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1. Content

What’s New in Oracle RDC 4.6

Oracle RDC 4.6.0 is a fully web-enable interface: eCRF can be accessed from any qualified computer without installing additional software.

Interface has been improved on several points regarding previous versions of Oracle RDC:

- Conflicts between data entry and batch validation executing minimized
- Access restricted
- Possibility of a flexible study design (dynamism per page or visit)
- Conditional branching (dynamism per variable)
- Hidden discrepancies or protect (read only)

Important

Please remember you are not authorized to access an eCRF prior to receiving training to the appropriate version of the system. This training can be an eLearning, a face-to-face training session or a demonstration by an authorized user. At the end of the training, you will receive a certificate that should be kept in your study file.
Getting Help

Getting Help with the eLearning

A general Oracle Clinical RDC 4.5.3/4.6 eLearning is published on the Internet Portal provided by Quintiles. This eLearning is organized in short modules that demonstrate how to perform specific activities according to your role on the study. This eLearning will remain accessible during the course of your study, even after its initial completion: you can access any modules at any time if you need to review some specific processes.

Getting Help with this Manual

This manual is intended for a day-to-day use. It will help you in remembering activities and options learned during the eLearning or any other formal demonstration. It also contains some tips and information about the product features or some processing instructions. Please refer to the table of content to identify the section that suits your needs.

Getting Help with the Oracle RDC Onsite 4.6 Online Help

Online generic help functionality is accessible from Oracle RDC 4.6. This help file is the most complete one, it also means that it contains many information that do not fit specifically to your role on the study. You can refer this online help at any time via the ‘Help’ link in the right upper corner of Oracle RDC 4.6 main window (see Figure 1: Oracle RDC Onsite 4.6 Online Help).

Getting Help with the Helpdesk

If none of the supports described above answers your questions about Oracle RDC 4.6, do not hesitate to contact your dedicated helpdesk or your study representative. Either they will give you an answer or put you through to the appropriate person. For specific helpdesk contact information, go to your Study ePortal.
2. Getting Started with Oracle RDC

Starting and Closing Oracle RDC 4.6

Click on the Web link available on your study ePortal or enter the Web address provided by the Sponsor. Web address can be added to your favorites list to start quickly next sessions.

The system prompts for a User Name and Password: enter those provided by the Sponsor.

Information

The password is case sensitive, identifier should be entered exactly the same way it has been sent you. Please check if your keyboard is in upper or lower case, or if the numeric pad is activated before typing it. Special characters are not taken into account in eCRF identifiers. If you fail to connect or you lock your account with too many unsuccessful attempts, contact your helpdesk to reset your password.

From the RDC interface, click ‘Logout’ in the header of the window to close the application (see Figure 2: Close Application)

Important

Always use the ‘Logout’ button. Do not close the window of your Internet browser to leave the application; it may expose the system to security issues and tampering.

When navigating in the Data Entry Window of Oracle RDC, always close the window with the red cross / white bottom. If you close the window with the ‘Close’ button of your web browser, changes will not be taken into account (see Figure 3: Close Data Entry Window).
Navigate Through Tabs

Oracle RDC 4.6 main window is made of several tabs, each one containing distinct links or information.

4 main tabs are accessible from RDC Homepage (see Figure 4: RDC Homepage tabs):

- **HOME**: Page displayed immediately after log in. It contains links to reach main activities available according to your profile.
- **CASEBOOKS**: New entry of eCRF pages is available from this tab only. It is the easiest way to access eCRF pages that should be modified.
- **REVIEW**: It proposes to perform several types of actions on pages already entered via 4 sub-tabs (‘CRFs’, ‘Discrepancies’, ‘Investigator Comments’ and ‘Special Listings’). Except initial entry, all other activities could be managed from this tab.
- **REPORTS**: Display options to generate a Patient Data Report (eCRF book with patient pages) or a blank eCRF.

Exploring Tab ‘Home’

This tab contains several areas (see Figure 5: RDC Homepage):

- **NEWS**: This area displays messages addressed to all RDC users or specifically to the user logged to the system. Follow the link to display the message.
- **ACTIVITIES**: Depending on profile logged to the system, this notification area displays all activities available regarding eCRF management. Each link will bring the user to the appropriate section of the ‘Review’ tab, with filters pre-entered to manage the due tasks.
- **LINKS**: Predetermined web links are available in this area.
- **LOGIN INFORMATION**: This notification area displays the name and login of the user logged to the system, and associated profile (investigator, CRA, Sponsor …). If information reported is not accurate, contact immediately your helpdesk.
- **FILTER INFORMATION**: Drop-down lists to select studies and sites you will work on (if any). Mostly used for users with multi-sites responsibilities (CRA, Medical reviewers …)
- **SEARCH**: Expand this area to access simple filters about patients to retrieve: patient number, new or existing patients, eCRF book assigned, and discrepancy status. ‘Activities’ links are more convenient to perform simple tasks, and ‘Search’ menu from ‘Casebooks’ tab is more complete, so you wouldn’t need to use it so often.
- **PATIENTS SELECTION**: Area that displays patients available for study conduction for a specific site.
Navigating through tabs

Oracle RDC 4.6 booklet

Exploring Tab ‘Casebooks’

This tab Casebooks (see Figure 6: RDC Tab ‘Casebooks’) is intended for a data entry purpose. It contains 2 main sections:

> **SEARCH:** A filter applied in this section modifies data displayed in the following one.

> **eCRF NAVIGATION AREA:** In this area, each patient is represented by one row, and each column represents a single page available for the corresponding visit. Click in a cell of this grid to open the corresponding eCRF page for a given patient.
Exploring Tab ‘Review’

This tab Review is intended for all kind of data review activities. It contains 4 sub-tabs containing the same Search area:

> **CRFs:** (see Figure 7: RDC Tab ‘Review’ - CRFs) It allows a review of all entered eCRF pages

  **DISCREPANCIES:** (see Figure 8: RDC Tab ‘Review’ - Discrepancies

> ) Discrepancy management is done from this page

  **INVESTIGATOR COMMENTS:** (see Figure 9: RDC Tab ‘Reviews’ - Investigator Comments

> ) This tab summarize all investigator comments entered on eCRF pages.

> **SPECIAL LISTINGS:** (See Figure 10: RDC Tab ‘Reviews’ - Special Listings) This section contains listings for MEDDRA and WHODRUG coding.

