

# CRA OC RDC PDF 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://edc.ppd.com>

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## ACCESSING OC RDC

### Steps for Access

- 1) In LMS, complete training on **SOP CL-03-10** (Electronic Data Capture Using Oracle Clinical Remote Data Capture)
- 2) Register in LMS for Instructor-Led training - **CLN3-01574** (OC RDC 4.5.1 Application Training)
- 3) Contact the EDC Support Center for assistance with installation of OC RDC. You cannot access the system until the software has been installed on your computer.
- 4) Advise your PM or CTM when you have completed training and they will request your account to be set up via eFUSION. A separate request is required in eFUSION for each new study.
- 5) Your Username/Password will be emailed within 5 business days of the request in eFUSION being submitted.

### Existing OC RDC PDF Account Users:

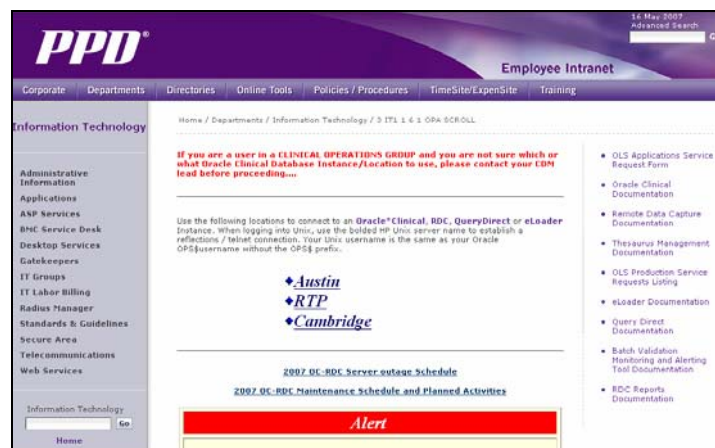
If you get assigned to another PDF study on the same server (database), the PM for the study will need to request access for you via eFUSION. Your Username and Password will remain the same and you will choose the study you wish to view in OC RDC after you log in using the Change Study button.

If the new study is on a different server, the PM will need to request an account for you on that server and access to the study for you via eFUSION. Your Username will remain the same, but you will receive a new password for that server.

If you have access to multiple servers, you can reset your password so that it will be the same for each server.

### LOGGING ON TO OC RDC

- A. When working in a PPD office, access your study database from the intranet using URL:  
[http://intranet.ppd.com/3/IT1/3\\_IT1\\_1\\_6\\_1\\_OPA\\_SCROLL.htm](http://intranet.ppd.com/3/IT1/3_IT1_1_6_1_OPA_SCROLL.htm)



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## LOGGING ON TO OC RDC con't

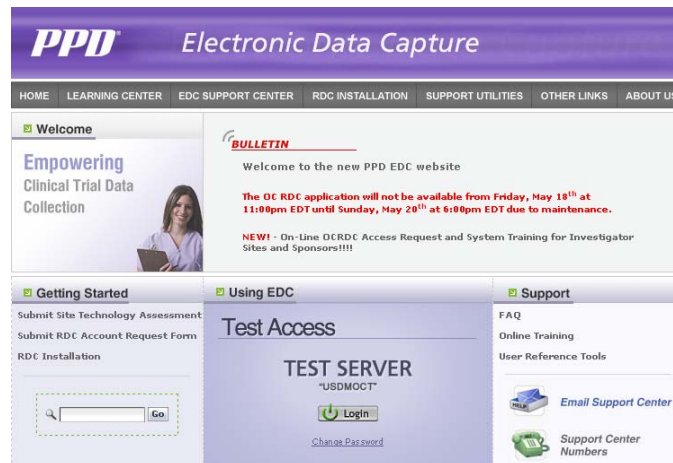
- B. Outside of a PPD office when you are **not connected to the PPD VPN**, access your study database via the external website for your study. Use of the external website will increase system performance because you will not be crossing firewalls multiple times to access your study.

### Study Servers:

RTP (RTPOCP): <http://edc.ppdi.com/server1/>

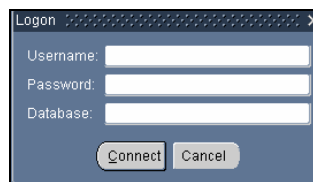
CAMBRIDGE (BRUOCP): <http://edc.ppdi.com/server2/>

AUSTIN (AUSOCP & AUSOC2P): <http://edc.ppdi.com/server3/>

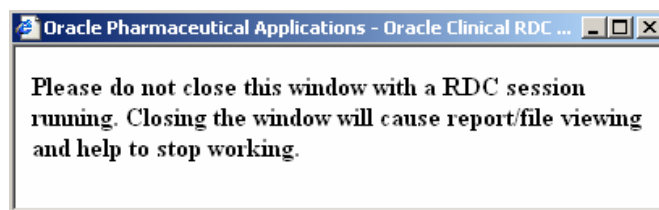


### Steps for Logging On

- 1) Click the Login button on the edc.ppdi.com/ website specific to your study (Server 1, Server 2 or Server 3)
- 2) Enter the OC RDC **Username**, **Password** and assigned **Database**  
*Note: Text is not case sensitive. The user is allowed three log on attempts after which the account will lock. The user will need to call the EDC Support Center to unlock the account.*
- 3) Click the **Connect** button



**NOTE:** Upon successful log in, the following window will appear. **DO NOT CLOSE** this window. It will automatically minimize to the Task Bar at the bottom of the screen. Leave this window open during your entire session of OC RDC to avoid errors.



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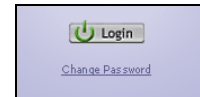
**LOGGING ON TO OC RDC con't**

**IMPERATIVE ACTION:** Do not click the **×** button to close an open eCRF or any window within the application. Use the function buttons within each window. The system will not recognize that the eCRF is closed and users will receive the following error message: **“This action cannot be performed as an active PDF form is currently open. Please close the PDF form before continuing with this action.”** Users will be forced to log out of OC RDC and then log back into the system.

**CHANGE PASSWORD**

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

- Upon initial log in
- Every 90 days
- As needed if users feel someone knows their password

**To change your password:**

- 1) From the *EDC Website*, click the **Change Password** link
- 2) On the Logon window, enter the OC RDC **Username**, **Password** and assigned **Database**
- 3) Click the **Connect** button
- 4) On the **Change Password** screen, enter the existing password and the new password twice for confirmation
- 5) Click the **Change Password** button
- 6) The *News* window displays

**LAPTOP AND SYSTEM 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 PDF system. Users should log off of the OC RDC if they need to step away from the laptop.

If the laptop is inactive (no keyboard or mouse activity) for 30 minutes while there is an open eCRF, the system automatically times out. Users will lose any unsaved work and they will need to log back into the system to continue working.

**Display Message will read RDC Session Timed Out:**

- Click the **OK** button
- An additional error message box displays
- Click the **OK** button
- The OC RDC Launch window displays
- Log back into OC RDC PDF to continue working

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## THE CHANGE STUDY SCREEN

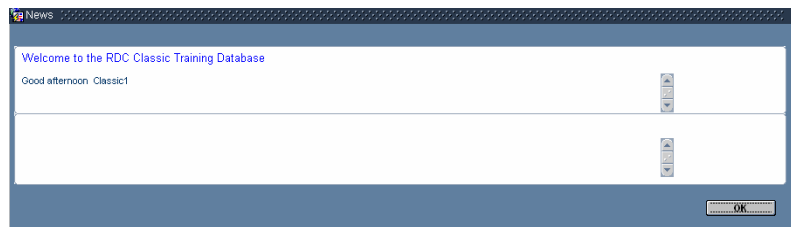
*(Applicable only for CRAs doing multiple OC RDC studies)*

After users have logged into the system, the first screen that displays if this is the **first time** users are logging into OC RDC PDF **and** they have **access to multiple protocols** is the Change Study screen.

The Change Study screen lists all of the protocols a user has been granted access to and allows them to select a protocol to work with. This screen can also be accessed at any time during the OC RDC PDF session to select a different study.

### To select a protocol:

- Highlight a protocol number from the list **or**
- Type the full protocol number in the Find field (it must match exactly) **or**
- Use the “wildcard” feature by typing in a portion of the study number in the Find field, e.g., 102%, clicking the **Find** button and highlighting the desired protocol number listed
- Click the **OK** button
- The *News* window may display
- Click the **OK** button (not the X in the upper right corner) to view the *Activity List* window or the *Search* window



## THE ACTIVITY LIST

The Activity List will display after users have logged into OC RDC PDF and if applicable, selected a study. If users have access to only one protocol, the Activity List window will display after the *News* window is closed.

The Activity List is used to select a task or the data that they wish to view on the *OC RDC Main Spreadsheet*. Additionally, the list can be accessed at any time during the OC RDC PDF session to select other tasks.

The protocol number selected from the Change Study window or the protocol number of the study worked with prior to exiting the last OC RDC Classic session displays in the left hand **Navigation Pane**.

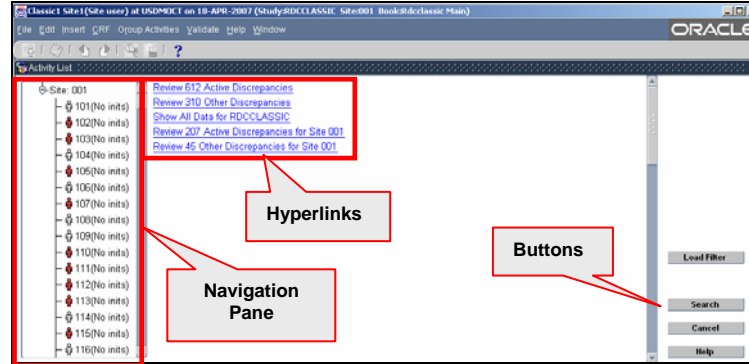
The associated site and patient numbers are listed below the protocol number. The protocol, site and patient numbers display automatically. Patient numbers are populated by PPD for viewing in the **Navigation Pane**.

To expand or open the site and list of patient numbers, click the (+) symbol to the left of the protocol or site number. When expanded, the (+) symbol becomes a (-) symbol.

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## THE ACTIVITY LIST con't



Subject icons display next to the patient numbers once data has been entered and saved. If patient initials are being populated in the Navigation Pane, users will see the initials displayed after they have been entered by PPD.

If your study has not contracted for initials to be entered for the study, then (*No inits*) will display next to the patient number.

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.

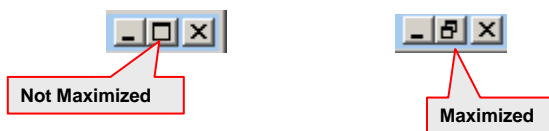
When a protocol, site or patient number is highlighted in the **Navigation Pane**, the **Task Pane** displays a list of pre-set tasks, represented as [hyperlinks](#), which are associated with the current selection. The hyperlinks provide access to the *OC RDC Main Spreadsheet* to view or enter data.

