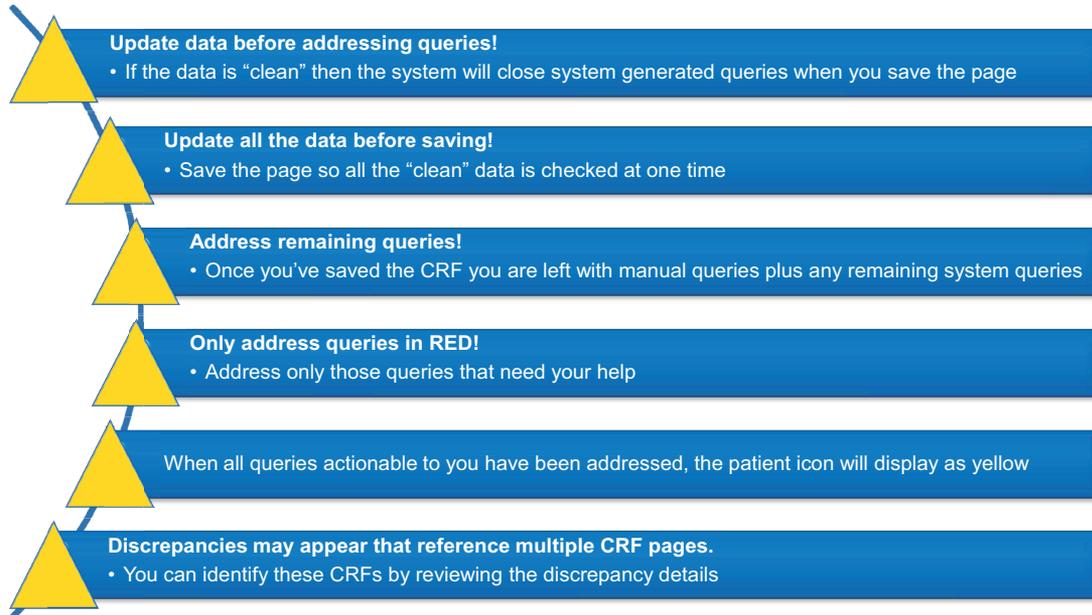


Tips and Tricks to Addressing Discrepancies

In order to save you time in addressing discrepancies and updating data, here are some quick tips to help you through the process...



Query (Discrepancy) Management

Discrepancies are data errors within RDC and result in a query being generated in RDC.

Discrepancy Definition

DISCREPANCY ↔ QUERY

A discrepancy is data that falls outside of an expected range of values. It is in essence a data error and is known as a query when conducting a paper study.

A query can be created in two ways:

Batch Validation: A process that executes all edit checks built into the database to cross-check multiple data fields possibly on multiple case report forms. This can be run manually by a user or nightly by the RDC system.

System Queries

- A system generated query alerts you that there may be a problem with a response, or a group of responses in the data field(s).
- This may be related to the data entered or missing data. System generated queries are automatically created:
 - During data capture
 - Immediately after data is saved
 - After batch validation is run on the study database.

Manual Queries -

- A manual, or user-generated, query is the result of someone else, such as your Clinical Monitor/CRA, creating a query based on Source Document Review/Verification.

Distinguishing Between Manual and System Queries

Manual queries can be distinguished from system queries by reviewing the query details.

The image displays two side-by-side screenshots of a software interface showing query details. Each window has a 'Details' header and two tabs: 'Related Values' and 'History'.
The left window shows a query with the following details:
Description: Update to clarify Mixed Race
Type: **MANUAL FIELD** (circled in red)
Review Status: Investigator
Reason: Data Manager Comment
Comment: Joe Smith
By: [Redacted]
Date: 05-APR-2010
An arrow points from the circled 'Type' field to a text box that reads: 'Manual Queries will have a query type beginning with "MANUAL"'.
The right window shows a query with the following details:
Description: 'Does the subject have any ongoing or resolved medical or surgical history?' is YES, however, the Medical History CRF is not completed. Please review and update as needed.
Type: **MULTIVARIATE** (circled in red)
Review Status: Site
Comment: Joe Smith
By: [Redacted]
Date: 24-AUG-2010 11:52:22
An arrow points from the circled 'Type' field to a text box that reads: 'System Queries will have a query type of "MULTIVARIATE" or "UNIVARIATE"'.
Both windows have an 'Action' dropdown menu and a 'Go' button at the bottom.

