OC RDC Onsite User Guide
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Logging In

1. Open the OC RDC Onsite website.
2. Enter your username and password.
3. Click the Login button.

Changing your Password

On first log in, you are required to change your password.

1. Enter your old password.
2. Enter your new password.
3. Click the Apply button.
### Password Guidelines

<table>
<thead>
<tr>
<th>DO</th>
<th>Use multiple characters in your password</th>
<th>✔️</th>
</tr>
</thead>
<tbody>
<tr>
<td>DO</td>
<td>Use numbers, letters and special characters</td>
<td>✔️</td>
</tr>
<tr>
<td>DO</td>
<td>Change your password regularly</td>
<td>✔️</td>
</tr>
<tr>
<td>DO</td>
<td>Hide your username and password so they cannot be seen by others</td>
<td>✔️</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Use a password that is identical to your username</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Use a password that is easy to guess</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Use a password that is used by anyone else</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Use a password that is hard to remember</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Write your password down on a sticky note</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Share your username and password</td>
<td>✗</td>
</tr>
<tr>
<td>DO NOT</td>
<td>Work in the system using another person’s credentials</td>
<td>✗</td>
</tr>
</tbody>
</table>

### Security Features

- After 30 minutes of inactivity you will be logged out
- Incorrect entry of your password 3 times will result in your account being locked
- Contact the helpdesk to reinstate access

**Contact the Helpdesk to reinstate your access**
Navigation

The *Home page* is the starting point for all of your tasks.

**Navigation Tabs**

Use the four navigation tabs available in the left top corner of the *Home page* allow you to move to each area of the application.

<table>
<thead>
<tr>
<th>Home</th>
<th>Used to navigate to the Home page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casebooks</td>
<td>Used to access eCRFs for patients and to enter data</td>
</tr>
<tr>
<td>Review</td>
<td>Used to search for eCRFs, Discrepancies and Investigator Comments</td>
</tr>
<tr>
<td>Reports</td>
<td>Used to run 2 standard OC RDC reports</td>
</tr>
</tbody>
</table>
## Navigation

### Links

These are available in the top right corner of the Home page.

![OC RDC Onsite Home page](image)

<table>
<thead>
<tr>
<th><strong>Logout</strong></th>
<th>Used to log out of OC RDC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferences</strong></td>
<td>Used to set up your display and layout preferences</td>
</tr>
<tr>
<td><strong>Change Password</strong></td>
<td>Used to change your OC RDC password</td>
</tr>
<tr>
<td><strong>Help</strong></td>
<td>Used to open the online Help tool</td>
</tr>
</tbody>
</table>

### User Information

On the upper right of the Home page you can see the:

- Username
- User Role
- Database
- Date and time of the last change
Study and Site Selection

Below the user information, use the Study and Site dropdown menus to select your study and site.
Study and Site Summary

The Study and Site Summary report displays a summary of the patients and eCRFs for your study and site. This information is updated after an action is performed and saved.

To Open the Study and Site Summary Report:

1. Click the **Study and Site Summary** link.

   ![Study and Site Summary report](image)

   The **Study and Site Summary** report displays.
Activities Section

News

The News links display any news or communication for your study and site.

To View a News Item:

1. Click a link in the News section. E.g. Click the Welcome link.

The News Details window opens.

Activities

The Activities links are used to navigate to tasks that you need to perform frequently. The links are shortcuts to these tasks.
To Access an Activity:

1. Click on an Activity link. Eg. Click the Review Active Discrepancies link.

All discrepancies that must be reviewed by the site display.

Links

Links to relevant websites may be added here by ICON. This is typically not used.
Patient Search

The *Patient Search* area is accessed on the *Home page* and is used to search for patients.

1. Click the + sign to open the *Search* field.
2. Enter your *Search* criteria.
3. Click the *Go* button.
Results display on the *Home page*.

Patient Icons

There are 4 patient icons used in OC RDC Onsite.

