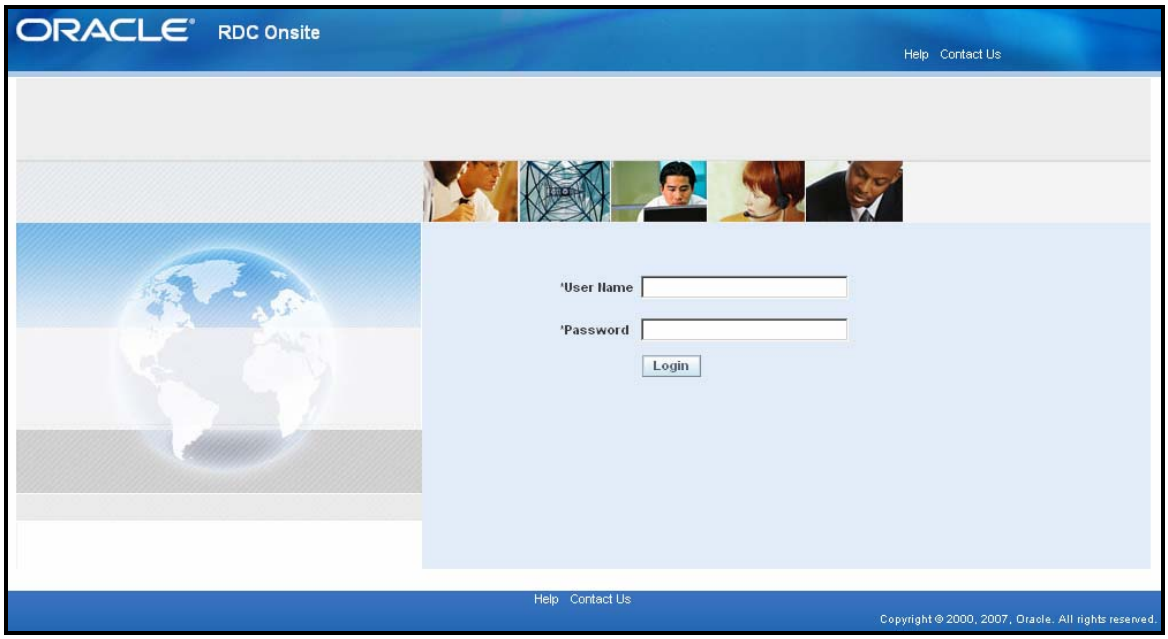
OC RDC 4.6 Read-Only User Guide



If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

TABLE OF CONTENTS

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

ACCESSING OC RDC

Steps for Obtaining Access

In order to gain access to Oracle Clinical Remote Data Capture 4.6 for this clinical trial, you must complete the following:

1. Perform Oracle Clinical Remote Data Capture (OC RDC) system training.
2. Complete and submit an online Training Completion Form.
3. Complete and submit an online RDC Account Request Form.
4. File your copy of the Training Completion form in your Study Binder.

You will receive your login information, via e-mail within 5 business days. If you do not receive your access information within 5 business days, please contact the EDC Support Center.

For detailed instructions refer to the **OC RDC 4.6 Online Training for Sites, Sponsors and External CRAs/Clinical Monitors** document on the EDC Website in the User Reference Materials link.

NOTES:

- PPD OC RDC 4.6 Training is only required to be performed once, regardless of the number of PPD OC RDC 4.6 studies you participate in.

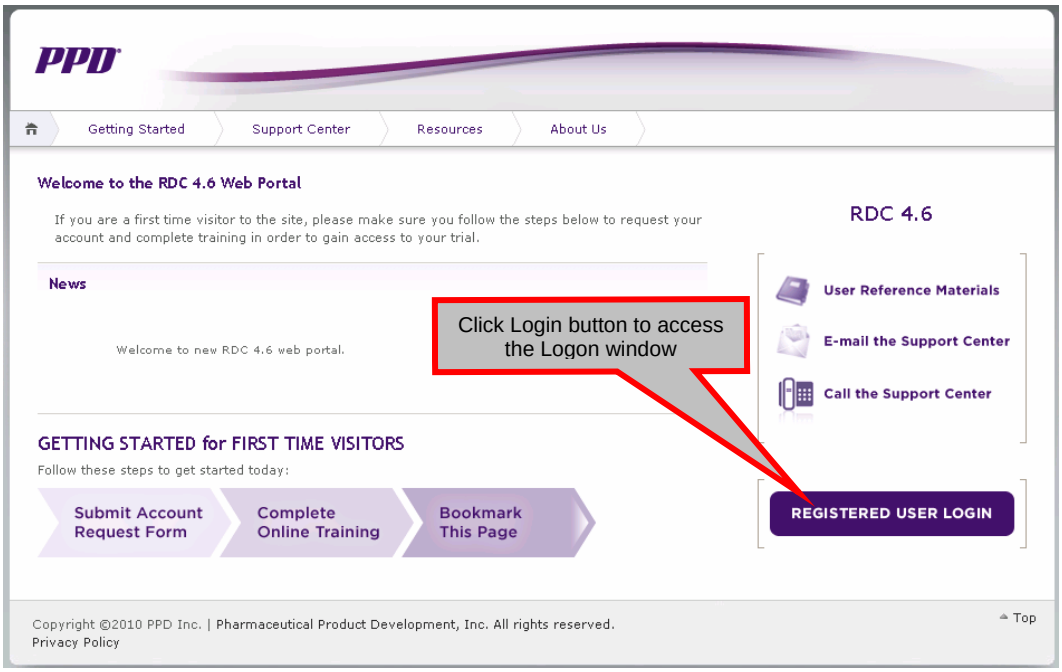
- A PPD RDC Account Access Request Form must be completed for each study you require access to.

- If you will be participating in User Acceptance Testing (UAT) for your study, you must complete training and submit all required forms prior to test access being granted.

- Add your study URL to your Internet Explorer Favorites folder list for rapid access to your study website.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

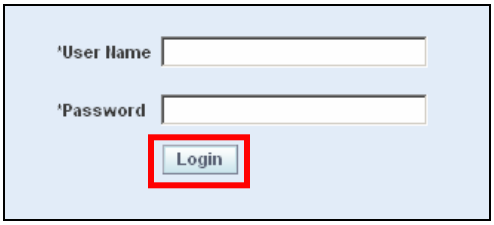
PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.



Logging On

You will receive your user name and study URL, via email. Your password will be the one that you submitted in your Account Access Request Form. If you forget your password call the EDC Support Center.

- Navigate to the correct URL for your study.
- Click the Login button on the edc.ppdi.com/46 website specific to your study
- Enter the OC RDC **Username** and **Password**.
  - Text is not case sensitive.
  - Passwords will expire ever 90 days.
  - Passwords can not be reused.
  - The user is allowed three log on attempts after which the account will lock - call the EDC Support Center to unlock the account.
  - DO NOT share your login information with anyone.
- Click the **Login** button.



If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

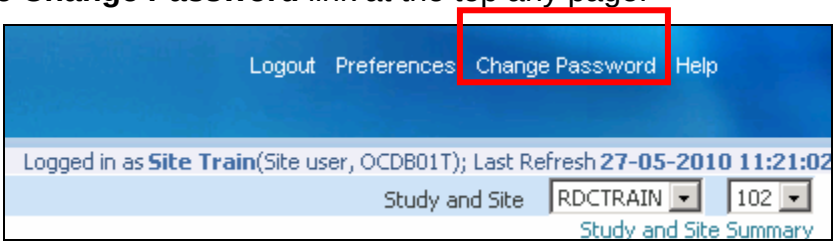
Password Changes

There are instances in which users are required to change their password:

- Upon initial log in
- Every 90 days
- As needed if there is a potential breach in security

To change your password:

- Click the **Change Password** link at the top any page.

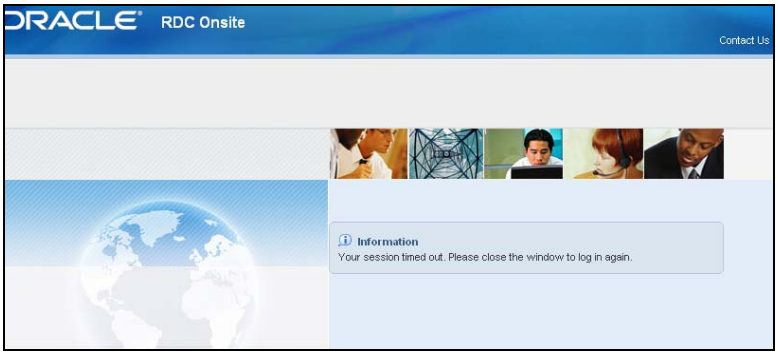


- Enter your Old Password.
- Enter your New Password.
- Re-enter the New Password for confirmation.
- Click on the Apply button.