On the right side of the screen, **Buttons** are available for selecting another study if users have access to multiple protocols, accessing the *Search* window, canceling out of the *Activity List* and launching the *Oracle RDC Online Help*.

Site Users will need to highlight the site or patient number from the **Navigation Pane** in the *Activity List* window and click the desired hyperlink from the **Task Pane** to display the *OC RDC Main Spreadsheet*.

### To display the Main Spreadsheet

- Highlight the site or patient number from the **Navigation Pane**
- Click the desired hyperlink from the **Task Pane** to display the Main Spreadsheet
- Click the **Maximize** button on the top right corner of the Main Spreadsheet to obtain a full screen view



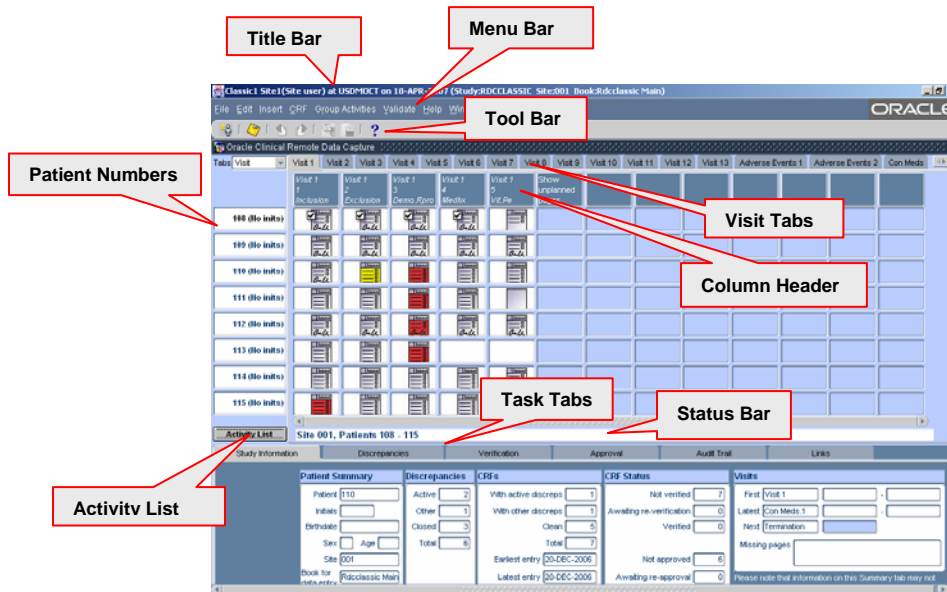
**Note:** When the *OC RDC Main Spreadsheet* is maximized, you will be able to view the scrollbar on the right, allowing you to scroll up and down.

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## OC RDC MAIN SPREADSHEET

The **title bar** displays the current protocol, site and user information.

The **toolbar** and **menu** options contain the same options and gives access to the most frequently used commands.



The main spreadsheet consists of columns and rows. Each row and column is uniquely identified with descriptive information in the form of **visit names**, **page numbers** and **patient numbers**.

Due to space limitations, additional visit name tabs can be displayed by clicking the **double arrows** on the top right hand side of the screen.



A patient number and the associated row of eCRF cells make up a **patient row**. The center of the main spreadsheet contains **cells**. Each cell represents a single eCRF, which may contain one or more pages. Some of the eCRF cells may be blank or empty, indicating data has not been captured in the eCRF.

An eCRF cell containing an icon indicates that data has been captured in the eCRF. The different icons and their colors identify the status of data entry, discrepancy management, verification and approval.

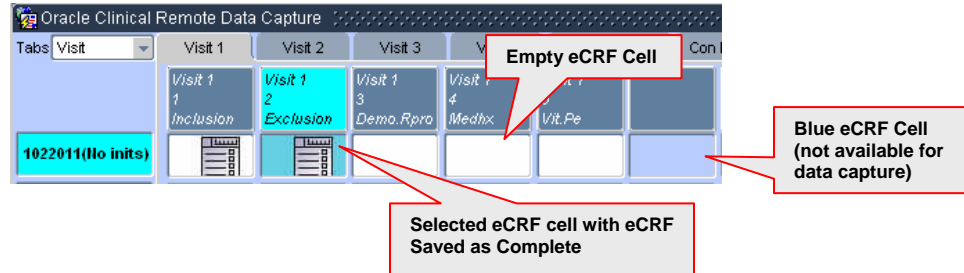
At the bottom of the patient numbers list, the Activity List window can be accessed by clicking the **Activity List** button. The data selected from the Activity List or Search window displays in the **Status Line**.

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## eCRF CELLS

An eCRF cell represents a single eCRF that may contain one or more pages. When an eCRF cell or an icon in an eCRF cell is clicked, the eCRF opens allowing users to capture, update or view data.



eCRF cells that are active and available for data capture are displayed with a white background. An eCRF cell for which data capture has not yet started is referred to as an empty eCRF cell.

The eCRF cell also displays with a white background when data capture has begun in the eCRF or if an eCRF has been marked as blank.

When an eCRF cell is selected or clicked, the background color of the eCRF cell, patient number and page name changes to aqua.

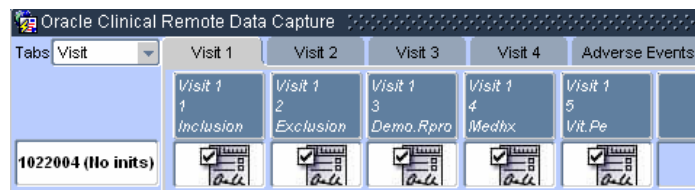
Blue eCRF cells are not associated with any visit, page or patient and are not available for data capture or any other actions.

## eCRF ICONS

In addition to colors, eCRF cells also contain icons. Icons appear in eCRF cells to represent the data capture, discrepancy, verification, and approval status of an eCRF.













eCRF icons allow users to see what work needs to be done by simply looking at the main spreadsheet. Please refer to the table below to view the icons and their descriptions.

The goal for each study is to have all icons white, saved as complete, verified by the CRA and approved by the Investigator such as in the screenshot below.



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## eCRF ICON DESCRIPTIONS

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 someone else's attention.
 Created	The eCRF page has been saved but no data has been entered yet.	 Verified by CRA	The eCRF has been source verified by the CRA.
 Entry Started	At least one field in the body of the eCRF contains data and the eCRF has been saved as Incomplete.	 Requires Re-Verification	The data on the page has been changed since CRA verification.
 Entry Complete	This icon represents several items which include: - all data fields have been captured and the eCRF has been saved as Complete - the eCRF contains no discrepancies or closed discrepancies - the eCRF has not been verified by the monitor	 Approved	The eCRF has been approved by the Investigator.
 Batch Loaded	The data has been electronically loaded 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 at PPD.

### THE OC RDC PDF DATA ENTRY WINDOW

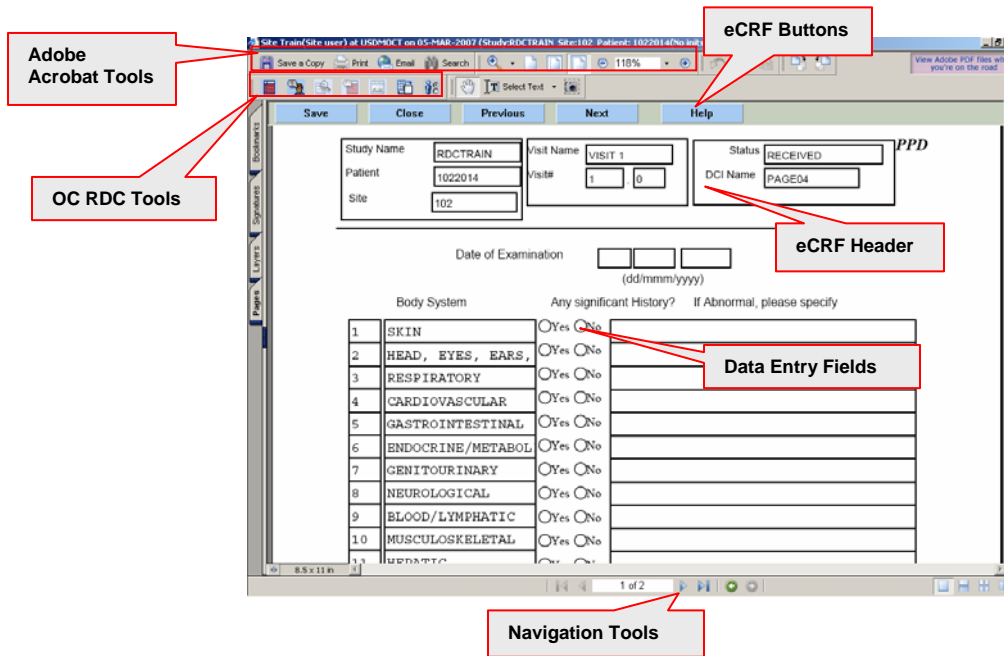
The OC RDC PDF eCRF displays when an eCRF cell or icon is clicked and is used to capture, modify or view patient data. While the PDF looks similar to a paper CRF, the eCRF is part of a study specific database.

Once an eCRF is opened, toolbar buttons appear at the top of the screen. Some of these tools are common to Adobe Acrobat, while others have been specifically developed for use in the OC RDC PDF system. Navigation buttons will be located at the bottom of the screen.

**IMPORTANT NOTE:** Do not click the  button in the upper right corner to close an eCRF. The system will not recognize that the eCRF is closed and users will receive an error message stating: **“This action cannot be performed as an active PDF form is currently open. Please close the PDF for before continuing with this action.”** If Users receive this message they will be forced to completely log out of OC RDC and then log back in.

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**THE OC RDC PDF DATA ENTRY WINDOW con't**



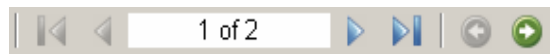
**Moving around the eCRF page**

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

**NAVIGATION TOOLS**

To navigate through an eCRF that contains multiple pages, **Navigation tools** appear at the bottom of the eCRF.

The navigation tools that appear at the bottom center of the eCRF include the number of pages contained in the eCRF and the current page a user is on as well as arrows for moving from one page to the next. If there are multiple pages in the eCRF, the arrow with the line will take you to the first or the last page in the eCRF.



On the far right bottom section of the eCRF you can choose to view single eCRF pages or continuous eCRFs by selecting one of the following icons.











**RDC TOOLS**

RDC tools provide access to common tasks performed within the application. The table below outlines the specific tool and its associated tasks.



