

Source Document Verification (CRAs Only)

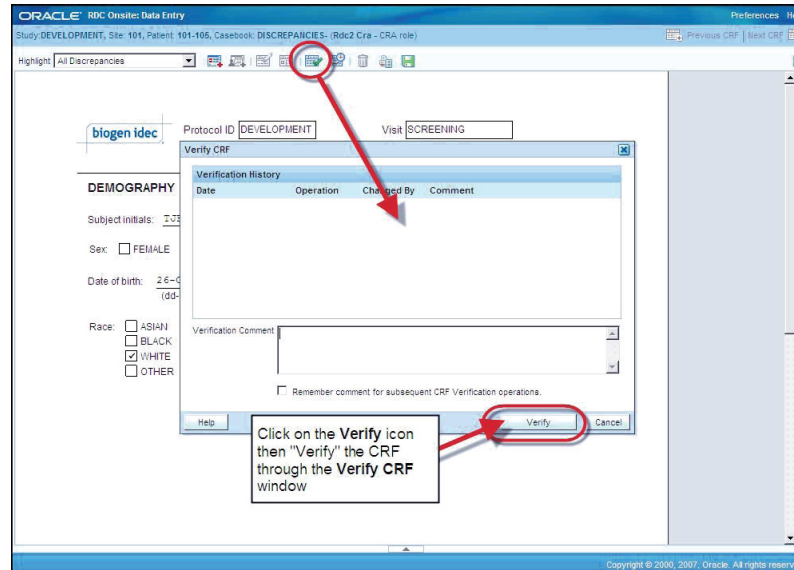
CRFs can be reviewed and source document verified according to the monitoring plan once a site has:

- Finished data entry
- Resolved all discrepancies

Important: Group verification is not standard practice.

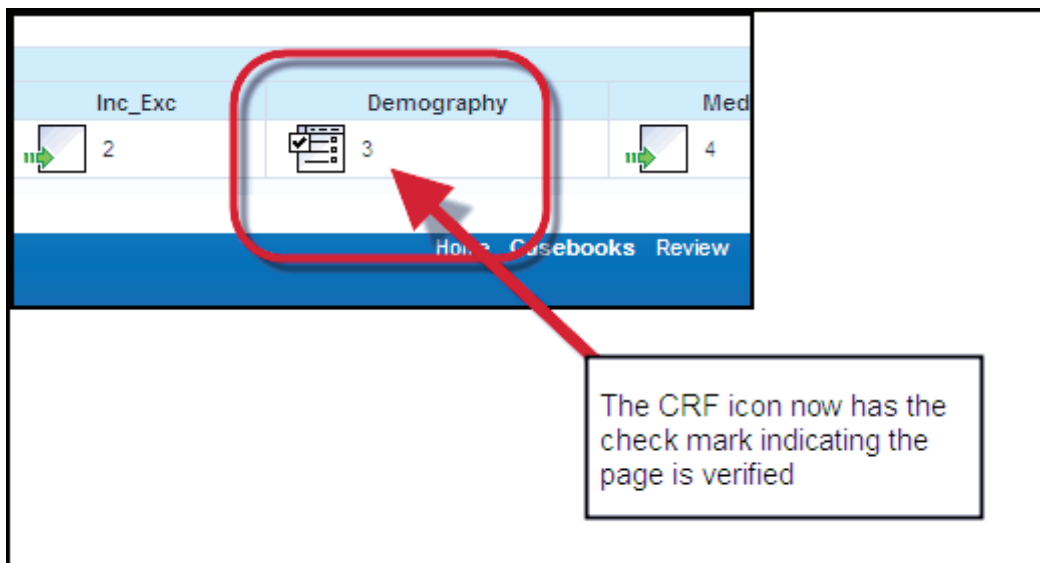
DO NOT group verify or un-verify CRFs without prior approval from your study team.

Click on the Verify icon and the Verify CRF dialog box will display. A comment does not need to be provided unless appropriate. You are able to view the Verification History in the Verify CRF dialog window.



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Once verified, the CRF icons will now display a check mark indicating the information contained on the CRF has been verified to source.