Figure 7: RDC Tab ‘Review’ - CRFs
Figure 8: RDC Tab ‘Review’ - Discrepancies

Figure 9: RDC Tab ‘Reviews’ - Investigator Comments
Exploring Tab ‘Reports’

This tab Reports (see Figure 11: RDC Tab ‘Reports’) allows the generation of a blank CRF, completed CRFs for some specific patients or other reports, as defined by the sponsor of the study.
eCRF Icons

eCRF Icons for Data Entry Status

<table>
<thead>
<tr>
<th>Icon</th>
<th>CRF Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placeholder</td>
<td>Empty eCRF page available for new data entry.</td>
<td></td>
</tr>
<tr>
<td>Created</td>
<td>eCRF page where only header information have been completed, and saved as incomplete. NOT APPLICABLE TO ASP-BRIDGE STUDIES.</td>
<td></td>
</tr>
<tr>
<td>Blank</td>
<td>All sections of this eCRF page are marked as blank.</td>
<td></td>
</tr>
<tr>
<td>Pass 1 started</td>
<td>Data entry started and page saved as ‘incomplete’. NOT APPLICABLE TO ASP-BRIDGE STUDIES.</td>
<td></td>
</tr>
<tr>
<td>Entry Complete</td>
<td>Data entry finished and page saved</td>
<td></td>
</tr>
<tr>
<td>Pass 2 Started</td>
<td>(Only for documents entered by the CRO) The second pass of data entry has started. NOT APPLICABLE TO ASP-BRIDGE STUDIES.</td>
<td></td>
</tr>
<tr>
<td>Pass 2 Complete</td>
<td>(Only for documents entered by the CRO) The second pass of data entry is completed. NOT APPLICABLE TO ASP-BRIDGE STUDIES.</td>
<td></td>
</tr>
<tr>
<td>Batch loaded</td>
<td>The CRF’s data were loaded by the CRO. This is an operation mainly in relation with central examinations. NOT APPLICABLE TO ASP-BRIDGE STUDIES.</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Data Entry Status Icons

eCRF Icons for Discrepancy Status

<table>
<thead>
<tr>
<th>Icon</th>
<th>CRF Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Discrepancies</td>
<td>There are no Other or Active discrepancies associated with the CRF. (Note that there may be closed discrepancies associated with the CRF or there may open discrepancies but for another profile.)</td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>There is at least one Active discrepancy in the CRF, to be addressed by you.</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>There is at least one discrepancy that must be addressed by a user in a role other than yours.</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Discrepancy Status Icons

Information
If a CRF contains both Active and Other discrepancies, the icon remains red until you address the Active discrepancy. At that point, if the discrepancy with a status of Other is still open, the icon changes from red to yellow. When a CRF does not have any discrepancies, or all discrepancies are closed, the icon has no color.
**eCRF Icons for Verification Status**

Verification process in Oracle RDC stands for Source Data Verification (SDV) by Clinical Operations or Medical Reviewers.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="icon1.png" alt="Icon" /></td>
<td>None</td>
<td>The CRF has not been verified.</td>
</tr>
<tr>
<td><img src="icon2.png" alt="Icon" /></td>
<td>Verified</td>
<td>The CRF has been verified.</td>
</tr>
<tr>
<td><img src="icon3.png" alt="Icon" /></td>
<td>Re-verification Required</td>
<td>At least one modification has occurred in eCRF page since the last verification (data change, discrepancy resolution, comment added …). The CRF must be re-verified.</td>
</tr>
</tbody>
</table>

Table 3: Verification Status Icons

**eCRF Icons for Approval Status**

Approval process in Oracle RDC stands for the electronic signature by authorized site personnel (i.e. investigator).

<table>
<thead>
<tr>
<th>Icon</th>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="icon1.png" alt="Icon" /></td>
<td>None</td>
<td>The CRF has not been approved.</td>
</tr>
<tr>
<td><img src="icon2.png" alt="Icon" /></td>
<td>Approved</td>
<td>The CRF has been approved.</td>
</tr>
<tr>
<td><img src="icon3.png" alt="Icon" /></td>
<td>Re-approval Required</td>
<td>At least one modification has occurred in eCRF page since the last approval (data change, discrepancy resolution, comment added …). The CRF must be re-approved.</td>
</tr>
</tbody>
</table>

Table 4: Approval Status Icons

**Multiple-status CRF Icons**

In real situations, eCRF pages will show a combination of icons.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Label/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="icon1.png" alt="Icon" /></td>
<td>Entry complete, at least one active discrepancy, verified, approved.</td>
</tr>
</tbody>
</table>
| ![Icon](icon3.png) | Pass 2 complete, active discrepancy requires re-verification, requires re-approval.  
**NOT APPLICABLE TO ASP-BRIDGE STUDIES.** |
| ![Icon](icon4.png) | Entry complete, other discrepancy, verified, requires re-approval, locked. |

Table 5: Multiple Status Icons
Data Entry

In this chapter, you will work mainly with tabs ‘Home’ and ‘Casebooks’. You will focus on creating and modifying eCRF pages for your patients.

Identify a Patient Status

According to their status, patients are displayed with distinct icons in Oracle RDC 4.6.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🧔🏻</td>
<td>Patient with no data, available to start a new entry.</td>
</tr>
<tr>
<td>🧔🏻</td>
<td>Patient with at least one eCRF page and no discrepancy at all.</td>
</tr>
<tr>
<td>🧔🏻</td>
<td>Patient with at least one eCRF page and at least one discrepancy requiring an action from you.</td>
</tr>
<tr>
<td>🧔🏻</td>
<td>Patient with at least one eCRF page and at least one discrepancy requiring an action from another user.</td>
</tr>
</tbody>
</table>

Table 6: Patient Status Icons

Open eCRF Page to Enter

From the ‘Home’ tab, tick the box on the left of an available patient number: 🧔🏻.
Select ‘Open Patient Casebooks’ in the drop-down list, and press ‘Go’: focus is moved to the ‘Casebooks’ tab.

Verify that the ‘Casebook View’ menu corresponds to the eCRF book to complete, and select the appropriate visit in the upper filter area.
Click on a page to start your entry.
The Data Entry Window appears.
Navigate in Data Entry Window

The Data Entry Window (DEW) opens when you click on an eCRF page icon. It is composed of specific areas.

![Data Entry Window](image)

**Page information**

Display identifiers for the study, site, patient, casebook and user profile. Check this bar if you are unsure about the page you are entering.

**Preferences**

Customize the eCRF elements to highlight depending on your activities. Choices are:

- **NONE**: no highlighted element
- **ACTIVE DISCREPANCIES**: highlight in red all fields with discrepancies to be managed by you.
- **ACTIVE AND OTHER DISCREPANCIES**: highlight fields with discrepancies to be managed by you (red) or another user (yellow).
- **CLOSED DISCREPANCIES**: highlight in green all fields with closed discrepancies.
- **ALL DISCREPANCIES**: highlight in red, yellow or green all fields with discrepancies.
- **INVESTIGATOR COMMENTS**: highlight in purple all fields with investigators comments.
- **AUDIT HISTORY**: highlight in blue all fields modified since initial entry.
- **CHANGED SINCE LAST VERIFIED**: highlight in blue all fields modified since last CRA SDV.
- **CHANGED SINCE LAST APPROVED**: highlight in blue all fields modified since last Investigator signature.
**Toolbar**

**ADD DISCREPANCY:** select an item and click on this icon to add a manual discrepancy. Only to be used by CRA, medical reviewers and data managers.

**ADD INVESTIGATOR COMMENT:** select an item and click on this icon to add an investigator comment. Only to be used by investigators and study nurses.

**DELETE ROW:** select a repeated row and click on this icon to delete a whole row. This feature MUST never be used.

**BLANK FLAG TOOL:** click this icon to display section names and mark them as having no responses.

**Information**

Flagging a section as blank has the same meaning as crossing it out on a paper CRF: this section is considered as not applicable for this patient.

