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 <u>per study basis</u> 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.

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Login Process

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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**

Site Login Process:

- The system will send you a new, temporary password via email from helpdesk@medtronic.com or 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

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)

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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

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System Overview

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System Overview: Global Links

System Overview: Tabs

Tabs
- **Home**: Main screen where patients are selected
- **Casebooks**: Where data entry occurs
- **Review**: Where data review occurs
- **Reports**: Where reports are run

System Overview: Study and Site Selection
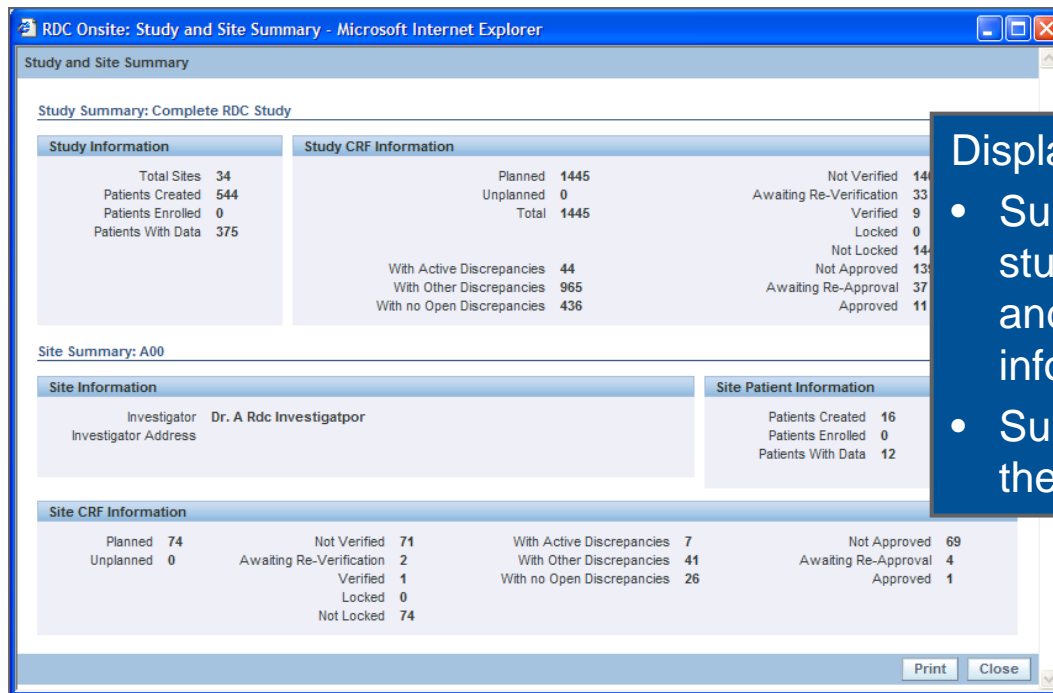

Study and Site selection

- 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

System Overview: Study and Site Summary
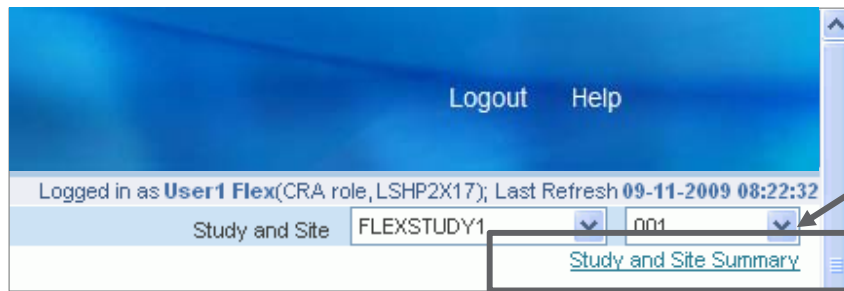
Clicking **Study and Site Summary** opens a display window

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

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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

- **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

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

Patients

Select Patients and... Open Patient Casebook

Select All | Select None

Click on a patient icon to display a patient summary

Select	👤	Patient Number	Last Modified	Casebook
☐	🧍	X1		
☐	🧍	X2		
☐	🧍	X3		
☐	🧍	X4		
☐	🧍	X5		
☐	🧍	X6		
☐	🧍	X7		
☐	🧍	X8		
☐	🧍	X9		
☐	🧍	X10		