- **No data have been entered for this patient.**
- **Patient data have been entered – there are no open discrepancies.**
- **Patient data have been entered – there is at least one discrepancy to be reviewed by another user. This is called an Other discrepancy.**
- **Patient data have been entered – there is at least one discrepancy to be reviewed by the user logged in. This is called an Active discrepancy.**
## eCRF Icons

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Icon" /></td>
<td>No data have been entered.</td>
</tr>
<tr>
<td><img src="image2" alt="Icon" /></td>
<td>Data have been entered – there are no discrepancies.</td>
</tr>
<tr>
<td><img src="image3" alt="Icon" /></td>
<td>The eCRF has been marked as blank.</td>
</tr>
<tr>
<td><img src="image4" alt="Icon" /></td>
<td>Data have been entered – there is at least one open discrepancy to be addressed by another User (Other Discrepancy).</td>
</tr>
<tr>
<td><img src="image5" alt="Icon" /></td>
<td>Data have been entered – there is at least one open discrepancy to be addressed by User logged in (Active Discrepancy).</td>
</tr>
<tr>
<td><img src="image6" alt="Icon" /></td>
<td>The eCRF has been verified by the CRA.</td>
</tr>
<tr>
<td><img src="image7" alt="Icon" /></td>
<td>The eCRF must be re-verified by the CRA. At least one data field in the verified eCRF has been modified since verification.</td>
</tr>
<tr>
<td><img src="image8" alt="Icon" /></td>
<td>The eCRF has been verified by the CRA and approved by the Investigator.</td>
</tr>
<tr>
<td><img src="image9" alt="Icon" /></td>
<td>The eCRF must be re-approved by the Investigator. At least one data field in the approved eCRF has been modified since approval.</td>
</tr>
<tr>
<td><img src="image10" alt="Icon" /></td>
<td>The eCRF must be re-approved and re-verified. At least one data field in the verified and approved eCRF has been modified since verification and approval.</td>
</tr>
</tbody>
</table>
The eCRF has been verified and reviewed by Data Management.
Data Entry

Data Entry is initiated from the Casebooks screen. Enter your Search criteria in the search field and click the Go button to complete the search. To see all patients, leave the Search fields empty then click the Go button.
Searching for Patients for Data Entry

To Search for a Patient for Data Entry:

1. Select 'Patients with no data entered' in the Show menu.
2. Click the Go button.

All unassigned eCRFs display for empty patients.

- The Screening visit eCRFs display for all empty patients.
• The patient icons indicate that no data have been entered for these patients.

• The eCRF icons indicate that no data have been entered on these eCRF pages.
eCRF Page Navigation

The Highlight dropdown menu is used to highlight particular fields in the eCRF.

The Audit History arrow opens the Audit History pane, which allows the user to view the Audit History for a data field.

The CRF Navigator arrow opens the CRF Navigator pane, which allows the user to view Discrepancies and Investigator Comments.

eCRF Action Buttons

<table>
<thead>
<tr>
<th>Action Buttons</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Discrepancy</td>
<td>Add a discrepancy to the CRF data.</td>
</tr>
<tr>
<td>Approval History</td>
<td>View the approval history for a data field.</td>
</tr>
<tr>
<td>Add Investigator Comment</td>
<td>Add an investigator comment to the CRF data. (Note: Not used on all studies.)</td>
</tr>
<tr>
<td>Verification History</td>
<td>View the verification history for a data field.</td>
</tr>
<tr>
<td>Delete Row</td>
<td>Delete a row from the CRF data.</td>
</tr>
<tr>
<td>Delete eCRF</td>
<td>Delete the CRF page. (Deletes data entered on an eCRF page – does not delete or inactivate the page.)</td>
</tr>
</tbody>
</table>
Performing Data Entry

To Perform Data Entry:

1. Click the eCRF icon to open the page.

The eCRF displays.
2. Complete the date field. Manually enter the date or use one of the shortcuts below:
   - T=Today's date
   - Y=Yesterday's date
   - L=Last date entered

3. Exit the eCRF.
   - To save, click the green save button.
   - To open the next eCRF, click the Next CRF link. You are first prompted to save your changes
   - To close the eCRF, click the red x button. You are first prompted to save your changes.

4. Click the Next CRF link to go to the next eCRF page

5. Click Save to save your changes.
6. Click the **Date of Birth** field.

7. Click the **Calendar** icon.

8. Use the Calendar to select the Patient's date of birth.  
   Note: The date can also be entered manually.
9. Click the **Save** button when the eCRF is complete.

10. Click the red x button to close the eCRF and return to the **Casebooks** page.

- The eCRF icons now indicate that 2 eCRF pages have been completed, and that there are no discrepancies.
- The patient icon now indicates that data have been entered for this patient, and that there are no discrepancies.