Computer System and Security

Security is an important issue when working with a remote data capture (RDC) system. To limit unauthorized access, security features have been incorporated in the OC RDC system. Users should log off of the OC RDC if they need to step away from the computer.

If the computer is inactive (no keyboard or mouse activity) for a specified amount of time, the system automatically times out. Users will lose any unsaved work and they will need to log back into the system to continue working. The following message box displays:



The window will have to be closed to log in again.

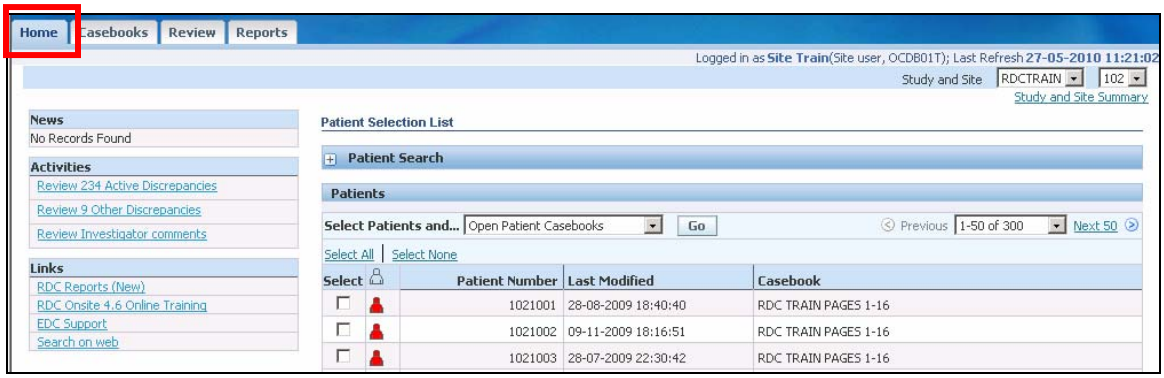
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

VIEWING DATA IN OC RDC

Study and Site

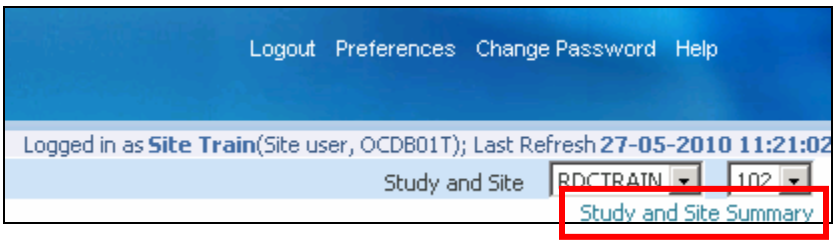
The RDC **Home** tab displays after users have logged into OC RDC HTML, and will be the starting point for all activities.



The RDC Home Tab is used to select the patient(s) and data that you wish to view on the RDC main spreadsheet. The Home tab can be accessed at any time during the OC RDC HTML session.

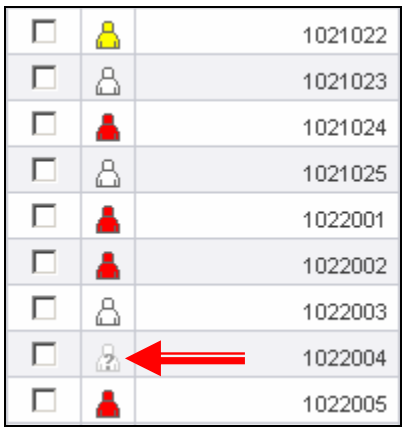
The RDC Home Tab will display with a default Study and Site Patient Selection List. Other studies and/or sites can be accessed from the drop-down list(s).

Summary information can be viewed by clicking on the **Study and Site Summary** link on the upper right-side of the Home Tab.



Patient summary information can be viewed by clicking on any given patient icon.

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

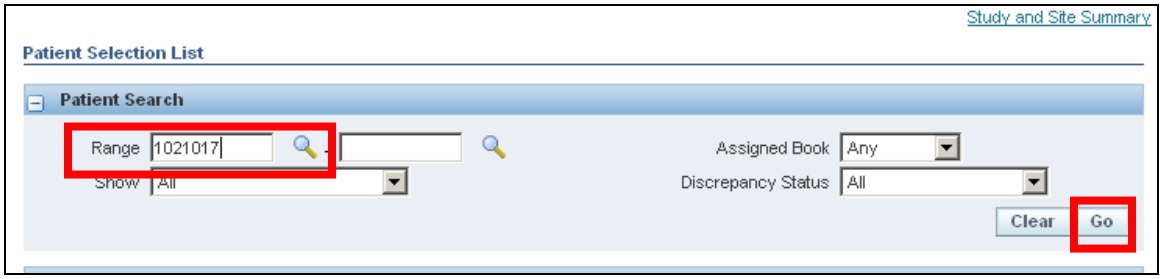


Also note that the icons have color coding, which indicate the presence or absence of discrepancies (data errors):

- **Red** indicates a discrepancy actionable to the person or user group logged into the system.
- **Yellow** indicates a discrepancy actionable to someone within a different user group (i.e. CRA, DM or PVG).
- **White** indicates there are no discrepancies on the patient data.
- A **grey question mark** indicates a patient number without data.

Selecting and Opening a Casebook Spreadsheet

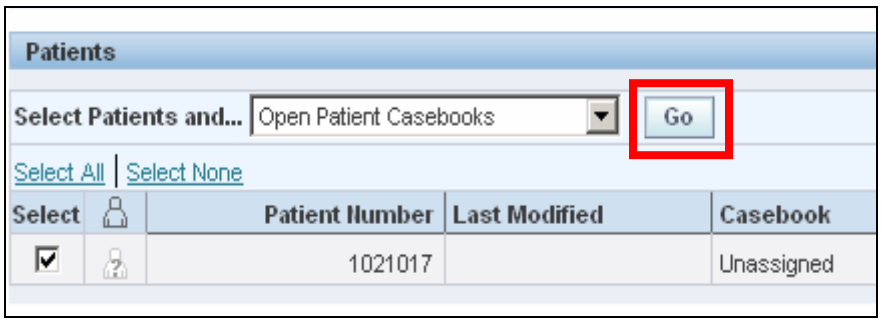
- Navigate to the **Patient Search** area.



- Use the + sign to expand the Patient Search section.
- Enter your assigned subject number in the first **Range** field, or use the **Magnifying glass** icon to select a patient number from the List of Values available.
- Click the **Go** button.
- Place a checkmark in the box to the left of the desired patient number.
- Click the **Go** button.

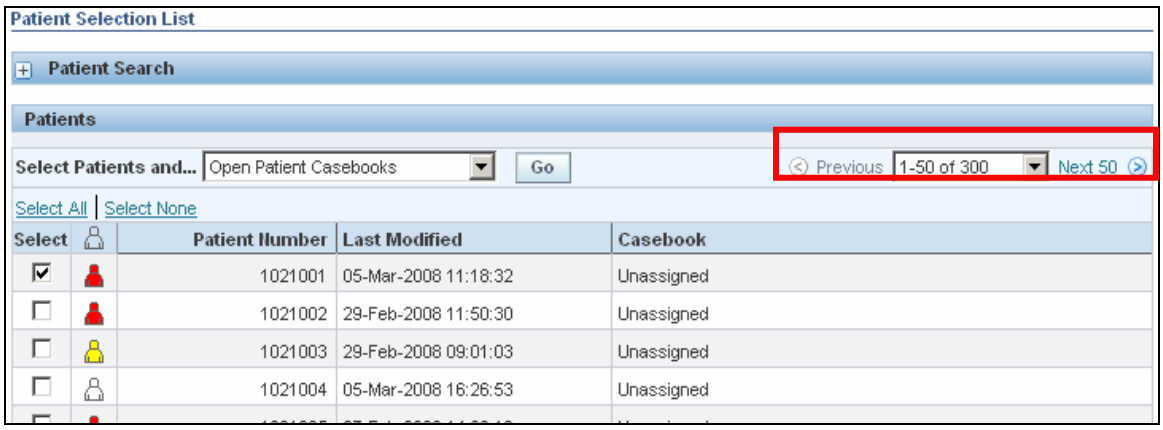
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

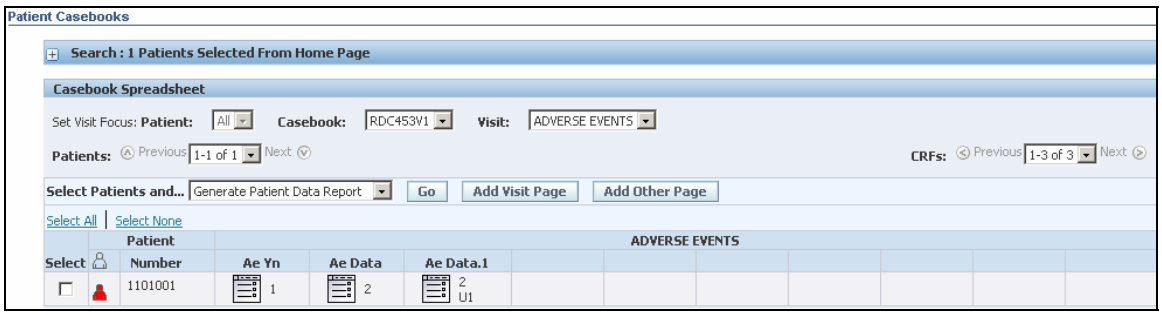


NOTE: Patients can also be selected directly from the Patient list area for the study site, as illustrated bellow. Using the **Next 50 drop-down list or hyperlink** is another way to display a different set of patient numbers:

- Place a checkmark in the box to the left of the desired patient number.
- Click the **Go** button.