Select Patients and... Open Patient Casebook

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

Patient Summary : X1

Patient Information

Patient	X1
Birthdate	1960-09-01
Gender	Male
Age	51
Site	394425
Latest Update	09-Feb-2012

Discrepancies

Active	17
Other	178
Closed	1
Total	196

CRFs

With Active Discrepancies	8
With Other Discrepancies	13
With no Open Discrepancies	19
Total	40
Earliest Entry	23-Oct-2007
Latest Entry	09-Feb-2012

CRFs Status

Not Verified	40
Awaiting Re-Verification	0
Verified	0
Not Approved	40
Awaiting Re-Approval	0
Approved	0

Visits

First	Enrollment 01-Dec-2007
Latest	Eiq - Retired 01-Jan-2011
Next	null null

configuration.

Print Close

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

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Data Entry

Data Entry: Patient Selection

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

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

2. Select **Open Patient Casebooks**

3. Click **Go**

Data Entry: Casebook Spreadsheet

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
- Approved

- Requires re-verification
- Requires re-approval

Multiple statuses may be displayed. For example, a CRF can
show a discrepancy, require re-approval and re-verification.
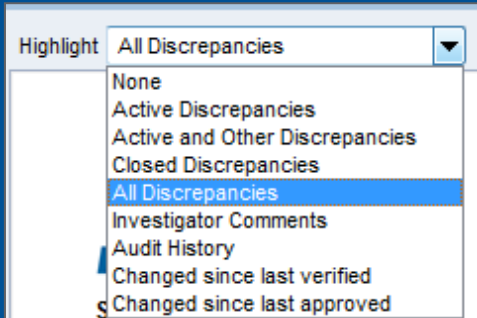
Data Entry: Entering a New CRF

- 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
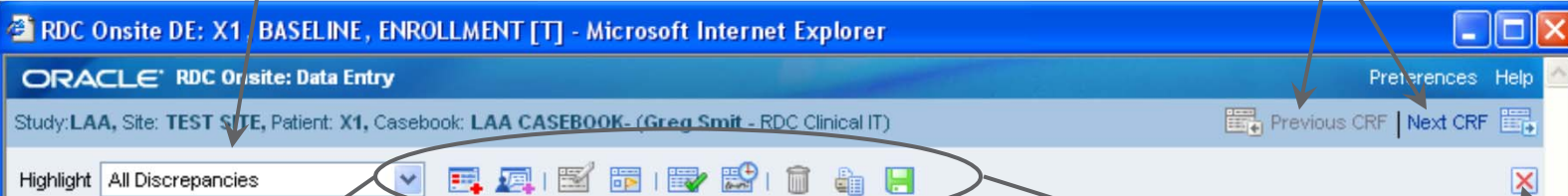
Data Entry: Data Entry Window

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   Preferences Help

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

Highlight All Discrepancies

Close CRF

Add Discrepancy

Delete Row

Verify

Delete CRF

Save

Add Investigator Comment

Blank Flag Tool

Approve

Print

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Data Entry: Entering Data

Header

Doc. No:

Subject ID:

Body - Data entered here

1. DEMOGRAPHICS

1.1 Patient Initials: _____ (first two

1.2 Date of Birth: [_____]

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

1.3 Gender: ○ Male
 ○ Female

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

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

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

☐ American Indian or Alaska Native ☐ White
☑ Asian ☑ Other, specif [____] 🔍
☐ Black or African American ☐ Subject Refused
☐ Native Hawaiian or Other Pacific Islander

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"

- **<u>Do not</u> enter any subject data as an Investigator Comment**

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Data Entry: Adding Investigator Comments

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

crosoft Internet Explorer

ORACLE RDC Onsite: Data Entry

Study: **LAA**, Site: **TEST SITE**, Patient: 2, Casebook: **LAA CASEBOOK-** (Greg Smit - RDC Clinical IT)

Highlight | All Discrepancies | Page 4/4

11. Is the subject currently taking an antiplatelet?
- ⊘ Yes; indicate all medications and start dates below:
- ○ No
  - ☐ Aspirin; start date: 02-APR-2008 (dd-mon-yyyy)
  - ☐ Plavix; start date: _____ (dd-mon-yyyy)
  - ☐ Other, specify: _____ start date: _____ (dd-mon-yyyy)

2. Click the Investigator Comment icon in the toolbar.

Add Investigator Comment

Investigator Comment | Medication start date may be off by a couple days

Help   Cancel   OK

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

Data Entry: Viewing/Editing Investigator Comments

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

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**.