**VERIFICATION HISTORY:** click this icon to display the dates when the current eCRF page has been verified by the CRA.

**APPROVAL HISTORY:** click this icon to display the dates when the current eCRF page has been approved (electronically signed) by the investigator.

**DELETE CRF:** click on this icon to delete the current eCRF page. After deletion, previous data of the eCRF page will not remain accessible from Oracle RDC, even in the audit trail.

**PRINT:** click on this icon to send a copy of the current eCRF page to the local printer.

**SAVE:** click on this icon to record changes applied in the eCRF page (any changes to data, discrepancies or comments)

**Navigation Buttons**

Click on ‘Previous CRF’ or ‘Next CRF’ to open the previous or the next page of the same visit. If you try to display another page without saving your modifications, the system will prompt you if you want to save it or not.

These buttons are not available if the page to reach belongs to another visit. In this situation, close the current page. Then, from the Oracle RDC tab ‘Casebooks’, select the appropriate visit and click on the page to open.
Navigator Pane

Click on the black arrow located on the right border of the DEW to display the ‘Navigator’ pane (see Figure 14: DEW - Navigator Pane).

This pane contains 2 tabs:
- One tab to manage ‘Discrepancies’
- One tab to manage ‘Investigator Comments’

Each tab is divided in two parts:
- One part to list all discrepancies / investigator comments available on this eCRF page (shown as red / yellow / green colored bullets for discrepancies and purple bullets for investigator comments).
- One part to display the details of the point selected above.

The ‘Action’ dropdown list is also available at the bottom. User will choose in this list the action to apply to close their discrepancies.

In tab ‘Discrepancies’, the ‘Details’ section contains ‘Related values’ and ‘History’ buttons. Selecting ‘Related values’ displays any data points that are validated with the current selected discrepancy.

The ‘History’ button opens up the discrepancy history view for the selected discrepancy.

Click the black arrow on the top right corner or the button ‘Close’ on the lower right corner to close the ‘Navigator’ pane.
Audit Trail Pane

Click on the black arrow located on the lower border of the DEW to display the ‘Audit History’ pane (see Figure 17: DEW - Audit History Pane). When there is focus on an item in the eCRF page, this pane displays the history of values previously entered in this item. When focus is moved from an item to another, content of this pane is refreshed automatically in a few seconds.

Click the black arrow pointing to the bottom to close the ‘Navigator’ pane.

![Figure 17: DEW - Audit History Pane](image)

Enter Data in eCRF page

Navigation can be done with either the mouse or keyboard shortcuts.

With the mouse, List of Values (LOV) associated to fields is displayed by clicking on the magnifying glass: that appears beside the entered question.

Keyboard shortcuts

- **Tab:** Moves focus to either the next field.
- **Shift Tab:** Moves focus to either the previous field.
- **Spacebar:** Tick or untick the checkbox that held the focus.
- **Alt+S:** Saves all updates made since the last Save or since the eCRF page was opened (same action as Green Floppy icon).
- **Alt+L:** Opens the list of values (LOV).
- **Alt+N:** Opens the next CRF in the DEW (same action as the Next CRF link).
- **Alt+P:** Opens the previous CRF in the DEW (same action as the Previous CRF link).
- **Ctrl+W:** Closes the Data Entry Window.

Save Data Entered in eCRF Page

Once data are entered or discrepancies managed, click the Green Floppy icon in the toolbar to save your page.

![Figure 18: DEW - Confirmation of page saved](image)
‘Save complete’ means that initial entry is finished, so other users can start their review. It also allows automatic checks to verify the page content. This is the system default for ASP-Bridge studies.

‘Save incomplete’ means that entry is ongoing. Once all information is collected and entered, the page can be saved as complete.

Information

After eCRF page entry, if you return to the eCRF tab ‘Casebooks’, you will not always see any change to the eCRF page icon. Click on web button ‘Refresh’ to update this area (see Figure 19: Casebooks - Refresh eCRF Icons).

 Modify an eCRF Page

To open a page previously entered and modify it, select it as described in chapter ‘Open eCRF Page to Enter’.

Each time you modify a value and move your pointer to the next field, the system displays a window ‘Reason for Change’ (see Figure 20: DEW - Reason for Change). Select the most appropriate reason in the list of values (content of this list depends on your study design).
Information
A ‘Reason for change’ is required each time a modification is done on eCRF data after its initial entry. The previous value is recorded in an audit trail (see chapter about ‘Audit Trail Pane’).

Insert an Investigator Comment

Sometime, eCRF design does not allow entry for a comment that could help patient review or provide explanations for an unexpected value. Oracle RDC allows entry of a comment that is associated with an eCRF element (field, tick box ….) and could be reviewed later by other users.

Information
Feature ‘Investigator Comment’ is available to all users that need to enter data in eCRF. Depending on studies, it may include investigator, study nurses …

In the eCRF page, click on the item that requires a comment, and then click on icon ‘Add Investigator Comment’ of the toolbar.

Window ‘Add Investigator Comment’ appears (see Figure 21: DEW - Investigator Comment). Enter the comment, click OK and save your page.

Figure 21: DEW - Investigator Comment

Information
Addition of an investigator comment is also available via a right click when pointer is focused on the appropriate eCRF item. Select ‘Investigator Comment’ in the contextual menu.

If the investigator comment is entered after the initial page entry, it is considered as a modification to the page content, so it is combined with the audit trail window (see Figure 22: DEW - Audit Trail for Investigator Comment): comment could be entered, but a ‘Change Reason’ is also required.
Investigator comments can be modified at any time. To open an investigator comment created previously, open the Navigator pane. Select the Investigator Comment that needs to be modified. Detail of this comment appears in the lower part of the window.

Click on icon ‘Update’ to access the investigator comment previously entered.

Information
Audit history is also available in investigator comments. Click on button ‘History’ of the Navigator pane to access the investigator comments previously entered.

Mark a section as Blank (or Not Applicable)

Depending on eCRF design, a single page can contain one or several sections. In general, consecutive sections are separated by a horizontal line.
Sometimes, and according to eCRF completion guidelines, it may happen that some eCRF sections are not applicable to a patient, either because the patient did not attend an examination or because questions do not correspond to his status (e.g. male and menopausal status). In a paper CRF, these sections are crossed-out. Oracle RDC offers the same feature, called ‘Blank Flag Processing’.

If a section of an eCRF page is not applicable, click on the icon ‘Blank Flag Processing’ of the Data Entry Window. The related window appears.
There are 2 possibilities:

> Marking this CRF as having no responses: the entire eCRF page will be considered as crossed out.
> Marking one or several sections as having no responses: only the related section will be considered as crossed out.

All enterable items of a blank section appear as greyed out. Audit Trail of greyed fields is no longer accessible when section is flagged as having no responses (see Figure 25: DEW - Example of Blank Section).

**Eligibility**

Does the subject meet the eligibility criteria?  
- YES  
- NO

**Important**

When all fields of a section are left empty, this section will be automatically flagged as blank when you will save the page.

**Un-blanking a section as Blank (or Not Applicable)**

Section can be un-blanked via the same icon ‘Blank Flag Processing’. Identify the section to make available for data entry and un-tick the related box.

