

# RDC

## REMOTE DATA CAPTURE

## Accessing the RDC Support Website

Study access and support for RDC is through the RDC Support Website:

<http://rdcsupport.biogenidec.com>

The website provides:

- 1) **Bulletins**  
Informational Updates for RDC Onsite
- 2) **Getting Started**  
Where to go for
  - a. **Training**
  - b. **Requesting Accounts**
- 3) **RDC Onsite Login**  
Where to log into RDC Onsite studies
- 4) **RDC Support**



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## RDC Support Center

The RDC Support Center can help with...

- Difficulty logging in to RDC
- Account password resets
- Trouble with network connections
- RDC performance problems
- RDC messages

Report RDC issues right away to receive help for...

- Equipment needs
- Technical problems
- Data Entry problems

RDC Support Center supports only RDC and not...

- IVRS
- Clinical Portals
- Non-Biogen Idec Studies
- Clinical Site IT structure

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### Getting an RDC Account

To do work in RDC a potential user must get a user account.

1) **Notify**

Site users should inform the site CRA that there are new users

2) **Train**

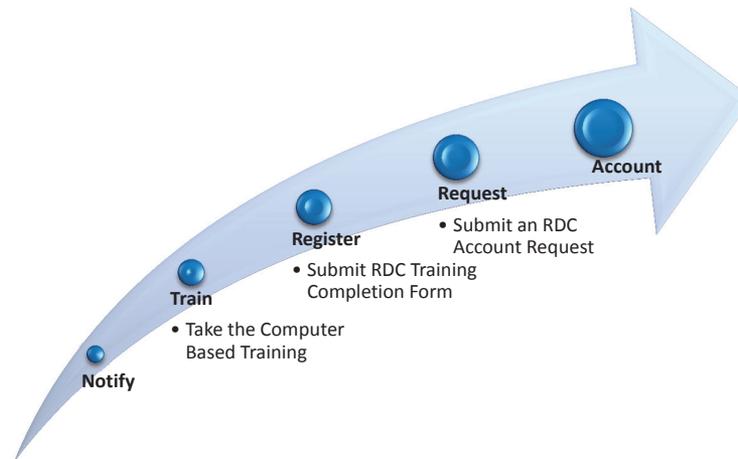
Complete the RDC Computer Based Training

3) **Register**

Register training by submitting a Training Completion Form

4) **Request**

Request access to the study by submitting an Account Request Form



Once an account is requested it will take up to **FIVE business days** for the user to receive their account information.

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## RDC Compliance

- Biogen Idec RDC is to be used only for purposes designated by Biogen Idec
- Users will not share usernames and/or passwords
- Users will log out of the system when not in use
- Users will use RDC in adherence to 21 CFR Part 11 (Electronic Records; Electronic Signatures)

### Violations of this agreement will result in:

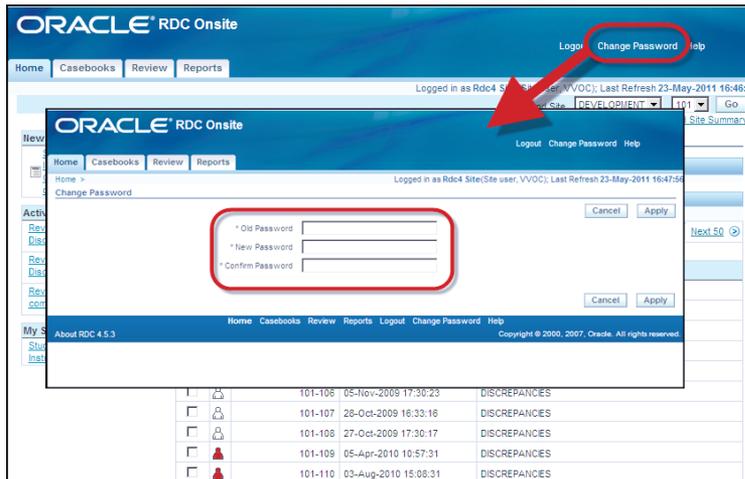
- Loss of RDC privileges
- A Remediation Plan

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### Changing Your Password

How to manually change your password:



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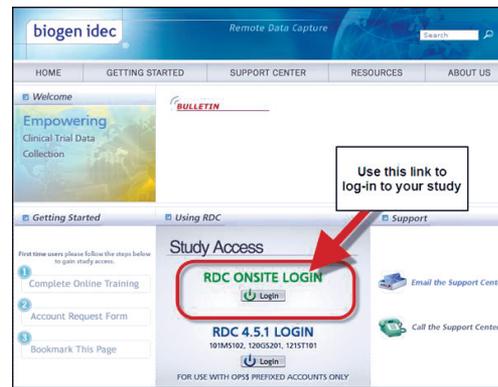
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### Accessing your study

You will access your study through the RDC Support website.

When logging in to RDC, there are a few things to remember:

- Passwords are not case sensitive, but must start with a letter and may include numbers.
- Your password should be 6-10 characters in length.
- You are prompted to change the initial password upon first time login
- Passwords will expire every 90 days and cannot be reused
- Your account will be locked after three unsuccessful log-in attempts due to erroneous username or password entries.



**Contact the RDC Support Center for any account or technical issues**

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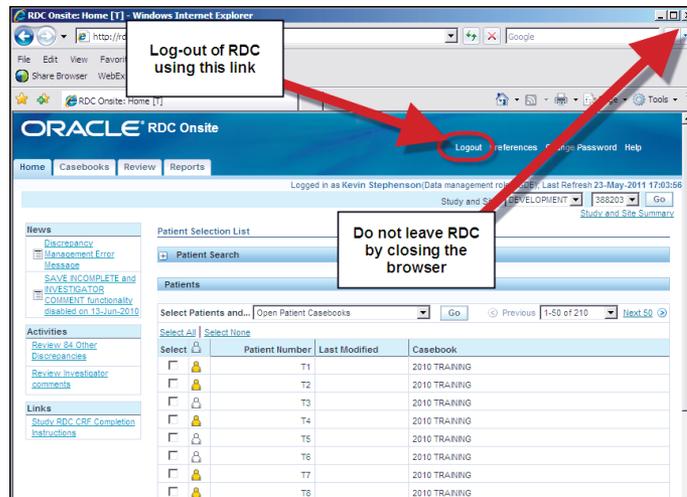
### Logging out of RDC

**Important:** Always use the OC RDC Logout option.

**Do not use the browser's standard close button** as this only closes the browser window but does not properly log you out of RDC.

Before logging out ensure that you save your work and close any open eCRFs.

**NOTE:** RDC will automatically log you out after **30 minutes** of inactivity. **Any data that has not been saved will be lost.**



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### Blank Casebook Report

The Blank Casebook Report creates a hard copy of the casebook. The report output is similar to the PDR, but no patient data is included.

**Note:** A generic report is generated when the patient number is left blank.

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. The 'Reports' section is active, showing a search area with 'Job Name' and 'Show Jobs' dropdown. A callout box points to a 'Go' button with the text 'Click on this button to produce a Blank Casebook Report'. Below the search area is a 'Report Jobs' table with columns for 'Job Name', 'Start Time', and 'End Time'. A red circle highlights the 'New Blank Casebook Report' button. A second screenshot shows the 'Report Parameters' form. A callout box points to the 'Patient Number' field with the text 'Leave blank for a generic casebook'. The 'Job Parameters' section shows 'Report Server' as 'REPORT\_SERVER', 'Job Name Prefix' as '223A3302', 'Job Id' as '493268', 'Job Name' as '223A3302\_493268', and 'Output File Name' as 'tcamcp01'. A red circle highlights the 'Submit Job' button with the text 'Submit the request'.