The **Casebook Spreadsheet** for the selected patient will display, once the Go button is clicked.



The Casebook Spreadsheet is the only page where you can initiate data entry for an electronic eCRF.

The eCRF icons appear on the Casebook Spreadsheet. The eCRF is opened by clicking on its associated icon.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

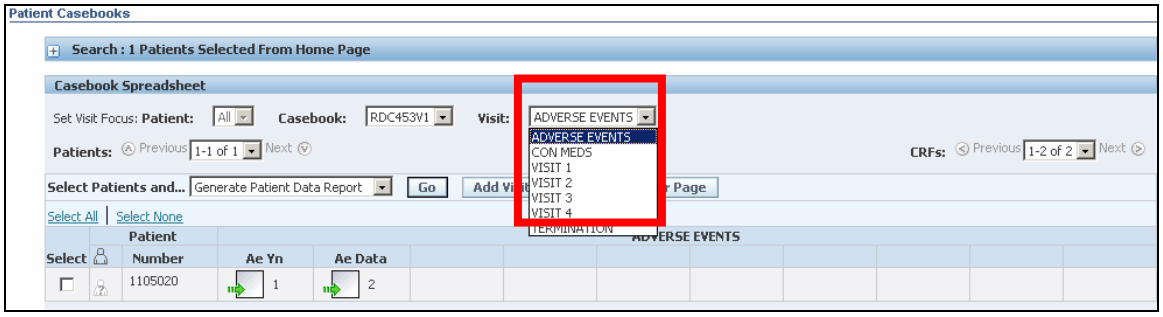
PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

Icons for eCRFs

Icon	Description	Icon	Description
Blank CRF	The eCRF has been marked as blank.	Other Discrepancy	The eCRF has at least one open discrepancy that requires another users' attention.
Entry expected	No data has been entered yet.	Verified	The eCRF has been source verified by the CRA.
Created	Header information present but no response data has been entered.	Requires Re-verification	The data on the page has been changed since CRA verification.
Entry complete	All required eCRF header and Section header information is complete and at least one question area response field is completed.	Approved	The eCRF has been approved by the Investigator.
Batch Loaded	The data has been entered electronically via batch data load into the database by data management. (i.e. Central Lab, ECG) In some instances, batch loaded data may not be visible.	Requires Re-Approval	Data on the page has been changed since Investigator approval.
Active Discrepancy	The eCRF has at least one open discrepancy that requires the current users' attention.	Locked	All eCRF data has been collected and verified. A locked eCRF may be viewed in a read-only mode and its data cannot be updated. The locking task is typically performed by a data manager.

Selecting and Opening an eCRF

- Click the **Visit** drop-down list.
- Select the desired visit from the list.



- Click on the desired eCRF icon to open the page.
- Maximize the eCRF window.

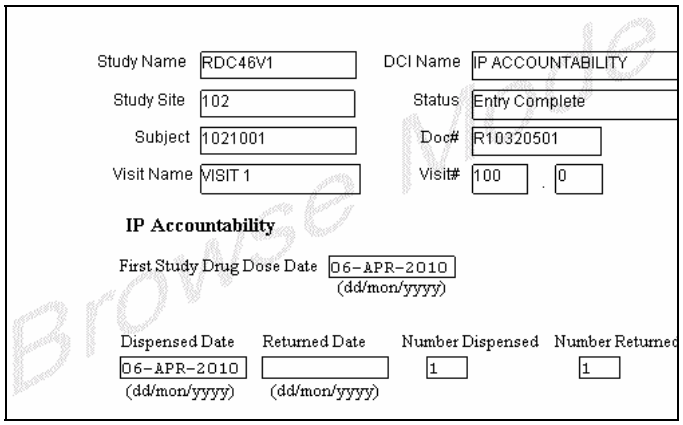
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

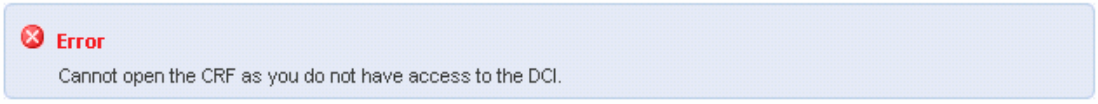
NOTES:

- The patient drop-down list in the Set Visit Focus area of the Casebook Spreadsheet is present for all studies, but only enabled for flexible study designs (see later section).

- You will notice a ***Browse Mode*** watermark on the eCRF indicating that you do not have entry / update access:



- If you attempt to view an eCRF before data has been entered, you will encounter the following error message:



Navigation Buttons

- To navigate through an eCRF that contains multiple pages, Navigation tools appear at the bottom of the eCRF.
- The navigation tool that appears at the top right corner of the eCRF is a toggle button for moving to the **Previous CRF or the Next CRF**.

- The TAB key moves the curser form field to field on the eCRF page.
- Clicking in a data field using the mouse moves the cursor to the selected data field
- Use the scroll bars to navigate through and view the eCRF fields.

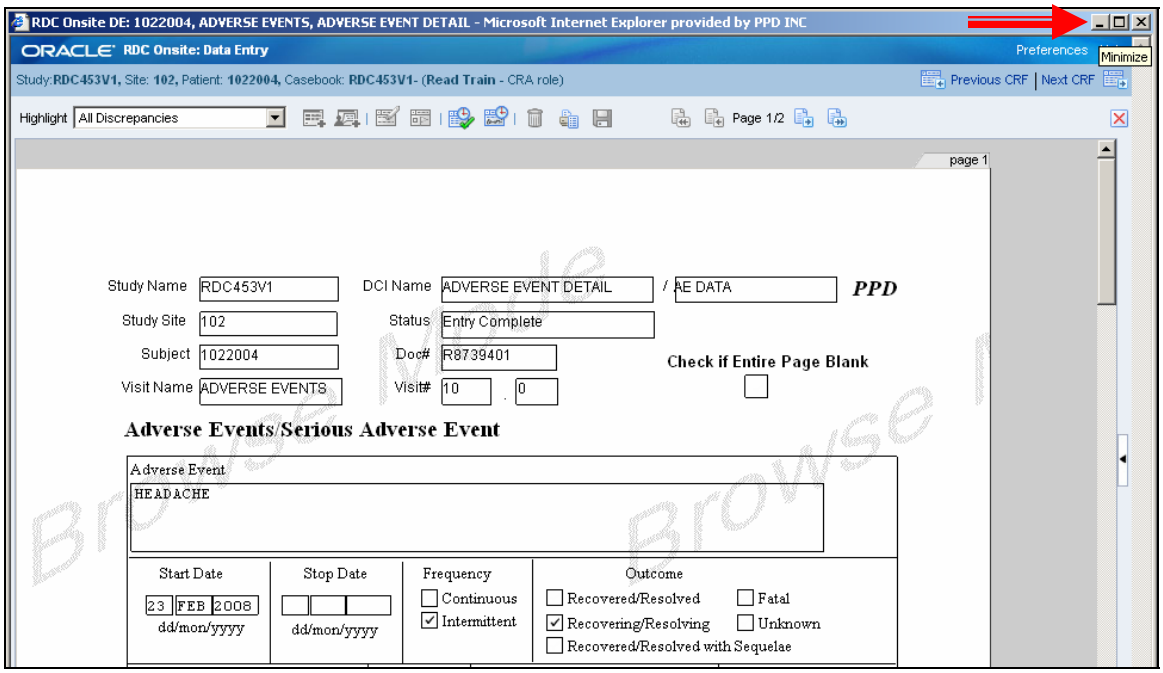
PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

Opening Multiple eCRFs

There may be times when you would like to compare data on multiple eCRFs. Whether you are working from the Casebook tab or the Review tab, OC RDC allows you to open a maximum of three eCRFs at once to do data comparison. An example could include cross-checking dates on an Adverse Events page and a Concomitant Medications page. You can compare data on eCRFs across one visit for multiple patients, as well as across multiple visits for one patient.