Reviewing Queries

You can review queries for your patient by using the Activities link on the Home tab or by navigating to the Review tab.

The screenshot shows the ORACLE RDC Onsite interface. The top navigation bar includes 'Home', 'Casebooks', 'Review', and 'Reports'. The user is logged in as Kevin Stephenson (Data management role, PSDE). The interface displays a 'Patients' section with a table of active discrepancies. A callout box points to the 'Review 231 Active Discrepancies' link in the 'Activities' sidebar.

Use this link to review your "Active" queries

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	101-101	13-May-2011 09:13:44	DISCREPANCIES
<input type="checkbox"/>	101-102	09-May-2011 14:08:57	DISCREPANCIES
<input type="checkbox"/>	101-103	09-May-2011 14:08:57	DISCREPANCIES
<input type="checkbox"/>	101-104	09-May-2011 14:08:57	DISCREPANCIES
<input type="checkbox"/>	101-105	09-May-2011 14:09:02	DISCREPANCIES
<input type="checkbox"/>	101-106	22-Apr-2011 11:13:14	DISCREPANCIES
<input type="checkbox"/>	101-107	07-Apr-2011 16:10:07	DISCREPANCIES
<input type="checkbox"/>	101-108	22-Apr-2011 11:11:34	DISCREPANCIES
<input type="checkbox"/>	101-109	05-Apr-2010 10:57:31	DISCREPANCIES
<input type="checkbox"/>	101-110	09-May-2011 14:08:57	DISCREPANCIES
<input type="checkbox"/>	101-111	02-Dec-2009 04:41:15	DISCREPANCIES

On a CRF page you have the following color scheme:

- A **red field** contains a discrepancy actionable to you
- A **yellow field** contains a discrepancy actionable to someone in another user role
- A **green field** indicates that there was a discrepancy on that field that has been manually closed

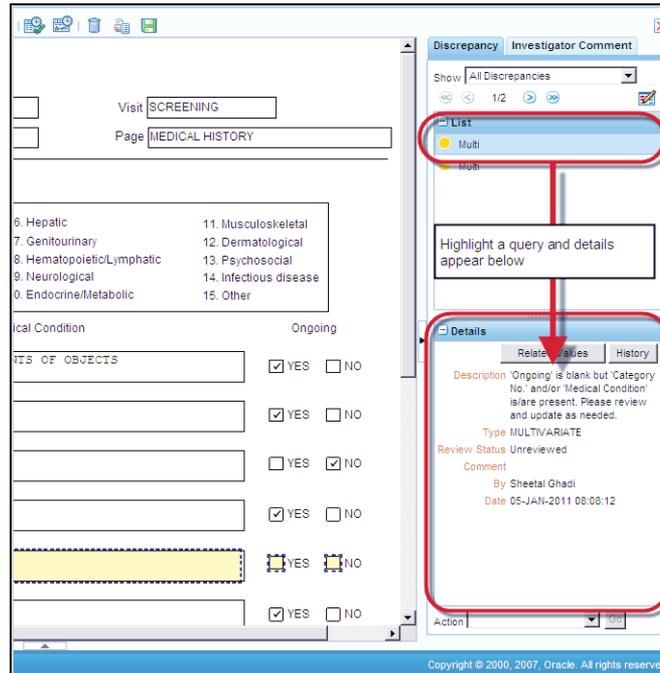
The screenshot shows a web interface for a Clinical Research Form (CRF) page. At the top, there are fields for 'biogen idec', 'Protocol ID DEVELOPMENT', 'Visit SCREENING', 'Subject T2', and 'Page PHYSICAL_EXAMINATION'. Below this is the title 'PHYSICAL EXAMINATION (Page 1 of 2)' and a date field 'Date of examination: 01-JAN-2010 (08-mon-2010)'. The main table has two columns: 'Body system' and 'Abnormal examination findings'. The rows are color-coded: SKIN (red), HEENT (yellow), LYMPH NODES (green), and NECK AND THYROID (white). Each row has checkboxes for 'NOT DONE', 'NORMAL', and 'ABNORMAL'. The 'ABNORMAL' checkbox is checked for SKIN, HEENT, and LYMPH NODES. Three callout boxes on the right point to the rows: 'Query actioned to you' points to the SKIN row, 'Query actioned to another user or role' points to the HEENT row, and 'Closed query (field level only)' points to the LYMPH NODES row.