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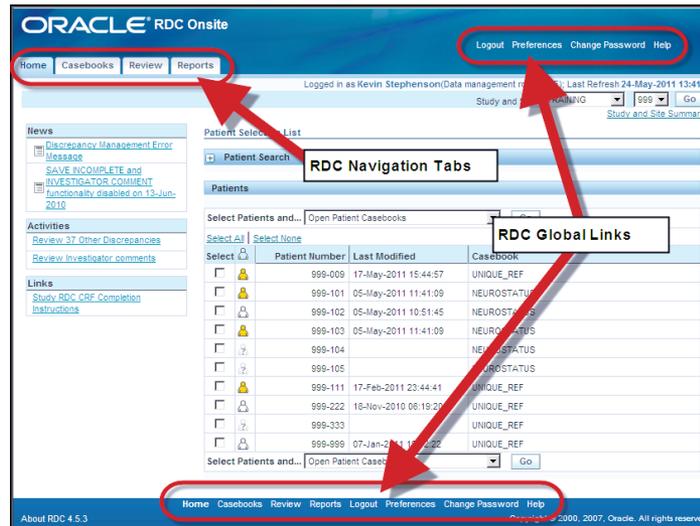
### Navigating the RDC Environment

On the RDC home page you will see four navigation tabs:

- Home
- Casebook
- Review
- Reports

These global links also allow you to log out of the system, change your password and access online RDC help.

The Global Links are found at the top and bottom of each tab window. These links allow you the flexibility to access information via the tabs or via the hyperlinks.

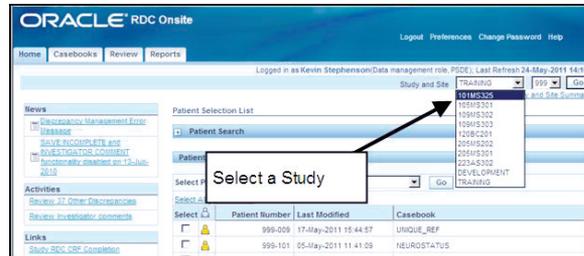
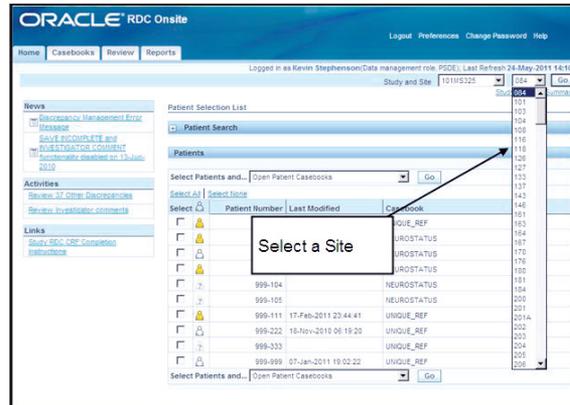


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### Finding Your Study and Site

If you have access to more than one study or site in the application, you need to select the appropriate study and site from the drop-down lists located at the top right of the screen.



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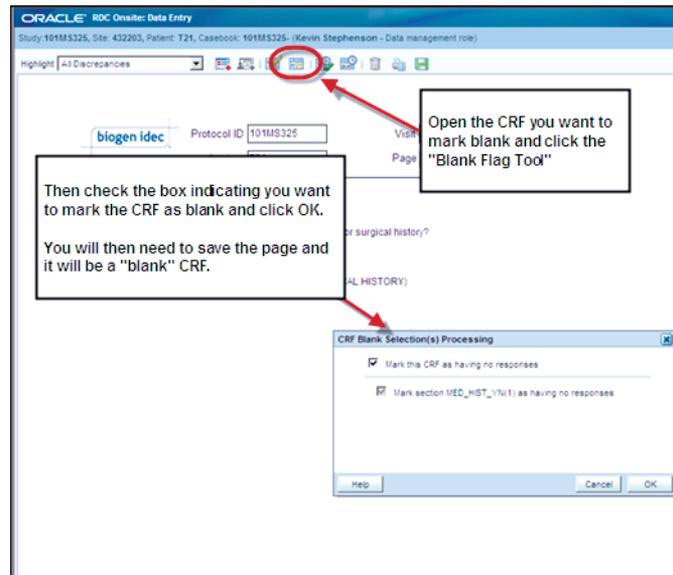
### Marking a CRF as Blank

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.



