRF Next CRF

Highlight All Discrepancies

**Click this button [X] to close the CRF.**

**Medtronic** DEMOGRAPHICS Doc. No: R48117225

Subject ID: X1 Visit Date:

**1. DEMOGRAPHICS**

1.1 Age on day of Study Consent: (whole number) \_\_\_\_

1.2 Gender:  Male  
 Female

1.3 Education:

<input type="radio"/> Grade 6 or less	<input type="radio"/> Graduated 2-year college/technical school
<input type="radio"/> Grade 7 to 12 (without graduating high school)	<input type="radio"/> Graduated 4-year college
<input type="radio"/> Graduated high school or high school equivalent	<input type="radio"/> Part graduate/professional school
<input type="radio"/> Part college	<input type="radio"/> Completed graduate/professional school

**2. WEIGHT & HEIGHT**

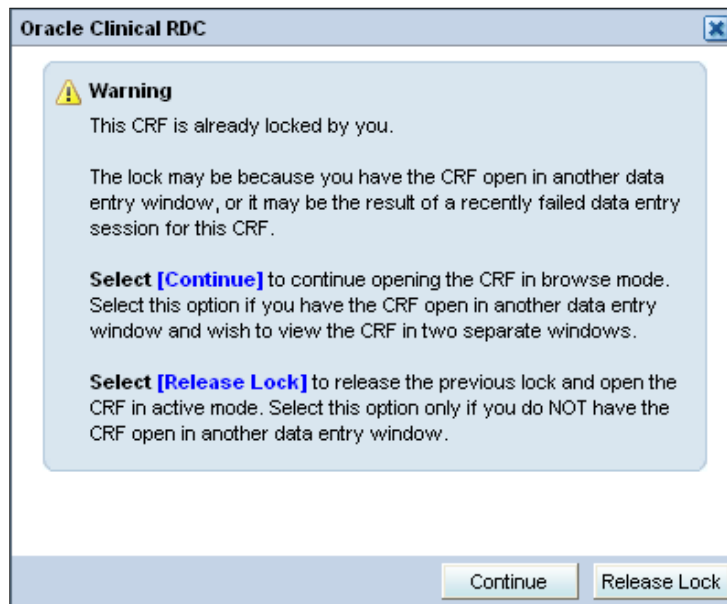
2.1 Weight \_\_\_\_ kg

2.2 Height \_\_\_\_ cm

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# Data Entry: Viewing CRFs

- OnSite will allow you to view, enter and/or update up to three CRFs simultaneously
- If you try to open a CRF you currently have open you will get the following message:

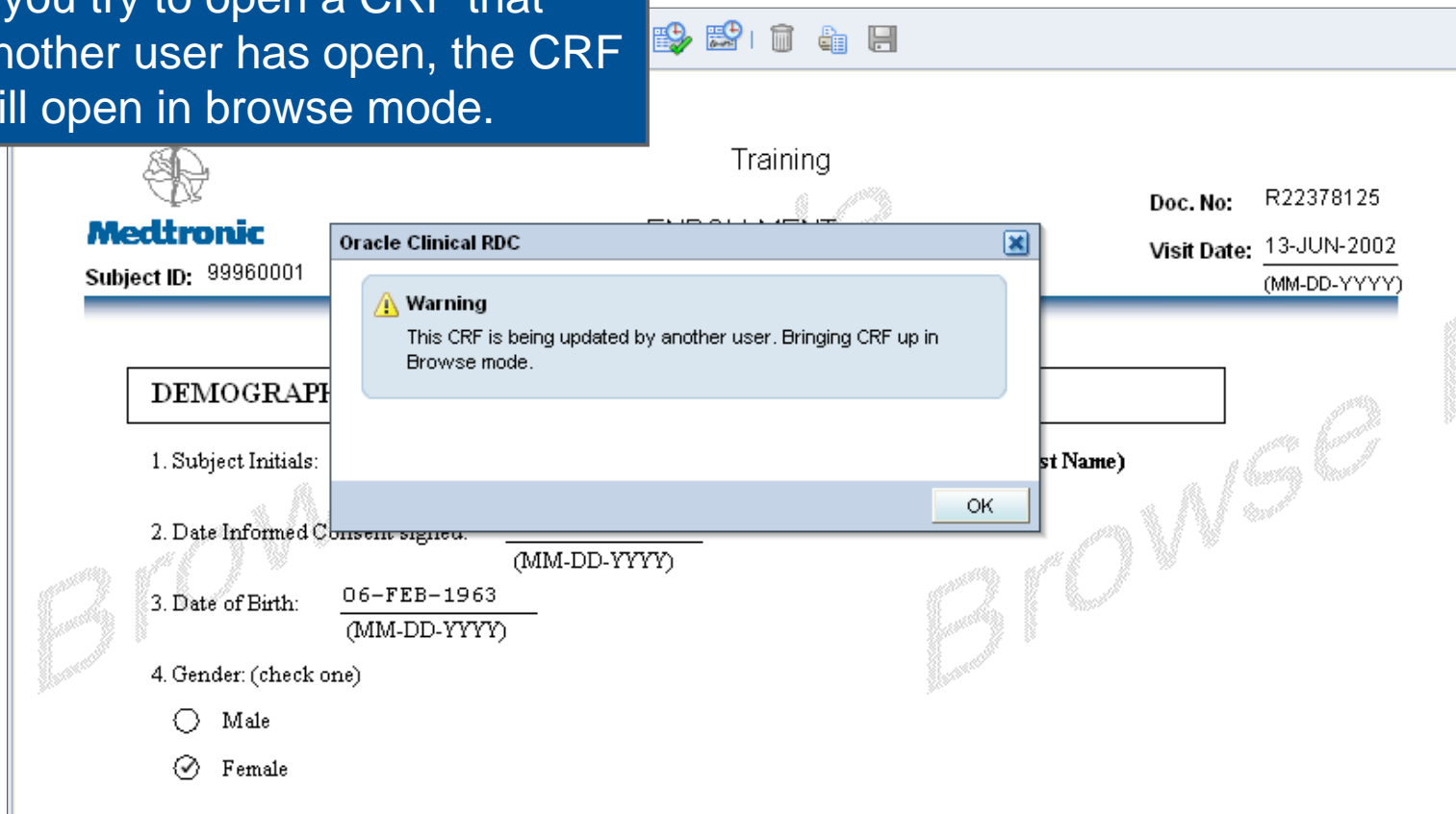


If you select **Release Lock** and close the original CRF a fatal error message will appear when closing.

Click **OK** to close the CRF. The OnSite session will not end.

# Data Entry: Viewing in Browse Mode

If you try to open a CRF that another user has open, the CRF will open in browse mode.