If the section is marked as blank after the initial page entry, it is considered as a modification to the page content, so it is combined with the audit trail window (see Figure 26: DEW - Audit Trail for Blank Flag Processing): flag could be modified, but a ‘Change Reason’ is also required.
Delete an eCRF page

If an eCRF page is no longer applicable, click on the icon ‘Delete’ of the Data Entry Window toolbar. The related window appears (see Figure 27: DEW - Delete an eCRF Page).

Important
Page deletion could not be reversed, nor previous data accessed via RDC. Do not delete an eCRF page unless you are certain it should be.

Manage an Immediate System Discrepancy

Depending on eCRF design decided by the Sponsor, fields accept only some type of entries: numbers, characters, a maximum length, a value chosen in a list of values … If data entry does not meet these criteria, the system raises a discrepancy when cursor is moved to the following item or menu. For example, you cannot enter characters in a defined lab result field that requires numerals.
Complete list of potential immediate discrepancy types is:

- Length (comment too long)
- Data type (characters entered where numbers are expected)
- Decimal place, if number of characters after the comma exceeds the predefined length
- Upper or Lower bound exceeded
- Value not chosen in authorized List of Values.

Information

Field settings are defined at study setup in compliance with Protocol and Sponsor’s requirements. However, if you consider that an item is not associated with the appropriate format / list of values ..., please inform your study representative. Your proposal will be submitted to the eCRF designer for review.

If you enter data that conflicts with defined validation rules, Oracle RDC 4.6 alerts you accordingly with a ‘Validation Error’ window (see Figure 28: Example of Immediate System Discrepancy). To process a Validation Error, check that your entered data matches the source data and:

- Click Cancel if the entered data is incorrect or you want to navigate back to the response field. The ‘Validation Error’ window closes. Oracle RDC 4.6 will blank the field and return the value previously entered (if any) or a blank field.

Or in rare circumstances if the value is deemed correct:
- Enter an explanatory comment if desired.
- Select action ‘Data Confirmed’ and click OK. The ‘Validation Error’ window closes. You can resume data entry.

Figure 28: Example of Immediate System Discrepancy
Dynamism

Oracle RDC 4.6 allows 3 types of dynamism to be implemented: Interval rule, DCI rule and Conditional branching.

**Interval Rule**

Interval rules have the potential to enable one or more intervals, where an interval includes a set of visits and pages.

For example, if the patient is considered as eligible to the study during screening visit (trigger), the baseline visit (target) appears into the eCRF (see Error! Reference source not found. Information). This type of dynamism is reversible only in specific case. If the condition responsible of the dynamism is no more respected and no data has been entered in the interval page(s), the interval disappears. However, if the condition responsible of the dynamism is no more respected and data has been entered in the interval page(s), the interval does not disappear.

Figure 29: Dynamism – Example of Interval rule
DCI Rule

DCI rules have the potential to enable individual pages, based on responses to questions in the CRF. DCI rules can be made to apply to the current visit only or across different visits.

For example, the menopausal page (target) appears only for female patient (trigger).
(See Figure 30: Dynamism – Example of DCI rule).

Information

This type of dynamism is reversible only in specific case.
If the condition responsible of the dynamism is no more respected and no data has been entered in the target page, the target page disappears.
However, if the condition responsible of the dynamism is no more respected and data has been entered in the target page, the target page does not disappear.

Figure 30: Dynamism – Example of DCI rule

Conditional Branching

Conditional branching supports the design of CRF pages where you are directed to a different set of questions on a page, depending upon the response entered for a single source question.

For example, if abnormalities are observed for an examination (trigger), the field where the abnormalities need to be reported becomes available (target).
Information

This type of dynamism is reversible.

If trigger is no more respected and no data has been entered in the target field, the target field becomes unavailable.

Moreover, if the trigger is no more respected and data has been entered in the target page, the target field becomes unavailable and data entered disappear. However, as long as the page is not saved (by clicking on the green floppy), the data previously entered in the target field is not deleted from system. By consequence, if the trigger is again respected before page is saved, the data previously entered in the target field re-appear.

Figure 31: Dynamism – Example of Conditional branching
3. Discrepancy Management

eCRF is designed to collect specific data in pre-formatted fields. Oracle RDC 4.6 verifies data entry, and it eventually raises some discrepancies to alert users about a potential problem with data format or consistency. Depending on problem identified, discrepancies are generated at specific time points:

> During data entry, when you move focus out of the concerned field. It involves all simple discrepancies about data format. Please refer to chapter ‘Manage an Immediate System Discrepancy’ to learn more about their management.
> When a page is saved after a page entry or modification. These discrepancies compare data collected within one eCRF page.
> The day after eCRF pages entry or modification. These discrepancies compare data collected among several eCRF pages.
> Finally on a regular basis according to study specification. It concerns mainly complex discrepancies that require a manual review before posting to the eCRF, or reconciliation with external data such as randomization system data or centralized laboratory results. These discrepancies are generally displayed several days after eCRF page entry or modification.

This chapter describes how to manage the three last types of discrepancies from the eCRF page itself or via a dedicated interface of Oracle RDC 4.6.

Identify Patients and Pages with Discrepancies

Oracle RDC 4.6 displays colors for patients and pages according to their discrepancy statuses:

> A red patient icon means there is at least one active query to be managed by you for this patient. According to chapter ‘eCRF Icons for Discrepancy Status’, it also means there is at least one page displayed as red for this patient.

<table>
<thead>
<tr>
<th>Select</th>
<th>Number</th>
<th>P0001</th>
<th>P0002</th>
<th>P0003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>00011</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

> A yellow patient icon means there is no discrepancy active for you, but other users have to manage discrepancies that are open for them.

<table>
<thead>
<tr>
<th>Select</th>
<th>Number</th>
<th>P0001</th>
<th>P0002</th>
<th>P0003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>00001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Important

As an Oracle RDC 4.6 user, you are supposed to manage all discrepancies displayed as RED for you. You are not authorized to manage yellow discrepancies since they should be managed by another user. Green discrepancies cannot be managed because it is a final status, the query is closed.
Manage all Active Discrepancies

Discrepancies can be managed manually, patient by patient, visit by visit, page by page or in any sequential order as described in chapter 'Manage a Single Discrepancy'. It is also possible to access them from a specific module of Oracle RDC 4.6 to focus on problems only.

From Oracle RDC 4.6 homepage, select the patients with red icons only and choose Review Discrepancies in the drop-down list above the list of patients (see Figure 32: Discrepancies - Select Patient with Discrepancies). Press Go.

This link opens the Discrepancy Review tab with a pre-entered filter on active and other discrepancies for your selected patients.

CRA and Medical reviewers will also select patients with Yellow icons if they want to check discrepancies currently addressed to the site.

It is also possible to reach manually this section: from Oracle RDC 4.6 homepage, select the tab ‘Review’, and then sub-tab ‘Discrepancies’ (see Figure 8: RDC Tab ‘Review’ - Discrepancies)

This manual selection allows focusing only on ‘active discrepancies’ instead of ‘active and other discrepancies’.

