ORACLE® RDC ONSITE
INVESTIGATOR TRAINING
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://edc.medtronic.com/ (Bookmark this site)

- Click the **Change password** link to create a new password or generate a new one if forgotten

- Enter your User ID and click **Next**

SECURED ACCESS

**Forgotten Password?**

Please help us identify who you are.

Enter your userid:

[Submit]
SITE LOGIN PROCESS:

- The system will send you a new, temporary password via email
  - If your email address changes contact sponsor
- Click on the **Return to login screen**

- Enter your Username and temporary password on the login screen
- 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
SITE LOGIN PROCESS: ACCESS TO MULTIPLE STUDIES

- If you have access to more than one study, the following page will display.

Selecting a study from the drop-down and clicking **Submit** will open RDC to that study.

- If a user has access to only one study, this page will not display and RDC will open automatically from the LOGIN button.
LOGIN PROCESS: BROWSER COMPATIBILITY CHECK

- If you attempt to login with an unsupported browser, the following screen will display. You will need to close the window and open with a supported browser. Medtronic strongly recommends using Internet Explorer 11.

COMPATIBILITY CHECK

To use the current version of this app (RDC 5.1), please open it in one of the following browsers:

- **Mobile Operating Systems**
  - iOS 7.1.2 — iPad and OS X 10.7.5 — for RDC Onsite only

- **Supported Browsers**
  - Microsoft Internet Explorer versions depend on the operating system:
    - Microsoft Windows 7 (32-bit): Internet Explorer 9
    - Microsoft Windows 7 (64-bit): Internet Explorer 9, 10, or 11
    - Microsoft Windows Server 2008; Release 2; Service Pack 1 (64-bit): Internet Explorer 9, 10, or 11
    - Microsoft Windows 8/81 (64-bit): Internet Explorer 10 or 11
  - Safari 7.0.3 on iOS 7.1.2, for Oracle RDC Onsite only
LOGIN PROCESS: COMPATIBILITY SETTINGS CHECK

- If you do not have the proper browser compatibility settings in place, you will receive the following message with instructions on updating the compatibility settings.
LOGIN PROCESS: PASSWORD REMINDERS

- If your login fails 4 consecutive times due to the entry of an incorrect password, the system will lock your account
  - If you know your password, wait 10 minutes and then try to login again
  - If you do not know your password, you can reset it to unlock your account
  - If you are still unable to login, contact the Medtronic RDC Help Desk

- **Passwords expire after 3 months for site users.**
  - The system will notify the user if the password has expired
  - An account with an expired password will be enabled again upon resetting the password

- 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
LOGGING OUT

- Make sure to logout of the system when finished working in RDC
- Logout by selecting ‘Logout’ link located at the top right of the page:

- Once logged out of RDC, close all Internet Explorer browser windows

**Important:** the system times out after 30 minutes of inactivity and you will not be warned of an impending timeout. Any unsaved changes will be lost. Remember to save periodically.
SYSTEM OVERVIEW
SYSTEM OVERVIEW: TABS

Tabs

- **Home**: Main screen where patients are selected
- **Patient 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
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
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.

*Save Incomplete functionality not enabled in all study databases
**DATA ENTRY: ENTERING DATA**

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### Header

- **Doc. No:**

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### Body - Data entered here

#### 1. DEMOGRAPHICS

1.1 Patient Initials: (first two letters)

1.2 Date of Birth: [input field]

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
   - Asian
   - Black or African American
   - Native Hawaiian or Other Pacific Islander
   - White
   - Other: [input field]

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#### 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.

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

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

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#### List of Values with Checkboxes - click the choice or tab and press space bar (check all that apply)
DATA ENTRY: INVESTIGATOR COMMENTS

**Note:** Investigator Comment functionality is not enabled in all study databases

- 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.

*If working in a database without this functionality enabled, the icon will be greyed out for site users.
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**.
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 *

*Save Incomplete functionality not enabled in all study databases
DATA ENTRY: CLOSING THE CRF

Click this button to close the CRF.
DISCREPANCY MANAGEMENT
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: 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.
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.
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.
1. Click the **Review** tab.