Body system	Abnormal examination findings
SKIN	NOT DONE <input type="checkbox"/> NORMAL <input type="checkbox"/> ABNORMAL <input checked="" type="checkbox"/>
HEENT	NOT DONE <input type="checkbox"/> ABNORMAL, NOT CLINICALLY SIGNIFICANT <input checked="" type="checkbox"/> NORMAL <input type="checkbox"/> ABNORMAL <input checked="" type="checkbox"/>
LYMPH NODES	NOT DONE <input type="checkbox"/> ABNORMAL, NOT CLINICALLY SIGNIFICANT <input checked="" type="checkbox"/> NORMAL <input type="checkbox"/> ABNORMAL <input checked="" type="checkbox"/>
NECK AND THYROID	NOT DONE <input type="checkbox"/> NORMAL <input checked="" type="checkbox"/>

Discrepancy Details

When reviewing a query in the Discrepancy List, you will see the details of the discrepancy in the lower section of the Navigation Pane.

In the Details section, you will see a description as to why the discrepancy was created along with other detailed information.



System Queries

Site users can:

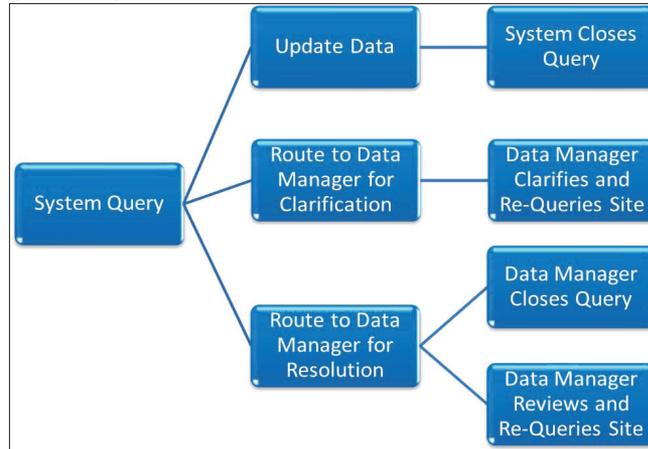
- Make an update to the data associated with the query
 - If data is updated to meet the requirements of the system edit check, the query is automatically closed and no longer displayed by the system
- Route the discrepancy to the Data Manager
 - If a query is routed to Data Management, it must be accompanied by a comment requesting clarification OR
 - Confirming that the information provided is correct

The comment is then reviewed to determine if it satisfies the data issue. If it is determined that discrepant data does not need to be updated, the query will be manually closed by the Data Manager.

If the Data Manager determines that further information is required, the query can be routed by to the site for clarification.

Tip: In order to keep the data as clean as possible, you should address the discrepancies that were generated during batch validation on a regular basis.

System Query Process Flow



Manual Validation

You can validate (run edit checks) on a patient casebook in RDC.



ORACLE RDC Onsite

Home Casebooks Review Reports

Logged in as Rdc4 Site user: VVDC: Last Refresh: 01-Jun-2011 14:37:35

Study and Site: DEVELOPMENT 101 Go

Study and Site Summary

Patient Casebooks

Search: 4 Patients Selected From Home Page

Casebook Spreadsheet

Patients: 1-4 of 4 Next Casebook View: 2010 TRAINING Visit: SCREENING CRFs: 1-6 of 9 Next

Select Patients and... Validate Go

Select All Select None

Patient	Number	DOV	Inc_Exc	Demography	MedHist_Yn	MedH2	Vita	Scr_Prior
<input checked="" type="checkbox"/>	101-105	1	2	3	4	5	6	8
<input type="checkbox"/>	101-106	1	2	3	4	5	6	8
<input type="checkbox"/>	101-107	1	2	3	4	5	6	8
<input type="checkbox"/>	101-108	1	2	3	4	5	6	8

