CRA
OC RDC Classic
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.ppdi.com

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TABLE OF CONTENTS

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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 - **CLN3-01816** (OC RDC 4.5.1 Classic 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 Classic Account Users:

If you get assigned to another Classic 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.ppdi.com/3/IT1/3_IT1_1_6_1_OPA_SCROLL.htm
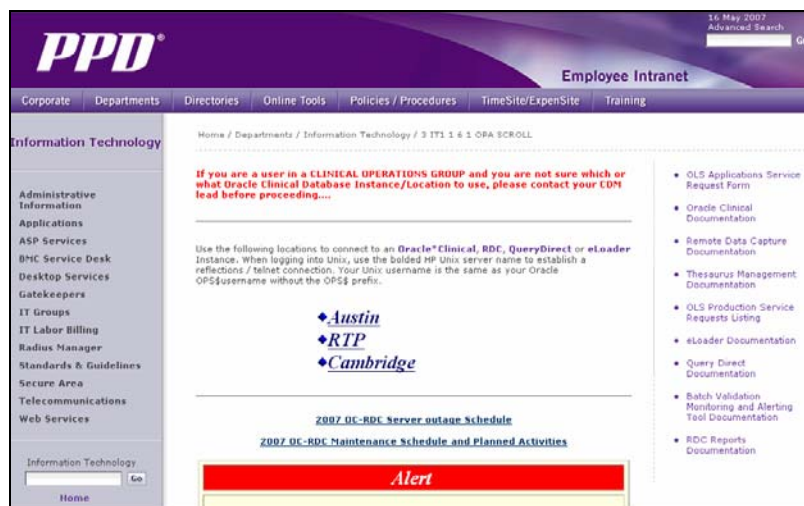
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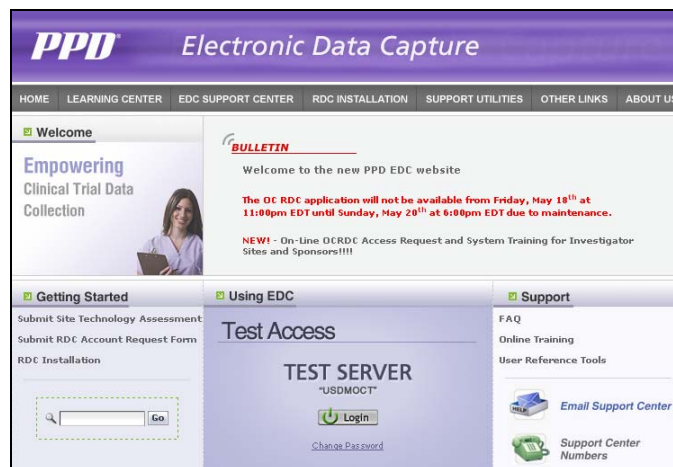
LOGGING ON TO OC RDC con't

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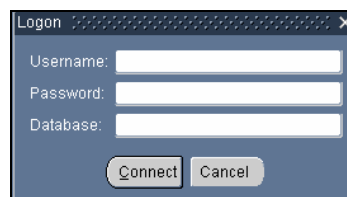
NOTE: Upon successful log in, the following window will appear. **DO NOT CLOSE** this window. It will automatically minimize to the Task Bar at the bottom of the screen. Leave this window open during your entire session of OC RDC to avoid errors.
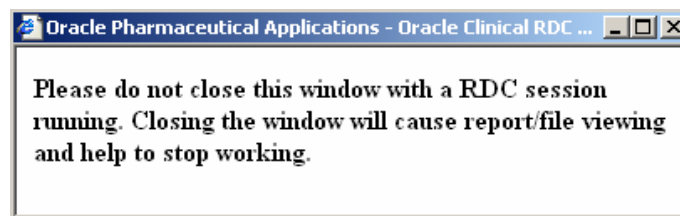