To open up to 3 pages simultaneously in OC RDC:

- From the Casebook tab or the Review tab, click on the first desired eCRF icon to be opened. The eCRF is displayed.
- Click on the Minimize button, to uncover the Casebook or Review Tab.

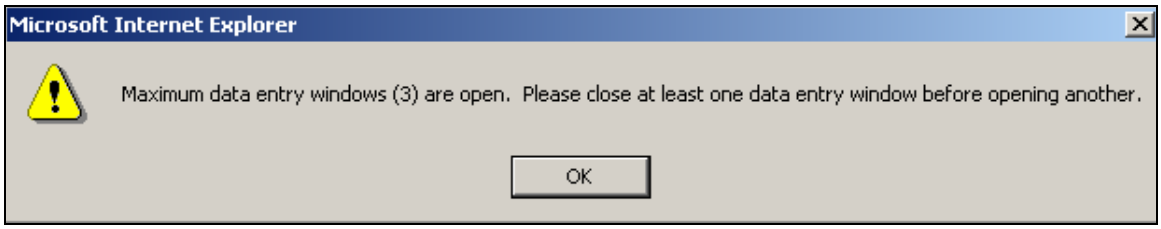


- From the Casebook tab or the Review tab, click on the second desired eCRF icon to be opened.
- Click on the Minimize button, to uncover the Casebook or Review Tab.
- From the Casebook tab or the Review tab, click on the third desired eCRF icon to be opened.
- With all three desired eCRFs open, you can then alternate move and/or resizing the eCRF windows to view and compare the data.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

NOTE: If you attempt to open a fourth eCRF page, the system will return an error/alert message window to inform that the maximum amount of data entry windows is open.



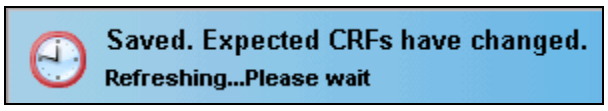
Flexible Study Designs

THIS SECTION IS ONLY APPLICABLE TO STUDIES WHICH ARE DEFINED AS FLEXIBLE IN OC RDC

The visit(s) and assessment(s) that a patient is expected to complete sometimes vary for different patients within the same trial. For example, patients in different cohorts or treatment arms may follow different visit schedules, or Oncology patients assessed as having a rapidly progressing disease state may be dosed more frequently.

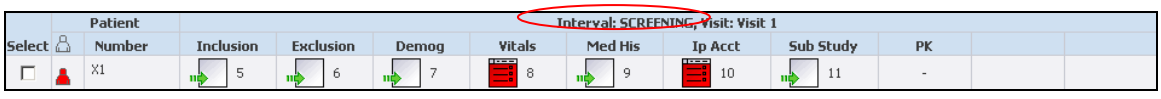
The OC RDC flexible study design feature supports efficient navigation and data entry within such complex trial designs. Selected visits and/or CRFs are enabled by rules defined in the background based on the response to a specific 'trigger' question.

If a visit or CRF is not enabled, it may indicate that the trigger question has not been answered, or that the response does not meet the appropriate criteria. The user is notified during the save procedure when a data change has an impact on the expected CRFs for a patient:



Visit Handling in Flexible Study Designs

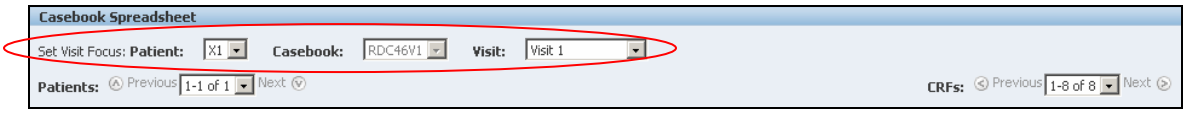
The response to a specific question may trigger a visit, or a group of related visits (known as an interval) to be enabled. In studies where intervals have been defined, the interval name may be displayed as a prefix to the visit name (this is an OC RDC option):



If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

The visits that a patient is expected to perform can be identified using the **Set Visit Focus** filters in the Casebook Spreadsheet. When a specific patient is selected from the **Patient:** drop-down list, only the casebook(s) and/or visit(s) currently expected for that patient can be selected from the subsequent drop-down lists:

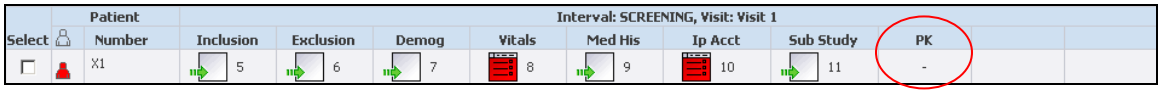


NOTE: The patient drop-down list in the Set Visit Focus area is present for all studies, but only enabled for flexible study designs.

CRF Handling in Flexible Study Designs

The response to a specific question may trigger an eCRF to be enabled at one visit, or at all visits in which that eCRF appears.

Within an expected visit, a dash (-) indicates that an eCRF is not currently expected for the patient in question:



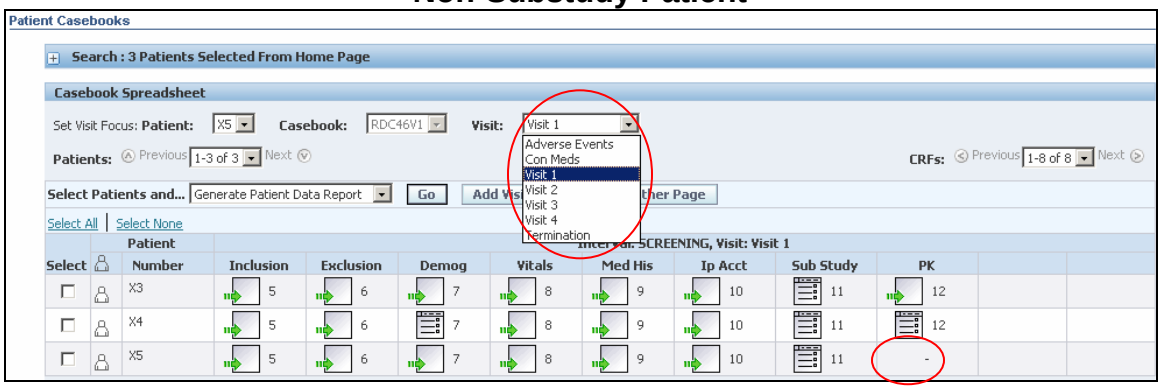
If an eCRF is completed and then subsequently the data changes such that the eCRF is no longer expected, the data on that eCRF will remain. A small N will be displayed to the bottom right of the eCRF icon as an indication that the entered data is no longer expected:

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

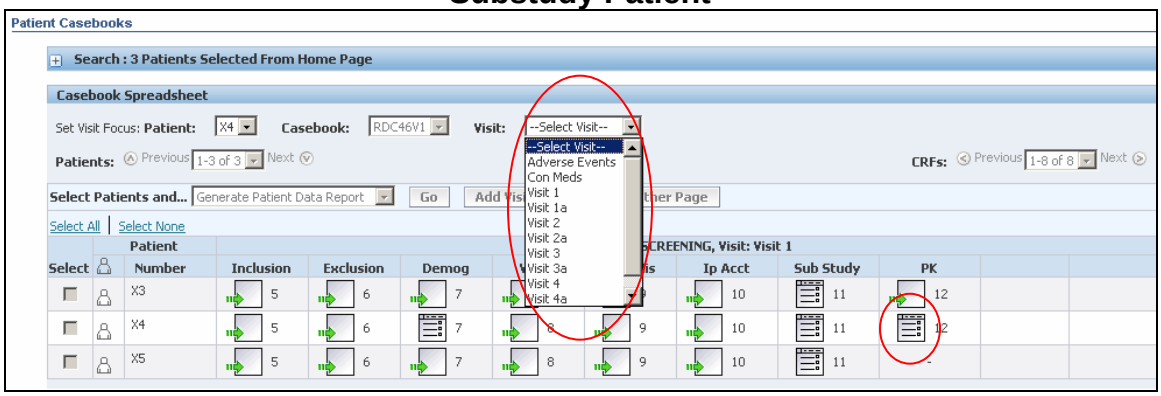
Example of Flexible Study Design

In the trial illustrated below, a number of the patients will participate in a sub-study. These patients will have a PK sample drawn at each clinic visit, as well as at 4 additional interim visits. The Sub-Study eCRF at Visit 1 indicates whether the patient will be participating in the sub-study – observe the differences in the visit drop-down list and the PK eCRF shown in the screenshots below:

Non-Substudy Patient



Substudy Patient



NOTE: This functionality only applies to the user interface – the Patient Data and Blank Casebook reports will display CRFs and/or Visits regardless of whether they are enabled (exception: if the CRF is hidden to the user who executes the report then it will not be included).