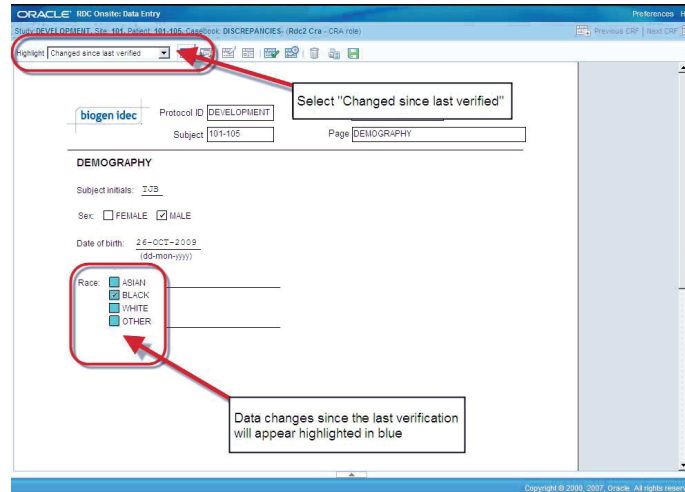
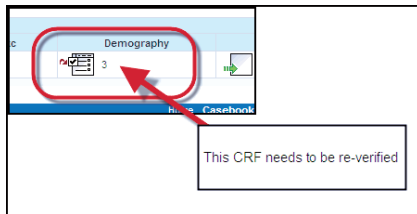


NOTE: CRFs intentionally marked as blank by the site also need to be verified by the Clinical Monitor/CRA.

Re-Verifying the eCRF

If data or discrepancies are modified (changed, added or deleted) after the CRF has been verified, the CRF may require re-verification.

For these CRFs, a red arrow will display next to the verified icon. This indicates that you need to re-verify the CRF due to updated information on the case report form.

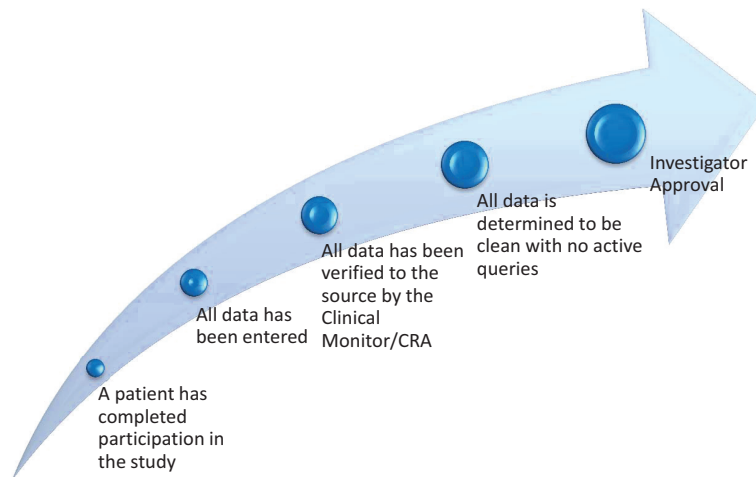


Tip: Change the **Highlight** selection to “Changed since last verified” to view changes to data fields that may have been changed since you verified the CRF.

Electronic Approval

Investigator approval of data for most studies occurs when the study team determines when a patient casebook is complete at which time they will request the Investigator to perform the approval process.

Note: By approving a CRF, the Investigator is confirming that all data on the page is complete and correct. This approval is equivalent to an electronic signature.



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In order to approve all of the pages in a patient casebook at one time, you need to be in the Casebook Spreadsheet.



- 1) Select the patient.
- 2) Click the **Select Patients and... select “Approve”**.
- 3) Click the Go button.

ORACLE RDC Onsite

Home Casebooks Review Reports

Logged in as Investigator Train/Investigator: PSEI; Last Refresh 17-Aug-2010 12:14:0

Study and Site: DEVELOPMENT 301 [Go]

Patient Casebooks

Search: 1 Patients Selected From Home Page

Casebook Spreadsheet

Patients: 1 of 1 Visit: Casebook View: 2010 TRAINING Visit: SCREENING CRFs: 1 of 1

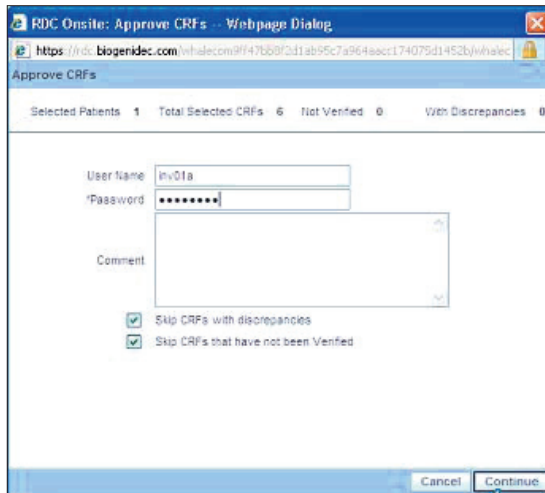
Select Patients and... Approve Go Add Visit Page Add Other Page Refresh