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CHANGE PASSWORD

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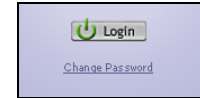
1) From the *EDC Website*, click the **Change Password** link
2) On the Logon window, enter the OC RDC **Username**, **Password** and assigned **Database**
3) Click the **Connect** button
4) On the **Change Password** screen, enter the existing password and the new password twice for confirmation
5)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

## *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 Classic **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 Classic 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
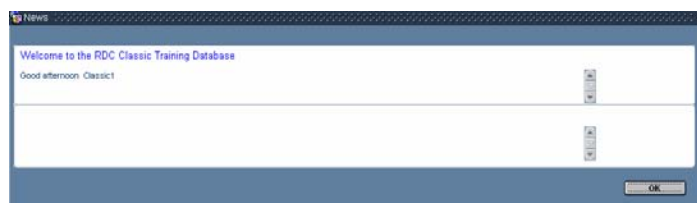
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Toll free numbers and a Support Center email form can be found at http://edc.ppdi.com

Version 1.0
May 16, 2007

Page 5 of 37

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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 Classic system. Users should log off of OC RDC if they need to step away from the laptop. Do not share usernames and passwords with other users.

THE SEARCH WINDOW

Upon logging into OC RDC Classic as a CRA, the *Search* window will display if the study is only in the Classic mode.

In the instance where a study is in both PDF and Classic and the user has access to both PDF and Classic modes for the same study, the CRA will log into PDF by default and have access to the *Activity List* window. To change to the Classic mode, the user will need to go to the **Edit> Preferences** menu command and select the Classic mode. At this point, the user will see the *Search* window.

Users are able to use the *Search* window to:
- sub-set or filter data for display
- specify data display in greater detail
- assist with work flow for data capture and discrepancy management

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.

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.

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Version 1.0
May 16, 2007
Page 6 of 37

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THE SEARCH WINDOW con't

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.

Steps to Perform a Search
1) Click a **Specify...** button and the applicable *Subsearch* window allows users to select the data to display for each option selected.
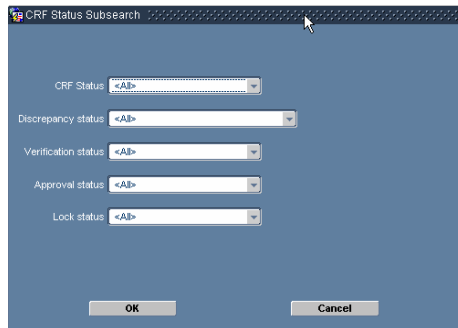
2) Click the **OK** button to close the *Subsearch* window
3) The *Search* window displays
4) Click the **OK** button to close the *Search* window
5) The *OC RDC Main Spreadsheet* displays and any search criteria selected is noted on the **Status Line** on the *OC RDC Main Spreadsheet*

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 or click the **Search** button
- The *Search* window displays with the options defaulted to <All>

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

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THE ACTIVITY LIST

The *Activity List* window will display for site users after they have logged into OC RDC Classic 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.

NOTE: CRAs for studies that are only in the Classic mode will see the *Search* window only and never the *Activity List* window. The *Activity List* window is not shown once a CRA who has access to a study that is in both the PDF and Classic modes have used the **Edit > Preferences** function to view data in the Classic mode. Upon changing to Classic mode, the CRA will see the *Search* window for the rest of this work session.

The *Activity List* is used to select a task or the data a user wants to view on the *OC RDC Main Spreadsheet*. Additionally, the list can be accessed at any time during the OC RDC Classic 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.
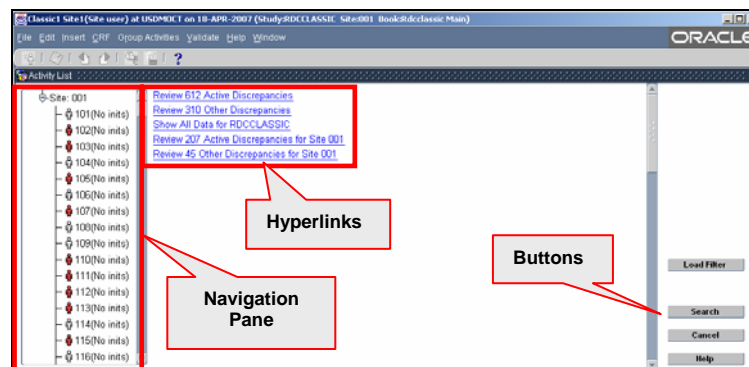
Subject icons display next to the patient numbers once data has been entered and saved. If patient initials are being populated in the Navigation Pane, users will see the initials displayed after they have been entered by PPD.