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**OC RDC TOOLS con't**

Toolbar button	Name	Description
	Data Entry/Hand	The default tool that allows users to navigate the CRF, perform initial data entry, and data update. This tool is part of the Adobe Reader/Acrobat application.
	Discrepancy Management	Allows site users to review or edit existing discrepancies.
	Investigator Comment	Allows users to review or edit existing investigator comments and to initiate new investigator comments (subject to appropriate privilege).
	Audit Trail	Allows users to review the Audit Trail for response fields in the current CRF.
	Navigator	Allows users to view a list of Investigator Comments, open Discrepancies, and audit history. This tool also allows users to navigate to individual entries, and update entries (subject to appropriate privilege).
	CRF Activities	Allows users based on their privilege to access the Delete CRF, Verify CRF, and Approve CRF functions.
	Blank Flag Processing	Allows users to mark the entire CRF or one or more individual sections blank.
	RDC User Preferences	Preferences are preset for users based on roles/privileges.

**RIGHT-CLICK FUNCTIONALITY**

Right-click functionality is available when working in an eCRF. The popup menu that displays provides some of the same options as the OC RDC tools.

With the **Hand tool** selected, **right-click** on a data field in an eCRF and choose to address or view a discrepancy, view the audit history of the field, create, view or modify an investigator comment, view the entire text contained in a field through a popup box or delete all of the responses in the row of a question group. Some options may not be available depending upon the status of the field selected.

On an open eCRF, **right-click** on a data field to display the list. Select the desired option from the list and proceed with the action selected.

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## eCRF BUTTONS

The **eCRF Buttons** appear at the top of each eCRF page and allow users to take certain actions on and navigate through the current eCRF that is open. Some of the buttons are available in all situations, while the presence of others is dependant on context.

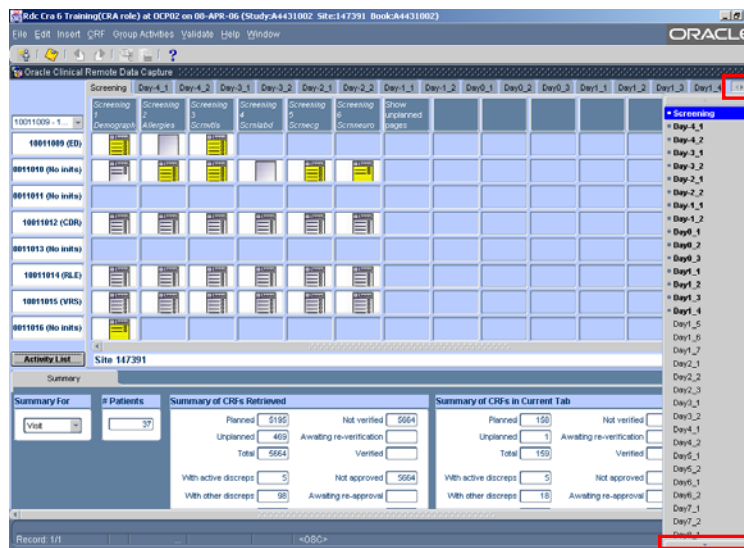
Button	Description
Save	Saves any new or modified data or responses to discrepancies in the eCRF. Users are given the option of saving the eCRF as <b>Complete</b> or <b>Incomplete</b> if the eCRF was never saved as Complete. It is only present on eCRFs that are open in active mode.
Close	Closes the PDF Data Entry window and indirectly saves any new or modified data and responses to discrepancies. Users must click the button a second time to close the eCRF if work has been indirectly saved. The <b>Close</b> button is present on eCRFs in both active and browse mode.
Make Browse	Changes the <a href="#">CRF mode</a> from active (data entry) to browse (read only). Multiple eCRFs may be open in browse mode at any one time. This button is only displayed for active CRFs that have been saved at least once.
Make Active	Changes the <a href="#">CRF mode</a> from browse (read only) to active (data entry). While in active mode, users are able to enter and update data or respond to discrepancies. Only one eCRF may be open in active mode at any one time. It is only present on eCRFs that are in browse mode.
Previous	Closes the current CRF and opens the previous CRF in sequence. This button also indirectly saves any new or modified data and responses to discrepancies. It is necessary to click the button a second time if work has been indirectly saved. The Previous button is only present on eCRFs that are open in active mode. This action is not available if users are on the first eCRF in the first visit in their study
Next	Closes the current CRF and opens the next CRF in sequence. This button also indirectly saves any new or modified data and responses to discrepancies. It is necessary to click the button a second time if work has been indirectly saved. The Next button is only present on eCRFs that are open in active mode. This action is not available if users are on the last eCRF in the last visit in their study.
Help	Opens the Oracle Clinical Response Field Help window and displays information about the data field that is selected.

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## SELECTING A VISIT

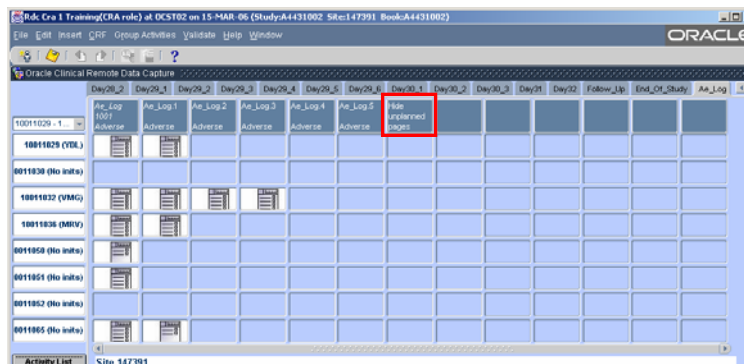
Because data for eCRFs do not need to be reviewed in the order in which the visits appear on the *OC RDC Main Spreadsheet*, users are able to select another visit at any time and begin the data review process. This provides a high degree of flexibility within the OC RDC PDF system.

- Click the **Maximize** button on the top right corner of the *OC RDC Main Spreadsheet* to obtain a full screen view
- Due to space limitations across the top of the *OC RDC Main Spreadsheet*, it may be necessary to click the **double arrows** on the top right side of the screen to display a list of all visits and logs
- Use the arrows at the top and bottom of the list to scroll through and display all of the visits
- Click the desired unplanned or log visit from the list - the selected visit or log page tab displays on the *OC RDC Main Spreadsheet*



## SHOW OR HIDE UNPLANNED PAGES

If users elect to view an Unplanned visit or log page and additional visits or pages have been manually added by the site, the option of hiding or showing the eCRF cells for the eCRFs is available by clicking the **Hide/Show unplanned pages** column header as shown on the screen shot below.



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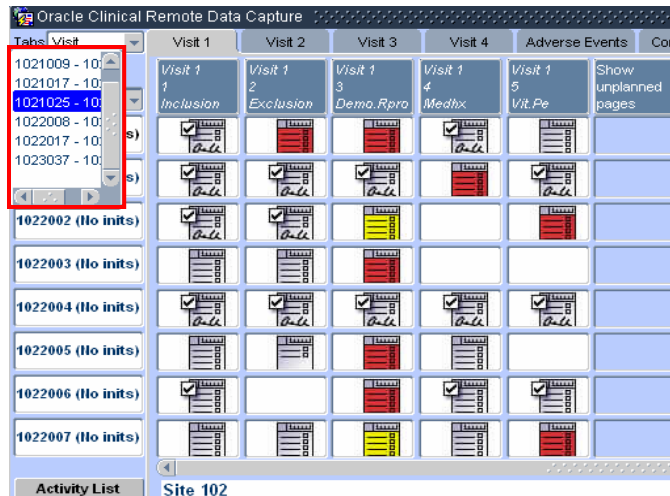


## SELECTING A NEW GROUP OF PATIENTS

Other groups of patients can be selected from the **Patient Selection List** on the *OC RDC Main Spreadsheet*. The selection list is not available until eight patient numbers are listed. Patient numbers are listed and displayed in groups of eight when the **Patient Selection List** is used.

### To display a different set of patient numbers:

- From the *OC RDC Main Spreadsheet*, click the drop-down arrow in the *Patient Selection List*
- Highlight the desired group of numbers
- The selected patient numbers display in the *Patient List* on the *OC RDC Main Spreadsheet*



**NOTE:** When entering eCRF data, select the patient number from the *Activity List* window and access the *OC RDC Main Spreadsheet* using the hyperlink.

By having only one patient on the *OC RDC Main Spreadsheet* at a given time, the user will be less likely to open an eCRF page and Source document verify data on the wrong patient record.

## DISCREPANCY MANAGEMENT

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”.

A discrepancy can be created automatically by the system or manually by a user with appropriate privileges. Also, discrepancies may be created on a single data field or on a section within an eCRF.

A **System Generated** discrepancy alerts the user that there may be a problem with data that has been captured or is missing from a data field. System generated discrepancies are created:

- 1) Automatically during data capture
- 2) Immediately after data is saved as complete
- 3) After a validation process which occurs nightly in the database
- 4) After a manual validation

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## DISCREPANCY MANAGEMENT *con't*

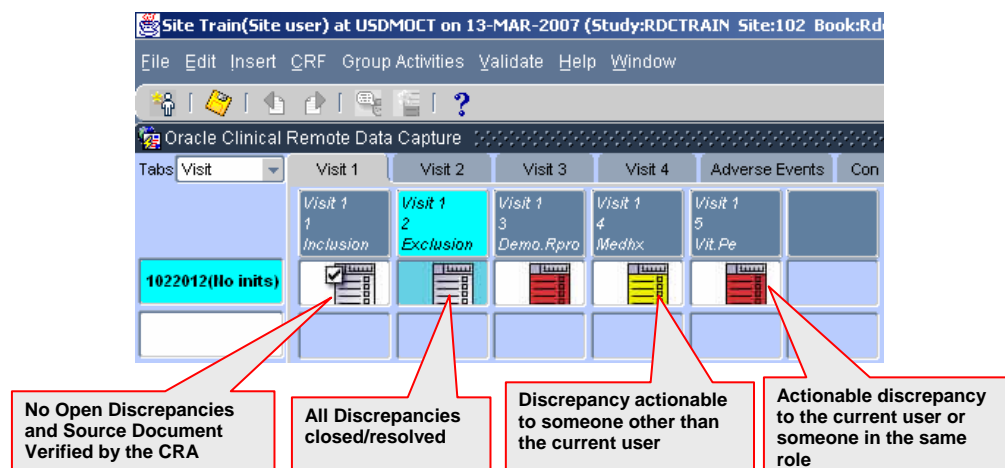
### System Generated Discrepancies may appear:

- If data captured in a data field is not in the correct format or is not part of the acceptable list of values (LOV) for that data field. Examples include incorrect date format, missing data, lab values out of range, etc. These discrepancies will appear as soon as the user tabs off of the field containing incorrect data.
- Where data comparisons are made against multiple data fields, such as selecting 'Other', but not providing a 'Specify'. Discrepancies will appear as soon as the page has been saved.
- If there is inconsistent or inaccurate data across multiple data pages, such as cross checking information on the adverse event page against the medication page. Discrepancies will not appear until after a validation process is run either during the nightly automatic validation or by a manual validation by the user.