To manage all discrepancies addressed to you, perform a filter with the ‘Search’ section of the page: select the discrepancy status ‘Active’ on the last filter box. Click Go.
It is also possible to combine one or more specific filters:

- Manage a range of patients only by selecting first and last patients with the magnifier glass.
- Manage discrepancies according to eCRF page status (entry started or complete, page verified by CRA or not, page approved or not, etc)
- Manage discrepancies of specific eCRF visits or pages only

**Information for CRA / Medical Reviewers**

From the Search pane, of the Discrepancy Review tab, users can also select ‘Open (Active and Other)’ Discrepancies to review both their discrepancies (red ones) and those that should be answered by the site (yellow ones).

Filtering Active discrepancies displays all red queries for your site (see Figure 34: Review Discrepancies - Search Result). This section contains one query per row, ordered by patient, visit and page. To access discrepancy details from the search results, click the hyperlinked text or details icon. To access the CRF from here, click on the CRF icon.

![Figure 34: Review Discrepancies - Search Result](image-url)

Click on the Detail icon of a row to check a single discrepancy. The ‘Discrepancy Details’ window provides details about error message, concerned values and discrepancy history (see Figure 35: Discrepancy Review - Discrepancy Details Window).
Section ‘Related Values’ refers to the one described in chapter ‘Manage a Single Discrepancy’. It lists all values in relation to the current discrepancy, in order to determine with a quick overview which value(s) has generated the potential error. However, this Discrepancy Details window also provides a direct link to the concerned pages (see Figure 36: Discrepancy Review - Open Page from Details Window).

From this point, discrepancy is then managed as described in chapter ‘Manage a Single Discrepancy’:

**IF AN UPDATE IS REQUIRED**, go to the concerned item and modify the entry according to your source documents. The system will prompt you for a Reason for Change: enter the one that is the most appropriate to your situation (see Figure 20: DEW - Reason for Change). Figure 21: DEW - Investigator Comment Return to your discrepancy message and choose action ‘Data Updated’ in the
Oracle RDC 4.6 prompts you for an optional comment (see Figure 39: Discrepancies - Optional Comment). Click OK and save your page.

> **IF NO UPDATE IS NECESSARY**, open your discrepancy in the Navigator pane and choose ‘Data Confirmed’ in the dropdown list Action. At this stage, Oracle RDC 4.6 prompts you for an optional comment (see Figure 39: Discrepancies - Optional Comment). When confirming a value, a comment is most welcome for avoiding repeating re-queries. Click OK and save your page.

Once the eCRF page is closed, close the Discrepancy Details window.

The discrepancy is still present in the Discrepancy Review tab, and the associated page is still red. Click on button Refresh on the left side of the section. Depending on its origin, an answered discrepancy will:

> Disappear from the Discrepancy Review window if your eCRF update solves the automatic check. Associated page will also appear with no colour, unless there is another open discrepancy related to this page.

> Become yellow in the Discrepancy Review window if the query was confirmed or created manually by another user and should be closed by him. Associated page will become yellow until the final resolution by another user, unless there is another open discrepancy related to this page.

All discrepancies are to be managed until all of them are yellow or have disappeared.

**Manage a Single Discrepancy**

From the ‘Home’ tab, identify a patient who has a discrepancy to manage (patient's icon is red). Select this patient and select ‘Open Patient Casebooks’. Press Go.

Open the eCRF page of this patient that is red. This page can be at any patient's visit.

By default, all fields in relation to open discrepancies are displayed in red.
Information

Even if there is only one discrepancy on an eCRF page, if this discrepancy involves several fields, all these fields will be red: number of red fields does not represent the number of open discrepancies.

In addition, if the same discrepancy involves fields on other pages too, these fields will appear as red when pages will be open.

To read discrepancy text in relation to red fields, open the ‘Navigator’ pane on the right side of the window. Several discrepancies may be open at the same time on the same page. Discrepancies are then figured out as several colored bullets in the Discrepancies tab of the Navigator pane. To access the one that is relevant for the highlighted field(s) you want to manage, click on this eCRF field: the focus will be done on this specific bullet in the Navigator pane. Click on this bullet to display the related error message.

Read the discrepancy text. To understand why this error has been generated, click on the ‘Related Values’ button of the Navigator pane: Oracle RDC 4.6 displays all values involved in the check, even those that have been entered on another page (see Figure 38: Discrepancies - Related Values).

Information

Using the Related Values button saves time because it gives you an overview of the potentially discrepant eCRF content without opening multiple eCRF pages to check your entry. From this overview, you can decide which value should be corrected (if any), and then go and correct the appropriate field.
After a review of all data involved in a discrepancy, you can decide whether the eCRF requires an update or if the current entry is confirmed.

**IF AN UPDATE IS REQUIRED**, return to the concerned item, and modify the entry according to your source documents. The system will prompt you for a Reason for Change: enter the one that is the most appropriate to your situation (see Figure 20: DEW - Reason for Change). Figure 21: DEW - Investigator Comment Return to your discrepancy message and choose action ‘Data Updated’ in the drop-down list Action at the bottom of the navigator pane. At this stage, Oracle RDC 4.6 prompts you for an optional comment (see Figure 39: Discrepancies - Optional Comment). Click OK and save your page.

- **IF NO UPDATE IS NECESSARY**, after a complete review of all items concerned by the discrepancy via the button ‘Related Values’, and you consider that your entry is appropriate and do not need to be modified, open your discrepancy in the Navigator pane and choose ‘Data Confirmed’ in the drop-down list Action. At this stage, Oracle RDC 4.6 prompts you for an optional comment (see Figure 39: Discrepancies - Optional Comment). When confirming a value a comment is most welcome for avoiding repeating re-queries. Click OK and save your page.

```
Discrepancy Action - Data Updated
```

![Figure 39: Discrepancies - Optional Comment](Image)

Depending on its origin, an answered discrepancy will:

- Disappear from the Navigator pane if your eCRF update solves the automatic check. Fields involved in the check will also appear with no colour, unless there is another open discrepancy related to these fields.

```
Date of randomization
```

![Figure 40: Discrepancies - Look of a Closed Atomatic Discrepancy](Image)
Become yellow if the query was confirmed or created manually by another user and should be closed by him. Fields involved in the discrepancy will become yellow until the final resolution by another user, unless there is another open discrepancy related to these fields. After the final resolution by this user, fields and discrepancy will appear as green.

**Figure 41: Discrepancies - Look of an Answered Manual Discrepancy**

**Access all Active Discrepancies from Homepage**

From the Homepage of Oracle RDC 4.6, there is a link to access directly all active discrepancies to manage.
In the section ‘Activities’ from Home tab, click on the link ‘Review XX Active Discrepancies’ (see Figure 42: Access all Active Discrepancies from Homepage).
This link will open the Review Discrepancies tab, with a filter already applied on all active discrepancies (red ones).

**Information for CRA / Medical Reviewers**
The link ‘Review XX Other Discrepancies’ works the same, it will display all open queries to be managed by other users (i.e. site users) as yellow for you. This link is useful to have a global overview of site activities before a monitoring visit.