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.

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Version 1.0
May 16, 2007
Page 8 of 37

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THE ACTIVITY LIST con't

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.*

OC RDC MAIN SPREADSHEET

Once you have accessed the *OC RDC Main Spreadsheet*, click the **Maximize** button on the top right corner to obtain a full screen view.

Not Maximized
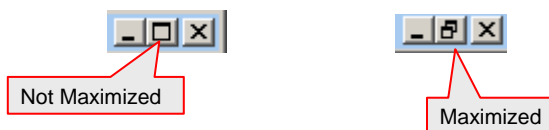
Maximized

Note: When the *OC RDC Main Spreadsheet* is maximized, you will be able to view the scroll bar on the right, allowing you to scroll up and down.
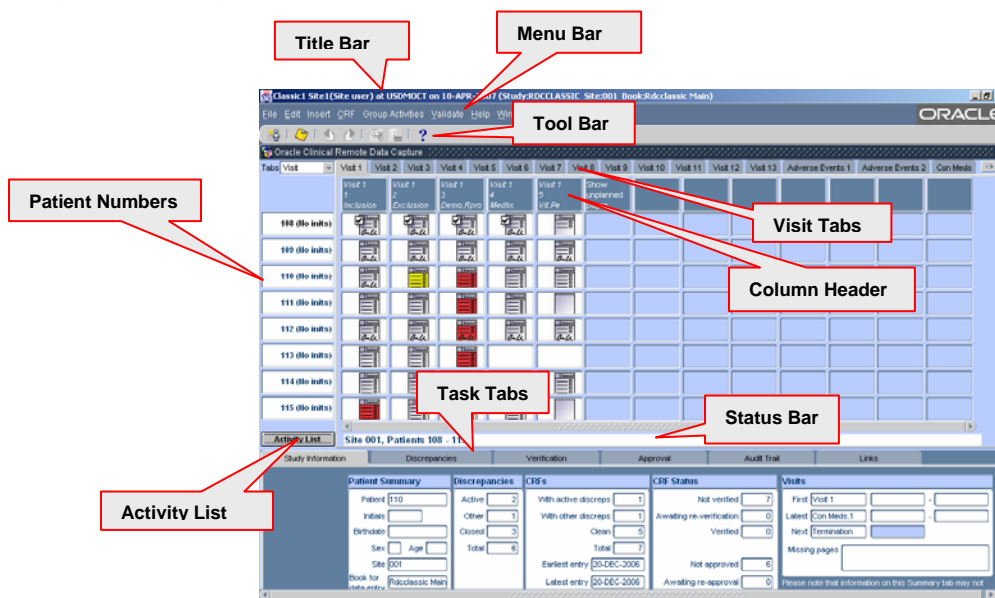
The **title bar** displays the current protocol, site and user information.

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

The *OC RDC 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**.