A **Manual Discrepancy** is created by someone who has the appropriate privilege to do so. A **CRA** may create a manual discrepancy based on Source Document Verification (SDV) or remote review of the data. Data Management and PVG are also able to create and close manual discrepancies in the system. Site users have the ability to create manual discrepancies in the system; however, it is not recommended that they do so.

There is a color scheme associated with the eCRF icons on the *OC RDC Main Spreadsheet* and with the data fields on an eCRF when a discrepancy is present. The color scheme indicates the status of the discrepancy and who the discrepancy is actionable to.

The discrepancy color is automatically visible on the *OC RDC Main Spreadsheet* and on data fields when an eCRF is open. If a discrepancy has been created on a section within an eCRF, the discrepancy color displays as a colored bar to the left of the data fields associated with the discrepancy.

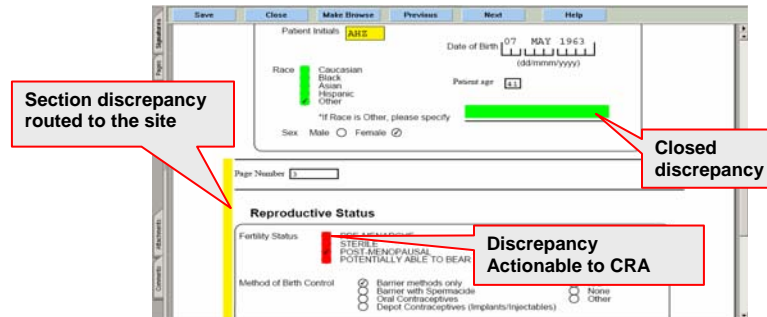


If you experience any problems with OC RDC, contact the EDC Support Center  
Toll free numbers and a Support Center email form can be found at <http://edc.ppd.com>

## DISCREPANCY MANAGEMENT con't

### Discrepancy Colors:

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



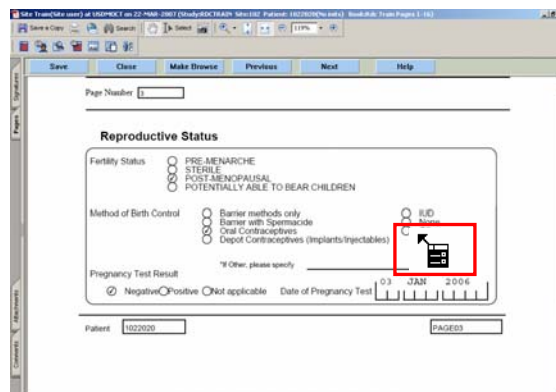
## CREATING A MANUAL DISCREPANCY

A manual discrepancy is a discrepancy that is created on a specific eCRF field or on an entire eCRF section. A manual discrepancy may be created to communicate information to other users about the data value or the condition of the source data.

More than one open **section discrepancy** can be associated with an eCRF section and a single data field can have **one manual** and **one system generated discrepancy** at any given time.

If an eCRF has been marked as Incomplete, the option to place a manual discrepancy on a single data field is not available.

- From an open eCRF, navigate to the field or a field within the eCRF section requiring a discrepancy
- Click the **Discrepancy Management** tool
- The cursor changes to an image of the tool
- Click on the data field



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## CREATING A MANUAL DISCREPANCY con't

- The *Discrepancy Management* window displays

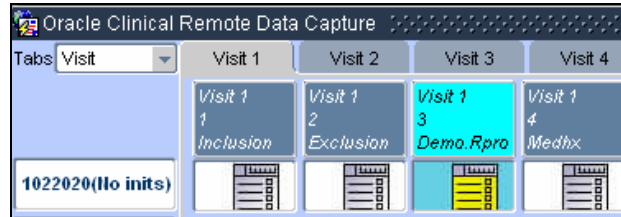
- Click either the **Add Discrepancy** or **Add Section Discrepancy** tab
- Click the drop down arrow and select an option from the Reason list
- Type in the reason for the discrepancy in the Error Message text area
- If desired, type instructions for the site in the Comment area
- Select **Send to Investigator** in the **Action** drop down list
- Click the **OK** button
- The eCRF displays with the discrepant field section displayed in yellow

- Click the **Hand** tool
- Click the **Save** button on the eCRF to save the created manual discrepancy

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## CREATING A MANUAL DISCREPANCY con't

- Upon closing the eCRF, the OC RDC Main Spreadsheet displays a yellow icon in the eCRF cell



**NOTE:** If a discrepancy was created in error, enter a comment stating that the discrepancy was created in error on the *Discrepancy Management* window and select the **Closed-Resolved** option from the *Action* field. The field will turn green and a white icon will display on the OC RDC Main Spreadsheet.

## ROUTING A DISCREPANCY BACK TO THE SITE

The site may occasionally assign or route a discrepancy to someone on the clinical study team at PPD for guidance or instructions on how to address a discrepancy. To route a discrepancy back to the site after review:

- From the OC RDC Main Spreadsheet, click the eCRF cell containing a red icon
- The eCRF displays and the field containing the discrepancy displays in red
- Click the **Discrepancy Management** tool and the *Discrepancy Management* window displays

The screenshot shows the 'Discrepancy Management' dialog box. It has a title bar with a close button. The main area is divided into several sections:
 

- Question Information:** Section: Demography, Question: Race.
- Add Discrepancy:** Includes a red 'Open Discrepancy' button and an 'Add Section Discrepancy' button.
- Discrepancy Error Details (422652):**
  - Reason:** Single Event and Single DCM
  - Error Message:** Patient's race is '99' - Other but details of Other race are not provided. Please clarify.
  - Comments (optional):** Please type 'Unknown' in the Specify field.
  - A '>> Show Discrepancy History...' button is located below the comments field.
- Discrepancy Action:**
  - Status:** INV Review
  - Action:** Send to Investigator
  - Resolution Comment:** (Empty text field)

 At the bottom, there are 'Help', 'OK', and 'Cancel' buttons.

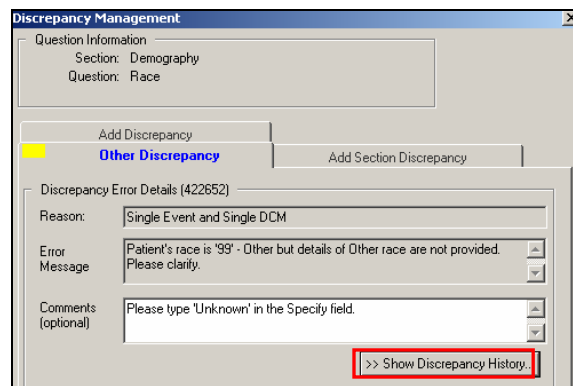
- If necessary, click the **Open Discrepancy** tab
- Review the discrepancy reason and any text in the Comments area
- Type instructions for the site in the Comments area
- Select **Send to Investigator** from the Action drop down list and click the **OK** button
- The eCRF displays with the discrepant field section displayed in yellow
- Click the **Save** button on the eCRF to save the routed discrepancy
- Upon closing the eCRF, the OC RDC Main Spreadsheet displays with a yellow icon in the eCRF cell

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## SHOW DISCREPANCY HISTORY

Once a discrepancy is saved to an eCRF, users are able to view the history of the discrepancy by clicking the **Show Discrepancy History** button on the *Discrepancy Management* window. The button is not available until the eCRF is saved. To view the discrepancy history:

- From the *OC RDC Main Spreadsheet*, click the eCRF cell for the eCRF containing a discrepancy of any status
- The eCRF displays
- Navigate to the colored field or to the vertical red bar to the left of the data fields
- Click the **Discrepancy Management** tool
- Click on the field or colored bar to the left of the data fields
- The *Discrepancy Management* window displays



- Click the **Open Discrepancy** tab, if necessary
- Click the **Show Discrepancy History** button
- The *Change History* window displays
- To review the discrepancy changes, it may be necessary to resize the columns and/or use the horizontal scroll bar to view an entire list item in the *Change History* window
- When finished viewing the history, click the **Close** button
- The *Discrepancy Management* window displays
- If you do not wish to update the discrepancy: Click the **Cancel** button
- The eCRF displays
- Click the **Hand** tool

## VERIFYING AN INDIVIDUAL eCRF

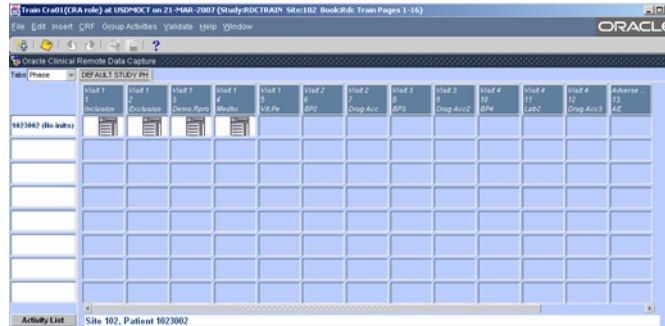
Once the site has finished data capture, saved the eCRFs as completed and resolved any system generated discrepancies, the eCRFs can be reviewed and source document verified according to the monitoring plan. OC RDC PDF does not allow eCRFs saved as **Incomplete** to be marked as verified.

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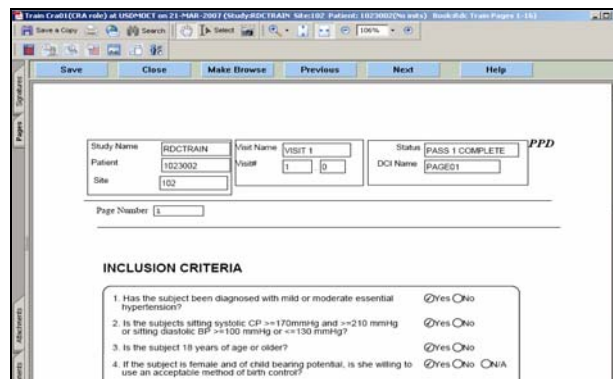
### VERIFYING AN INDIVIDUAL eCRF con't

- From the OC RDC Main Spreadsheet, click the eCRF cell for the visit, page and patient to verify.

