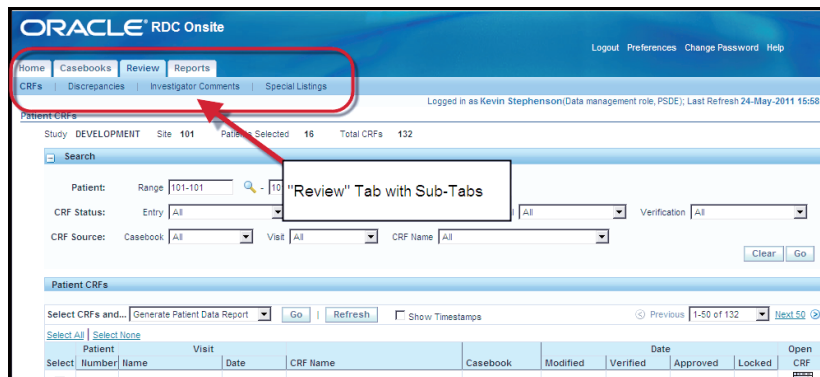


The Review Tab

The Review tab is used to access information about CRFs and Queries.

Using the sub-tabs, you are able to select CRFs or Discrepancies, and the information will display based on the original search values.

These reports are covered in more detail in the Reports and Listings section of this reference guide.



Opening a CRF

To open the CRF from the Casebook Spreadsheet, select the icon for the CRF you want to access.

The screenshot shows the ORACLE RDC Onsite interface. At the top, there are navigation tabs: Home, Casebooks, Review, and Reports. The 'Casebooks' tab is selected. Below the tabs, there is a header area with 'Logged in as Kevin Stephenson(Data management role, PSDE); Last Refresh 24-May-2011 16:33:32'. To the right of the header, there are links for Logout, Preferences, Change Password, and Help. Below the header, there is a section for 'Patient Casebooks'. A search bar indicates 'Search : 3 Patients Selected From Home Page'. Below the search bar, there is a 'Casebook Spreadsheet' section. This section contains a table with columns for Patient, DOV, Inc_Exc, Demography, Medh1_Yn, Medh2, Vitals_Scr, Phys_Exam, Chemistry, and Medhist. The table has three rows of patient data. A red circle highlights the CRF icon for Medh2 in the row for patient 201-101. A callout box with the text 'Select a CRF to open' points to this icon.

Select	Patient	DOV	Inc_Exc	Demography	Medh1_Yn	Medh2	Vitals_Scr	Phys_Exam	Chemistry	Medhist
<input type="checkbox"/>	201-100	1	2	3	4	5	6	7	7.1	
<input type="checkbox"/>	201-101	1	2	3	4	5	6	7	7.1	
<input type="checkbox"/>	201-102	1	2	3	4	5	6	7	7.1	5

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As the CRF opens, a **Processing...** indicator will display. It may take a couple of seconds for the CRF page to load.

The CRF will then open and allow you to enter data, make data updates or perform other actions within the CRF.

Tip: For best viewing and data entry, maximize the eCRF window.

NOTE: RDC allows you to open a maximum of **three** CRFs at once to do data comparison. If you already have three CRFs open, the system prompts you to close at least one CRF before you will be allowed to open another.

When you are finished working with all the CRFs, you will need to close each one individually.



CRF Scroll Bars

In order to see all fields on the eCRF, it may be necessary to use the scroll bar on the right section of the window.

ORACLE RDC Onsite: Data Entry Preferences Help

Study: 101MS325, Site: 432203, Patient: T21, Casebook: 101MS325- (Kevin Stephenson - Data management role)

Previous CRF Next CRF

Highlight All Discrepancies Page 1/2

The scroll bar allows you to move down the CRF and see all the fields present

page 2

biogen idec Protocol ID 101MS325 Visit SCREENING

Subject T21 Page PHYSICAL_EXAMINATION

PHYSICAL EXAMINATION (Page 2 of 2)

Body system	Abnormal examination findings
VASCULAR	NOT DONE <input type="checkbox"/> NORMAL <input type="checkbox"/> ABNORMAL <input type="checkbox"/>
ABDOMEN	NOT DONE <input type="checkbox"/> NORMAL <input type="checkbox"/> ABNORMAL <input type="checkbox"/>

Saving Data

After all data has been entered on the CRF, it must be saved.