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Version 1.0
May 16, 2007
Page 9 of 37

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OC RDC MAIN SPREADSHEET con't

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.
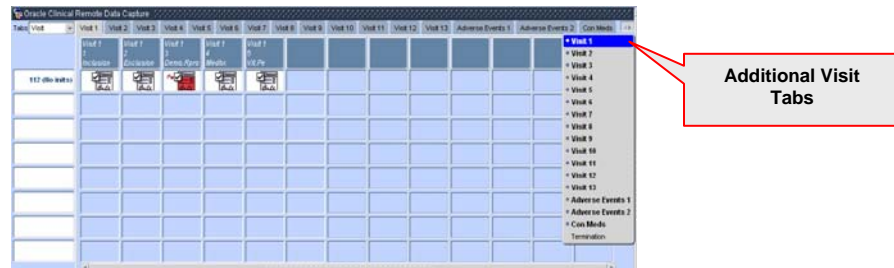
A patient number and the associated row of eCRF cells make up a **patient row**. The center of the *OC RDC Main Spreadsheet* contains **cells**. Each cell represents a single eCRF, which may contain one or more pages.

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 *Search* window can be accessed by clicking the **Search** button. The data selected from the Search window displays in the **Status Bar.**

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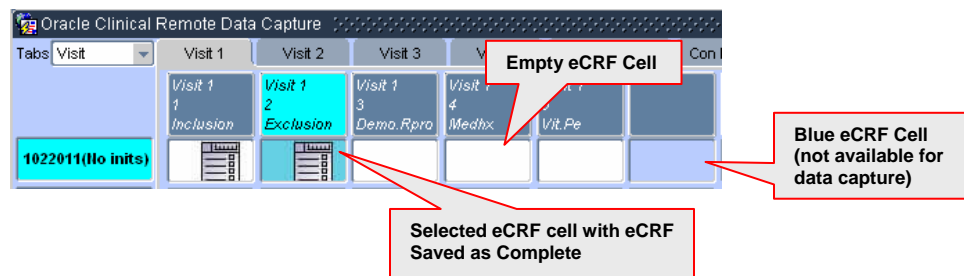
eCRF cells that are active and available for data capture are displayed with a white background. An eCRF cell for which data capture has not yet started is referred to as an empty eCRF cell.

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.
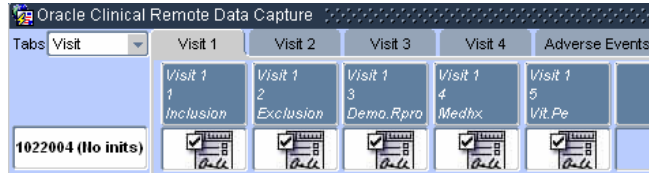
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://edc.ppdi.com
Version 1.0
May 16, 2007
Page 10 of 37
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eCRF ICONS

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 *OC RDC 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.

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.

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Version 1.0
May 16, 2007

Page 11 of 37

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THE OC RDC CLASSIC DATA ENTRY WINDOW

The OC RDC Classic Data Entry Window displays when an eCRF cell or icon is selected and is used to capture, modify or view patient data. The Data Entry Window (DEW) is developed as part of a study specific database.

The first action to perform after opening a Data Entry Window is to resize the window for easier viewing of data capture fields. After the DEW has been resized, the new size will hold for this data capture session. After logging out, the window size will need to be reset again.

The user may **resize the DEW** in two ways:

1) Single click the blue bar at the top of the window and a *Sizing Window for Data Entry* appears.
   a. Move the cursor to the upper left corner of the window and place it so that the single arrow turns into a double arrow.
   b. Click, hold and drag the window to a larger size
   c. Click the **Done** button
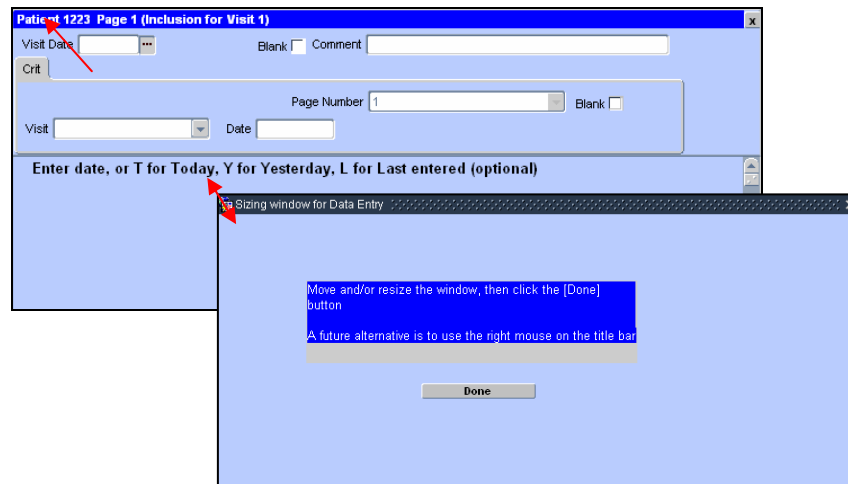
2) Users may also right-click on the blue bar at the top of the window and select an option from the menu.