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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.

Data Entry: Saving the CRF

1. Click the **Save** icon in the toolbar.

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!

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Data Entry: Closing the CRF

Click this button ☒ to close the CRF.

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:
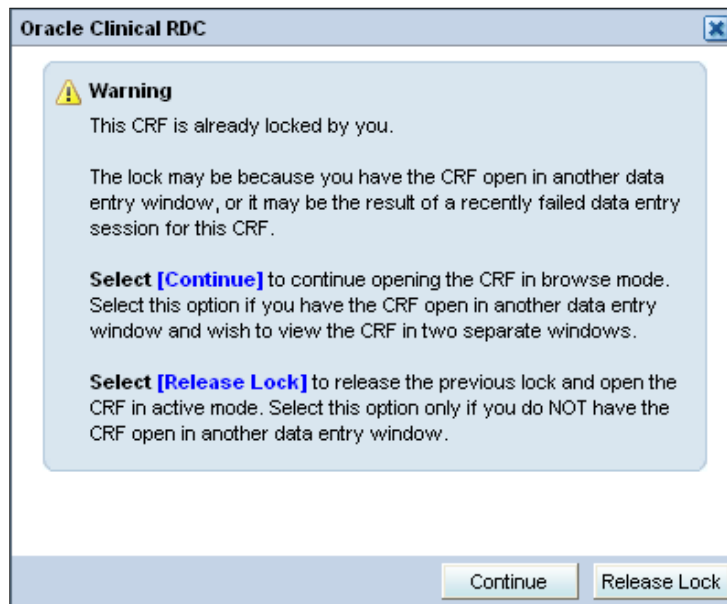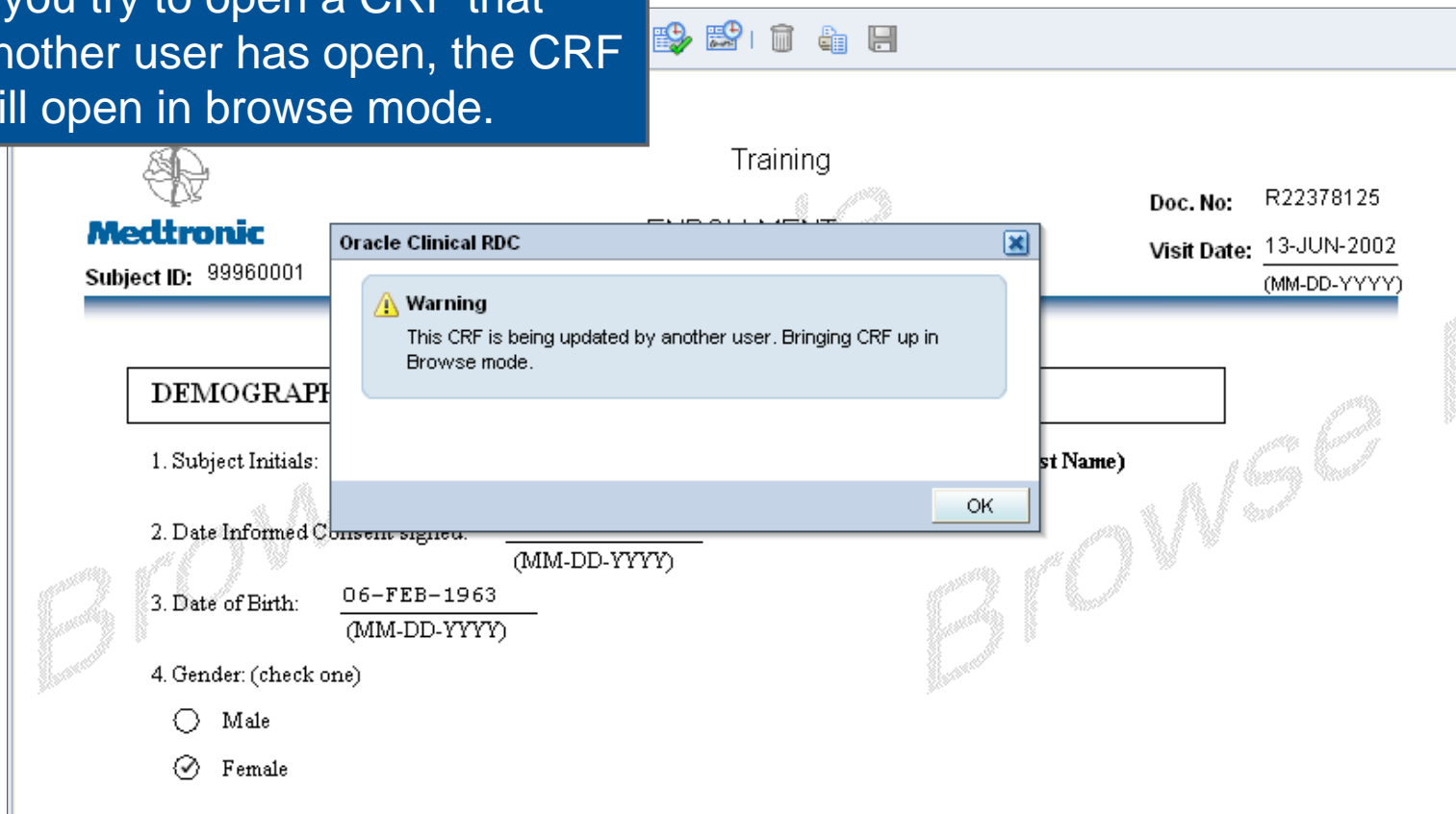