**Figure 42: Access all Active Discrepancies from Homepage**
Discrepancy Management Wrap-Up

> Only Red discrepancies are to be managed.
> Answered discrepancies, depending on their origin, will
  o become Yellow if your answer needs a peer review
  o become Green after review of your answer by another user
  o disappear if your answer closes an automatic question
> Do never apply an action on a discrepancy that does not appear as Red because this one is not intended for you. Data Management will regularly produce listings to review discrepancies not answered by the appropriate user and will resend them.
> Discrepancies can be managed on a page-by-page basis or globally from the Discrepancy Review tab. This last solution is more comfortable to answer several open discrepancies.
4. Manual Queries

Oracle RDC allows users with sufficient privileges to address some manual queries to the site for clarification. Each manual query sent by a user should be verified and closed by a user with the same privilege level after site review.

Creation of a manual query in the eCRF

Inside the eCRF page, identify the data which requires a site review. Place the pointer on this field and right click: from the contextual menu, choose ‘Add discrepancy’.

A window ‘Add discrepancy’ appears (see Figure 43: Manual query - add a query). Several fields are to be completed:

1. Reason: this field defaults to ‘DM Query’, choose the appropriate reason to suit your role. For example, if you are a CRA, choose ‘CRA query’, or ‘MR query’ if you are a Medical reviewer …

Important

If the field ‘Reason’ is not properly completed per your profile in Oracle RDC, you will NEVER be forwarded the answer to this query, so follow up will be impossible.
2. Description: it is the place where the question should be asked.
3. Action: indicate from the codelist who is the addressee of this manual query. For the investigator, select ‘To be reviewed by site’.
4. Click ‘OK’ to validate your entry.

The related field will then appear as yellow with your profile (unless there is another query to be answered by you on the same field) and red for the investigator. Investigator will then view and manage this query as any other system queries.

**Information**

Only one manual query can be created on one field. It includes manual queries already closed. If you try to create a manual query on a field already associated to a previous manual query, the query text will appear pre-populated with the previous query text. Click then on ‘Cancel’ and create your query on another field of the same eCRF page. Alternatively you can create a ‘Section Discrepancy’ instead of ‘Field Discrepancy’.

**Reviewing and closing manual queries**

Immediately after the management of a manual query by the site staff, this query is displayed as yellow for the site and not accessible for issuer of the query. The Data Manager will forward on a daily basis the answered query to the CRA or MR, it is only after this action that it will appear as red for the issuer deemed most appropriate to deal with the query at this stage. If your profile allows query management, it is possible to access these queries from 2 paths:

- Either follows the link ‘Review XX active discrepancies’ from the Oracle RDC Homepage (see Figure 44: Manual queries - Select answered queries).

- Or, from the ‘Review – Discrepancy’ tab, expand the Search pane and apply the filter Discrepancy status ‘Active’, press Go and sort the answered queries of your site by Review Status (click on the column label with the same name to sort table content) (see Figure 45: Manual queries - Select answered queries - List).
From this list of queries with review status ‘CRA VERIFY’, open the queries by clicking on the page icon at the end of each line.

Inside the eCRF page, display the Discrepancy management pane and identify your manual query. Check the consistency of the answer with your question: investigator answer may consist in eCRF update or in a note reported in the field ‘Comment’. Depending on the answer, the query may require to be resent to the site for further clarification, or can be closed immediately.

> If the query is to be resent to the site, just apply action ‘To be reviewed by site’, and update the query text to add more details if necessary and press Go.

> Otherwise, if the answer corresponds to the question, close the query with action ‘CRA – Resolved’ and press Go. A pop-up window ‘Discrepancy Action’ will then require a ‘Resolution Reason’. Select in the codelist the most appropriate one within ‘Data updated’ or ‘Data confirmed’.

When page will be saved, the field where the manual query was created will appear as yellow in case the query was resent, or as white in case the query was closed.
5. Investigator Comments Review

Investigator Comments Selection

Investigator Comments are reported at an item level in eCRF pages. They can be reviewed manually, i.e. by entering each eCRF page and reviewing its whole content, or globally.

The easiest, but also less specific way, to open all investigators comments is to click on the link 'Review Investigator Comments' from the section 'Activities' on the left of Oracle RDC 4.6 homepage (see Figure 47: Access all Investigator comments for review from Homepage). This link will open the Review – Investigator Comments tab and display all investigator comments for all patients, all pages.

It is also possible to select only some patients to review. From Oracle RDC 4.6 homepage, select required patients only and choose Review Investigator Comments in the drop-down list above the list of patients. Press Go. This link opens the Investigator Comments Review tab with comments displayed for your selected patients.

Finally, it is also possible to open directly the Review - Investigator Comments tabs and apply a manual filter at this step (e.g. on all informed consent pages, date of birth …).

Information for CRA / Medical Reviewers

The addition of an investigator comment on a page removes the status ‘verified’. If all your pages were verified at the last visit and you want to review all new comments, go in Review – Investigator Comments tab, unfold the Search pane, and apply a filter on all eCRF pages ‘Awaiting Re-Verification’. Only new or modified comments will be displayed.
**Investigator Comments Review**

List displayed in Review – Investigator Comments tab contains patient, visit and page identifiers. Each comment is associated with the name of the item it was created on as well as its current value. If needed, the whole eCRF page where the comment stands can be displayed by clicking the page icon at the right end of the row.

![Figure 49: Investigator Comments - Review All Comments](image)

For more details about management of investigator comments inside a page, please see chapter Insert an Investigator Comment.
6. eCRF Page Verification (for CRA only)

Source Data Verification is an important step in eCRF processing. If this step is not done regularly, it will become more and more difficult to identify new or modified eCRF data from one monitoring visit to the following one. It is recommended to flag a page as verified as soon as it has been checked. A page can have different statuses regarding verification:

- **NOT VERIFIED**: the Source Data Verification process has not started on this page, or the verification status has intentionally been removed from this page by the CRA (see Verification Undone).
- **VERIFIED**: data reviewed and approved by the CRA
- **AWAITING RE-VERIFICATION**: page has been verified at least once, but a change on data, discrepancies or comments has occurred since this verification. Modified content needs to be checked again.
- **VERIFICATION UNDONE**: verification status has been applied by mistake so CRA has removed it. This status is included in Not Verified pages.

Please see chapter eCRF Icons for Verification Status for related eCRF icons in workspace.

**Find eCRF Pages to Verify**

‘Activities’ section from the Oracle RDC 4.6 homepage proposes a direct link to ‘Review non-blank CRFs ready for initial verification’ (see Figure 50: Verification - Review non-blank CRFs ready for initial verification). This link will open the Review CRFs tab, with a filter pre-defined on pages complete, without open discrepancies and never verified before. That is an easy point to start verification activities, however it will not allow a complete check of your site CRFs.

Please follow the steps below for a complete overview of the verification process.

From Oracle RDC 4.6 homepage, select the Review tab, and then sub-tab CRFs (see Figure 7: RDC Tab ‘Review’ - CRFs). Then, in the Search pane, put the Verification status to ‘Not Verified’. Press Go. This manual selection focuses only on eCRF pages that have never been verified (including pages flagged as having no data, i.e. blank pages).