Note: Ensure that the six tabs at the bottom of the *OC RDC Main Spreadsheet* are still viewable after resizing.

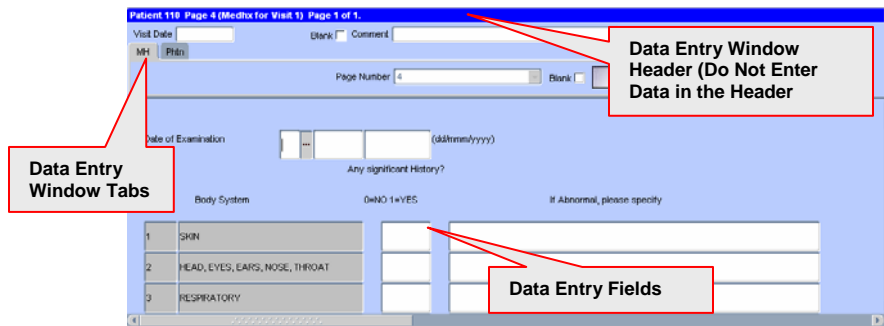## *NAVIGATING THE DATA ENTRY WINDOW*
The TAB key moves the cursor from field to field within the Data Entry Window.

A blinking cursor will appear in the Visit Date field of the DEW header. Do not enter any data in the header section of the eCRF. Press the Tab key to move the cursor forward. This will move the cursor into the Data Entry Window tabs. Always enter patient data in the DEW tab(s).

NAVIGATING THE DATA ENTRY WINDOW con't

Use the tab key, the mouse or the Up/Down arrows on the keyboard to navigate from field to field. The Data Entry window may contain one or more DEW tabs. Upon completion of the final data entry field of the first tab, the system will auto-progress to the next DEW.

Use the scroll bars to navigate through and to view the eCRF fields.

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

	The **Insert Patient** icon allows users to insert a different patient number on the spreadsheet to work with.
	The **Save** icon is used to directly save data.
	The **Previous CRF** icon moves users back to the previous eCRF containing data in the current or previous Visit tab.
	The **Next CRF** icon advances users to the next eCRF containing data in the current or previous Visit tab.
	The **Investigator Comment** icon is used to place and view investigator comments on a data field.
	The **Discrepancy (manual)** icon is used by PPD staff to create a manual discrepancy on a data field.

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Version 1.0
May 16, 2007
Page 13 of 37

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DATE ENTRY OPTIONS

Dates can be captured in the eCRF using the List of Values (LOV) or by manually entering the date. A complete date should always be captured for project specified date fields.

If partial or unknown dates are allowed in the eCRF, use the List of Values (LOV) to select the appropriate response. Verify that the correct date populates. Discrepancies will be generated if you do not enter the correct format for dates.