If you select **Release Lock** and close the original CRF a fatal error message will appear when closing.

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

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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.

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Subject ID: 99960001

Doc. No: R22378125

Visit Date: 13-JUN-2002

(MM-DD-YYYY)

DEMOGRAPH

Oracle Clinical RDC

⚠️ **Warning**

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

OK

st Name)

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

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.

RDC Onsite DE: X4, BASELINE, CRF 2: BASELINE [T] - Microsoft Internet Explorer

Preferences   Help

SEBOOK- (Greg Smit - RDC Clinical IT)

Previous CRF | Next CRF

4. Save the CRF.

page 1

1. Change the data.

the Cardioblate Clo...

Medtronic   CRF 2: BASELINE

Visit Name: BASELINE   Subject ID: X4

Date of Evaluation: 06-NOV-2008   (dd-mon-yyyy)

PRE-OPERATIVE SUBJECT INFORMATION

1. Age at evaluation: 46 years

2. Gender:
    ● Male
    ○ Female

3. Race: (check all th...
    ☐ American Indian
    ☐ Asian
    ☐ Black or African
    ☐ Native Hawaiian
    ☑ White

Reason for Change

*Reason   Data Entry Error

Comment (optional)   accidentally typed the wrong number

Help   Cancel   OK

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

3. Click **OK**.

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Data Entry: Viewing Audit History

In the Highlight dropdown, select **Audit History**.

All fields with an audit history will be highlighted in blue.

Click this arrow ▬▲▬ to show audit history details.

Data Entry: Audit History Details

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.

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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.

Data Entry: Deleting a Row

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.

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

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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**.

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

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

All data fields will now be grayed out. Save and close this CRF. It is now marked as "blank" and will appear in the casebook grid with a blank icon.

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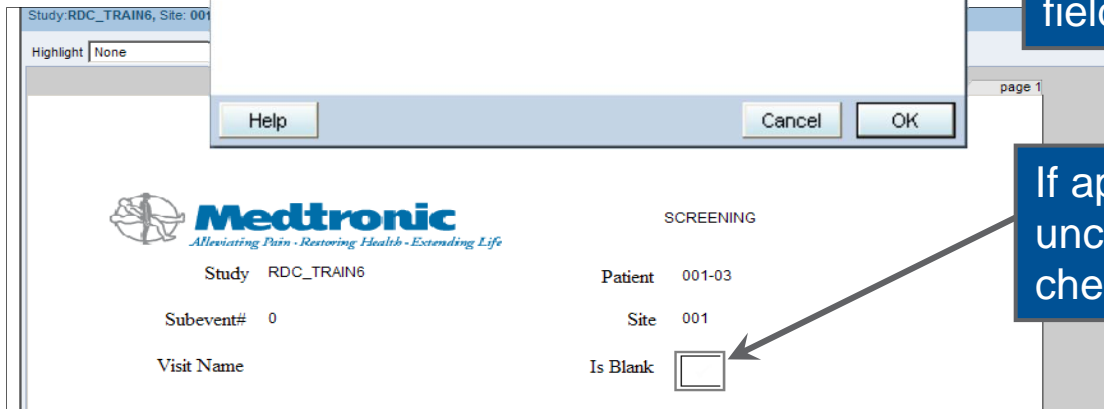
A CRF or sections of a CRF could also be automatically marked as blank if it is Saved Complete, but no data have been entered.