The screenshot shows a web browser window displaying a Medtronic Oracle Clinical RDC form. A warning dialog box is overlaid on the form, indicating that the CRF is being updated by another user and is being opened in browse mode. The form is titled "Training" and "ENROLLMENT". The subject ID is 99960001. The document number is R22378125 and the visit date is 13-JUN-2002. The form includes a "DEMOGRAPHIC" section with the following fields:

- 1. Subject Initials: \_\_\_\_\_
- 2. Date Informed Consent signed: \_\_\_\_\_ (MM-DD-YYYY)
- 3. Date of Birth: 06-FEB-1963 (MM-DD-YYYY)
- 4. Gender: (check one)
  - Male
  - Female

The warning dialog box contains the following text:

**Warning**  
This CRF is being updated by another user. Bringing CRF up in Browse mode.

OK

# Data Entry: Changing Data

Changes to data after the CRF is Saved Complete will be maintained in the system's audit trail for further reference.

The screenshot shows a Microsoft Internet Explorer browser window displaying a Medtronic CRF form. The browser title is "RDC Onsite DE: X4, BASELINE, CRF 2: BASELINE [T] - Microsoft Internet Explorer". The page title is "SEBOOK - (Greg Smit - RDC Clinical IT)". The browser address bar shows "Previous CRF" and "Next CRF" buttons. The page content includes the Medtronic logo, "CRF 2: BASELINE", "Visit Name: BASELINE", and "Subject ID: X4". The "Date of Evaluation" is "06-NOV-2008". The "PRE-OPERATIVE SUBJECT INFORMATION" section includes: "1. Age at evaluation: 46 years", "2. Gender: Male", and "3. Race: (check all that apply) White". A "Reason for Change" popup window is open, showing "\*Reason: Data Entry Error" and "Comment (optional): accidentally typed the wrong number". The popup window has "Help", "Cancel", and "OK" buttons. The browser status bar at the bottom shows "Copyright © 2000, 2007, Oracle. All rights reserved."

4. Save the CRF.

1. Change the data.

2. A popup window will appear requesting a reason and an optional comment.

3. Click OK.

# Data Entry: Viewing Audit History

The screenshot shows the Oracle RDC Onsite Data Entry application interface. The browser title is "RDC Onsite DE: X4, BASELINE, CRF 2: BASELINE [T] - Microsoft Internet Explorer". The application header includes "ORACLE RDC Onsite: Data Entry" and navigation links for "Previous CRF" and "Next CRF". The study information is "Study: LAA, Site: TEST SITE, Patient: X4, Casebook: LAA CASEBOOK- (Greg Smit - RDC Clinical IT)".

A dropdown menu titled "Highlight" is open, showing options: None, Active Discrepancies, Active and Other Discrepancies, Closed Discrepancies, All Discrepancies, Investigator Comments, **Audit History** (highlighted in blue), Changed since last verified, and Changed since last approved. An arrow points from a text box to the "Audit History" option.

The main form area displays "Study of the" and "CRF 2: BASELINE". Below this, it shows "Visit Name: BASELINE" and "Subject ID: X4". The "Date of Evaluation" is "06-NOV-2008" (dd-mon-yyyy).

The "PRE-OPERATIVE SUBJECT INFORMATION" section contains the following fields:

- Age at evaluation: **46** years (highlighted in blue)
- Gender:
  - Male
  - Female
- Race: (check all that apply)
  - American Indian or Alaska Native
  - Asian
  - Black or African American
  - Native Hawaiian or Other Pacific Islander
  - White

An arrow points from a text box to the blue highlight on the age field. Another arrow points from a text box to a small upward-pointing arrow at the bottom of the form, which is used to show audit history details.

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# Data Entry: Audit History Details

The screenshot shows the Oracle RDC Onsite Data Entry interface. At the top, the title bar reads "ORACLE® RDC Onsite: Data Entry" with "Preferences" and "Help" options. Below the title bar, the study information is displayed: "Study: LAA, Site: TEST SITE, Patient: X4, Casebook: LAA CASEBOOK- (Greg Smit - RDC Clinical IT)". There are navigation buttons for "Previous CRF" and "Next CRF". A "Highlight" dropdown menu is set to "Audit History". The main content area shows "page 1" and the text "Closure Device for the LAA". Below this, the Medtronic logo is visible, along with "CRF 2: BASELINE", "Visit Name: BASELINE", and "Subject ID: X4". The "Date of Evaluation" is "06-NOV-2008" in a date format "(dd-mon-yyyy)". The section "PRE-OPERATIVE SUBJECT INFORMATION" contains two items: "1. Age at evaluation: 46 years" and "2. Gender: Male" (selected with a radio button) and "Female" (unselected). At the bottom, the "Audit History: 1. Age at evaluation" table is shown with one row of data. A "Details" icon is visible in the table's last column.

Click on a field to display the audit history below.

Click the Details icon for an expanded view.

There will be 1 row for each change to the selected data field.

Date	Changed From	Changed To	By	Reason	Comment	Details
08-NOV-2008 14:03:32	45	46	Greg Smit	DATA ENTRY ERR	accidentally typed wrong r	



# Data Entry: Deleting a CRF

**1. Open the CRF to be deleted and click the Delete CRF icon.**

**2. A popup window will ask for a change reason and an optional change comment.**

**3. Confirm that this CRF really should be deleted.**

The screenshot shows the 'ORACLE RDC Onsite: Data Entry' window with the following details:  
Study: LAA, Site: TEST SITE, Patient: X5, Casebook: LAA CASEBOOK- (Greg Smit - RDC Clinical IT)  
Highlight: Active and Other Discrepancies  
Toolbar icons: Home, Print, Refresh, Save, Delete CRF (trash icon), etc.  
Background form: PRE-OPERATIVE SUBJECT INFORMATION  
1. Age at evaluation: 45 years  
2. Gender:  Male,  Female  
3. Race: (check all that apply)  
 American Indian  
 Asian  
 Black or African American  
 Native Hawaiian  
 White  
  
Delete CRF Dialog:  
\*Change Reason: Data Entry Error  
Change Comment (optional):  
 Remember comment for subsequent Delete CRF operations  
Buttons: Help, Cancel, Delete  
  
Delete CRF Confirmation Dialog:  
Warning: Are you sure you wish to delete this CRF ?  
Buttons: Cancel, OK

# Data Entry: Deleting a Row

Highlight All Discrepancies

If all data in a row should be removed, the delete row feature should be used. Deleting an individual field will generate discrepancies for missing data.

1. Click anywhere in the row that you want to delete.

2. Click on **Delete Row** Icon or Right Click and choose **Delete Row**.

3. Provide the reason for change when prompted.

Drug Name (generic or Brand Name)	Indication	Start Date	Stop Date	Dose	Dose Unit	Schedule	Route	Reason for Stopping	Specify Other Reason:
<i>Lopressor</i>	<i>Hypertension</i>	<i>15-May-2007</i>	<i>01-Sep-2007</i>	100	mg	QD	Oral	Poor response	
Ranitidine	GERD	01-JAN-2009		150	mg	BID	Oral		



# Data Entry: Permanently Missing CRFs


There are situations where protocol-planned CRFs may never be available. For example, a patient may be unable to complete a Follow-up Visit due to unusual circumstances.