DATA CAPTURE FIELDS

There are different types of data entry fields. Some data entry fields contain a List of Values (LOV), which allow users to select a response from a pre-defined list. Other fields require users to click a checkbox.
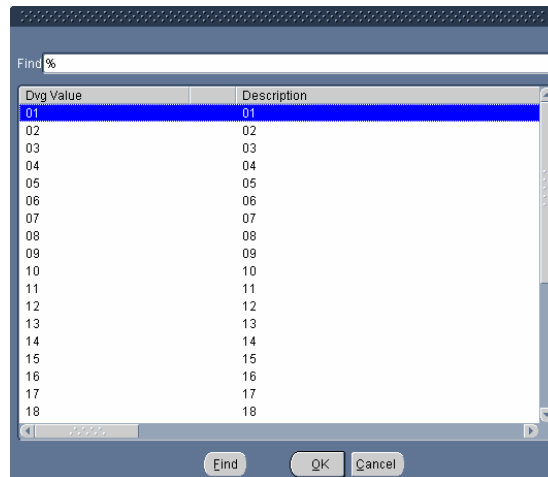
If a field contains a LOV:
When users tab or click into a field, a gray box with three dots will appear to the right of the data entry field if there is a LOV available.

1) Click on the gray box to display the LOV or use the **F9** key on your keyboard to display the list

2) Select a value from the list

3) Click the **OK** button to populate the data entry field or double click the value and it will populate the field.

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Version 1.0
May 16, 2007

Page 14 of 37

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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 unless there are more than eight patients displayed in the *OC RDC Main Spreadsheet*. 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*
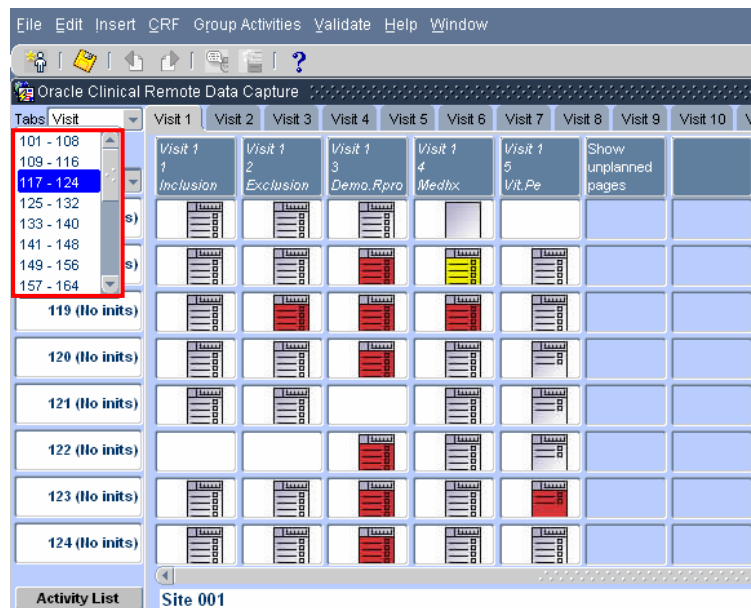
NOTE: When entering eCRF data, select the patient number from the *Activity List* Window and access the *OC RDC Main Spreadsheet* using the hyperlink.

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 enter data incorrectly on another 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.

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Version 1.0
May 16, 2007
Page 16 of 37

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DISCREPANCY MANAGEMENT con't

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 may be 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

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. The field will display with a yellow background and blue text.

- 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 and the eCRF icon in the DEW and *OC RDC Main Spreadsheet* will appear red.

- If there is inconsistent or inaccurate data across multiple DEW tabs. (i.e. Cross checking adverse event information against ConMeds). 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 Pharmaco Vigilance Group (PVG –Safety) are also able to create and close manual discrepancies in the system.
- The data field will display with a yellow background and blue text.

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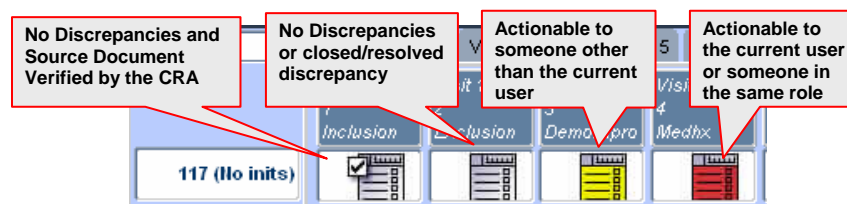

Discrepancy Management is performed using the Discrepancy tab at the bottom of the *OC RDC Main Spreadsheet.*

For each discrepancy listed in the Discrepancies List tab, there is a corresponding individual tab, which displays the complete set of information related to a single discrepancy.