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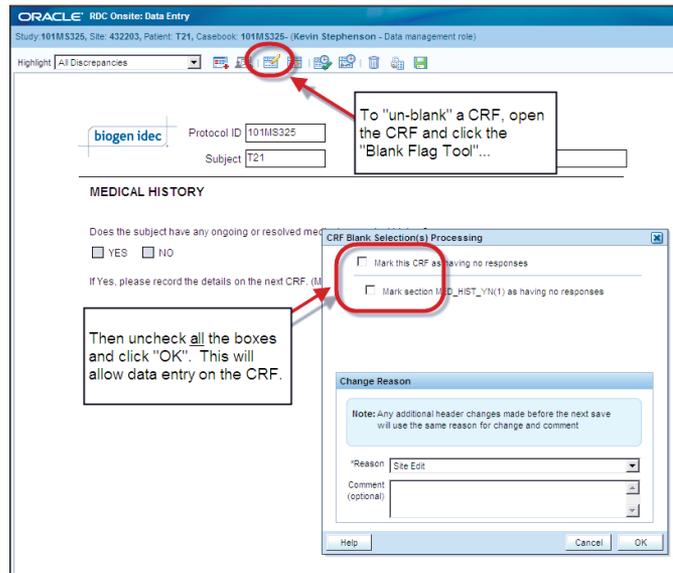
### Unmarking a CRF as Blank

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, all the checks must be removed.

The Change Reason area displays and you are required to provide a reason for the change by selecting the appropriate reason from the drop down list.



### Data Field Colors

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

biogen idoc Protocol ID DEVELOPMENT Visit SCREENING  
Subject T2 Page PHYSICAL\_EXAMINATION

PHYSICAL EXAMINATION (Page 1 of 2)

Date of examination: 01-JAN-2010 (dd-mon-yyyy)

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

Query actioned to you

Query actioned to another user or role

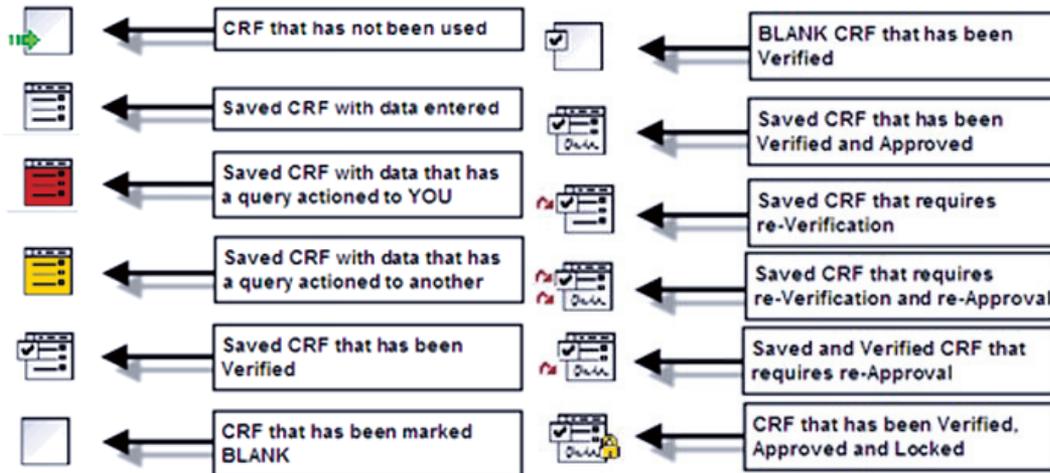
Closed query (field level only)

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### CRF Icons

CRF Icons will appear with different colors and symbols depending on the actions that have been performed or are needed.



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### Data Entry Short Cuts – TODAY'S DATE

Enter a "T" into the date field and when leaving the field will populate with the current date.

The diagram illustrates the process of entering today's date. On the left, a form titled "biogen idec" with Protocol ID "DEVELOPMENT" and Subject "T12" is shown. The "VITAL SIGNS" section has a "Date:" field containing the letter "T". A red circle highlights this field, and a red arrow points to the right. On the right, the same form is shown, but the "Date:" field now contains "06-SEP-2011". A red circle highlights this field, indicating that the system has automatically populated it with the current date.

### Data Entry Short Cuts – YESTERDAY'S DATE

Enter a "Y" into the date field and leaving the field will populate the date field with yesterday's date.

The diagram illustrates the process of entering yesterday's date. On the left, a form titled "biogen idec" with Protocol ID "DEVELOPMENT" and Subject "T12" is shown. The "VITAL SIGNS" section has a "Date:" field containing the letter "Y". A red circle highlights this field, and a red arrow points to the right. On the right, the same form is shown, but the "Date:" field now contains "05-SEP-2011". A red circle highlights this field, indicating that the system has automatically populated it with the date from the previous day.