When **any** planned/required CRF will not be collected:

- A Protocol Deviation Form should be completed
- The missing CRF should be entered in the database with a *blank flag*, if required for the study

# Data Entry: Marking a CRF as Blank

**1. Open the CRF that will be marked blank.**

**2. Click the **Blank Flag Tool** icon  to display the popup window.**

**3. Check all boxes and click OK.**

**CRF Blank Selection(s) Processing**

- Mark this CRF as having no responses
- Mark section SITE CARDIAC MRI(1) as having no responses

**Help** **Cancel** **OK**

**If applicable for the study, mark the "Is Blank" checkbox instead of using the **Blank Flag Tool**.**

Study: RDC\_TRAIN6, Site: 001, Patient: 001-03, Casebook: RDC DEMO STUDY- (Dm One - Data management ro)

Highlight: None

page 1

**Medtronic**  
Alleviating Pain - Restoring Health - Extending Life

Study RDC\_TRAIN6

Subevent# 0

Visit Name

SCREENING

Patient 001-03

Site 001

Is Blank

# Data Entry: Marking a CRF as Blank (cont.)

ORACLE RDC Onsite: Data Entry

Study: TPVF, Site: TEST SITE, Patient: X1, Casebook: MELODY CASEBOOK- (Greg Smit - RDC Clinical IT)

Highlight: All Discrepancies

Medtronic

TPV Feasibility Study

CRF 09: SITE MRI

Visit Name: UNPLANNED MRI

Subject ID: X1

1. Date of CMR:  (dd-mon-yyyy)

2. Follow-up interval

- Pre-implant
- 6 months
- Non-protocol exam

3. Height and Weight

Height  cm  Unable to assess

Weight  kg  Unable to assess

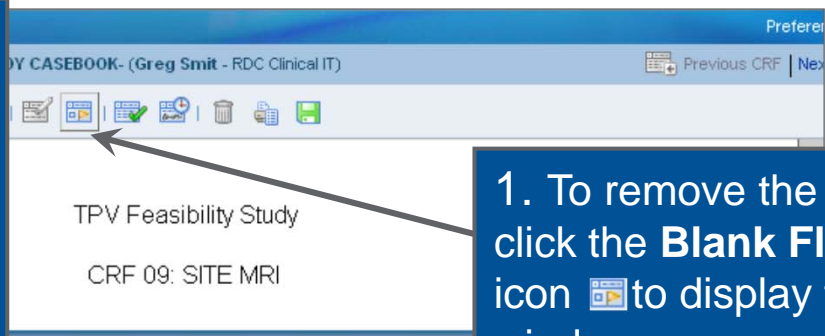
4. Data

Heart Rate	<input type="text"/>	bpm	<input type="checkbox"/> Unable to assess
Right Ventricular End Diastolic Volume	<input type="text"/>	ml	<input type="checkbox"/> Unable to assess
Right Ventricular End Systolic Volume	<input type="text"/>	ml	<input type="checkbox"/> Unable to assess
Left Ventricular End Diastolic Volume	<input type="text"/>	ml	<input type="checkbox"/> Unable to assess
Left Ventricular End Systolic Volume	<input type="text"/>	ml	<input type="checkbox"/> Unable to assess
Left Ventricular Mass	<input type="text"/>	g	<input type="checkbox"/> Unable to assess
Right Ventricular Mass	<input type="text"/>	g	<input type="checkbox"/> Unable to assess
Pulmonary Forward Flow	<input type="text"/>	ml/beat	<input type="checkbox"/> Unable to assess
Pulmonary Backward Flow	<input type="text"/>	ml/beat	<input type="checkbox"/> Unable to assess

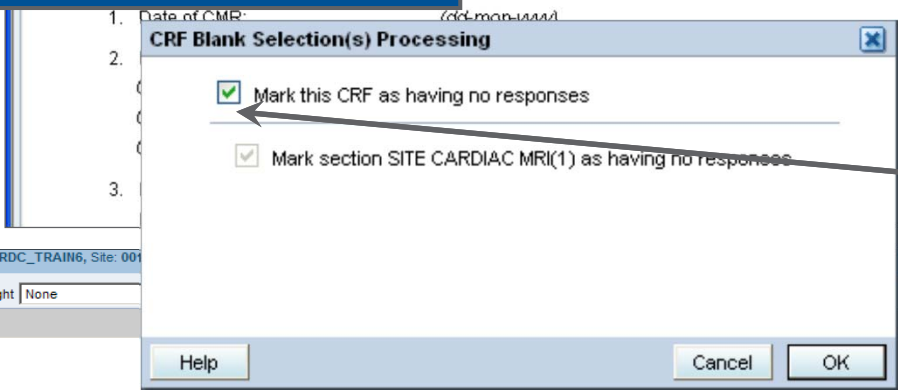
Copyright © 2000, 2007, Oracle. All rights reserved.

# Data Entry: Reversing a Blank Flag

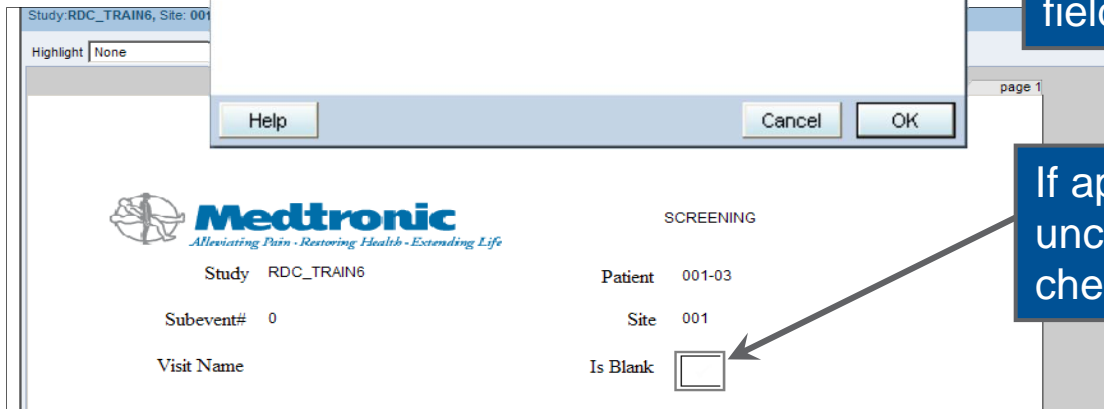
A CRF or sections of a CRF could also be automatically marked as blank if it is Saved Complete, but no data have been entered.



1. To remove the blank flag, click the **Blank Flag Tool** icon  to display the popup window.



2. Uncheck all checkboxes, and click **OK**. This will make the data fields enterable again.



If applicable for the study, uncheck the "Is Blank" checkbox to enter data.

# Data Entry: Unplanned CRFs

**Add Visit Page** or **Add Other Page** are used to collect unplanned CRFs. Refer to study materials for further guidance on when these functions should be used and for the applicable CRFs.