The sequence number for each discrepancy in the Discrepancies List tab will correspond with the individual sub-tabs.(i.e. in the screen shot below, 1 – Active, 2 – Other).

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DISCREPANCY MANAGEMENT con't
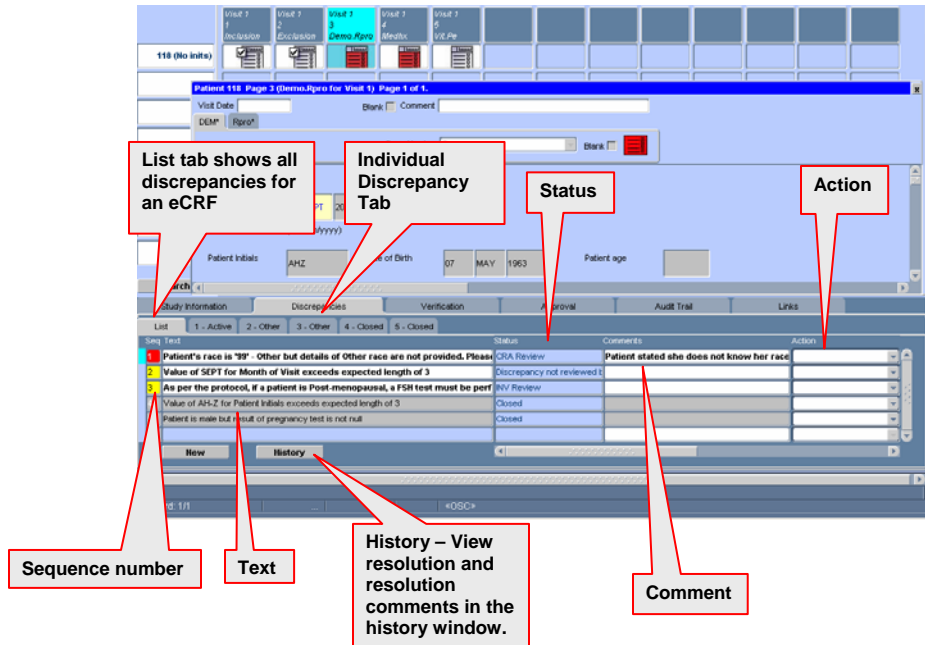
To access an individual discrepancy, click the appropriate tab. When you do this, the tab you select is displayed "on top," and you can view or work with that discrepancy.

When discrepancies occur during the data capture process, a number of actions can be taken by the site:

1. Correct the data immediately
2. Accept the discrepancy and correct later
3. Route the discrepancy to the CRA

When the discrepancy is routed to the CRA, one of the following actions may be performed by the CRA.

- If the discrepancy needs to be routed back to the site, select **Send to Investigator** in the Action drop down list.
- If the discrepant data has been corrected or an appropriate resolution has been met by the site, choose **Close – resolved** in the Action drop down list.

ROUTING A DISCREPANCY BACK TO THE SITE
- From the *OC RDC Main Spreadsheet*, click the eCRF cell containing a red icon
- The DEW tab displays
- Click the Discrepancies tab at the bottom of the *OC RDC Main Spreadsheet*
- Click the **Active** tab associated with the discrepancy to be addressed
- Review the reason for the discrepancy in the field just below the **Active** title
- Click the Action drop down menu and select **Go to data field**
- The cursor will highlight the data in the field requiring your attention
- Review the information in the data field
- Select **Send to Investigator** in the Action drop down list

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Version 1.0
May 16, 2007
Page 18 of 37

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DISCREPANCY MANAGEMENT con't

- The *Internal Comments for Discrepancy* window appears
- Delete the comment that the site has entered, and type in your response. When writing the response to the site, provide clear, concise direction on how the site is to correct the data.
- Click the **Save** button
- The discrepancy will display with a yellow sequence number and the sub-tab will display as Other.