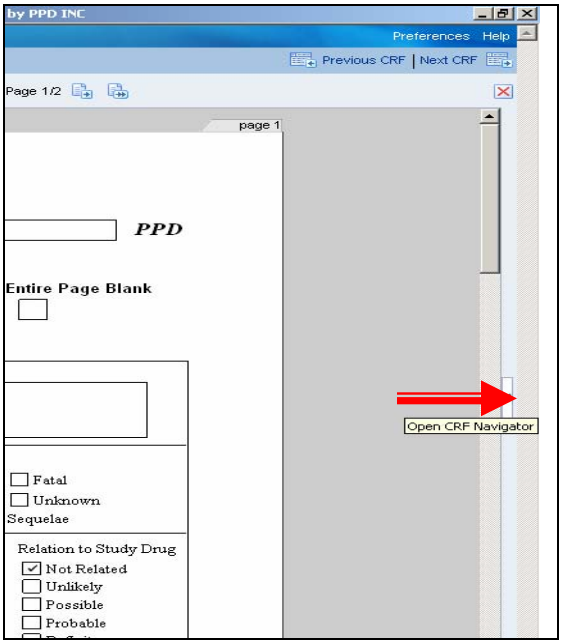
Oracle is a registered trademark of Oracle Corporation.

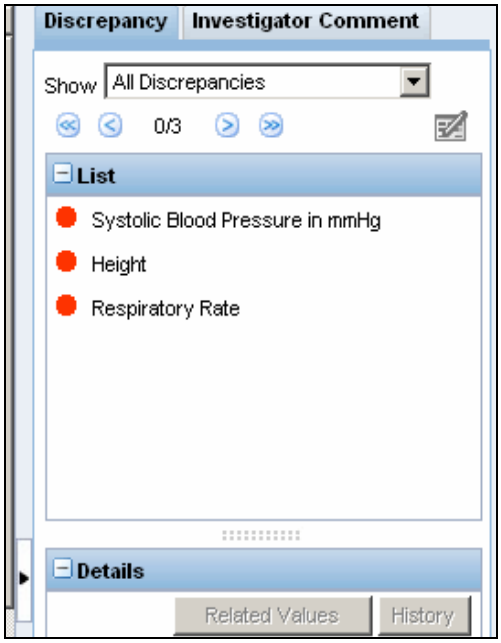
OC RDC Features

CRF Navigator

The CRF Navigator is a window pane on the right side of an eCRF that contains two tabs listing Discrepancies and Investigator Comments. To view the CRF Navigator:

- From the OC RDC Casebook Spreadsheet, click an eCRF icon to display the eCRF.
- Click the **Open CRF Navigator** button to the right of the eCRF to open the CRF Navigator Pane.





Viewing Discrepancy Details

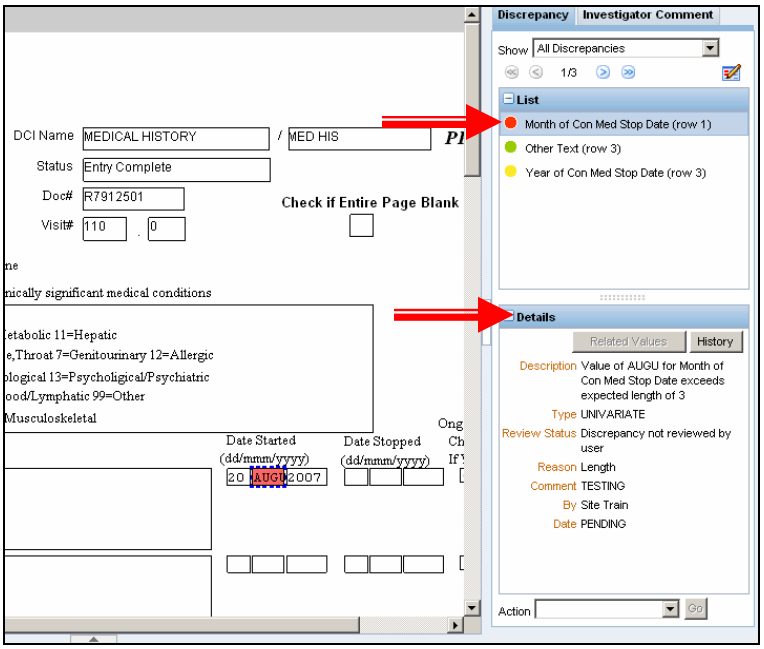
A discrepancy within OC RDC is defined as “Data that falls outside of an expected range of values or is otherwise 'flagged' during the edit check process”. eCRF icons and data fields are color coded to indicates the status of the discrepancy:

- A **red** icon on the OC RDC Casebook Spreadsheet and a **red** field or bar on the eCRF indicates the discrepancy requires action by the person logged in or someone else who shares the same role.

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

- A **yellow** icon on the OC RDC Casebook Spreadsheet and a **yellow** eCRF field or bar indicates that the discrepancy is actionable to someone outside of your role.
- A white icon on the OC RDC Casebook Spreadsheet and **green** field or bar indicates the discrepancy is closed.

To view a discrepancy from the CRF Navigator pane, click on the desired Discrepancy in the **List** to display the **Details** below:



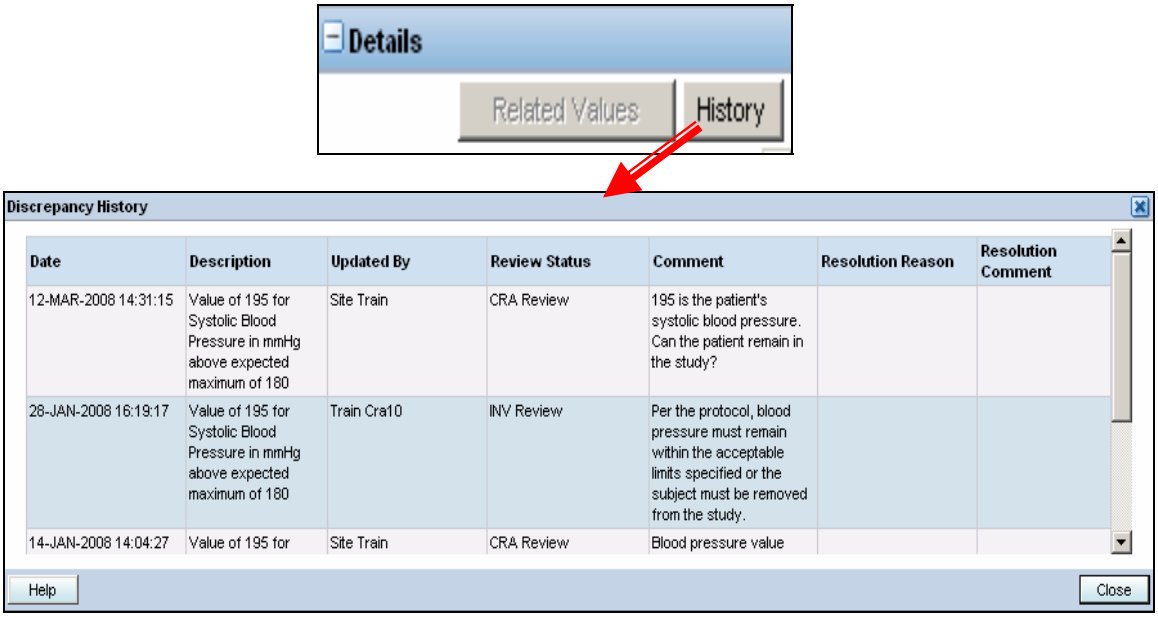
Viewing Discrepancy History

Once a discrepancy is saved to an eCRF, users are able to view the history of the discrepancy in the CRF Navigator.

To view the discrepancy history:

- From the OC RDC Casebook Spreadsheet, click the eCRF icon containing a discrepancy of any status. The eCRF displays.
- Click the CRF Navigator button to the right of the eCRF to expand the CRF Navigator Pane.
- CLICK on the desired Discrepancy in the List, to display the details below.
- Click the **History** button to display the **Discrepancy History** window.