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### Data Entry Short Cuts – LAST DATE ENTERED VALUE

Enter “L” into a date field and leaving the field will populate the date field with the last date entered.

biogen idec Protocol ID DEVELOPMENT Subject T12

STUDY DRUG ADMINISTRATION LOG (Page 1 of 4)

Week	Date (dd-mon-yyyy)	Time (24-hour clock)	Location of drug administration	Not Done
0	01-DEC-2010	09:00	<input checked="" type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>
2	L		<input type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>
4			<input type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>

biogen idec Protocol ID DEVELOPMENT Subject T12

STUDY DRUG ADMINISTRATION LOG (Page 1 of 4)

Week	Date (dd-mon-yyyy)	Time (24-hour clock)	Location of drug administration	Not Done
0	01-DEC-2010	09:00	<input checked="" type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>
2	01-DEC-2010		<input type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>
4			<input type="checkbox"/> THIGH <input type="checkbox"/> ABDOMEN <input type="checkbox"/> ARM	<input type="checkbox"/>

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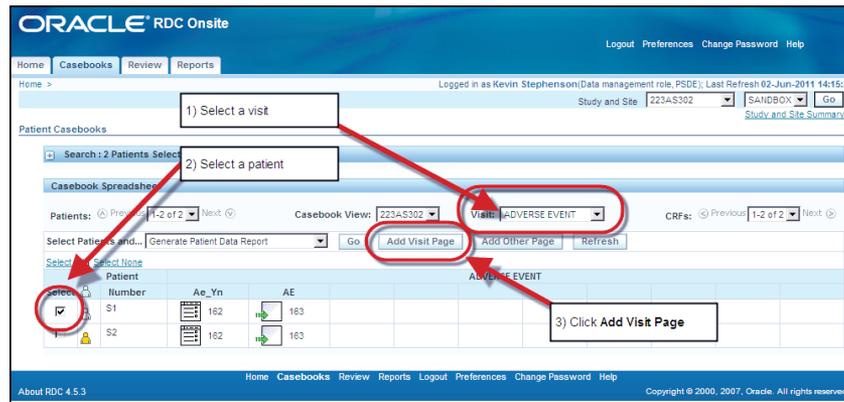
### Insert Additional CRFs



The **Add Visit Page** button allows you to insert an unplanned CRF if you have completed data entry on all available CRF pages, but still have additional data to enter.

**NOTE:** The **Add Other Page** button should only be used if specifically indicated in the CRF Completion Instructions

**Important:** Confirm that you are on the correct visit prior to adding a visit page.



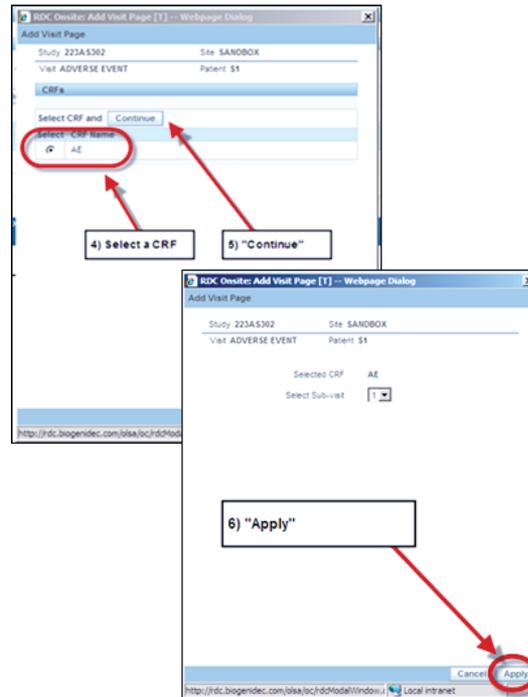
## Insert Additional CRFs (continued)

The Add Visit Page dialog box displays. Select the CRF that you wish to add to this visit using the radio button next to the CRF Name.

A second Add Visit Page dialog window displays. Leave the default value in the Select Sub-visit drop down list and click **Apply**.