Note: If the CRF is not saved then all data entered or updated will be lost.

A **Saving...** indicator will appear and it may take several seconds for the page to save.

The screenshot displays the 'ORACLE RDC Onsite: Data Entry' web application. The top navigation bar includes 'Study: 101MS325, Site: 432203, Patient: T21, Casebook: 101MS325 - (Kevin Stephenson - Data management role)' and links for 'Previous CRF' and 'Next CRF'. A toolbar at the top contains various icons, with the 'Save' icon (a green floppy disk) circled in red. A red arrow points from this icon to a text box that reads 'Click on the SAVE icon to save data on the CRF'. Below the toolbar, the 'biogen idec' logo is visible next to fields for 'Protocol ID' (101MS325), 'Visit' (SCREENING), 'Subject' (T21), and 'Page' (DEMOGRAPHY). The main section is titled 'DEMOGRAPHY' and contains form fields for 'Sex' (with 'FEMALE' selected), 'Date of birth' (JAN-1970), and 'Race' (with 'BLACK OR AFRICAN AMERICAN' selected). A blue box with a red circular arrow and the text 'Saving...' is overlaid on the form, with a red arrow pointing to it from a text box that reads '"Saving..." will appear while the CRF data is being saved'.

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A dialog box displays confirming the save operation and you will need to click the **OK** button.

The screenshot displays the Oracle RDC Onsite: Data Entry application. The top navigation bar includes the Oracle logo, the text 'RDC Onsite: Data Entry', and a 'Preferences' link. Below this, a status bar shows 'Study: 101MS325, Site: 432203, Patient: T21, Casebook: 101MS325- (Kevin Stephenson - Data management role)' and buttons for 'Previous CRF' and 'Next CRF'. A 'Highlight' dropdown menu is set to 'All Discrepancies'. The main form area contains fields for 'Protocol ID' (101MS325), 'Visit' (SCREENING), 'Subject' (T21), and 'Page' (DEMOGRAPHY). The 'DEMOGRAPHY' section includes checkboxes for 'Sex' (FEMALE is selected), 'Race' (WHITE is selected), and 'Date of birth' (JAN-1970). A red rectangular box highlights a modal dialog box titled 'Oracle Clinical RDC' which contains the text 'Saved.' and an 'OK' button. A red arrow points from a text box to the 'OK' button.

Oracle Clinical RDC

Saved.

OK

A dialog box displays confirming the save operation. Click the **OK** button to confirm.

Closing a CRF

Once data has been saved, you can click the Red **X** to close the CRF and return to the Casebook Spreadsheet.

Tip: Click Next CRF to go to the next CRF page for this visit.

Note: If you are on the last CRF page for this visit, you will need to close the CRF to open a CRF for another visit.

The screenshot shows the ORACLE RDC Onsite: Data Entry interface. At the top, the title bar reads "ORACLE RDC Onsite: Data Entry". Below it, the study information is displayed: "Study: 101MS325, Site: 432203, Patient: T22, Casebook: 101MS325 - (Kevin Stephenson - Data management role)". A toolbar contains various icons, including a red X icon. A red box highlights the "Previous CRF" and "Next CRF" buttons, with a red arrow pointing to the red X icon. A text box on the right side of the interface contains the following instructions: "Use the X to close a CRF." and "Use Previous CRF and Next CRF to navigate to the previous or next CRF." The main content area shows the "biogen idec" logo, the Protocol ID "101MS325", and the Subject "T22". Below this, the "MEDICAL HISTORY" section is visible, with a question: "Does the subject have any ongoing or resolved medical or surgical history?" and two radio buttons: "YES" and "NO". The "NO" button is selected. At the bottom, a note states: "If Yes, please record the details on the next CRF. (MEDICAL HISTORY)".