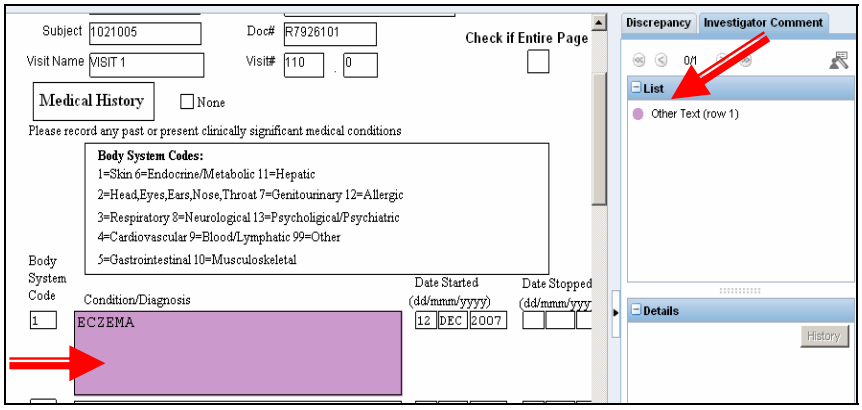
PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.



- When finished viewing the history, click the Close button

Viewing Investigator Comments

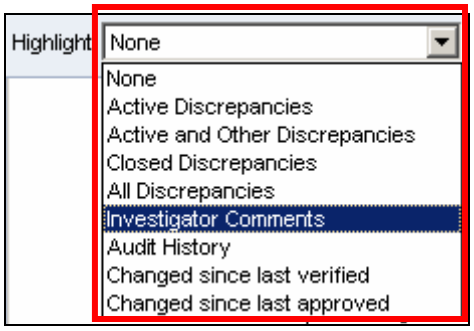
When the CRF Navigator - Investigator Comment tab is selected, all data fields which contain an Investigator comment are listed.



To view a comment:

- On an open eCRF, select the Investigator Comment **Highlight**, from the drop-down list in the top left corner of the eCRF.

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.



- Any field containing a comment appears in magenta (purple-pink).
- Select the investigator comment item from the List or the eCRF.
- Details of the Investigator comment will display in the CRF Navigator pane.
- Additional information can be reviewed by clicking the **History** button.

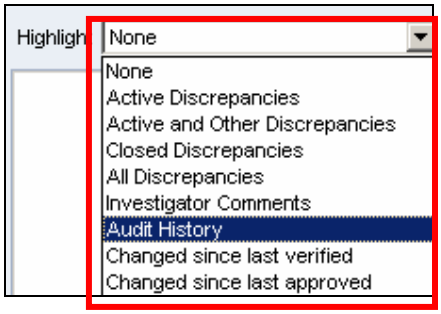
Viewing Audit History

OC RDC automatically keeps a history of any data changes that have occurred for each field after the eCRF has been saved the first time.

The system prompts users to supply a change reason when data is modified on an eCRF that has been saved. The history contains information on who changed the data, the previous value, the date and time the modification occurred and a reason for the change. Any field that has an audit history displays in **blue** when the **Audit History** highlight is selected.

To view the history of a data field:

- On an open eCRF, select the Audit History Highlight, from the drop-down list in the top left corner of the eCRF.

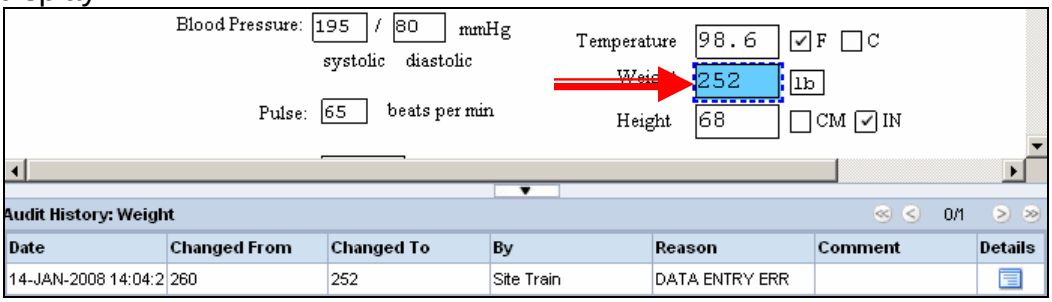


- Any field containing a history displays in **blue**.
- Click the **Audit History** button at the bottom of the eCRF to expand the Audit History pane.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

- In the Audit History pane, information regarding fields with audit history will display.



- A separate Audit History Details window can be viewed, by clicking on the **Details** button.

CRF Search Criteria

Once data capture has begun for the study, users are able to use search criteria to sub-set or filter data for display. The Search feature in helps you locate specific information from different eCRF pages.

On the Casebook and Review tabs, CRF search criteria fall into two sub-categories:

1. CRF Status Criteria

Under this category, you select search parameters based on the status of the eCRF. The various eCRF status parameters are:

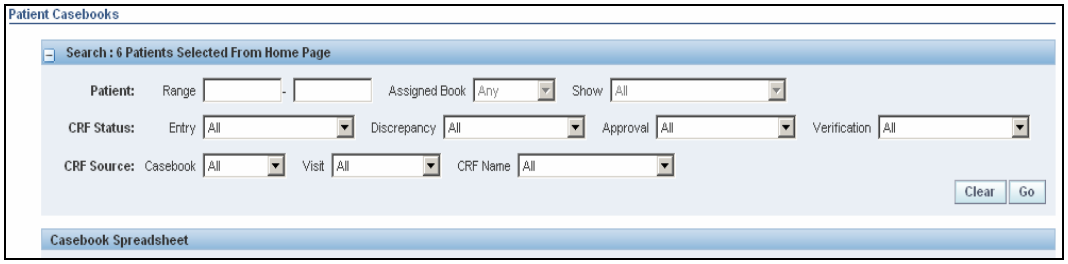
- Entry: Select the entry status of the eCRF to locate. Your options are- All, Blank, Entry Complete, and Batch Loaded.
- Discrepancy: Select the discrepancy status of the eCRF to locate. Your options are - All, Active, Other, Open (Active & Other), Clean (None or Closed). The Clean option is replaced by Closed on the Review tab.
- Approval: Select the approval status of the eCRF to locate. Your options are- All, Not Approved, Approved, Awaiting re-approval, and Approval Undone.
- Verification: Select the verification status of the eCRF to locate. Your options are- All, Not Verified, Verified, Awaiting re-verification, and Verification Undone.

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

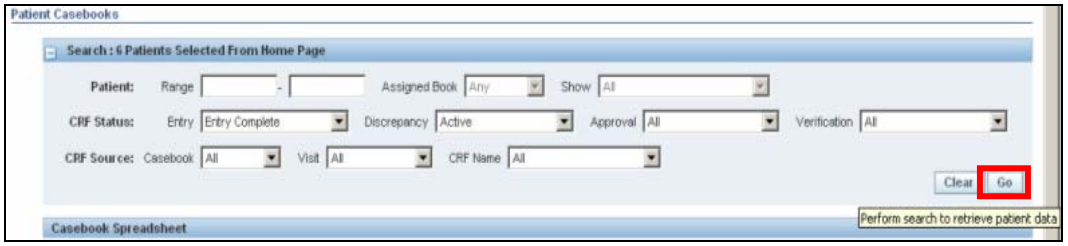
2. CRF Source Criteria

You can select search parameters based on the source of the eCRF. There are three sources from which to locate an eCRF.

- Casebook: Select the casebook used at the time of initial data entry into the eCRF. Your options are All or individual casebooks in the study, sorted alphabetically in the drop-down selection list. This parameter is useful if patients, whose data was entered using an earlier version of the casebook, are reassigned to a new version of the casebook.
- Visit: Select the number of the visit during which the eCRF data was collected. If a casebook is specified, OC RDC displays only the visits defined for the selected casebook in the drop-down selection list. If the casebook selection is All, OC RDC displays all visits defined for the study.
- CRF Name: Select the name of the eCRF to review from the drop-down list. This parameter is useful in reviewing all eCRFs of a certain type, for example, all Adverse Events forms, or all Concomitant Medications forms.



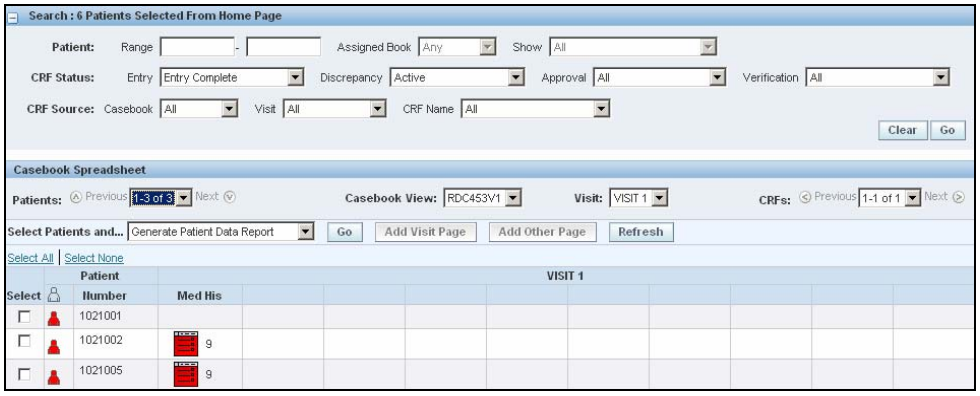
The Search features allow users to specify the data display in greater detail. This is a useful tool which has the potential of assisting users with their work flow for data capture and discrepancy management.