Patient Casebooks

Search : 1 Patients Selected From Home Page

Casebook Spreadsheet

Patients: Previous 1-1 of 1 Next

Casebook View: COMPLETE Visit: SCREENING

Go Add Visit Page Add Other Page

1. Select the visit.

2. Select a patient (only one).

3. Click appropriate button.

Select	Patient	Demog	History	Labcon	VIT	History.1
<input checked="" type="checkbox"/>	A00.00	1	2	3	4	U

# Data Entry: Unplanned CRFs

Patient Casebooks

+ Search : 1 Patients Selected From Home Page

Casebook Spreadsheet

Patients: Previous 1-1 of 1 Next Casebook View: COMPLETE Visit: SCREENING

Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page

Select All Select None

	Labcon	VIT	History.1	
	3	4	U	

RDC Onsite: Add Visit Page -- Web Page Dialog

Add Visit Page

Study RDC0553 Site A00

Visit SCREENING Patient A00.00

CRFs

Select CRF and Continue

Select CRF Name

- History
- Labcon
- VIT

RDC Onsite: Add Visit Page -- Web Page Dialog

Add Visit Page

Study RDC0553 Site A00

Visit SCREENING Patient A00.00

Selected CRF History

Select Sub-visit 1

4. From the popup, select the CRF and click **Continue**.



5. In the new popup, select the next available number for the visit.

6. Click on the **Entry Expected Icon** to enter data.



# Data Entry: Unplanned CRFs

Additional visits will have Sub-visit numbers

Event	Event.1
 28	 28 U1

The first visit is always visit 0.

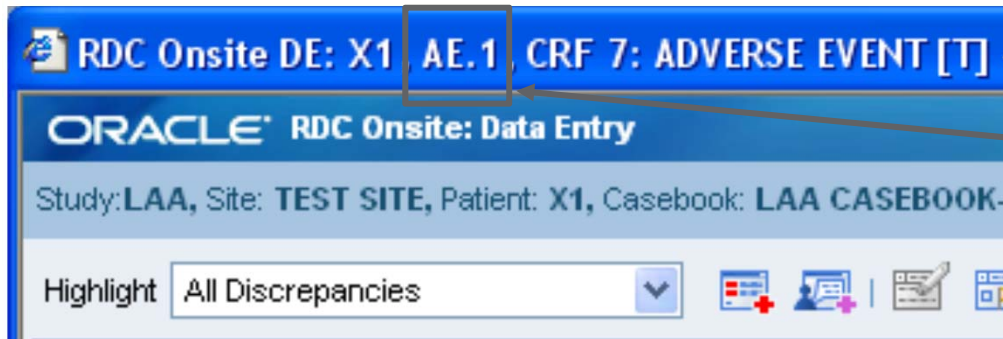
Additional visits are displayed with the CRF name followed by the Sub-visit number.

RDC Onsite DE: X1 AE.1 CRF 7: ADVERSE EVENT [T] -

ORACLE® RDC Onsite: Data Entry

Study: LAA, Site: TEST SITE, Patient: X1, Casebook: LAA CASEBOOK-

Highlight All Discrepancies



The Sub-visit number is also displayed on the top of the CRF.



# Discrepancy Management



# Discrepancy Management: Discrepancy types

- Discrepancies result when data fail to pass specified validation criteria

Discrepancies can be created 3 different ways:

1. **Univariate:** As data are entered, a discrepancy is created on that individual field (e.g., An age of 92 is out of an expected range of 18 to 85).
2. **Multivariate:** When a CRF is *Saved Complete* (either immediately after or after a nightly batch validation), discrepancies are created that consider multiple data points (e.g., The date of a study procedure was earlier than the date informed consent was signed).
3. **Manual:** A discrepancy can be manually created on any section or field.

# Discrepancy Management: Univariate Discrepancies

As data are entered, some checks are performed on the data.


The screenshot shows a data entry form for a study. The form includes the Medtronic logo, the text "A Study of the Ca", "Visit Name: BASELINE", and "Date of Evaluation: 08 NOV-2008 (dd-mon-yy)". Below this is the section "PRE-OPERATIVE SUBJECT INFORMATION" with two items: "1. Age at evaluation: old years" and "2. Gender: Male". A "Validation Error" dialog box is overlaid on the form. The dialog box has a title bar "Validation Error" and a close button. It contains the following fields: "Reason" set to "Data Type", "Description" with the text "The response to question '1. Age at evaluation' must be a valid NUMBER. The current response is 'old'. Please confirm or correct.", "Comment (optional)" (empty), "Action" (empty), and "Review Status" set to "Discrepancy not yet reviewed". At the bottom of the dialog box are buttons for "Help", "Cancel", and "OK". An arrow points from the text box above to the "old" value in the form, and another arrow points from the "Cancel" button in the dialog box to the text box below.

If data are discrepant, a message will appear:

- Click **Cancel** to make corrections to the data
- Click **OK** to create a discrepancy

# Discrepancy Management: Adding Manual Discrepancies

1. Click on the field that will receive the discrepancy.

2. Click the **Add Discrepancy** icon  in the toolbar.

3. Choose the reason.

4. Enter description.

5. Select desired routing location, and click **OK**.

If a discrepancy applies to multiple fields within a section, select **Section Discrepancy**.

# Discrepancy Management: Colors

The screenshot shows a web-based form for a study visit. The form includes fields for 'Visit Name: BASELINE' and 'Date of Evaluation: 04-NOV-2008'. Under the heading 'PRE-OPERATIVE SUBJECT INFORMATION', there are four numbered sections. Section 1 shows 'Age at evaluation: 01d years' with '01d' highlighted in yellow. Section 2 shows 'Gender' with 'Male' selected. Section 3 shows 'Race' with 'Black or African American' selected. Section 4 shows 'Physical examination' with 'Height 105 inches' (105 highlighted in red) and 'Weight 196 pounds' (196 highlighted in green). A blue callout box in the upper right explains the colors: Yellow for active for another user role, Red for active for the current user role, and Green for manually closed. A second blue callout box with an arrow points to a left-pointing arrow on the right side of the form, instructing the user to click it to expand the Navigator Pane.

Discrepancies are represented by 1 of 3 colors:

- Yellow:** Discrepancy is active for another user role
- Red:** Discrepancy is active for the current user role
- Green:** Discrepancy has been manually closed

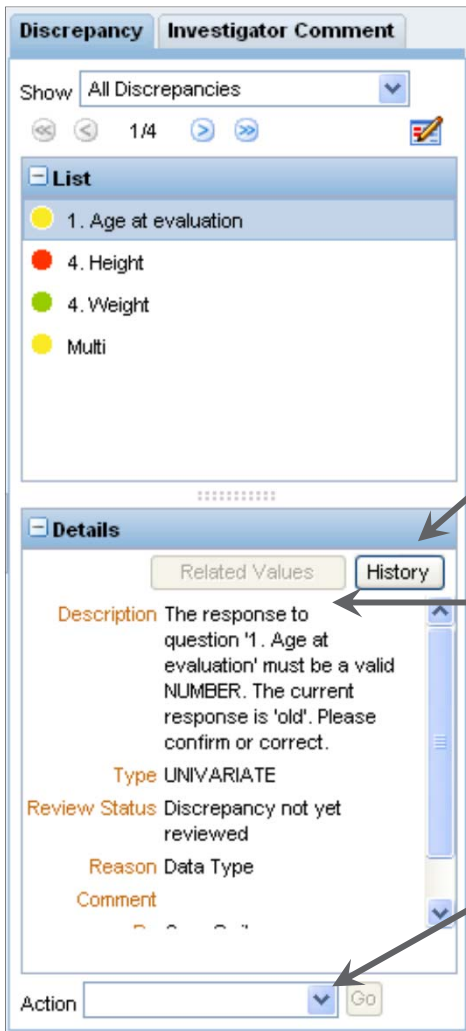
Click the left arrow to expand the Navigator Pane and work with discrepancies.