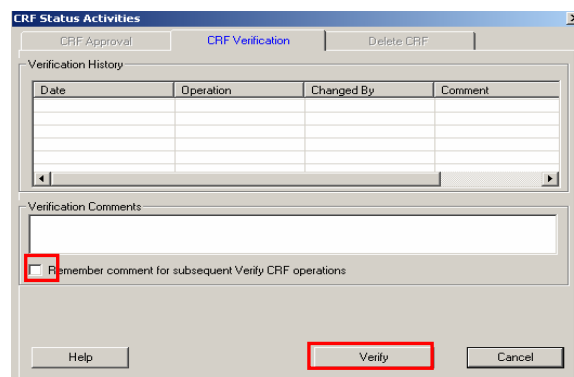


**NOTE:** If CRAs are performing “side-by-side” verification at the site and the same eCRF is being accessed by both parties, the first user to display the eCRF will be in **Active** mode. The other user will be in Browse mode. The eCRF will remain in Browse mode upon closing the eCRF until a refresh of the *OC RDC Main Spreadsheet* is performed by selecting the **File>Refresh** menu command. The eCRF can then be accessed in Active mode.

- The eCRF displays



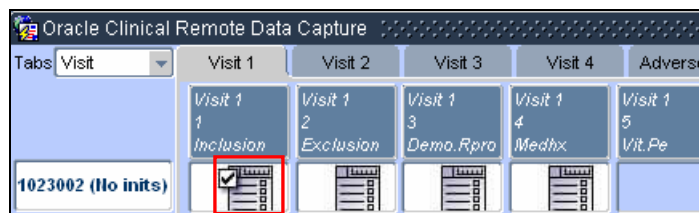
- Verify the responses entered in the data fields – use the scroll bar on the right side of the screen to view all fields
- Click the **CRF Status Activities** tool
- The *CRF Status Activities* window displays



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## VERIFYING AN INDIVIDUAL eCRF con't

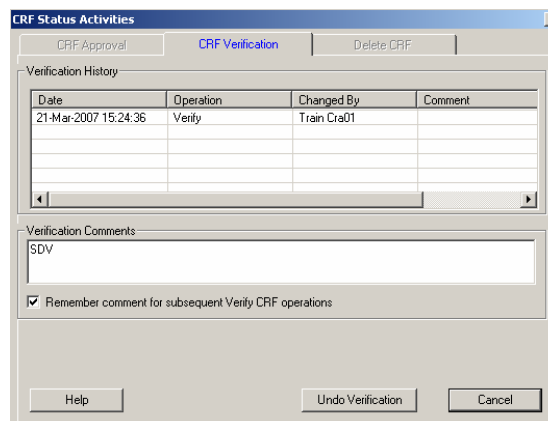
- In the Verification Comments text field, enter a comment, e.g., SDV to indicate the eCRF has been source verified
- If desired, place a checkmark in the **Remember comment for subsequent Verify CRF operations** checkbox to allow the verification comment to be included with all other eCRFs verified during the current session – if a checkmark is placed in the box, the comment will be attached to any eCRFs that have been individually or grouped verified
- Click the **Verify** button
- The eCRF displays and the verification is saved
- Click the **Close**, **Previous** or **Next** button on the eCRF. After closing the eCRF, the OC RDC Main Spreadsheet display with a verified icon in the eCRF cell indicating the eCRF has been verified



## UN-VERIFYING AN INDIVIDUAL eCRF

If an eCRF was verified in error, users have the ability to un-verify an eCRF.

- From the *OC RDC Main Spreadsheet*, click the applicable eCRF
- The eCRF displays
- Click the **CRF Status Activities** tool
- The *CRF Status Activities* window displays



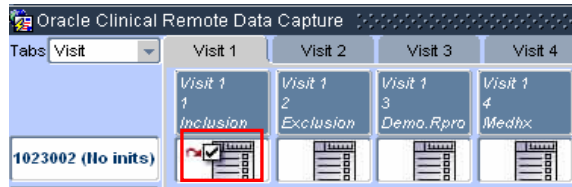
- If necessary, click the **CRF Verification** tab
- If desired, enter a comment in the text area
- Click the **Undo Verification** button
- The eCRF displays
- Click the **Close** button
- The *OC RDC Main Spreadsheet* displays with the eCRF cell no longer containing a verified icon

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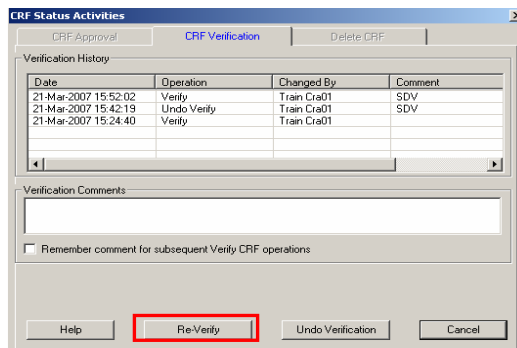
## RE-VERIFYING AN INDIVIDUAL eCRF

If data, investigator comments or discrepancies are modified (changed, added, deleted) after an eCRF has been verified, then a re-verification icon displays in the applicable eCRF cell. The eCRF may require re-verification.

- From the *OC RDC Main Spreadsheet*, click the applicable eCRF cell



- The eCRF displays
- Click the **CRF Status Activities** tool and the *CRF Status Activities* window displays
- If desired, place a checkmark in the **Remember comment for subsequent Verify CRF operations** checkbox to allow the verification comment to be included with all other eCRFs verified during the current session – if a checkmark is placed in the box, the comment will be attached to any eCRFs that have been individually or grouped verified
- If desired, type a comment in the text area



- Click the **Re-Verify** button
- Click the **Close** button on the eCRF
- The *OC RDC Main Spreadsheet* displays with the eCRF cell containing a verified icon

**NOTE:** Users can select the **Audit History** tool to view the history of a data field that was modified. Changes to investigator comments or discrepancies without data changes **will not** display in the **Audit History** tool. To view the history of changes to investigator comments or discrepancies, click the **History** button on the either the comment or discrepancy window

## GROUP VERIFYING eCRFs

OC RDC PDF allows users to group verify those eCRFs that have been “monitored” as part of the overall site visit and not individually source verified.

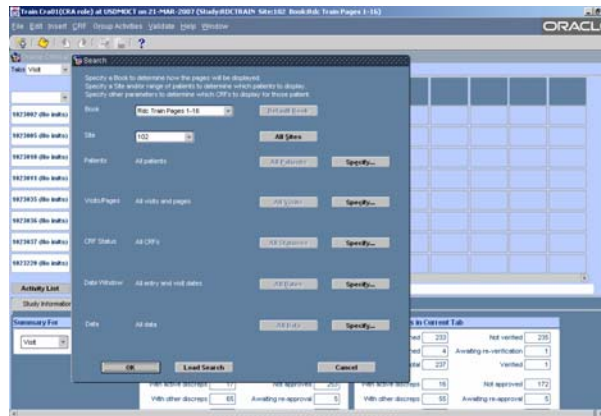
Since the monitoring plan specifies which data needs to be source document verified, it is useful to have a “verified” status which represents the amount of patient information that was processed or group verified at a particular monitoring visit, rather than represent only the individual eCRFs that were verified against the source.

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://edc.ppd.com>

## GROUP VERIFYING eCRFs

Group verifying eCRFs per monitoring visit allows CRAs to track the work that they did at a particular site visit. In order to group verify, use the Search window to filter the data that displays on the *OC RDC Main Spreadsheet*. OC RDC PDF will not mark eCRFs saved as Incomplete verified.

- From the *OC RDC Main Spreadsheet*., select the **File>New Search** menu command
- The Search window displays



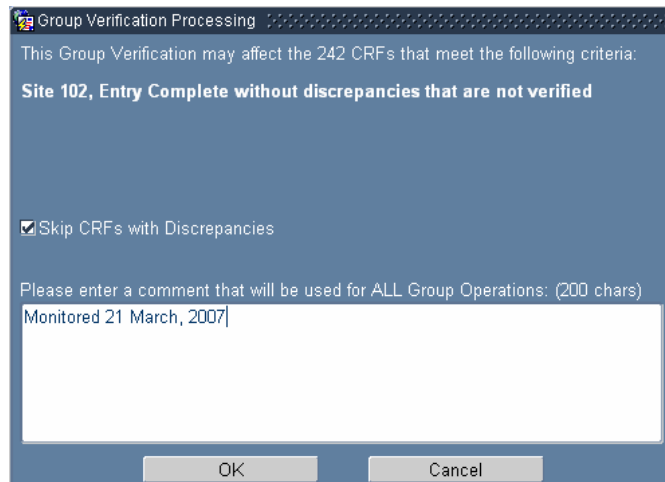
The Group Verify functionality does not work unless a specific site number is selected. If **ALL** is chosen for the **Site** option in the *Search* window, the **Group Verify** menu command is grayed out. Users must choose a specific site either in the *Activity List* or as part of their *Search* window criteria in order for the group verify functionality to be available. To specify parameters in the Search window:

- Click the drop down arrow for the **Site** option and select a specific site number
- Click the **Specify....** button to the right of the Patients option
- The *Patient Subsearch* window displays
- Click the drop down arrows for the **Patient** option to select a range of patient numbers
- Click the **OK** button
- The Search window displays
- Click the **Specify....** button to the right of the Visit/Page option
- The *Visit/Page Subsearch* window displays
- Click the drop down arrows for the appropriate option to select one phase or visit or a range of phases or visits
- Click the **OK** button
- The Search window displays
- Click the **Specify....** button to the right of the **CRF Status** option
- The *CRF Status Subsearch* window displays
- Click the drop down arrows for the appropriate options to select the eCRF status
- Click the **OK** button
- The Search window displays
- Click the **OK** button to close the Search window

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### GROUP VERIFYING eCRFs con't

- The *OC RDC Main Spreadsheet* displays with the selected dataset
- If desired, add a comment for all eCRFs group verified during the current session - include the date group verification was performed
- Select the **Group Activities>Verify CRFs** menu command
- The *Group Verification Processing* window displays



- The **Skip CRFs with Discrepancies** checkbox is automatically checked
- In the text area, enter a comment such as *Monitored 21 March, 2007*, to attach to any eCRFs group verified
- Click the **OK** button
- The *Group VERIFY Update Completed* window displays indicating how many eCRFs were marked as group verified



- Click the **OK** button
- The *OC RDC Main Spreadsheet* displays with the applicable eCRF cells containing a verified icon

**NOTE:** When group verifying eCRFs, it is recommended that users select the **Entry Complete** option from the *CRF Status* field, **Without discrepancies** from the *Discrepancy status* field and **Not verified or Awaiting re-verification** from the *Verification status* field.


