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
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)
  o 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)
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

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

- 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

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

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

- **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.

### 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

### Example Patient Summary

#### Patient Information
- **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

#### Visits
- First Enrollment: 01-Dec-2007
- Latest Visit: 09-Feb-2012
- Latest Update: 09-Feb-2012

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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.

<table>
<thead>
<tr>
<th>Select</th>
<th>Patient Number</th>
<th>Last Modified</th>
<th>Casebook</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>0205</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
<tr>
<td>✓</td>
<td>0206</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
<tr>
<td>✓</td>
<td>0207</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
<tr>
<td>✓</td>
<td>0208</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
<tr>
<td>✓</td>
<td>0209</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
<tr>
<td>✓</td>
<td>0210</td>
<td>09-Sep-2008 13:41:43</td>
<td>RDC_BOOK1</td>
</tr>
</tbody>
</table>

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

2. Select **Open Patient Casebooks**

3. Click **Go**
Data Entry: Casebook Spreadsheet

Each row is a patient and their CRFs

Each column is a CRF

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

Visit Selection

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

- 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

1. DEMOGRAPHICS

1.1 Date of Birth: ________________

1.2 Gender:  ○ Male
              ○ Female

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

1.4 Race: (check all that apply; you must check at least one)
          ○ American Indian or Alaska Native
          ○ Asian
          ○ Black or African American
          ○ Native Hawaiian or Other Pacific Islander

 Toolbar

 CRF Entry

 Audit History Pane

 Discrepancy Navigator Pane

 Version 3.0
 30-Oct-2012
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Data Entry: Toolbar

- Dropdown to control the highlighting of data entry fields
- Next and Previous CRFs in the Visit
- 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:**

**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.
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.
Data Entry: Viewing/Editing Investigator Comments

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 investigator comment can also be viewed in the Navigator pane.
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!
Data Entry: Closing the CRF

Click this button to close the CRF.

1. DEMOGRAPHICS
   1.1 Age on day of Study Consent (whole number) ___
   1.2 Gender:  
      - Male
      - Female
   1.3 Education:
      - Grade 6 or less
      - Grade 7 to 12 (without graduating high school)
      - Graduated high school or high school equivalent
      - Part college
      - Graduated 2-year college/technical school
      - Graduated 4-year college
      - Part graduate professional school
      - Completed graduate professional school

2. WEIGHT & HEIGHT
   2.1 Weight _____ kg
   2.2 Height _____ cm
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.

Oracle Clinical RDC

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

1. Change the data.
2. A popup window will appear requesting a reason and an optional comment.
3. Click OK.
4. Save the CRF.
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.
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**

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.**

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.
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.

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.

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.

1. Select the visit.

2. Select a patient (only one).

3. Click appropriate button.
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.
Data Entry: Unplanned CRFs

Additional visits will have Sub-visit numbers

The first visit is always visit 0.

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

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.

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.

- 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.

A blue dashed box is displayed around the question. Details are displayed in the bottom right Details pane.
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.

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

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

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.
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.

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

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

A message will indicate the report is being created.

To access the report select the Reports tab.
Reports: Generating single CRF Data

1. Click the Review tab.

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

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

3. Select from the various report parameters.

4. Then click **Submit Job**.
5. Click **Yes** when prompted.

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.
6. Click the link to open the report.

When the report is complete, the stoplight icon will disappear and the status will indicate success.
Reports: Blank Casebook Report Example

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.
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.