*Figure 50: Verification - Review non-blank CRFs ready for initial verification*

*Figure 51: Verification - List of Pages to Verify*
Each row describes eCRF page properties: identifiers, dates for modification, verification, approval and lock. Click on eCRF page icon at the right end of the row to open the corresponding page and review its content.

**Verify eCRF pages**

Once verification of the page content is finished, it should be marked as ‘Verified’ by the CRA. It can be done page-by-page, or globally for a selection of pages.

**Mark a Single Page as Verified**

Open the page to flag as ‘Verified’. On the toolbar, press icon Verify.

![Verify icon](image)

The window ‘Verify CRF’ appears (see Figure 52: Verification - Comment Window). An optional comment can be added at this stage. This window will also list all previous actions in relation to the verification process: date of the initial signature, when signature was removed, when page has been re-signed, etc.

![Verify CRF window](image)

**Figure 52: Verification - Comment Window**

Press Verify and save the page with the green floppy. A message warned you that nothing has changed, so there is no need to save the page, because content has not changed. Your signature is however taken into account and recorded.

Close the page and return to the workspace. Click on Refresh to update the eCRF page icon. The page is now flagged with a tick box.

**Information**

eCRF pages that have been modified after application of a verification status appear with a red arrow beside the tick box. These pages should be verified again. Modifications can be a data change, an answered query or a comment created.
Mark Several Pages as Verified

From Oracle RDC 4.6 homepage, select the Review tab, and then sub-tab CRFs (see Figure 7: RDC Tab ‘Review’ - CRFs). Then, in the Search pane, select the Verification status 'Not Verified'. Press Go.

The list of pages appears as described in Figure 51: Verification - List of Pages to Verify.

Once pages content checked, tick the box beside each eCRF pages to flag as verified, and select Verify in the menu above the list of pages. Press Go (see Figure 53: Verification - Verify Several Pages process).

A window Verify CRFs appears. Default is to approve all eCRF pages selected previously except those that have discrepancies. Verification status will indeed be removed when these discrepancies will be answered. You can however bypass this by un-ticking the box. You will at least know that these pages have been verified at least once, and then need to review only changes.

Press on Continue.

Figure 53: Verification - Verify Several Pages process

After an intermediate step to confirm your operation (Press Yes), system displays a confirmation message with the number of pages verified. The workspace is refreshed and pages now appear with the tick box.
Find eCRF Pages to Re-Verify

Re-verification is needed for pages that have been modified since the previous check. Process is the same as described in chapter Mark Several Pages as Verified, except that selection in Search pane should be verification status: ‘Awaiting Re-Verification’.

Remove Verification Status

If a verification status has been applied by mistake on one or several pages, it can be removed by the same way it was put.

For a single page, click on the Verify icon of the eCRF toolbar. Check the verification history and click on button ‘Undo Verification’ (see Figure 56: Verification - Remove for a Single Page). Save your page and refresh the workspace: the tick box does not appear anymore on the eCRF page icon.

For a range of pages, apply the appropriate filter in the Search pane of Review CRFs tab (e.g. pages verified for the concerned patients only) and press Go. Tick the boxes for all pages to un-verify, and select UnVerify in the menu above the list of pages. Press Go. A window Undo Verification on CRFs appears. Press Continue (see Figure 57: Verification - Remove for a Range of Pages).

After an intermediate step to confirm your operation (Press Yes), system displays a confirmation message with the number of pages unverified. The workspace is refreshed and selected pages now appear without the tick box.
Figure 57: Verification - Remove for a Range of Pages
7. eCRF Approval / Signature (for Investigator only)

eCRF Approval is an important step in processing: it is the electronic equivalent of the paper CRF signature. Signature is generally applied after the page verification by the CRA, because any change required by the CRA would remove the approval status.

It can be applied by any site-user that has been granted that right by the Sponsor: it is generally the principal investigator and/or co-investigators. Study nurses are not given the right to sign eCRF pages.

All eCRF pages should be signed before to close the study. Sponsor can make it mandatory for different milestones or at the end of the study, investigator can however sign pages on a more frequent basis than Sponsor’s requirements.

A page can have different statuses regarding signatures:

- **NOT APPROVED**: the investigator has not signed this page, or the approval status has intentionally been removed from this page by the investigator (see Approval Undone).
- **APPROVED**: data reviewed and signed by the investigator.
- **WAITING RE-APPROVAL**: page has been signed at least once, but a change on data, discrepancies or comments has occurred since this signature. Modified content needs to be signed again.
- **APPROVAL UNDONE**: approval status has been applied by mistake so investigator has removed it. This status is included in Not Approved pages.

Please see chapter eCRF Icons for Approval Status for related eCRF icons in workspace.

**Find eCRF Pages to Approve**

‘Activities’ section from the Oracle RDC 4.6 homepage proposes a direct link to ‘Review non-blank CRFs ready for initial approval’. This link will open the Review CRFs tab, with a filter pre-defined on pages complete, without open discrepancies and never approved before.

That is an easy point to start approval activities; however it will not allow a complete check of your site CRFs.

Please follow the steps below for a complete overview of the approval process.

From Oracle RDC 4.6 homepage, select the Review tab, and then sub-tab CRFs. Then, in the Search pane, put the Approval status to ‘Not Approved’. Press Go.
This manual selection focuses only on eCRF pages that have never been signed (including pages flagged as having no data, i.e. blank pages).

Each row describes eCRF page properties: identifiers, dates for modification, verification, approval and lock. Click on eCRF page icon at the right end of the row to open the corresponding page and review its content.

Approve eCRF pages

Once check of the page content is finished, it should be marked as ‘Approved’ by the investigator. It can be done page-by-page, or globally for a selection of pages.

Mark a Single Page as Approved

Open the page to flag as ‘Approved’. On the toolbar, press icon Approve.

The window ‘Approve CRF’ appears (see Figure 61: Approval - Comment Window). An optional comment can be added at this stage. This window will also list all previous actions in relation to the approval process: date of the initial signature, when signature was removed, when page has been re-signed ...
Press Approve and complete the next window (CRF Approval Signoff) with your Oracle RDC 4.6 login and password. System displays a window to confirm the new status of the page. Press Close.

![Figure 62: Approval - One Page Signature & Confirmation](image)

Save the page with the green floppy. Close the page and return to the workspace. Click on Refresh to update the eCRF page icon. The page is now flagged with a signature at the bottom of the icon.

**Information**

eCRF pages that have been modified after application of an ‘Approved’ status appear with a red arrow beside the signature. These pages should be signed again. Modifications can be a data change, an answered query or a comment created.

**Mark Several Pages as Approved**

From Oracle RDC 4.6 homepage, select the Review tab, and then sub-tab CRFs (see Figure 7: RDC Tab ‘Review’ - CRFs). Then, in the Search pane, select the Approval status ‘Not Approved’. Press Go. The list of pages appears as described in Figure 60: Approval - List of Pages to Approve.

Once pages content checked, tick the box beside each eCRF pages to flag as approved, and select Approve in the menu above the list of pages. Press Go.