2. Click the **Discrepancies** sub-tab.

3. Set the **Discrepancy Status** filter to **Active**.

4. Click **Search**.

A list of ALL your **Active** discrepancies will be displayed.
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.
ESIGNATURES: INVESTIGATOR APPROVAL OF INDIVIDUAL CRF

1. From Home tab, Select patient(s).

2. Select Multi-Patient View or Single Patient View.
3. Open a CRF that is ready for approval & review data.

4. If you approve, click the Approval icon.
5. Enter an approval comment (optional).
6. Click the **Approve** button.

7. Enter your username and password.
8. Click **OK**.

The CRF has been marked with an electronic signature.
ESIGNATURES: INVESTIGATOR APPROVAL OF MULTIPLE CRFS (GROUP APPROVAL)

1. Click the **Review** tab.
2. Enter search criteria (e.g., patient).
3. Click **Search**.
4. After search results display, select the rows of CRFs to approve.
5. Select **Approve** from the dropdown or select the **Approve icon**
6. Enter your username and password. CRFs that have open discrepancies can be skipped using the Exclude option.
   Example: de-select Exclude “CRFs with Discrepancies” if approval of CRFs with open discrepancies is desired. (If data changes after initial approval, the CRF will require re-approval.)

7. Click Continue.

8. Click Yes to approve.

9. Click Close in confirmation box.

CRFs have been marked with an electronic signature.
When using Group Approval remember the following:

- In the password window, the following Include/Exclude options are visible. However, only the ‘CRF with Discrepancies’ option is enabled for selection:
  - Exclude:
    - **CRFs with Discrepancies:** select if Approval of CRFs with open discrepancies is not desired
    - **Non-migrated CRFs entered from Oracle Clinical or RDC Classic**
    - **Batch Loaded CRFs**
  - Include:
    - **CRFs for this visit only (Otherwise, all visits for the selected patient(s))**

- Use the Review tab to select CRFs for Approval. **Do not use the links from the Home page.** This link contains filters and may not include all desired CRFs
1. Using the drop down in the approval section, select **Awaiting Re-Approval** for a list of CRFs that needs to be re-approved.
2. Click **Search**.

3. Open the CRF for review and select **Changes since last approval**. Changes are highlighted in blue.
4. If you approve, click the **Approval** icon.
REPORTS: TYPES

- Two types of reports are available:
  - **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.
  - **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.

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.

*NOTE: Medtronic is aware of potential issues that may occur when CRFs are rendered from an electronic format to a .pdf file to create the PDRs. Rendering issues are defined as CRF content, formatting, or layouts not rendering as expected. These issues can interfere with the readability of the .pdf file. Medtronic has consulted with Oracle to understand the root cause and recommended corrective action. Medtronic has tried to resolve issues to the best of our ability; however, issues may still be reflected in the PDRs. The study datasets that are used for data analysis are not derived from these PDRs, therefore these rendering issues do not impact the study data that are analyzed. Please reach out to your Medtronic study representative with any questions.*
1. Click the **Patient Casebooks** tab.

2. Search by patient.

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

4. From the Action drop-down, select “Generate Patient Data Report” and click **GO**.
A message will indicate the report is being created.

To access the report select the Reports tab.
1. Click the **Review** tab.

2. Search by patient.

3. Select the CRFs you want to include in the report.

4. From the Action drop-down, select “Generate Patient Data Report” and click **GO**.
To access the report select the **Reports** tab.

A message will indicate the report is being created.
REPORTS: SINGLE-CLICK PDR BUTTONS (INDIVIDUAL CRF)

- Patient Data Reports can be generated within an individual CRF
  - **Generate CRF Report:** generates a standard Patient Data Report for the opened CRF
  - **Generate CRF History:** generates a report of the audit history for the opened CRF

1. Select either the “Generate CRF Report” or “Generate CRF History” icon as desired

2. Once the report generates, a new icon will appear. Click this icon to download the report.

3. In the dialog window that appears at the bottom of the screen, select Open or Save.
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.
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

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