- Click the Go button to perform the search and retrieve the desired patient data.
- The Casebook or Review tab will update with the desired CRF Search Criteria.

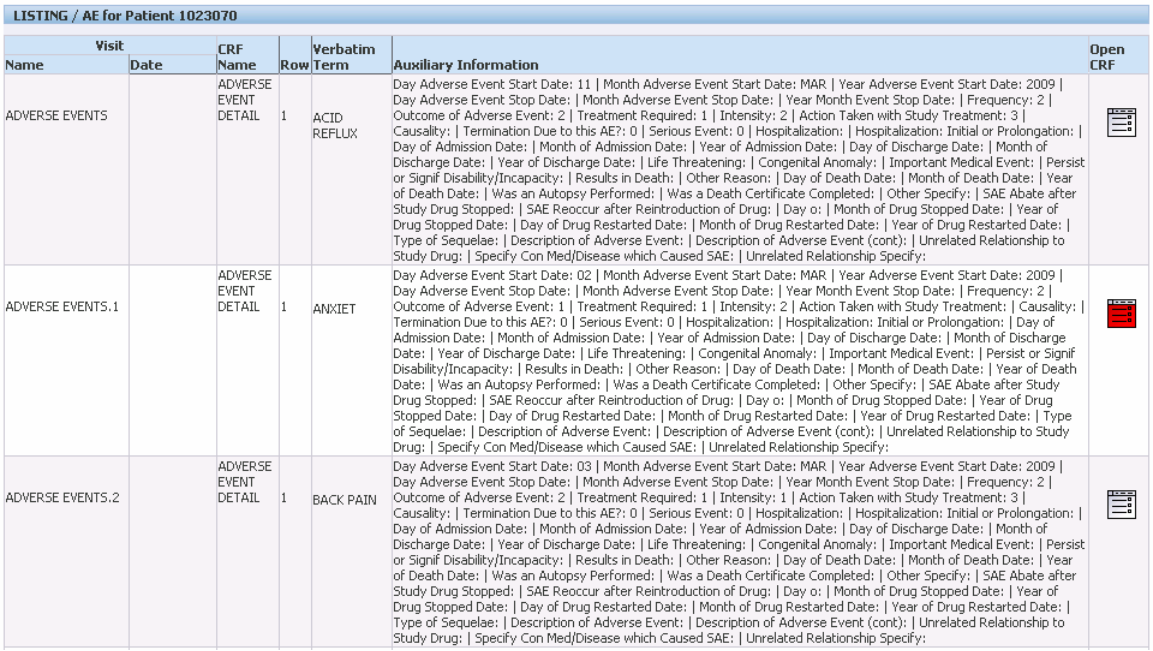
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.



Accessing Special Listings

Special Listings display data which is split across multiple eCRFs, such as Adverse Events, Concomitant Medications or Medical History, in a user-friendly tabular format that can be easily sorted to locate a specific entry. The associated eCRF can be accessed directly from the listing.



LISTING / AE for Patient 1023070

Visit Name	Visit Date	CRF Name	Row	Verbatim Term	Auxiliary Information	Open CRF
ADVERSE EVENTS		ADVERSE EVENT DETAIL	1	ACID REFLUX	Day Adverse Event Start Date: 11 | Month Adverse Event Start Date: MAR | Year Adverse Event Start Date: 2009 | Day Adverse Event Stop Date: | Month Adverse Event Stop Date: | Year Month Event Stop Date: | Frequency: 2 | Outcome of Adverse Event: 2 | Treatment Required: 1 | Intensity: 2 | Action Taken with Study Treatment: 3 | Causality: | Termination Due to this AE?: 0 | Serious Event: 0 | Hospitalization: | Hospitalization: Initial or Prolongation: | Day of Admission Date: | Month of Admission Date: | Year of Admission Date: | Day of Discharge Date: | Month of Discharge Date: | Year of Discharge Date: | Life Threatening: | Congenital Anomaly: | Important Medical Event: | Persist or Signif Disability/Incapacity: | Results in Death: | Other Reason: | Day of Death Date: | Month of Death Date: | Year of Death Date: | Was an Autopsy Performed: | Was a Death Certificate Completed: | Other Specify: | SAE Abate after Study Drug Stopped: | SAE Reoccur after Reintroduction of Drug: | Day o: | Month of Drug Stopped Date: | Year of Drug Stopped Date: | Day of Drug Restarted Date: | Month of Drug Restarted Date: | Year of Drug Restarted Date: | Type of Sequelae: | Description of Adverse Event: | Description of Adverse Event (cont): | Unrelated Relationship to Study Drug: | Specify Con Med/Disease which Caused SAE: | Unrelated Relationship Specify:	
ADVERSE EVENTS.1		ADVERSE EVENT DETAIL	1	ANXIET	Day Adverse Event Start Date: 02 | Month Adverse Event Start Date: MAR | Year Adverse Event Start Date: 2009 | Day Adverse Event Stop Date: | Month Adverse Event Stop Date: | Year Month Event Stop Date: | Frequency: 2 | Outcome of Adverse Event: 1 | Treatment Required: 1 | Intensity: 2 | Action Taken with Study Treatment: | Causality: | Termination Due to this AE?: 0 | Serious Event: 0 | Hospitalization: | Hospitalization: Initial or Prolongation: | Day of Admission Date: | Month of Admission Date: | Year of Admission Date: | Day of Discharge Date: | Month of Discharge Date: | Year of Discharge Date: | Life Threatening: | Congenital Anomaly: | Important Medical Event: | Persist or Signif Disability/Incapacity: | Results in Death: | Other Reason: | Day of Death Date: | Month of Death Date: | Year of Death Date: | Was an Autopsy Performed: | Was a Death Certificate Completed: | Other Specify: | SAE Abate after Study Drug Stopped: | SAE Reoccur after Reintroduction of Drug: | Day o: | Month of Drug Stopped Date: | Year of Drug Stopped Date: | Day of Drug Restarted Date: | Month of Drug Restarted Date: | Year of Drug Restarted Date: | Type of Sequelae: | Description of Adverse Event: | Description of Adverse Event (cont): | Unrelated Relationship to Study Drug: | Specify Con Med/Disease which Caused SAE: | Unrelated Relationship Specify:	
ADVERSE EVENTS.2		ADVERSE EVENT DETAIL	1	BACK PAIN	Day Adverse Event Start Date: 03 | Month Adverse Event Start Date: MAR | Year Adverse Event Start Date: 2009 | Day Adverse Event Stop Date: | Month Adverse Event Stop Date: | Year Month Event Stop Date: | Frequency: 2 | Outcome of Adverse Event: 2 | Treatment Required: 1 | Intensity: 1 | Action Taken with Study Treatment: 3 | Causality: | Termination Due to this AE?: 0 | Serious Event: 0 | Hospitalization: | Hospitalization: Initial or Prolongation: | Day of Admission Date: | Month of Admission Date: | Year of Admission Date: | Day of Discharge Date: | Month of Discharge Date: | Year of Discharge Date: | Life Threatening: | Congenital Anomaly: | Important Medical Event: | Persist or Signif Disability/Incapacity: | Results in Death: | Other Reason: | Day of Death Date: | Month of Death Date: | Year of Death Date: | Was an Autopsy Performed: | Was a Death Certificate Completed: | Other Specify: | SAE Abate after Study Drug Stopped: | SAE Reoccur after Reintroduction of Drug: | Day o: | Month of Drug Stopped Date: | Year of Drug Stopped Date: | Day of Drug Restarted Date: | Month of Drug Restarted Date: | Year of Drug Restarted Date: | Type of Sequelae: | Description of Adverse Event: | Description of Adverse Event (cont): | Unrelated Relationship to Study Drug: | Specify Con Med/Disease which Caused SAE: | Unrelated Relationship Specify:	

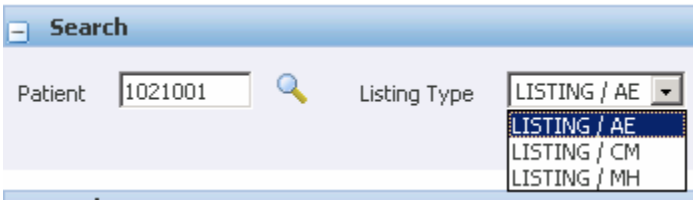
Special Listings can be accessed directly from the Review tab, or by drilling down from the Home tab or Casebooks tab.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