A window Approve CRFs appears (see Figure 63: Approval - Approve Several Pages). Default is to approve all eCRF pages selected previously except those that have discrepancies and those not verified yet by the CRA. Approval status will indeed be removed when discrepancies will be answered or verified by the CRA. You can however bypass this by un-ticking the boxes. You will at least know that these pages have been signed at least once, and then need to review only changes the next time.
After an intermediate step to confirm your operation, system displays a confirmation message with the number of pages verified. The workspace is refreshed and pages now appear with the signed icons.

Find eCRF Pages to Re-Approve

Re-approval is needed for pages that have been modified since the previous check. Process is the same as described in chapter Mark Several Pages as Approved, except that selection in Search pane should be approval status: ‘Awaiting Re-Approval’.
Remove Approval Status

If an approval status has been applied by mistake on one or several pages, it can be removed the same way it was put.

For a single page, click on the ‘Approval icon’ of the eCRF toolbar. Check the approval history and click on button ‘Undo Approval (see Figure 66: Approval - Remove for a Single Page). The system requires entering your Oracle RDC 4.6 login and password. After the confirmation message, save your page and refresh the workspace: the signature does not appear anymore at the bottom of the eCRF page icon.

For a range of pages, apply the appropriate filter in the Search pane of Review CRFs tab (e.g. pages approved for the concerned patients only) and press Go. Tick the boxes for all pages to un-sign, and select UnApprove in the menu above the list of pages. Press Go. Your Oracle RDC 4.6 login and password are required. A window UnApprove CRFs appears. Press Continue. After an intermediate step to confirm your operation, system displays a confirmation message with the number of pages unsigned. The workspace is refreshed and selected pages now appear without the signed icon.

Figure 66: Approval - Remove for a Single Page

Figure 67: Approval - Remove for a Range of Pages
Oracle RDC 4.6 booklet
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10. About Quintiles

Quintiles, Navigating the new health

Each Quintiles company has won industry respect and customer loyalty by combining highly specialized skill sets – such as therapeutic area expertise and an understanding of global and local regulatory environments – with an uncommon dedication to providing superlative service.

Together, our 21,000 specialized employees play an unequaled role in improving healthcare worldwide by providing a broad range of professional services, information and partnering solutions to the pharmaceutical, biotechnology and healthcare industries. In fact, Quintiles companies have helped develop or commercialize every one of the world’s top 30 best-selling drugs.

Founded in 1982 by Dennis Gillings, Ph.D., CBE, and headquartered near Research Triangle Park, North Carolina, we have offices in more than 50 countries and provide services in many more.

Our competitive edge lies in our ability to leverage data, therapeutic expertise, full-service capabilities and global resources through an integrated information technology network. We hone our competitive edge by constantly scanning the horizon for opportunities and offering our customers the best information to accelerate and improve healthcare decisions.

Corporate Snapshot

We help customers succeed by providing services and solutions via three major groups:

**QUINTILES® product development services**, which provides all clinical research aimed at regulatory approval, and post-launch research and consulting on product safety and value.

- **Phase I** Services for early-phase human drug development.
- **Global Clinical Development Services**, encompassing all Phase II-IV trial services, such as clinical trial management, medical and regulatory affairs, biostatistics, patient recruitment, ECG services, and drug safety and strategic research.
- **Global Central Labs** to support all phases of clinical trials.
- **Global Data Management** to capture, analyze and report patient-related data.
- **Global Consulting** on product development; reimbursement and pricing; health outcomes; regulatory compliance (e.g., FDA enforcement, quality systems); and due diligence for pharmaceutical, biotech and medical device companies.
- **Medical Education** involving the development and delivery of Continuing Medical Education (CME) programs for health care practitioners.

**INNOVEX® commercialization**, responsible for sales force and medical communication services.

- **Sales solutions**, including the recruitment, training and deployment of customer- or Innovex-managed primary and secondary sales teams; health management services; and vacancy management.
Medical communications to promote physician education and communications programs, including symposia, exhibition support at major scientific congresses, advisory boards and publication planning.

NOVAQUEST® strategic partnering solutions to help pharmaceutical and biotech companies optimize portfolio development, company growth and profits through innovative, tailored financial and strategic solutions.

- Structured finance: tailored financial solutions for customers needing financial support via funding, development or commercialization services.
- Strategic resourcing: long-term, strategic outsourcing or insourcing relationships that reduce fixed costs and increase resource flexibility.
- eBio: Specialized strategic and financial solutions for emerging biotech and pharma companies.

Further differentiating Quintiles' service delivery is its access to unique patient-level healthcare information and data products.

11. Version History

<table>
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| Changes from Version 1.3 to Version 2.1 | Front page updated.  
|                | Tables of Contents updated.  
|                | All tabs and figures named or renamed.  
|                | All blue bow: title modified into ‘Information’  
|                | Index updated.  
|                | Table of figures updated.  
|                | Version history updated.  
|                | - Entire document  
|                | Oracle Clinical RDC 4.5.3 replaced by Oracle Clinical RDC 4.6  
|                | - Section1: What’s new in Oracle RDC 4.6  
|                | Improvements described.  
|                | - Section 2: Starting and closing Oracle RDC 4.6  
|                | Figure 2 added.  
|                | - Section 2: Navigate through tabs  
|                | Figure 4 added.  
|                | - Section 2: Exploring tab ‘Home’  
|                | Description of area “Links” added.  
|                | Figure 5 inserted.  
|                | - Section 2: Exploring tab ‘Casebooks’  
|                | Figure 6 updated and inserted.  
|                | - Section 2: Exploring tab ‘Review’  
|                | Figures 7, 8 and 9 updated and inserted.  
|                | - Section 2: Exploring tab ‘Reports’  
|                | Figure 11 updated and inserted.  
|                | - Section 2: Open eCRF page to enter  
|                | Figure 12 updated.  
|                | - Section 2: Navigate in data entry window  
|                | Figure 13 updated.  
|                | Preferences: choice ‘None’ described  
|                | - Section 2: Navigator pane  
|                | Figures 15 and 16 updated. |
- Section 2: Audit trail pane
  Figure 17 updated.
- Section 2: Save data entered in eCRF page
  Green floppy icon added.
  Figure 19 updated.
- Section 2: Delete an eCRF page
  Sub-section inserted.
- Section 2: Dynamism
  Sub-section added.
- Section 3: Manage all active discrepancies
  Figures 32, 34, 35 and 36 updated.
- Section 3: Access all active discrepancies from homepage
  Figure 42 updated.
- Section 4: Creation of a manual query in the eCRF
  Figure 43 updated.
- Section 4: Reviewing and closing manual queries
  ‘Send to investigator’ replaced by ‘To be reviewed by site’.
  Figure 46 updated.
- Section 5: Investigator comments selection
  Figure 47 updated.
- Section 5: Investigator comments review
  Figure 49 updated.
- Section 6: Find eCRF pages to verify
  Figure 50 added.
  Figure 51 updated.
- Section 6: Mark several pages as verified
  Figure 54 updated.
- Section 6: Find eCRF pages to re-verify
  Figure 55 added.
- Section 6: Remove verification status
  Figure 57 updated and moved.
- Section 7: Find eCRF pages to approve
  Figure 58 added.
  Figures 59 and 60 updated.
- Section 7: Find eCRF pages to re-approve
  Figure 65 added.
- Section 7: remove approval status
  Approval icon added.