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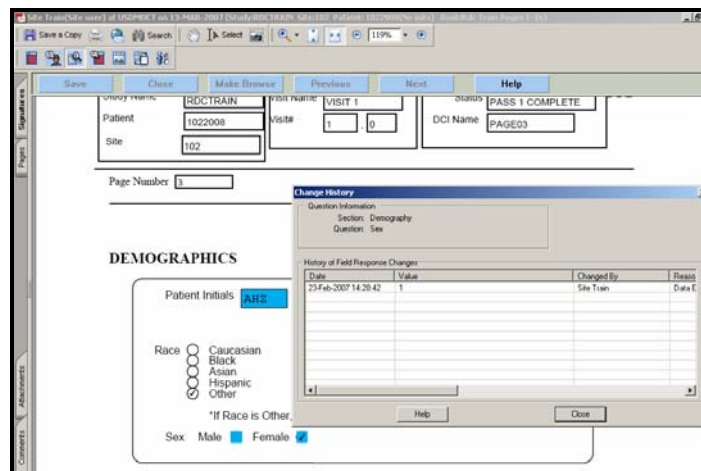
## AUDIT HISTORY TOOL

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 regardless of the save status (Complete or Incomplete).

The system prompts users to supply a change reason when data is modified on an eCRF that has been saved as **Complete**. 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** tool is selected.

### To view the history of a data field:

- On an open eCRF, click the **Audit History** tool 
- The cursor changes to an image of the tool and any field containing a history displays in **blue**
- Click on the blue field
- The *Change History* window displays



- To review the audit history, it may be necessary to resize the columns and/or use the horizontal scroll bar to view an entire list item in the *Change History* window. Also note that only the current value of the data field displays on the eCRF and only previous values display in the *Change History* window.
- When finished reviewing the history, click the **Close** button
- The eCRF displays
- Click the **Hand** tool
- The data field turns white


## THE CRF NAVIGATOR TOOL

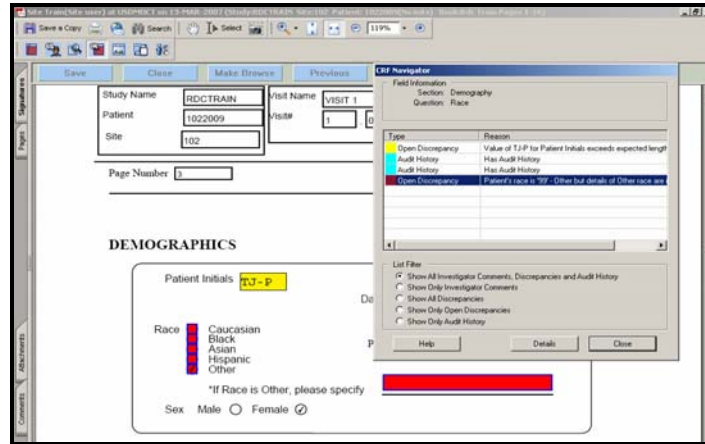
The **CRF Navigator** tool allows users to view, in a list format, any fields containing discrepancies, investigator comments or audit histories within an eCRF. By selecting an item in the list, the corresponding data fields will be outlined in blue for easy reference.

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## THE CRF NAVIGATOR TOOL *con't*

- On an open eCRF, click the **CRF Navigator** tool 
- The *CRF Navigator* window displays



- If desired, use the **Filter** radio buttons to further define and filter the displayed items in the list
- Highlight an item in the list
- The field containing the selected item is outlined in blue— it may be necessary to click and drag the *CRF Navigator* window to view the field
- Click the **Details** button

If a field containing a **discrepancy** was selected, the *Discrepancy Management* window displays. Users are able to view, route or resolve the discrepancy once the *Discrepancy Management* window has been opened.


If a field containing an **investigator comment** was selected, the *Investigator Comment* window displays. Users are able to view a comment.

If a field containing an **audit history** was selected, the *Change History* window displays. Users are able to view the history.

- When finished, close the displayed window
- The eCRF displays and the **Hand** tool is automatically selected

## VIEWING AN INVESTIGATOR COMMENT

**NOTE:** It is recommended that sites **DO NOT USE** Investigator Comments. Most protocols will have a comments log page where that information should be captured.

When the **Investigator Comment** tool  is active, all data fields for which a comment exists, appear in magenta. Use the scroll bar to navigate through the eCRF and to view all relevant fields. To view a comment:

- On an open eCRF, click the **Investigator Comment** tool
- Any field containing a comment appears in **magenta** (pink)
- Click on the data field - the *Investigator Comment* Window displays
- Review the comment in the text area

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## VIEWING AN INVESTIGATOR COMMENT *con't*

- If desired, click the **History** button on the *Investigator Comment* or the *Investigator Comment Change Reason* window to view the comment history. A history exists only if a comment was added or modified to a previously saved eCRF, regardless of the save status (**Complete** or **Incomplete**). If a comment was added during a data entry session, no history is available. The *Investigator Comment* or the *Investigator Comment Change Reason* Window will not display if an existing comment is deleted.
- When finished, click the **Cancel** button
- Select the **Hand** tool

## THE SEARCH WINDOW

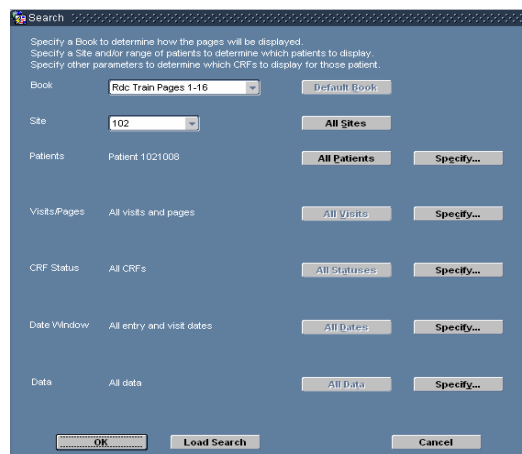
Once data capture has begun for the study, users are able to use the *Search* window to sub-set or filter data for display. The *Search* window is a useful tool that allows users to specify the data display in greater detail.

The *Search* window consists of a series of criteria that transition from general to more specific as users move down in the window. The first two options, **Book** and **Site**, establish the protocol to work with. The remaining five options, **Patients**, **Visit/Pages**, **CRF Status**, **Date Window** and **Data**, allow users to “drill-down” to display more specific data within the specified protocol.

It is recommended that the *Search* window be used to search for any eCRFs that may have inadvertently been left marked as **Incomplete** or for any eCRFs that contains active discrepancies. This ensures that all eCRFs are in a **Complete** status with closed discrepancies when it comes time to lock the database.

### To display the *Search* window:

- From the *OC RDC Main Spreadsheet*, click the **Activity List** button and then click the **Search** button -or-
- From the *OC RDC Main Spreadsheet* select the **File>New Search** menu command
- The *Search* window displays



Search

Specify a Book to determine how the pages will be displayed.  
Specify a Site and/or range of patients to determine which patients to display.  
Specify other parameters to determine which CRFs to display for those patient.

Book: Rdc Train Pages 1-16 (Default Book)

Site: 102 (All Sites)

Patients: Patient 1021008 (All Patients) (Specify...)

Visits/Pages: All visits and pages (All Visits) (Specify...)

CRF Status: All CRFs (All Statuses) (Specify...)

Date Window: All entry and visit dates (All Dates) (Specify...)

Data: All data (All Data) (Specify...)

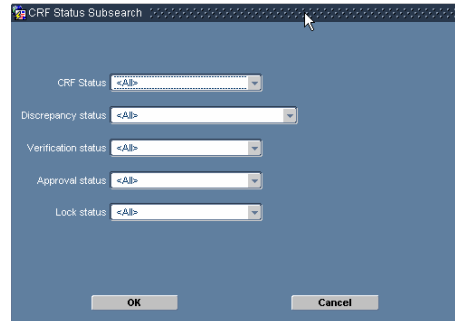
OK Load Search Cancel

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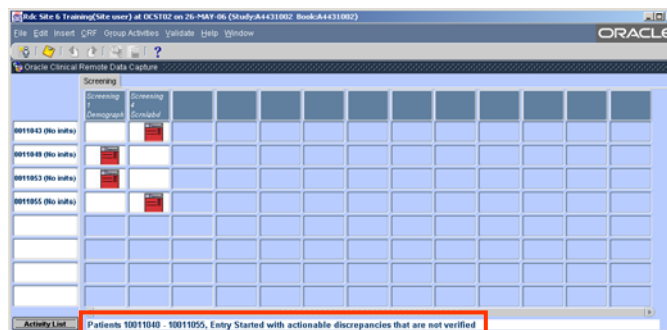
## THE SEARCH WINDOW con't

There is a default button adjacent to each option, noted by <All>. It remains inactive or grayed out until you make a selection that is something other than the default value for the option.

The **Specify...** button is adjacent to the default buttons, except for Book and Site. It gives users access to the *Subsearch* window associated with the current option, which allows them to select the subset of data to display. After clicking a **Specify...** button, the applicable *Subsearch* window allows users to select the data to display for each option selected.



- Click the **OK** button to close the *Subsearch* window
- The *Search* window displays
- Click the **OK** button to close the *Search* window
- The *OC RDC Main Spreadsheet* displays and any search criteria selected is noted on the **Status Line** on the *OC RDC Main Spreadsheet*



### To modify existing search criteria:

- From the *OC RDC Main Spreadsheet*, select the **File>Modify Search** menu command
- The *Search* window displays with the existing search criteria listed
- Modify the criteria on the desired options

### To default search criteria back to <All>:

- From the *OC RDC Main Spreadsheet*, select the **File=>New Search** menu command
- The *Search* window displays with the options defaulted to <All>

If you experience any problems with OC RDC, contact the EDC Support Center  
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## SYSTEM FUNCTIONS PERFORMED BY SITE USERS

### MARKING AN eCRF AS BLANK

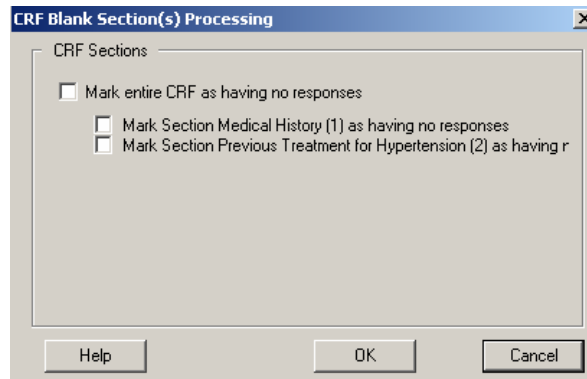
If an entire eCRF or section within the eCRF will not be completed for a particular patient, or if a patient misses a protocol defined visit, the eCRF or section should be marked as blank by the site users only.

Marking an eCRF as blank alerts the study team that the eCRF (or section) has not been inadvertently left blank. If an entire eCRF or section is marked as blank, users are not able to **Tab** to or use the mouse cursor to click in any data entry fields, as they will be grayed out.