# Discrepancy Management: Navigator Pane


The screenshot displays a web application interface for discrepancy management. At the top, a navigation bar includes a 'Highlight' dropdown set to 'All Discrepancies', a toolbar with various icons, and a 'Page 1/4' indicator. The main content area is divided into two panes. The left pane shows a form for 'CRF 2: BASELINE' with a 'Visit Name: BASELINE' and a 'Date of Evaluation: 02-SEP-2008'. Under the heading 'PRE-OPERATIVE SUBJECT INFORMATION', there are three questions. The first question, 'Age at evaluation: old years', has the word 'old' highlighted with a blue dashed box. The second question is 'Gender:' with radio buttons for 'Male' and 'Female'. The third question is 'Race: (check all that apply)' with checkboxes for 'American Indian or Alaska Native', 'Asian', 'Black or African American', 'Native Hawaiian or Other Pacific Islander', and 'White'. The right pane is titled 'Discrepancy Investigator Comment' and contains a 'List' of discrepancies: '1. Age at evaluation' (yellow circle), '4. Height' (red circle), '4. Weight' (green circle), and 'Multi' (yellow circle). Below the list is a 'Details' pane with 'Related Values' and 'History' buttons. The 'Description' field contains the text: 'The response to question '1. Age at evaluation' must be a valid NUMBER. The current response is 'old'. Please confirm or correct.' The 'Type' is 'UNIVARIATE' and the 'Review Status' is 'Discrepancy not yet reviewed'. A blue box at the bottom of the screenshot contains the following text:

- Univariate discrepancies are listed with the question name
- Multivariate discrepancies are listed as "Multi" since they may deal with more than one question across more than one CRF

# Discrepancy Management: Navigator Pane (cont.)

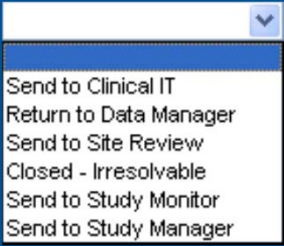


Click the **Update** icon  to update the discrepancy comment.

Click the **History** button  to show the history of the discrepancy.

For multivariate discrepancies, click the **Related Values**  button to see related values affected by the discrepancy.

Use the **Action** dropdown to route the discrepancy back to the Sponsor.  
**Note:** once a discrepancy has been made "Closed - Irresolvable", it can't be altered or re-opened in RDC. Create a new manual discrepancy or contact Data Management for assistance.





# Discrepancy Management: Discrepancy Review

1. Click the Review tab.

2. Click the Discrepancies sub-tab.

3. Set the Discrepancy Status filter to Active.

4. Click Go.

Discrepancies

Study TPVF Site TEST SITE Patients Selected 3 Total CRFs

Search

Patient: Range [ ] - [ ]

CRF Status: Entry All Approval All Verification All

CRF Source: Casebook All Visit All CRF Name All

Discrepancy: Status Active

Clear Go

Discrepancies

Refresh

Patient Number	Visit Name	Visit Date	CRF Name	Question / Section	Response	Review Status	Description	Open Detail	Open CRF
X2	PRE-IMPLANT		CRF 08: SITE ECHO	Followup interval		CLIN IT REVIEW	The question 'Followup interval' has not been answered. Please enter a response.		
X3	PRE-IMPLANT		CRF 02: BASELINE	<a href="#">MULTI</a>	<a href="#">MULTI</a>	CLIN IT REVIEW	RVOT Conduit Type is provided, please specify conduit size.		
X9	PRE-IMPLANT		CRF 02: BASELINE	<a href="#">MULTI</a>	<a href="#">MULTI</a>	CLIN IT REVIEW	Conduit size is specified, please determine RVOT Conduit Type.		

A list of ALL your Active discrepancies will be displayed.

# Discrepancy Management: Discrepancy Review (cont.)







If available, click the **Detail** icon to display details about the discrepancy.

Click the **CRF** icon to open the CRF and work on the discrepancy.

Clear Go

**Discrepancies**

Refresh

Patient Number	Visit		CRF Name	Question / Section	Response	Review Status	Description	Detail	Open CRF
	Name	Date							
X2	PRE-IMPLANT		CRF 08: SITE ECHO	Followup interval		CLIN IT REVIEW	The question 'Followup interval' has not been answered. Please enter a response.		
X3	PRE-IMPLANT		CRF 02: BASELINE	<a href="#">MULTI</a>	<a href="#">MULTI</a>	CLIN IT REVIEW	RVOT Conduit Type is provided, please specify conduit size.		
X9	PRE-IMPLANT		CRF 02: BASELINE	<a href="#">MULTI</a>	<a href="#">MULTI</a>	CLIN IT REVIEW	Conduit size is specified, please determine RVOT Conduit Type.		



## Discrepancy Management: Summary - Resolving Discrepancies (Site)

1. Review the discrepancy in the Navigator Pane.
2. Update the data on the CRF (if necessary) and save the changes.
3. If the discrepancy does not automatically close or if the data on the CRF does not need to be updated, route the discrepancy to the sponsor with a comment to indicate the status of the discrepancy (e.g., data updated or Event form added).

# Discrepancy Management: Validation Function

Some discrepancies will not fire until a patient's data have been validated. This occurs automatically once per day; however a user may force validation on their own.

Validation can be run on one or more subjects from the casebook tab. The option is only available to roles with update access in OnSite.

Select	Patier	Number	
<input checked="" type="checkbox"/>		99960001	
<input checked="" type="checkbox"/>		99960002	
<input checked="" type="checkbox"/>		99960003	
<input checked="" type="checkbox"/>		99960004	
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

1. From the casebook tab select the subjects to validate.
2. Select the **Validate** option and click **Go**.

# Discrepancy Management: Validation Function (cont.)



RDC Onsite: Validate Patients -- Web Page Dialog

**Validate Patients**

**Warning**  
You have requested validation for 4 patients. This may take several moments to execute. Do you wish to continue?