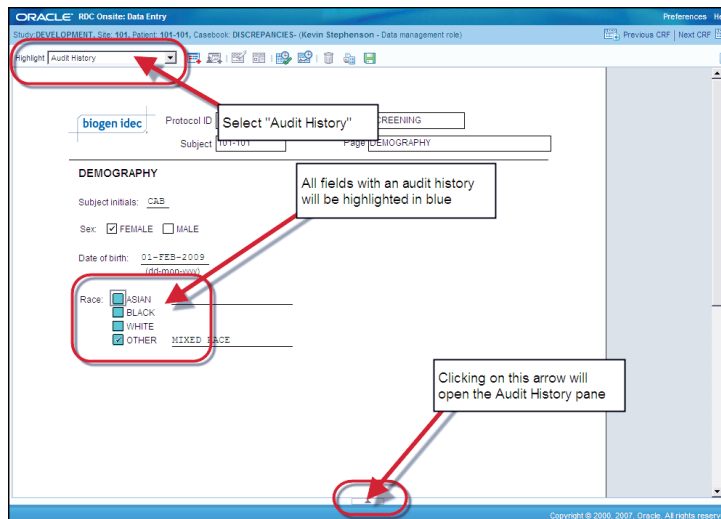
Audit History Pane

All initial data entry and changes are tracked in the application audit history. The audit history can be viewed within a CRF page for any data fields that contain changes after the initial Save.

Before expanding the Audit History pane, choose Audit History from the Highlight drop down list.

After you select Audit History in the Highlight drop-down list, all fields that contain an audit history on the CRF will be highlighted with a blue background.

To view the Audit History pane on an open CRF, you will click the small button on the lower center section of the window.



Click on any field highlighted in blue to display the audit information in the Audit History pane.

Note: Only fields which have been modified since the initial save will have an audit history.

Tip: The details icon provides a different view of the same information shown in the audit history pane and allows you to easily read a lengthy comment.

The screenshot shows the ORACLE RDC Onsite: Data Entry application. The main form displays patient information for Study DEVELOPMENT, Site 101, Patient 101-101, Casebook DISCREPANCIES - (Kevin Stephenson - Data management role). The form includes fields for Protocol ID (DEVELOPMENT), Visit (SCREENING), Subject (101-101), and Page (DEMOGRAPHY). The DEMOGRAPHY section shows Subject initials (CAB), Sex (FEMALE), Date of birth (01-SEP-2009), and Race (ASIAN). The Audit History pane at the bottom shows the history for the Race field, with a table containing one entry: Date 20-SEP-2009 15:44:07, Changed From BLACK, Changed To OTHER, By Rdc4 Site, Reason SITE EDIT, and Comment. A red box highlights the Race field in the main form and the Audit History pane. A callout box points to the Race field with the text "Select a data field you want to see the audit history for...". Another callout box points to the Audit History pane with the text "The Audit History pane will provide the data change history for the field selected.".

ORACLE® RDC Onsite: Data Entry

Study: DEVELOPMENT, Site: 101, Patient: 101-101, Casebook: DISCREPANCIES - (Kevin Stephenson - Data management role)

Highlight: Audit History

biogen idec Protocol ID: DEVELOPMENT Visit: SCREENING

Subject: 101-101 Page: DEMOGRAPHY

DEMOGRAPHY

Subject initials: CAB

Sex: ☒ FEMALE ☐ MALE

Date of birth: 01-SEP-2009

Race: ☒ ASIAN ☐ BLACK ☐ WHITE ☐ OTHER MIXED RACE

Select a data field you want to see the audit history for...

The Audit History pane will provide the data change history for the field selected.

Audit History: Race Code

Date	Changed From	Changed To	By	Reason	Comment	Details
20-SEP-2009 15:44:07	BLACK	OTHER	Rdc4 Site	SITE EDIT		

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Marking & Unmarking a CRF as Blank

The Blank Flag tool is used to intentionally mark a CRF, or a section of a CRF, as blank.

This is used when an assessment or visit was expected but not performed.

Marking the CRF blank notifies others that this page was not missed but intentionally left blank.

NOTE: If an entire visit is missed, each individual CRF within that visit must be marked as blank.