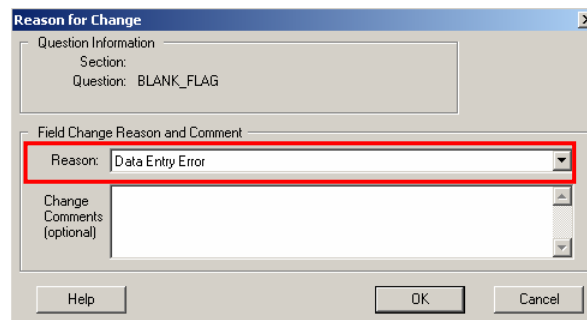
Refer to the **Study Specific eCRF Completion Guidelines** for instructions on when it may be appropriate to mark an entire eCRF or section as blank.

Users are also able to mark an eCRF that contains data as blank. All previously entered data on that eCRF page will be deleted.

- From the *OC RDC Main Spreadsheet*, open the eCRF which will be marked as blank; the eCRF displays
- Click the **Blank Flag Processing** tool
- The *CRF Blank Section(s) Processing* Window displays



- Click the applicable check boxes to mark an entire eCRF or an eCRF section as blank
- Click the **OK** button - the **Reason for Change** Window displays if a Complete eCRF is being marked as blank



- Click the drop down arrow and select a *Reason for Change*
- Click the **OK** button to close the *Reason for Change* Window
- Click the **Save** button, then click the **Close** button on the eCRF

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Toll free numbers and a Support Center email form can be found at <http://edc.ppd.com>

## UNMARKING AN eCRF AS BLANK

The eCRF or sections marked as blank can be unmarked as blank by the site users. This is helpful if an eCRF or an eCRF section was marked blank in error, or if a patient did show up for the scheduled visit.

### To unmark an eCRF as blank:

- From the *OC RDC Main Spreadsheet*, click the eCRF cell for the eCRF that has been marked as blank
- The eCRF displays
- Click the **Blank Flag Processing** tool
- The *CRF Blank Section(s) Processing Window* displays
- Remove the checkmarks from the necessary checkboxes
- Click the **OK** button
- The *Reason for Change Window* displays

The image shows a 'Reason for Change' dialog box. It has a title bar with a close button. The dialog is divided into three main sections: 'Question Information' at the top, 'Field Change Reason and Comment' in the middle, and 'Change Comments (optional)' at the bottom. The 'Question Information' section shows 'Section:' and 'Question: BLANK\_FLAG'. The 'Field Change Reason and Comment' section contains a 'Reason:' dropdown menu with 'Data Entry Error' selected. The 'Change Comments (optional)' section is a text area. At the bottom of the dialog are three buttons: 'Help', 'OK', and 'Cancel'.

- Click the drop down arrow in the **Reason** field and select a reason for change from the list
- Add a comment if desired
- Click the **OK** button
- When finished, click the **Save** button on the eCRF
- Click the **Close** button on the eCRF

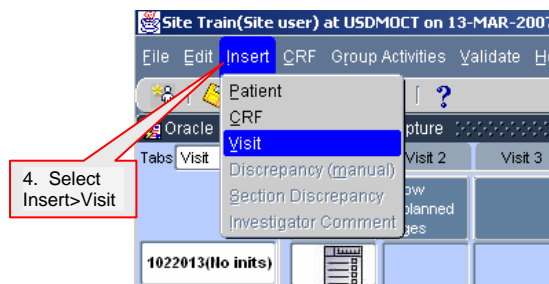
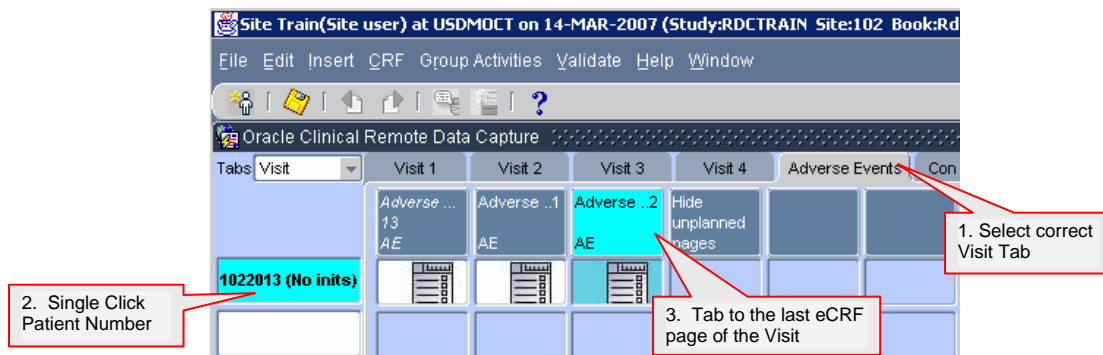
If you experience any problems with OC RDC, contact the EDC Support Center  
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## INSERTING ADDITIONAL VISITS

The site user(s) may need to insert an unplanned visit (eCRF pages) if they have completed data entry on all of the data fields on an eCRF page, but still have additional data to enter. (i.e. Adverse Events, Medical History, ConMeds, etc.) The Study Team should advise when to insert additional unplanned visits based on the protocol for the study.

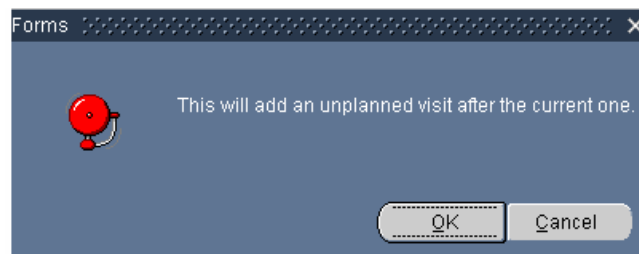
In this example, an Adverse Event visit will be added.

1. From the *OC RDC Main Spreadsheet*, Select the correct visit tab
2. Click the patient number which will highlight the field
3. Use the tab key to navigate to the last eCRF page of the visit. The aqua highlight is a visual for which page is selected.
4. Select **Insert >Visit** from the Menu Bar



**NOTE: ONLY choose INSERT >VISIT. Do not choose Insert>Patient or Insert >CRF from this menu.**

5. The following message will appear; select **OK**



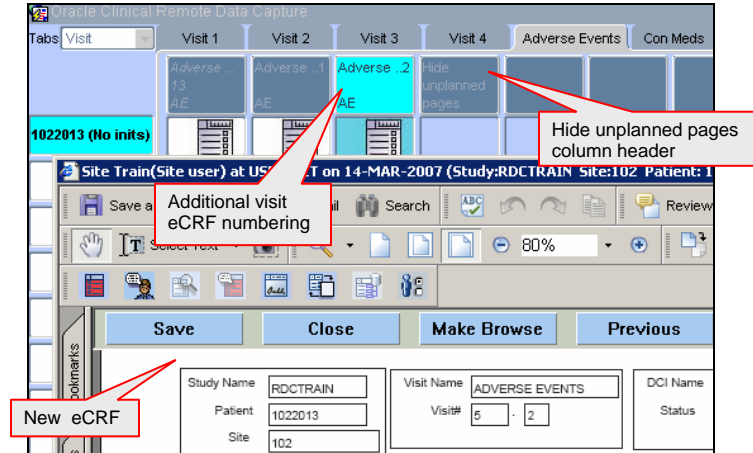
The inserted eCRF will open. If multiple eCRFs appear within the visit, the first eCRF will open while all others can be created by single clicking in the empty cell.

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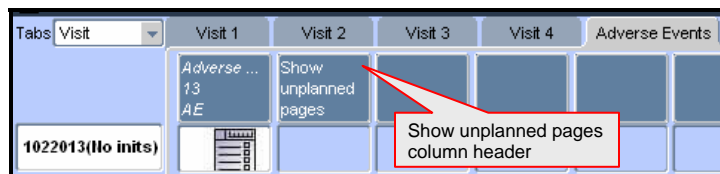


### INSERTING ADDITIONAL VISITS *con't*

The example below notes unplanned visits that have been added and how they are numbered. Also note the “**Hide unplanned pages**” column header indicating additional visits have been added.

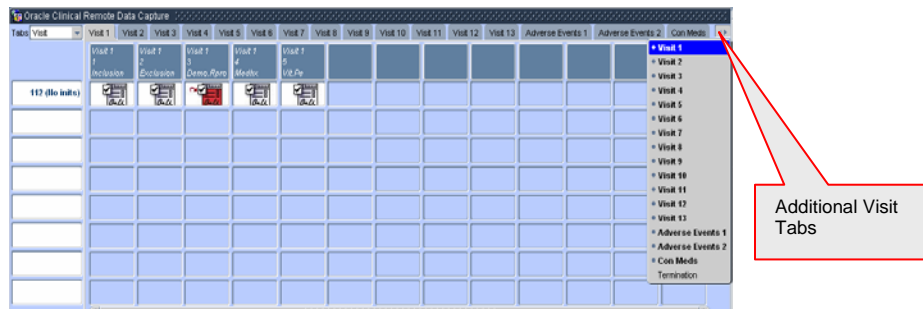


Upon subsequent log-ins, users will need to click on the “**Show unplanned pages**” column header to access the added visits.



### TIPS FOR INSERTING ADDITIONAL VISITS

- Do not create eCRF pages in visits that you have added if you do not need them
- Do not insert visits until you need them
- Due to space limitations across the top of the *OC RDC Main Spreadsheet*, it may be necessary to click the **double arrows** on the top right side of the screen to display a list of all visits (as shown on next page)
- Use the arrows at the top and bottom of the list to scroll through and display all of the visits
- ALWAYS select the **Insert >Visit** menu command



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## VALIDATING A SITE OR A PATIENT LEVEL

Each database has an automatic validation process to run edit checks on a nightly basis. These edit checks are part of the protocol specific database design and ensure that fields within an eCRF and across multiple eCRFs contain data that corresponds appropriately. If data fields contain data outside of the edit check parameters, a discrepancy will be generated by the system.

While these nightly edit checks are helpful, there may be instances when a site user would like to confirm that all data fields are correct as entered without waiting for the nightly validation.

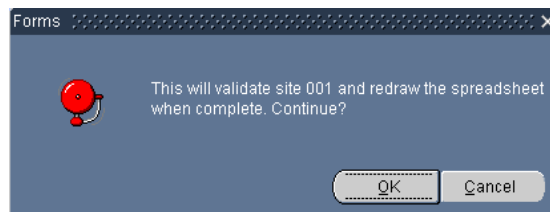
The site user is capable of running a validation at both the site level and an individual patient level.

### Site Validation

The site validation menu command runs validation on all eCRFs in a site that are saved as complete. This may include eCRFs that are not part of the current workset. Validating a site allows you to view and manage your discrepancies in real time.

#### To validate eCRFs associated with a site:

- 1) Select the appropriate site from the *Activity List* window or the *Search* window.
- 2) Select the **Validate > Site** menu command. A confirmation window displays a message that identifies the site that will be validated.