DY CASEBOOK- (Greg Smit - RDC Clinical IT)

Previous CRF | Ne

TPV Feasibility Study

CRF 09: SITE MRI

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

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
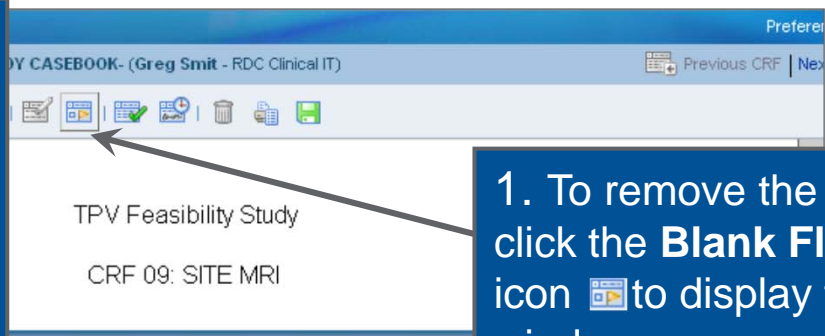
1. To remove the blank flag, click the **Blank Flag Tool** icon to display the popup window.
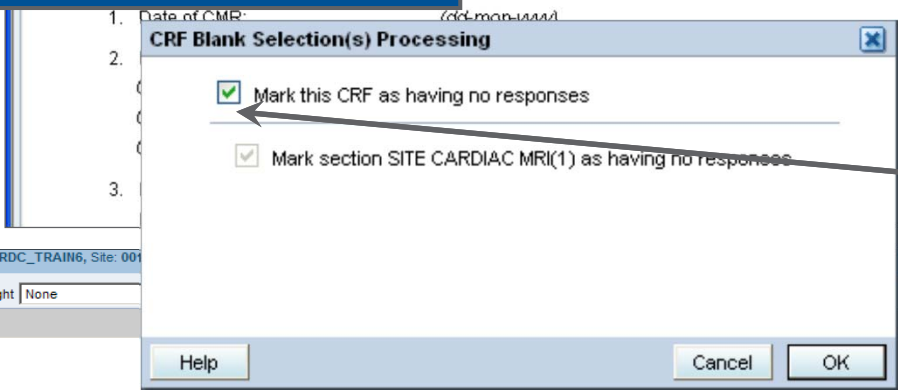
2. Uncheck all checkboxes, and click **OK**. This will make the data fields enterable again.

Study:RDC_TRAIN6, Site: 001

Highlight None

page 1

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SCREENING

Study   RDC_TRAIN6   Patient   001-03

Subevent#   0   Site   001

Visit Name   Is Blank   ☐

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.

Data Entry: Unplanned CRFs

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.

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Data Entry: Unplanned CRFs

Additional visits will have Sub-visit numbers

Event	Event.1
28	28 U1

The first visit is always visit 0.
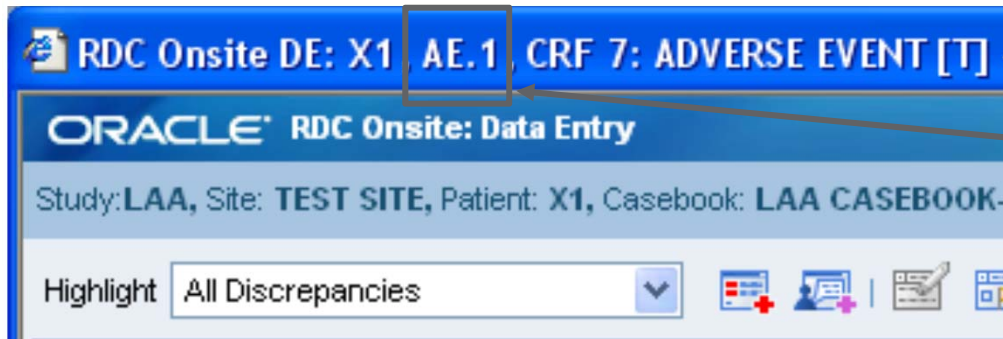
Additional visits are displayed with the CRF name followed by the Sub-visit number.