Cancel Continue

3. A pop-up box will appear.  
4. Click **Continue** to start validation.

5. A confirmation window will appear when validation is complete.



**Validate Patients**

**Confirmation**  
Validation successful.

Close



# eSignatures



# eSignatures: Monitor Verification

- Verified means monitored in RDC terminology (i.e. source document verified)
- Only Study Monitors have the capability to verify CRFs
- If data changes or discrepancies are added or closed on a verified CRF, the form will require re-verification



# eSignatures: Investigator Approval

- An approval is a 21 CFR Part 11 electronic signature. It is the equivalent of a handwritten signature on a paper CRF
- Only investigators have the capability to approve CRFs
- Coordinators cannot approve CRFs on the Investigator's behalf
- CRFs can be approved 2 ways:
  - Individual Approval: Each CRF is opened and approved
  - Group Approval: After reviewing a batch of CRFs you may approve them at the same time
- Regardless of the method used to approve, the Investigator is responsible for the data submitted and required to approve each CRF

Note: If you have just changed your password, log out of RDC and repeat login using the new password before approving any CRFs. This will ensure the new password is in effect during the Approval process.





# Reports



# Reports: Types

## Two types of reports are available:

1. **Patient Data Report:** Creates a PDF file containing all or selected CRFs entered for a patient(s). The data fields are populated with values entered for the CRFs. This report may be useful for investigator review of hardcopy CRFs, or for an FDA audit where patient data has been requested.
2. **Blank Casebook Report:** Creates a PDF file containing all the CRFs that may be collected during the study. This may be useful for creating source doc worksheets, or for becoming familiar with the CRFs at the start of the study.

Note: Patient Data Reports may be generated from the Home, Casebook, Review or Reports tabs. Blank Casebook Reports may be generated from the Reports tab only.

# Reports: Generating all data entered for Patient(s)

1. Click the **Casebooks** tab.

2. Search by patient.

3. Select the patient(s) you want to include in the report.

4. From the drop-down, select "Generate Patient Data Report" and click **GO**.

Home Casebooks Review Reports

Logged in as Cs Inv1(Investigator, CSOPA); Last Refresh 20-Oct-2011 16:15:3

Study and Site TPVFTR 129213 Study and Site Summary

Patient Casebooks

Search

Patients: Range - Assigned Book Any Show All

Entry: All Discrepancy All Approval All Verification All

Casebook: All Visit: All CRF Name: All

Clear Go

Spreadsheet

Patients: Patient: All Casebook: FULL BOOK Visit: PRE-IMPLANT

Previous: 1-10 of 10 Next

CRFs: Previous 1-10 of 13 Next

Actions and... Generate Patient Data Report Go Add Visit Page Add Other Page

Select Non-Patient

Approve  
UnApprove  
Review Discrepancies  
Review Entered CRFs  
Review Investigator Comments  
Validate  
Generate Patient Data Report

Number	1	2	4	Crf_7	Crf_25
99960001					144
99960002					144
99960003					144
99960004					144

# Reports: Generating all data entered for Patient(s) (cont.)

The screenshot shows the ORACLE RDC Onsite interface. At the top, there is a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports' tabs. A confirmation message states: '1 Patient Data Report job(s) have been submitted. Please select the Reports tab to view the status of your request(s)'. Below this, there is a search area for 'Patient Casebooks' with various filters. A 'Generate Patient Data Report' button is visible. At the bottom, a table lists patient data for 'PRE-IMPLANT' with columns for 'Patient Number' and various 'Crf' (CRF) forms.

**Confirmation**  
1 Patient Data Report job(s) have been submitted. Please select the Reports tab to view the status of your request(s).

**Patient Casebooks**

**Casebook Spreadsheet**

Patients: Previous 1-1 of 1 Next Casebook View: FULL BOOK Visit: PRE-IMPLANT CRFs: Previous 1-10 of 11 Next

Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page Refresh

Select All Select None

Select	Patient	Crf_1	Crf_2	Crf_7	Crf_8	Crf_9	Crf_10	Crf_17	Crf_18	Crf_23	Crf_25
<input type="checkbox"/>	99960004	1	2	4	5	7	8	9	11	122	144

A message will indicate the report is being created.

To access the report select the Reports tab.

# Reports: Generating single CRF Data

**ORACLE® RDC Onsite** Logout Help

Home Casebooks Review **Reports**

CRFs Discrepancies Investigator Comments

Patient CRFs

Study TPVFTR Site 129213 Patients Selected 1 Total CRFs 5

Search

Patient: Range 99960004 Assigned Book Any

Status: Entry All Discrepancy All Approval All Verification All

Source: Casebook All Visit All CRF Name All

Clear Go

CRFs and... Generate Patient Data Report Go

Patient Number	Visit Name	Date	CRF Name	Created	Locked	Open CRF
<input type="checkbox"/>	99960004 PRE-IMPLANT		12-LEAD ECG			
<input type="checkbox"/>	99960004 PRE-IMPLANT		BASELINE SUBJ CHARACTERISTICS	R11183813	FULL BOOK	12-Aug-2009
<input type="checkbox"/>	99960004 PRE-IMPLANT		SITE CARDIAC MRI	R23089613	FULL BOOK	19-Aug-2010
<input checked="" type="checkbox"/>	99960004 PRE-IMPLANT		SITE ECHO	R20499113	FULL BOOK	12-Aug-2010
<input checked="" type="checkbox"/>	99960004 PRE-IMPLANT		SUBJECT ELIGIBILITY-ENROLLMENT	R11183613	FULL BOOK	12-Aug-2009

Home Casebooks Review Reports Logout Preferences Change Password Help

2. Search by patient.  
3. Select the CRFs you want to include in the report.

1. Click the Review tab.

4. From the drop-down, select "Generate Patient Data Report" and click GO.

# Reports: Generating single CRF Data (cont.)

The screenshot displays the ORACLE RDC Onsite web application. At the top, there are navigation tabs for Home, Casebooks, Review, and Reports. The Reports tab is currently selected. Below the navigation, there is a confirmation message: "Confirmation: 1 Patient Data Report job(s) have been submitted. Please select the Reports tab to view the status of your request(s)." A blue callout box with white text points to the Reports tab and says "To access the report select the Reports tab." Another blue callout box with white text points to the confirmation message and says "A message will indicate the report is being created." Below the message, there is a search area with fields for Patient (Range: 99960004), CRF Status (Entry), Discrepancy (All), Approval (All), and Verification (All). A table of CRF data is shown below the search area. The table has columns for Patient Number, Name, Date, CRF Name, CRF Number, Casebook, Modified, Verified, Approved, Locked, and Open CRF. The table contains five rows of data for patient 99960004.