Select	Patient	DOV	Inc_Exc	Demo	SCREENING
<input checked="" type="checkbox"/>	301-003	1	2		MedH2 Vitals_Scr Phys_Exam

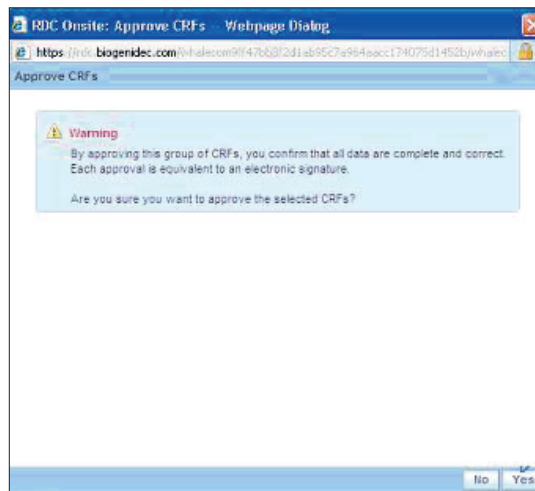
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- 4) The **Approve CRFs** dialog window displays and requires the Investigator (or designee) to input a User Name and Password.

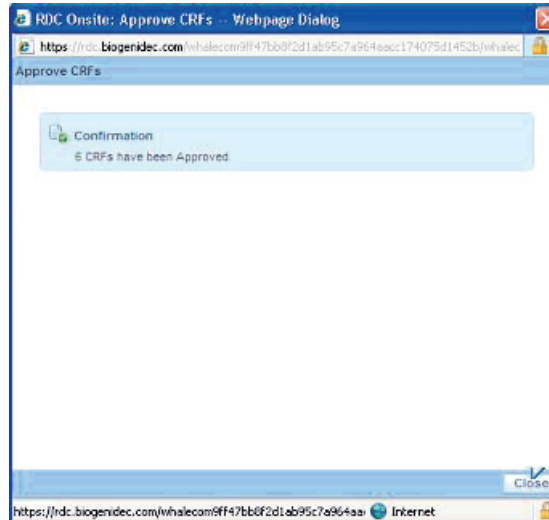


- 5) The **Approve CRFs Warning** dialog window displays to confirm that you want to approve the CRFs that have been verified by the Clinical Monitor/CRA and that have no discrepancies.



- 6) The **Approve CRFs Confirmation** dialog window displays indicating the number of CRFs that have been approved.

Remember that data should only be approved when it has been verified (indicated with a check mark against the CRF) and all discrepancies have been resolved.



7) A small signature appears at the bottom of the CRF icons indicating approval of the eCRF pages.

The screenshot displays the ORACLE RDC Onsite web application. The interface includes a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports' tabs. The user is logged in as 'Investigator Train/Investigator, PSDE'. The current study and site are 'DEVELOPMENT' and '301'. The main content area shows 'Patient Casebooks' with a search for 1 patient. A 'Casebook Spreadsheet' is displayed for 'Patient: 301-003' at 'Visit: SCREENING'. The spreadsheet has columns for 'Patient', 'DOV', 'Inc_Exc', 'Demography', 'Medhist_Yn', 'Medh2', 'Vitals_Scr', and 'Phys_Exam'. A red box highlights the bottom of the CRF icons for the 'DOV', 'Inc_Exc', 'Demography', 'Medhist_Yn', and 'Vitals_Scr' columns, where a small signature is visible. The footer contains 'About RDC 4.5.3' and 'Copyright © 2000, 2007, Oracle. All rights reserved.'

Individual CRF Approvals

There may be instances when a previously approved CRF will need to be re-approved due to a data change on the CRF or due to a study database modification.

RDC will identify these changes and mark the CRF with a red arrow next to the signature indicating the need for re-approval.

Once the CRF has been re-verified by the Clinical Monitor/CRA, the upper red arrow disappears, but the remaining lower arrow indicates you need to open the page for re-approval.



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Click the **Approve** icon then click the **Re-Approve** button.

The Approve CRF dialog window displays showing the Approval History for the CRF.

The CRF Approval Signoff window appears and you, the Investigator, are required to enter your User Name and Password.

The red arrow is now gone from the eCRF icon indicating that the page has been successfully re-approved.

NOTE: There is an Undo approval button that is used if a CRF was approved in error.