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.

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Discrepancy Management: Univariate Discrepancies

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

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

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

Click on a discrepancy in the list.

A blue dashed box is displayed around the question.

Details are displayed in the bottom right *Details* pane.

- 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

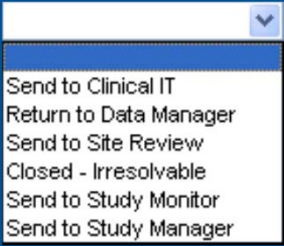# Discrepancy Management: Navigator Pane (cont.)
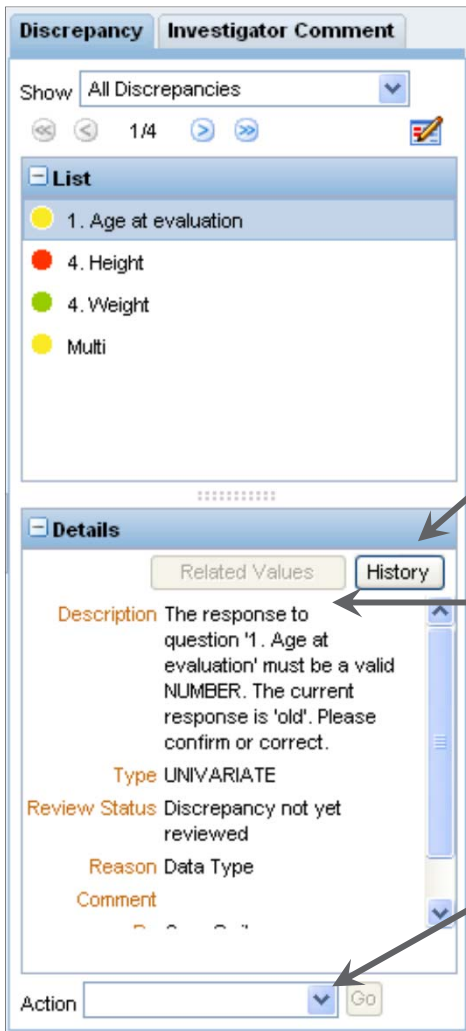
Click the **Update** icon to update the discrepancy comment.

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**.

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 Name	Date	CRF Name	Question / Section	Response	Review Status	Description	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	MULTI	MULTI	CLIN IT REVIEW	RVOT Conduit Type is provided, please specify conduit size.	🔳	🟥
X9	PRE-IMPLANT		CRF 02: BASELINE	MULTI	MULTI	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).

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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.

1. From the casebook tab select the subjects to validate.

2. Select the **Validate** option and click **Go**.

Discrepancy Management: Validation Function (cont.)

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

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

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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

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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.

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Reports

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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.

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Reports: Generating all data entered for Patient(s)

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

To access the report select the Reports tab.

A message will indicate the report is being created.

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Reports: Generating single CRF Data

Reports: Generating single CRF Data (cont.)

To access the report select the **Reports** tab.

A message will indicate the report is being created.

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.

Reports: Generating Blank Casebook

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.)

Blank Casebook report

3. Select from the various report parameters.

4. Then click **Submit Job**.

Patient Data report

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**

| No | Yes |

⚠ Warning

Are you sure you want to submit the report job "TEST_BOO_18894025"?

| No | Yes |

5. Click Yes when prompted.

About RDC 4.6.0   out   Preferences   Help
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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.

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

Reports

Search

Job Name [   ]
Show Jobs [All ▼]
[Go]

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

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**
TEST_BOO_18894325			SUBMIT_TO_RS	\\mspmxop06\log\ngopa\syverd2\o18894325.pdf	🚦

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Reports: Generating Blank Casebook (cont.)

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

6. Click the link to open the report.

Reports: Blank Casebook Report Example

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

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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.

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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.

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