Select	Patient Number	Name	Date	CRF Name	CRF Number	Casebook	Modified	Verified	Approved	Locked	Open CRF
<input type="checkbox"/>	99960004	PRE-IMPLANT		12-LEAD ECG	R12179113	FULL BOOK	12-Aug-2009		12-Aug-2009		
<input type="checkbox"/>	99960004	PRE-IMPLANT		BASELINE SUBJ CHARACTERISTICS	R11183813	FULL BOOK	12-Aug-2009		12-Aug-2009		
<input type="checkbox"/>	99960004	PRE-IMPLANT		SITE CARDIAC MRI	R23089613	FULL BOOK	19-Aug-2010				
<input type="checkbox"/>	99960004	PRE-IMPLANT		SITE ECHO	R20499113	FULL BOOK	12-Aug-2010	12-Aug-2010			
<input type="checkbox"/>	99960004	PRE-IMPLANT		SUBJECT ELIGIBILITY-ENROLLMENT	R11183613	FULL BOOK	12-Aug-2009		12-Aug-2009		

# Reports: Patient Data Report Example

Report contains bookmarks for easy navigation.

Printing a PDR from the Reports tab will result in all CRFs.

Printing a PDR from the Review tab allows you to select specific CRFs.

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# Reports: Generating Blank Casebook

Home Casebooks Review **Reports**

Logged in as Donna Syverson(RDC Data Manager, NGOPA); Last Refresh 22-Jan-2012 18:18: [Study and Site Summary](#)

Reports

Search

Job Name

Show Jobs All

Report Jobs

Previous 1-50 of 196 Next 50

Job Name	Start Time	End Time	Status	View Report	Stop Report
<a href="#">PT X1 18893625</a>	22-Jan-2012 18:03:09	22-Jan-2012 18:03:54	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18893625.pdf</a>	
<a href="#">16300529 18709825</a>	19-Dec-2011 14:37:20	19-Dec-2011 14:38:11	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18709825.pdf</a>	
<a href="#">16300529 18709425</a>	19-Dec-2011 14:11:34	19-Dec-2011 14:13:37	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18709425.pdf</a>	
<a href="#">CRFS 18483525</a>	16-Nov-2011 18:48:31	16-Nov-2011 18:48:31	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18483525.pdf</a>	
<a href="#">PT 16260101 18483125</a>	16-Nov-2011 18:48:31	16-Nov-2011 18:48:31	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18483125.pdf</a>	
<a href="#">PT X101 18482925</a>	16-Nov-2011 18:48:29	16-Nov-2011 18:48:29	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18482925.pdf</a>	
<a href="#">16303603 18474825</a>	15-Nov-2011 18:47:47	15-Nov-2011 18:47:47	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18474825.pdf</a>	
<a href="#">16303603 18474725</a>	15-Nov-2011 18:47:47	15-Nov-2011 18:47:47	SUCCESS	<a href="#">\\ns0mxop06\log\ngopa\syverd2\p18474725.pdf</a>	

1. Click the Reports tab.

2. Click on New Blank Casebook Report.

A Patient Data Report can also be requested from the Review tab.



# Reports: Generating Blank Casebook (cont.)

Home Casebooks Review Reports

Reports > Logged in as Donna Syverson(RDC Data Manager, NGOPA); Last Refresh 22-Jan-2012 18:43:

New Blank Casebook Report

\* Indicates required field

**Blank Casebook report**

Cancel Submit Job

**Report Parameters**

\* Casebook TEST\_BOOK Date Format dd-mon-yyyy(Standard)

Patient Number  Orientation  Portrait  LandScape

**TIP** You can select a patient to print a blank patient-specific casebook.

**Job Parameters**

Report Server REPORT\_SERVER

Job Name Prefix TEST\_BOO

Job Id 18894325

Job Name TEST\_BOO\_18894325

Output File Name \\mspmxop06\log\ngopa\syverd2\p18894325.pdf

Cancel Submit Job

3. Select from the various report parameters.

4. Then click **Submit Job**.

Home Casebooks Review Reports

Reports > Logged in as Donna Syverson(RDC Data Manager, NGOPA); Last Refresh 22-Jan-2012 18:23:5

New Patient Data Report

\* Indicates required field

**Patient Data report**

Cancel Submit Job

**Report Parameters**

\* Study Site 598325

Patient All

CRF Date Range No Limit

Casebook

Mark Values

Include Audit History

Include Discrepancy Details

Include CRFs entered in classic data entry

Date Format dd-mon-yyyy(Standard)

Orientation  Portrait  LandScape

**CRF Status:** Discrepancy All Approval All Verification All

**Job Parameters**

Report Server REPORT\_SERVER

Job Name Prefix

Job Id 18893825

Job Name 18893825

Output File Name \\mspmxop06\log\ngopa\syverd2\p18893825.pdf

Cancel Submit Job

# Reports: Generating Blank Casebook (cont.)

Home Casebooks Review Reports

Logged in as Donna Syverson(RDC Data Manager, NGOPA); Last Refresh 22-Jan-2012 18:36:26

**Warning**

Are you sure you want to submit the report job "TEST\_BOO\_18894025" ?

No Yes

No Yes

5. Click Yes when prompted.

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Home Casebooks Review Reports

Logged in as Donna Syverson(RDC Data Manager, NGOPA); Last Refresh 22-Jan-2012 18:51:11

Confirmation

Job TEST\_BOO\_18894325 has been submitted successfully. It may take several moments for the job to complete.

Reports

Search

Job Name

Show Jobs All

Go

Report Jobs

New Patient Data Report New Blank Casebook Report

Previous 1-50 of 197 Next 50

Job Name	Start Time	End Time	Status	View Report	Stop Report
<a href="#">TEST_BOO_18894325</a>			SUBMIT_TO_RS	\\mspmxop06\log\ngopa\syverd2\o18894325.pdf	

A message will indicate the report is being created. It may take 10 – 15 minutes for large reports.

A red stoplight icon indicates the report is still being created. Clicking it will stop the report.

## Reports: Generating Blank Casebook (cont.)

Home Casebooks Review Reports

Reports

Search

Job Name

Show Jobs All

Last Refresh 22-Jan-2012 18:18: Study and Site Summary

When the report is complete, the stoplight icon will disappear and the status will indicate success.