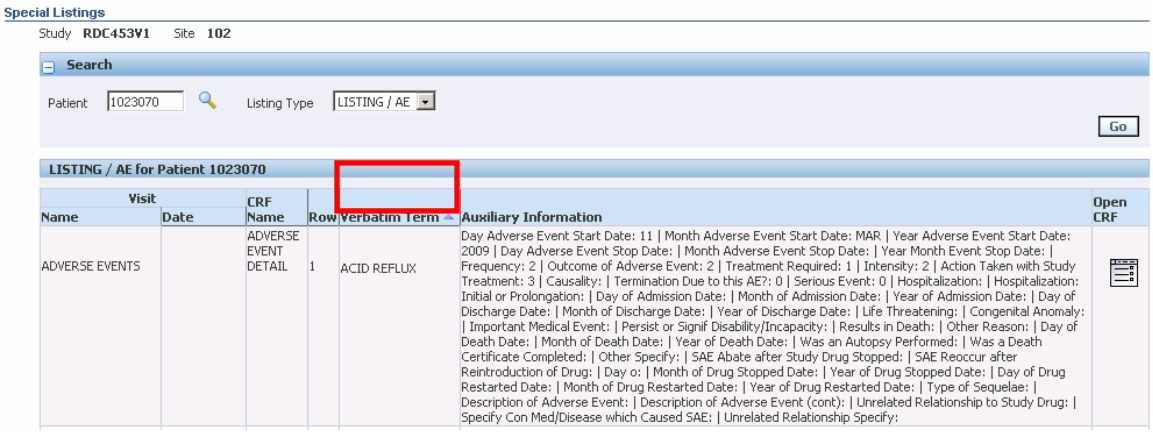
From the Review tab:

- Click the **Special Listings** sub-tab
- In the Search area, type the assigned patient number or use the **Magnifying glass** to select a patient from the available list
- Select the desired listing from the **Listing Type** drop-down list:



NOTE: In the study environment, the word LISTING will be replaced by the name of the coding dictionary utilized. The available listing options may include MedDRA / AE; WhoDRUG / CM; MedDRA / MH and so on.

- Click the **Go** button to display the listing.



- Click on the headers for the **Date**, **CRF Name**, **Row** or **Verbatim Term** columns to sort the information in the table. One click sorts in ascending order, a second click reverses to descending order. A small blue arrow next to a column header signifies the current sort filter.
- Click the eCRF icon in the final column to access the eCRF.

From the Home or Casebooks tab:

- Place a checkmark in the box to the left of the desired patient number
  NOTE: A special listing can only be displayed for one patient at a time.
- Open the **Select Patients and...** drop-down list
- Select Review *desired listing*
- Click the **Go** button to drill down to the Review Special Reports page and display the listing.

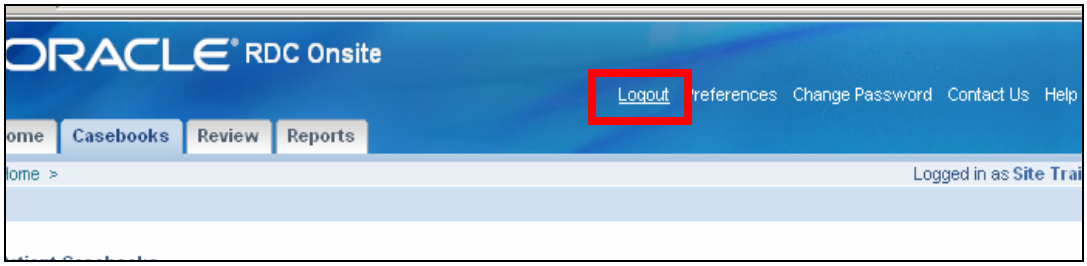
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

LOGGING OUT OF OC RDC

It is important that any work in an eCRF is saved before attempting to log out. Failure to save work results in the data or changes being lost. Properly logging out ensures that your account session is completely terminated.

To Log out:



- Click the **Logout link** at the top of the screen.
- Close all open windows.

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

OC RDC TRAINING SUPPORT

Training Options & Access Requests

OC RDC application training is available for all OC RDC users. Application training covers functionality of OC RDC.

- OC RDC is an eCRF and not a direct data entry system; source documentation is required.
- All equipment provided to the site should ***ONLY*** be used for OC RDC or other PPD approved applications.
- The PPD EDC Support Center is available 24 hours a day, 5 days a week, with weekend and holiday pager support. Multilingual translators are available.
- The PPD EDC Support Center is for technical questions only. Please contact the CRA for study protocol or eCRF related questions.
- At the end of the study, a CD of all subject data will be provided to the sites - Investigator confirmation and sign-off is required after receipt of the entire site's study data on the CD. Until the CD is received, sites must continue to have access to PPD and their OC RDC data.
- All training sessions must be documented before access to a study protocol in the OC RDC application is granted.

Training Materials

The following OC RDC training materials are available for all site users:

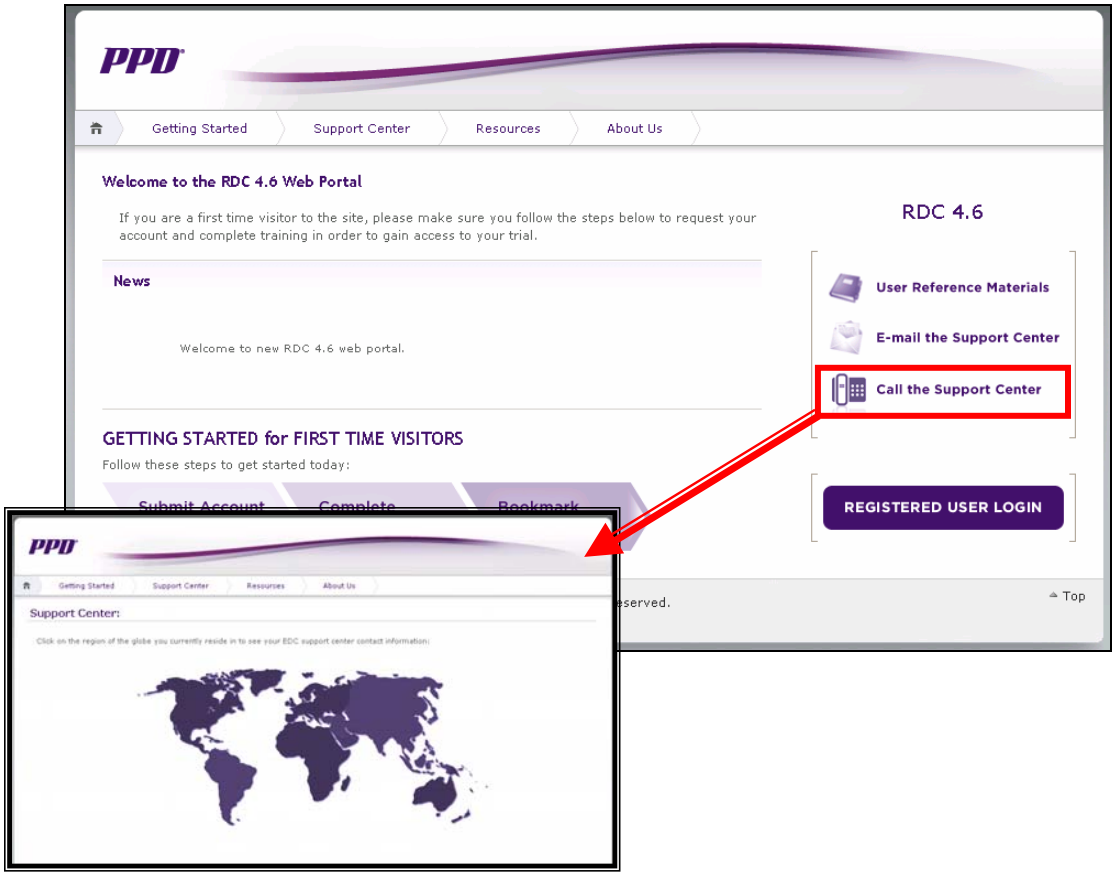
- On-line training
- Quick Reference Guide
- Investigator Site User Guide

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

PPD Proprietary
Oracle is a registered trademark of Oracle Corporation.

Need Technical Help?

CALL THE PPD EDC SUPPORT CENTER



EDC Support Center Phone Numbers

Global + 44 (0) 1223 374580
North America + 866-765-0279
World Phone toll free numbers outside the US and Canada
can be found at http://rdc.ppdi.com/

If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://rdc.ppdi.com/

Oracle is a registered trademark of Oracle Corporation.