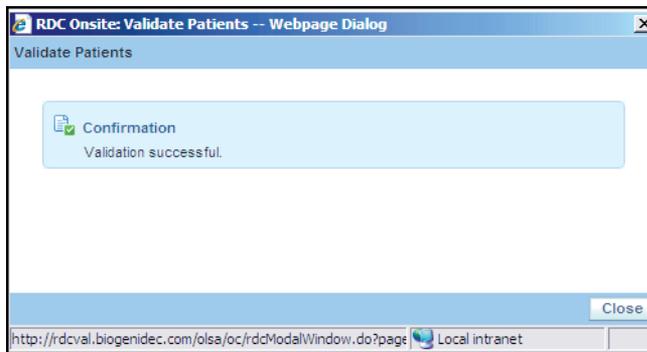
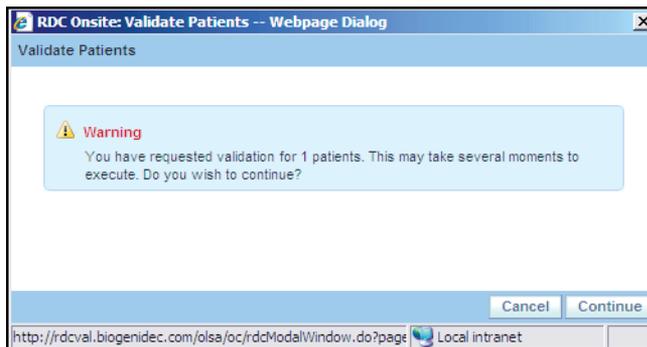
About RDC 4.5.3 Home Casebooks Review Reports Logout Change Password Help Copyright © 2000, 2007, Oracle. All rights reserved.

<http://rdcsupport.biogenidec.com>

Confirm that you want to run validation in the Validate Patients Warning window.

When this has run successfully, the Validate Patients Confirmation dialog window will display.

NOTE: Batch Validation is also automatically executed on a daily basis (usually overnight).



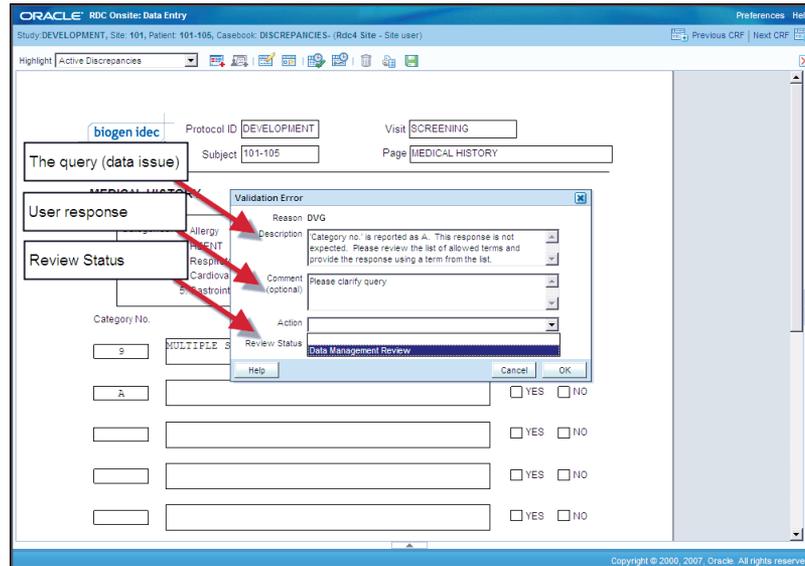
The Validation Error window

This window displays immediately after:

- You TAB off a discrepant data field
- Click into the next data field
- Save the CRF

The window allows you to take action on the discrepancy and provide a comment at the same time. If a data issue is not resolved by a data edit, you can route this discrepancy to the Data Manager from the same window.

Tip: Remember to enter a Comment as further explanation can assist the Data Manager in resolving the discrepancy.