Report Jobs

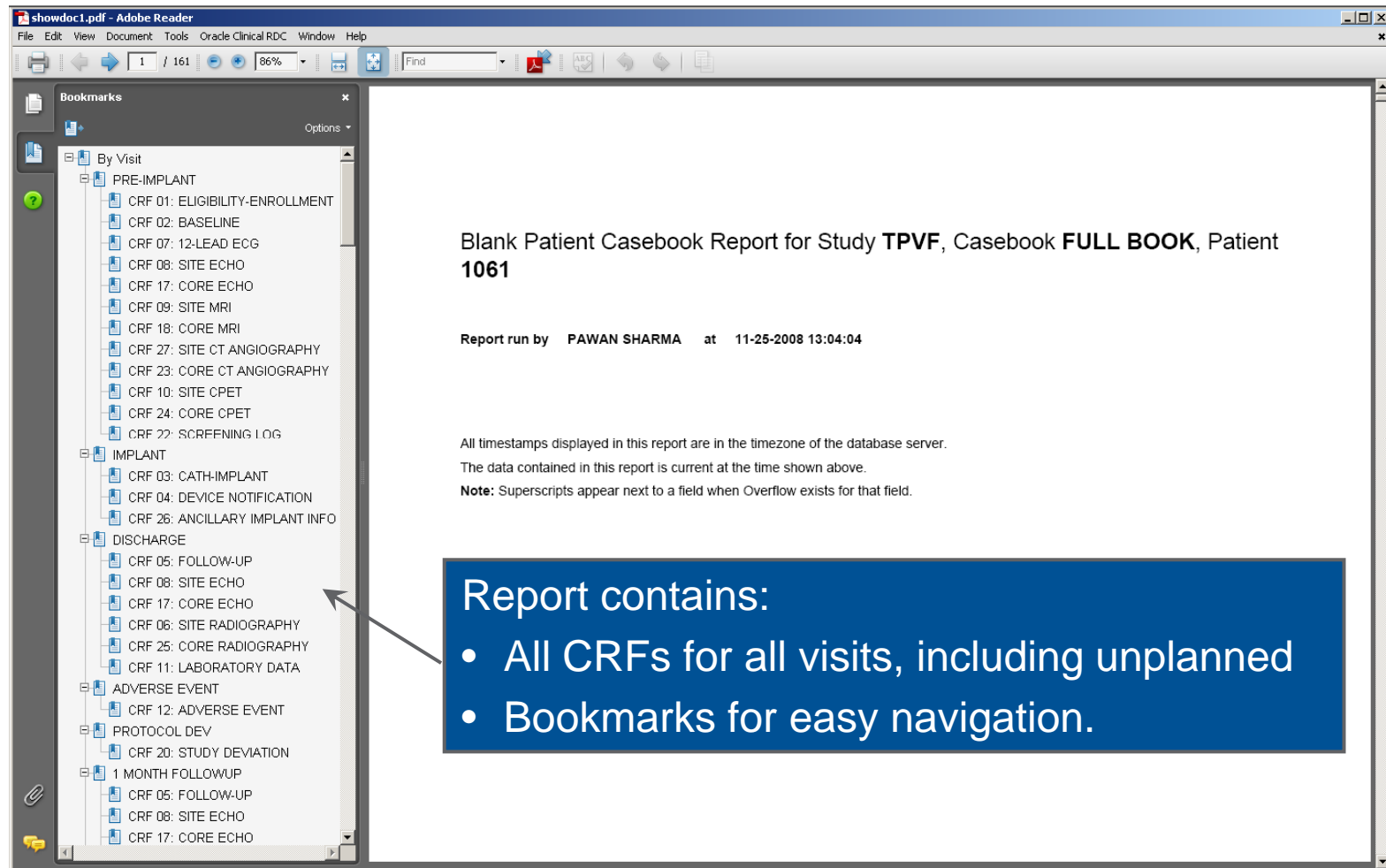
New Patient Data Report New Blank Casebook Report

Previous 1-50 of 196 Next 50

Job Name	Start Time	End Time	Status	View Report	Stop Report
<a href="#">PT_X1_18893625</a>	22-Jan-2012 18:03:09	22-Jan-2012 18:03:54	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18893625.pdf</a>	
<a href="#">16300529_18709825</a>	19-Dec-2011 14:37:20	19-Dec-2011 14:38:11	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18709825.pdf</a>	
<a href="#">16300529_18709425</a>	19-Dec-2011 14:11:24	19-Dec-2011 14:12:27	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18709425.pdf</a>	
<a href="#">CRFS_18483525</a>	16-Nov-2011 15:17:23	16-Nov-2011 15:17:28	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18483525.pdf</a>	
<a href="#">PT_16260101_18483125</a>	16-Nov-2011 15:16:07	16-Nov-2011 15:21:32	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18483125.pdf</a>	
<a href="#">PT_X101_18482925</a>	16-Nov-2011 15:14:27		RS_FAILURE	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18482925.pdf</a>	
<a href="#">16303603_18474825</a>	15-Nov-2011 09:16:43	15-Nov-2011 09:17:49	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18474825.pdf</a>	
<a href="#">16303603_18474725</a>	15-Nov-2011 09:12:13	15-Nov-2011 09:13:25	SUCCESS	<a href="#">\\mspmxop06\log\ngopa\svvverd2\o18474725.pdf</a>	

6. Click the link to open the report.

# Reports: Blank Casebook Report Example



showdoc1.pdf - Adobe Reader

File Edit View Document Tools Oracle Clinical RDC Window Help

1 / 161 86% Find

**Blank Patient Casebook Report for Study TPVF, Casebook FULL BOOK, Patient 1061**

Report run by PAWAN SHARMA at 11-25-2008 13:04:04

All timestamps displayed in this report are in the timezone of the database server.  
The data contained in this report is current at the time shown above.  
**Note:** Superscripts appear next to a field when Overflow exists for that field.

**Report contains:**

- All CRFs for all visits, including unplanned
- Bookmarks for easy navigation.

**Bookmarks:**

- By Visit
  - PRE-IMPLANT
    - CRF 01: ELIGIBILITY-ENROLLMENT
    - CRF 02: BASELINE
    - CRF 07: 12-LEAD ECG
    - CRF 08: SITE ECHO
    - CRF 17: CORE ECHO
    - CRF 09: SITE MRI
    - CRF 18: CORE MRI
    - CRF 27: SITE CT ANGIOGRAPHY
    - CRF 23: CORE CT ANGIOGRAPHY
    - CRF 10: SITE CPET
    - CRF 24: CORE CPET
    - CRF 22: SCREENING LOG
  - IMPLANT
    - CRF 03: CATH-IMPLANT
    - CRF 04: DEVICE NOTIFICATION
    - CRF 26: ANCILLARY IMPLANT INFO
  - DISCHARGE
    - CRF 05: FOLLOW-UP
    - CRF 08: SITE ECHO
    - CRF 17: CORE ECHO
    - CRF 06: SITE RADIOGRAPHY
    - CRF 25: CORE RADIOGRAPHY
    - CRF 11: LABORATORY DATA
  - ADVERSE EVENT
    - CRF 12: ADVERSE EVENT
  - PROTOCOL DEV
    - CRF 20: STUDY DEVIATION
  - 1 MONTH FOLLOWUP
    - CRF 05: FOLLOW-UP
    - CRF 08: SITE ECHO
    - CRF 17: CORE ECHO



# Tips and Tricks



## Tips and Tricks: Window Size Too Small

If any window, for example a CRF window, opens too small and you would like it to always open larger:

1. Close all Internet Explorer windows.
2. Open one Internet Explorer window.
3. Set the size of this window to the desired size when future windows are opened.
4. While pressing the **Shift** key, click the “X” in the upper right-hand corner of the window to close it.

Next time an Internet Explorer window is opened, it will default to this new size.



## Tips and Tricks: Hot Keys

- Alt + P: Moves to previous CRF
- Alt + N: Moves to next CRF
- Alt + S: Saves the CRF
- Ctrl + W: Closes CRF
- In date fields:
  - T: enters today's date
  - Y: enters yesterday's date
- Tab: moves to the next field on a CRF
- Shift Tab: moves to the previous field on a CRF
- Alt + Tab: Allows you to toggle between applications.