### Updating Existing Data

Site users may need to update data on an existing page.
To Update Existing Data:

1. Click the page icon to open it.

The eCRF page opens. The year in the date of birth is incorrect and must be changed.

2. Type the correct year in the date of birth field.

3. Click the Save button.
The *Reason for Change* window opens. The user must indicate a reason for every change made to existing data.

4. Select a reason from the dropdown menu

5. Click the **OK** button.

The *Reason for Change* window closes. The user can now close the eCRF.

**Audit Trail**

It is possible to view the audit history for an individual field in RDC Onsite.
To View the Audit History:

1. Select Audit History in the Highlight dropdown.

   Fields where data have been changed highlight in blue.

2. Open the Audit History pane.
   - Right click on the blue field and select Show Audit History
   - OR
   - Click the Audit History arrow at the bottom of the eCRF window

The Audit History pane displays at the bottom of the eCRF.

3. Click the Audit History arrow to close the Audit History pane.
Adding an Other Page

Site staff may need to add an extra page to a visit for additional data entry.

1. Click the patient checkbox to select the patient.
2. Click the **Add Other Page** button.

The **Add Other Page** dialog box displays.
3. Click the radio button next to the eCRF you wish to add.

4. Click the **Continue** button.

The *Add Other Page* dialog box closes and you are returned to the *Casebooks* page.

A new eCRF page has been added for the patient.

**Note:** If the user navigates away from the *Casebooks* page without completing the new eCRF, it will disappear and the user must add it again.
Discrepancy Management

All Active Discrepancies must be reviewed and answered by the site. eCRFs and patients with active discrepancies are coloured red.

There are two types of discrepancies generated in OC RDC:

- System – generated at site during data entry
- Manual – generated by an ICON user, eg. A CRA

All Other Discrepancies must be reviewed and answered by another user. eCRFs and patients with other discrepancies are coloured yellow.

**System Generated Discrepancy**

As data is being entered, OC RDC assesses the data to ensure it is consistent with the conditions specified by the sponsor. If data entered does not conform to the conditions, a **Validation Error** window opens.

**Validation Error**

**Example 1:**
During data entry, the user enters text into a field which should contain numbers.

1. Click into the diastolic field to continue with data entry.
The Validation Error box opens.

- The description of the error and the reason it occurred display.
- To correct the error immediately, click the cancel button. The Validation Error box will close and the user can continue with data entry.
- Otherwise, use the Action menu to route the discrepancy to another user for review.

2. Click the Cancel button to return to the eCRF and continue with data entry.

The Validation Error box closes and the blood pressure field is empty. The user can now re-enter the correct data.
**Example 2:**
Data entry is complete but the Start Date is incorrect – it occurs after the Stop Date.

1. Click the **Save** button.

   ![Image of the Save button](image)

   The Stop Date field is coloured red, indicating there is a discrepancy to be reviewed by the user logged in.

2. Click the left pointing arrow to open the **CRF Navigator** pane.

   ![Image of the CRF Navigator pane](image)

3. Click the **Multi** discrepancy in the **List** field to open the discrepancy details.

   ![Image of the discrepancy details](image)
4. Review the discrepancy description and update the eCRF details if necessary.

**Note:** Remember to indicate a Reason for Change if changing a previously saved field.

5. Amend the incorrect fields and save the eCRF.

**Note:** There is no longer a discrepancy on the page.
Active Discrepancies

Active discrepancies must be reviewed by the user logged in (the site) and are coloured red. There are 2 ways to navigate to Active Discrepancies.

**Method 1**
1. Click the **Review Active Discrepancies** link on the *Home page*.

**Method 2**
1. Click the **Review** tab to open it.
2. Select ‘Active’ in the *Discrepancy field*.
3. Click the **Go** button to search.
Reviewing Active Discrepancies

Site users will review each discrepancy and respond to it, returning it to Data Management, unless otherwise directed.

1. Click the red eCRF icon to open the page.

The eCRF opens. The Respiration Rate is coloured red to indicate it has an Active discrepancy.

2. Click the arrow on the right of the page to open the CRF Navigator pane.
3. Click the **discrepancy** in the **List** field to view its details.

4. Review the discrepancy details.
The Respiration Rate on this eCRF was incorrect and has been changed to 20.

**Remember:** Indicate a Reason for Change when making a change to a previously saved field.

---

**Routing a Reviewed Discrepancy**

Once the Site has responded to the discrepancy, they must return it to Data Management unless instructed otherwise in the query text.
To Route a Reviewed Discrepancy:

1. Select **Send to Data Manager** from the Action dropdown list (unless instructed otherwise).

2. Click the **Go** button.

The **Discrepancy Action** box displays.