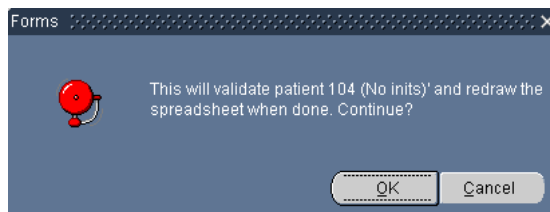
- 3) In the *Forms* window:
  - a. Click the **OK** button to proceed with the validation
  - b. Click the **Cancel** button to discontinue the validation

### Patient Validation

The Patient validation menu command runs validation procedures on all saved as complete eCRFs associated with the selected patient. Validating a patient allows you to view and manage your discrepancies in real time.

#### To validate eCRFs associated with a patient:

- 1) On the *OC RDC Main Spreadsheet*, highlight the patient number you wish to validate.
- 2) Select the **Validate > Patient** menu command.



- 3) In the *Forms* window:
  - a. Click the **OK** button to proceed with the validation
  - b. Click the **Cancel** button to discontinue the validation

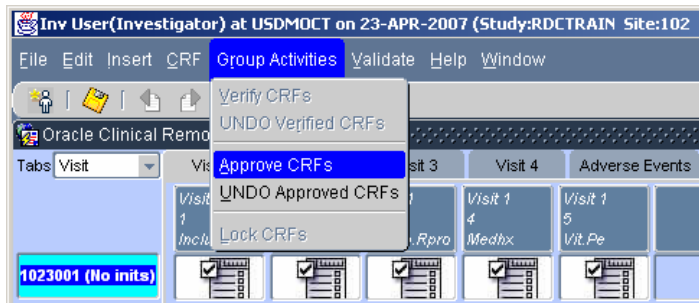
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## PRINCIPAL INVESTIGATOR APPROVAL PROCESS

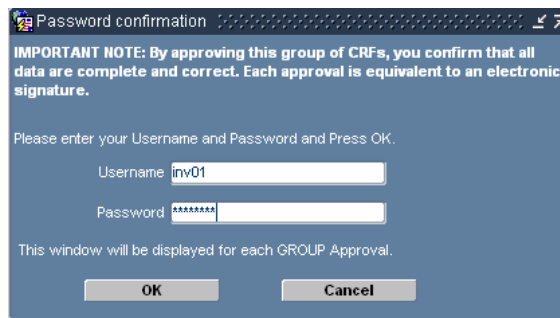
After eCRFs have been verified by the CRA and have no outstanding discrepancies, they are ready for approval by the Principle Investigator and/or their designee.

The following steps outline the process for approving eCRFs.

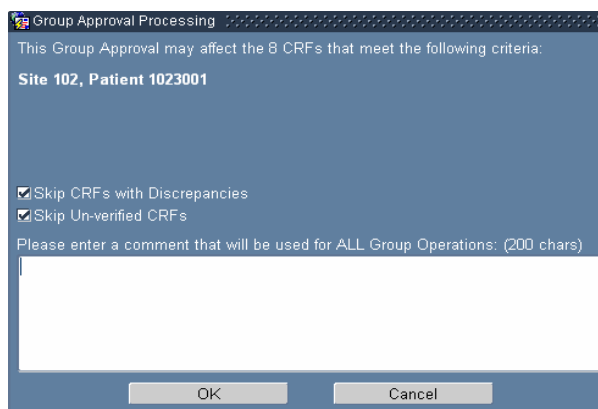
- 1) Log into OC RDC PDF using credentials emailed from PPD.
- 2) The Activity List window displays. Select a patient number on the left navigation pane.
- 3) Click the **Show All Data for Patient...** hyperlink
- 4) The *OC RDC Main Spreadsheet* displays
- 5) Click **Group Activities>Approve CRFs**



- 6) Enter Username and Password again.
- 7) Click **OK**.



- 8) The **Group Approval Processing** window displays. Leave default settings checked to Skip CRFs with Discrepancies and Skip Un-verified CRFs.
- 9) Click **OK**.



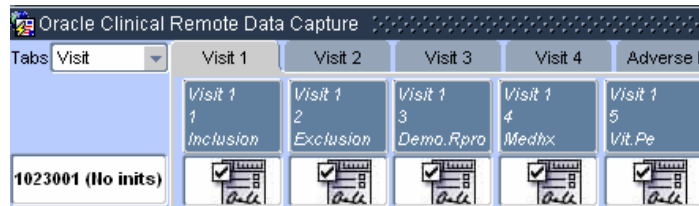
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### PRINCIPAL INVESTIGATOR APPROVAL PROCESS con't

- 10) The Group APPROVAL Update Completed window displays advising number of CRFs approved. Click **OK**.



- 11) The OC RDC Main Spreadsheet displays with approved eCRF icons in view.




**NOTE:** If a data change occurs on a page after Investigator Approval the re-approval icon will appear.



### Approve, Re-Approve or Undo Approval at the eCRF Page Level

The Investigator would conduct the following steps to approve, re-approve or undo approval of a single eCRF.

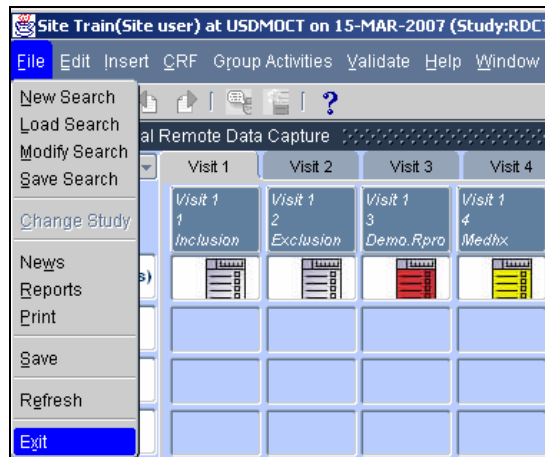
- 1) Click the eCRF cell that needs approval, re-approval or undo approval.
- 2) Click the **CRF Status Activities** icon. 
- 3) Select the **CRF Approval** tab.
- 4) The Investigator can Approve, Re-Approve or Undo Approval depending on the initial status of the eCRF.
- 5) Enter Username and Password in the *Password Confirmation* window.
- 6) Click **OK**.

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## LOGGING OUT OF OC RDC PDF

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. To Log out:

- Save any work completed
- The *OC RDC Main Spreadsheet* displays
- From the *OC RDC Main Spreadsheet*, select the **File =>Exit** menu command



- The *edc.ppd.com* website window displays
- Close the *edc.ppd.com* window by clicking the X in the upper-right corner of the window

## OC RDC TRAINING SUPPORT

### Training Options & Access Requests

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

- OC RDC PDF 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 PDF or other PPD approved applications.
- The PPD EDC Support Center is available 24 hours a day, 7 days a week, 365 days a year. Multilingual translators are available.
- The PPD EDC Support Center is for technical questions only. Site users will contact their CRA for study protocol or eCRF related questions.
- At the end of the study, a CD of all subject data per individual site will be provided to the sites. Until the CD is received, sites must continue to have access to PPD and OC RDC data.
- Training can be requested through the Study Team. All training sessions must be documented before access to a study protocol in the OC RDC PDF application is granted.
- **CRA Contextual Training** is currently available through LMS. CRAs should attend this class after they have completed a site visit. The Contextual training will provide instruction on how to utilize OC RDC to effectively track site progress in data entry/discrepancy management and to perform specific tasks for on-site and remote monitoring.

If you experience any problems with OC RDC, contact the EDC Support Center  
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## **TRAINING MATERIALS**

The following OC RDC PDF training materials are available for all users and can be found on the EDC internal web page:

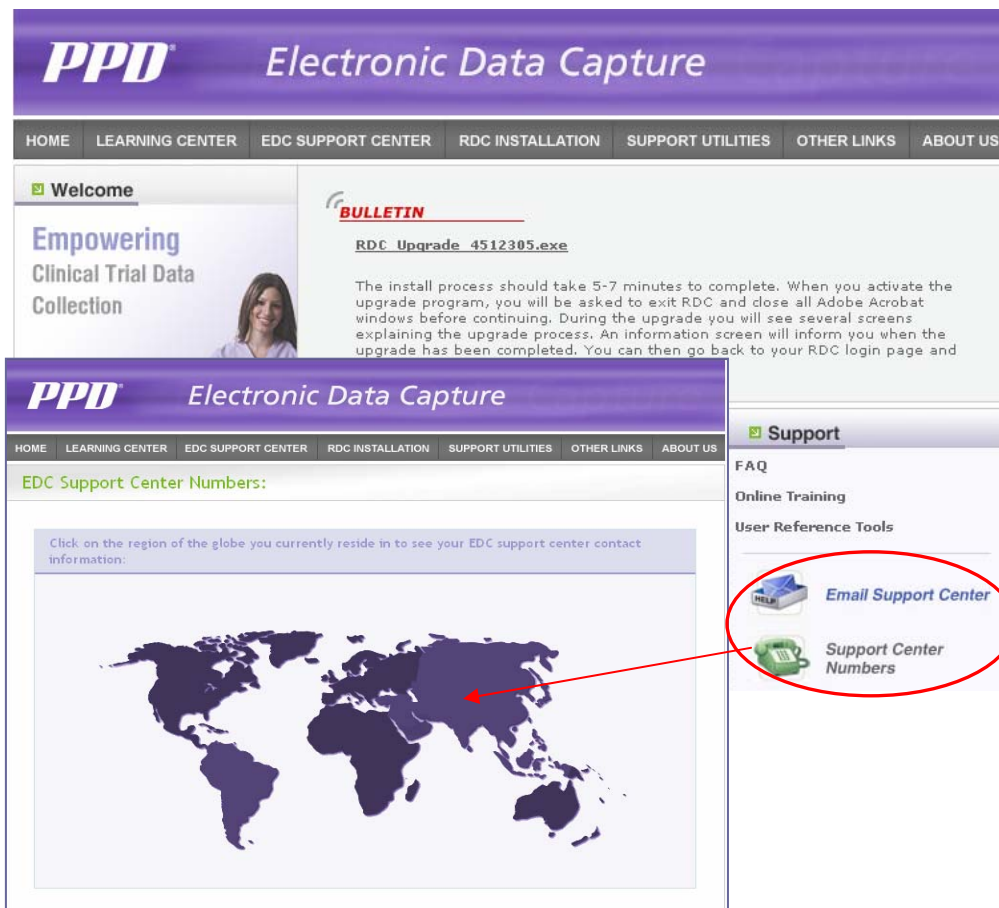
- On-line training
- Quick Reference Guide
- CRA User Guide
- Visit Reference Guides
- Functionality Guides for step-by-step instructions
- Investigator Site User Guide
- Investigator Site Training CD-ROM, if necessary

**If you experience any problems with OC RDC, contact the EDC Support Center  
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# 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://edc.ppd.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://edc.ppd.com>