A new, unplanned Visit Page is added to the Casebook Spreadsheet for the selected visit with a U next to the icon denoting this is an additional/unplanned visit page.

**NOTE:** The new visit page must be completed and saved immediately, or it will not be retained by the system.



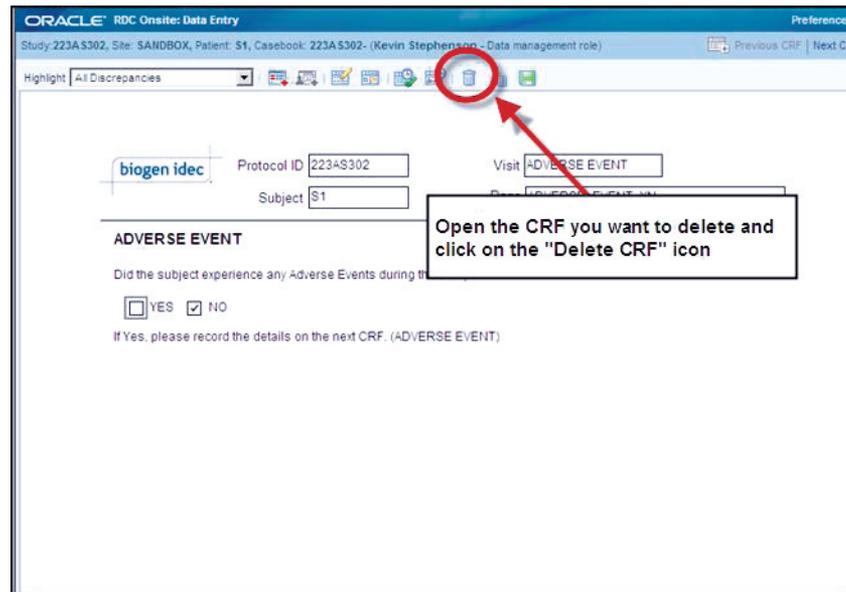
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### Delete a CRF

There may be times when you need to delete a CRF that was created in error.

Click the **Delete** button.



## Delete a CRF (continued)

The Delete CRF dialog box displays. Accept the default Change Reason. If necessary, type an optional comment in the Change Comment text box.



**Tip:** You may also check the box **Remember comment...** for subsequent Delete CRF operations if you want to use the same comment for subsequent actions within the same session. The comment will only be retained until you log out of RDC.

A dialog box will display to confirm you want to perform the deletion.



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### Reviewing Discrepancies (Queries)

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

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Logged in as Kevin Stephenson(Data management role, PSDE): Last Refresh 31-May-2011 13:35:22

Study and Site DEVELOPMENT 101 Go [Study and Site Summary](#)

News

- [Discrepancy Management Error Message](#)
- [SAVE INCOMPLETE and INVESTIGATOR COMMENT functionality disabled on 13 Jun-2010](#)

Activities

- [Review 231 Active Discrepancies](#)
- [Review 136 Other Discrepancies](#)
- [Review Investigator comments](#)

Links

- [Study RDC CRF Completion Instructions](#)

Patients

Select Patients and... Open Patient Casebooks Go Previous 1-50 of 274 Next 50

Select All Select None

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
<input type="checkbox"/>	101-112	02-Jan-2010 01:05:13	Unassigned

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### Finding Your Discrepancies (Queries) in RDC

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

Queries that are actionable to you are red. Click on the CRF icon to open the CRF and address.

1) Select "Review" tab

2) Select "Discrepancies"

3) Select your patients

4) View Open Discrepancies

Discrepancies						
Refresh						
Patient Number	Name	Visit	Date	CRF Name	Section	Response
210-001	DAY 0			TREATMENT_GROUPS	[MULTI]	[MULTI]
210-001	UNISCHNEURWDR			RELAPSE_CONSENT	[MULTI]	[MULTI]
210-004	SCREENING			INCLUSION_EXCLUSION_UNMET_C	Result or Finding in Original Units	Y
210-009	CONCOMITANT MED			CONCOMITANT_MEDICATION	Reported Name of Drug	FLOMAX

Red - Actionable to you

Yellow - Action for another