3. Enter a Comment in response to the discrepancy, indicating any changes made to the eCRF.

4. Click the **OK** button.
The *Respiration Rate* field on the eCRF is yellow and the discrepancy in the *CRF Navigator* pane is also yellow.

**Note:** This indicates that the discrepancy must be reviewed by someone other than the user logged in. (DM in this case).

5. Click the **Save** button.

6. Click the **red x** in the upper right corner to close the eCRF.

You are returned to the list of Active Discrepancies. The eCRF you worked on is now coloured yellow, indicating that the discrepancy must be reviewed by someone else.
Review and Approval

The Principle Investigator approves clean, verified eCRFs by entering his or her username and password. There are two ways to navigate to eCRFs for approval.

To Navigate to eCRFs for Approval:

Method 1
1. Click the ‘Review non-blank CRFs ready for initial approval’ link in the Activities area of the Home page.

Method 2
1. Click the Review tab to open.
2. Select **Not Approved** in the **Approval** dropdown menu.

3. Click the **Go** button.

All eCRFs ready for approval display. The eCRFs are clean and have been verified by the CRA.

### Group Approval

It is possible for the Principle Investigator to approve several eCRFs as a group. **Important:** All eCRFs must be reviewed before approval

**To Perform Group Approval:**

1. Use the Select checkboxes to select the eCRFs for approval. **Note:** To select all the eCRFs, click the Select All link.

2. Select **Approve** in the ‘Select CRFs and...’ dropdown menu

3. Click the **Go** button.
The Approve CRFs dialog box opens.

4. Enter your username and password.

5. Click the **Continue** button.

A warning message displays to confirm that you want to approve the eCRFs.

6. Click the **Yes** button to continue.

A confirmation message displays to indicate that you have approved the eCRFs.

7. Click the **Close** button.
The selected eCRFs have been approved.
The Signature icon appears on the approved eCRFs.

**Single eCRF Approval**

eCRFs may also be approved as single pages.

**To Approve a Single eCRF:**

1. Click the eCRF to open it.
2. Review the page and then click the Approve button.

3. Click the Approve button.

The Approve CRF window opens.

4. Enter your username and password.

5. Click the OK button.
The CRF Approval Signoff confirmation message displays.

6. Click the **Close** button

The eCRF closes and the selected eCRF has been approved. The Signature icon appears on the approved eCRF.

---

**Re-Approval**

It is possible for changes to be made to an eCRF after initial approval. These eCRFs must be re-approved.

**Important:** The Investigator must perform a manual search for eCRFs needing re-approval.
To Re-Approve an eCRF:

1. Click the **Review** tab on the *Home page*.

2. Select ‘**Awaiting Re-Approval**’ from the Approval dropdown menu.

3. Click the **Go** button to search.

All eCRFs requiring re-approval display.

**Note:** The red arrow next to the approval icon indicates the eCRF must be re-approved.

Pages can be re-approved using the Group Approval or Single Approval steps outlined above.
4. Select ‘Changed since last approved’ in the Highlight dropdown menu.

5. Use the Audit History pane at the bottom of the eCRF to review the change.

6. Click the Approve button.

The Approve CRF window opens.

7. Click the Re-Approve button.

The CRF Approval Signoff window opens.

8. Enter your username and password.

9. Click the OK button.

The CRF Approval Signoff confirmation message displays.

10. Click the Close button.
The eCRF has been re-approved.
The red arrow no longer displays.
OC RDC Onsite Reports

There are two types of reports available in OC RDC onsite:

- Patient Data Report – generates a report on complete eCRF pages for patient(s) enrolled at your site.

To Run a Report:

1. Click the Reports tab.

   ![Image of Reports tab](image)

   There is a button for each report.

2. Click the appropriate button to begin running your report.

   ![Image of button selection](image)

   Use the Report Parameters area to enter your search criteria.

3. Click the Submit Job button.

   ![Image of submitting job](image)
4. Click the Yes button to confirm you want to run the report.

The report is listed in the Report Jobs area, with the status indicating that the report has been submitted.

The report is ready when the status is SUCCESS.

5. Click the link in the View Report column to open the report.

The report opens as a PDF. It cannot be edited.