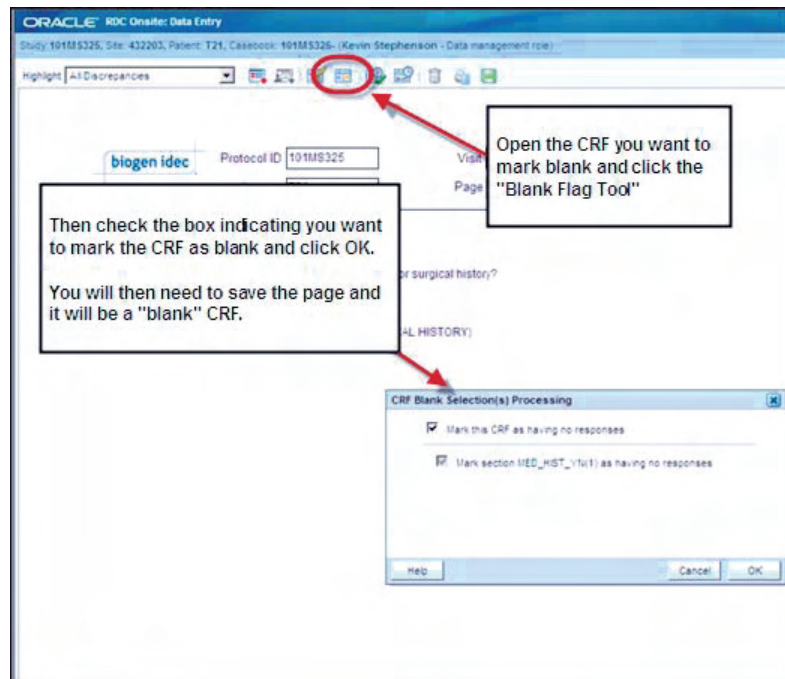
Using the Blank Flag Tool button

The Blank Flag tool can be used to mark an entire CRF as blank.

When the CRF Blank Selection(s) Processing window displays, you may check a CRF as having no responses.

Click the **OK** button to mark the CRF blank then click the **Save** button.

The data fields on the CRF will be grayed out indicating that the CRF is marked blank.



Unmarking a CRF as Blank

Once a CRF, or field(s), is grayed out (marked blank) you will need to click the Blank Flag tool and remove the check from the selected box in order to make these fields available for data entry.

Click the Blank Flag tool and the CRF Blank Selection(s) Processing window will open.

To enable the data entry fields on this eCRF, the checks must be removed.

The Change Reason area displays at the bottom of the CRF Blank Selection(s) Processing window. You are required to provide a reason for the change by selecting the appropriate reason from the drop down list.

Comments are optional and all changes are viewable in the audit history pane.

The screenshot displays the Oracle RDC Onsite: Data Entry application. At the top, the header shows 'Study 101MS325, Site 432203, Patient: T21, Casebook: 101MS325 - (Kevin Stephenson - Data management role)'. Below this, a toolbar contains various icons, with the 'Blank Flag Tool' (a flag icon) circled in red. A callout box points to this icon with the text: 'To "un-blank" a CRF, open the CRF and click the "Blank Flag Tool"...'. The main form area shows 'biogen idec' as the site name, with fields for 'Protocol ID' (101MS325) and 'Subject' (T21). Below this is the 'MEDICAL HISTORY' section, which includes a question: 'Does the subject have any ongoing or resolved medical conditions?' with 'YES' and 'NO' checkboxes. A second callout box points to the 'CRF Blank Selection(s) Processing' window, which is open. This window has two checkboxes: 'Mark this CRF as having no responses' and 'Mark section MED_HIST_YN(1) as having no responses'. A third callout box points to the 'Change Reason' section at the bottom of the window, which contains a note: 'Note: Any additional header changes made before the next save will use the same reason for change and comment.' Below the note is a 'Reason' dropdown menu (currently set to 'Site Edit') and a 'Comment (optional)' text area. The window has 'Help', 'Cancel', and 'OK' buttons at the bottom.

Then uncheck all the boxes and click "OK". This will allow data entry on the CRF.