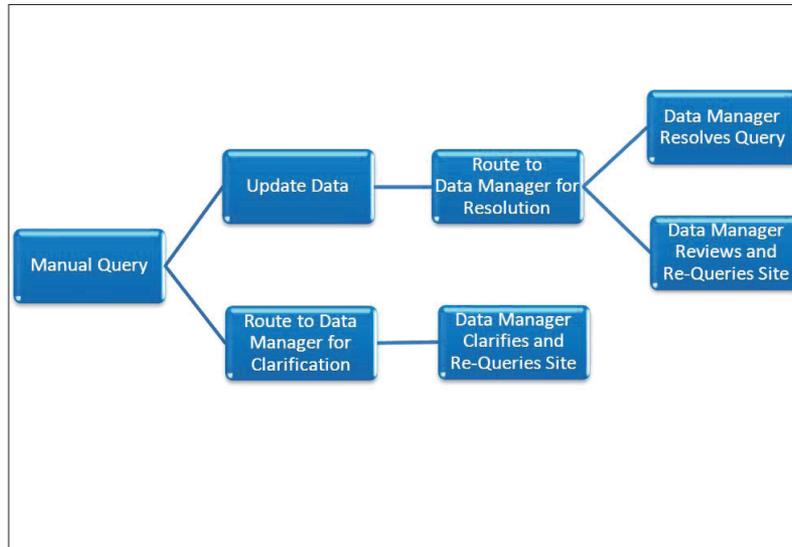


Manual Queries (User-Generated Discrepancies)

In the case of manual discrepancies, Site Users must:

- Update the data (if appropriate)
- AND
- Route the discrepancy for Data Management Review

NOTE: Discrepancies which have been created manually MUST always be closed manually by the Data Manager.



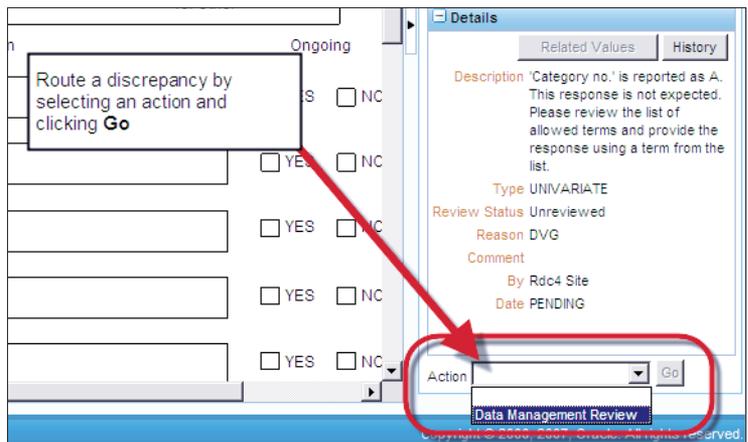
Routing Queries

When a query needs to be routed to Data Management this can be done through the discrepancy details pane by selecting "Data Management Review" and clicking the **Go** button.

Use the Comment field on the **Discrepancy Action - Data Management Review** window to provide additional information regarding the discrepancy.

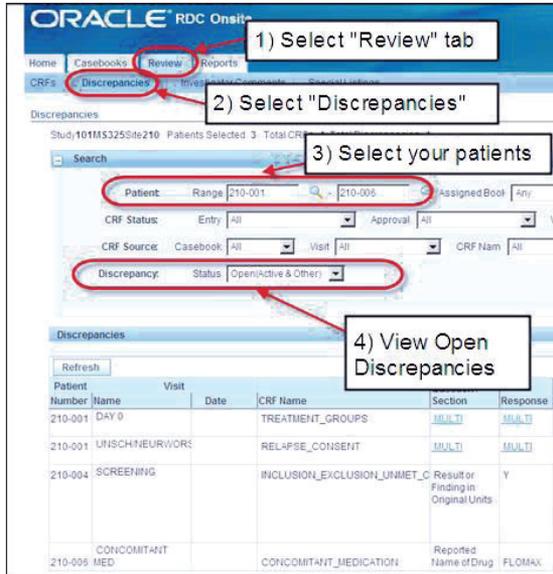
A query highlighted in yellow indicates you have successfully routed a query.

NOTE: After addressing discrepancies, remember to save the CRF.



Finding Your Queries in RDC

Use the **Review – Discrepancies Sub-Tab** to quickly find queries actioned to you.



In the search results, you will see queries that are actionable to you in red. Click on the CRF icon to open the CRF and address.