CLOSE – RESOLVING A DISCREPANCY

- From the *OC RDC Main Spreadsheet*, click the eCRF cell containing a red icon
- The DEW tab displays
- Click the Discrepancies tab at the bottom of the *OC RDC Main Spreadsheet*
- Click the **Active** tab associated with the discrepancy to be addressed
- Review the reason for the discrepancy in the field just below the **Active** title
- Click the Action drop down menu and select **Go to data field**
- The cursor will highlight the data in the field requiring your attention
- Review the information in the data field. If data has changed, you may review data change history in the **Audit Trail** tab.
- Select **Close - resolved** in the Action drop down list.
- The Resolution Reason window appears.
- From the Resolution drop down list select the appropriate action. Resolution comments may be added in the comment section. Click the **Save** button.
- The discrepancy will display with a gray sequence number and the sub-tab will display as Closed.

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Version 1.0
May 16, 2007
Page 19 of 37

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CREATING A MANUAL DISCREPANCY

- From the *OC RDC Main Spreadsheet*, click the eCRF cell containing the data field on which you need to place a discrepancy
- The DEW tab displays
- Click the Discrepancy (Manual) tool
- The *Comment* window displays. Type the discrepancy in the **Message** section of the *Comment* window.

- Select **Send to Investigator** from the Action drop down list
- The *Internal Comment* window appears. Do not enter comments in this window. Click **OK** or **Cancel** to close the window.
- Click **OK** to route the discrepancy to the site.
- The discrepancy will appear with a yellow sequence number and a corresponding sub-tab of Other.

VIEWING DISCREPANCY HISTORY

Once a discrepancy is saved to an eCRF, users are able to view the history of the discrepancy by clicking the **History** button at the bottom of the *Discrepancy* tab. 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
- Click the **Discrepancies** tab
- Highlight the discrepancy for which you want to view the history
- Click the **History** button
- The **History for discrepancy…** window displays
- Click **OK** to close the window

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Version 1.0
May 16, 2007
Page 20 of 37

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VERIFYING AN INDIVIDUAL eCRF

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

- From the OC *RDC Main Spreadsheet*, click the eCRF icon for the eCRF you wish to verify
- 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 **Verification** tab

- Enter a comment in the **Comment** text field, if applicable. i.e. SDV to indicate the eCRF has been source verified
- To allow the verification comment to be included with all other eCRFs verified during the current session, place a check mark in the **Keep comment between verifications** checkbox – if a check mark 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 verification is saved and the system will auto-progress to the next available eCRF page
- Verified eCRF icons display as shown in the screenshot below

NOTE: If CRAs are performing "side-by-side" verification at the site and the same eCRF is being accessed by both parties, only one party can verify an eCRF at a given time.

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 eCRF icon for the eCRF you wish to verify and the eCRF displays
- Click the **Verification** tab
- Click the **Undo Verify** button
- The system will auto-progress to the next available eCRF page
- The *OC RDC Main Spreadsheet* displays with the eCRF cell no longer containing a verified icon

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Version 1.0
May 16, 2007
Page 21 of 37

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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.
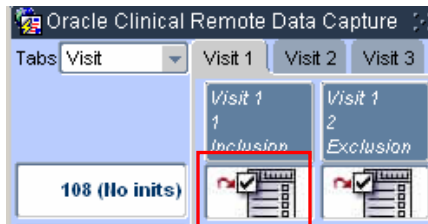
- From the OC *RDC Main Spreadsheet*, click the eCRF icon for the eCRF you wish to verify
- The eCRF displays
- Click the **Verification** tab
- Review changes to data fields – use the scroll bar on the right side of the screen to view all fields
- Enter a comment in the **Comment** text field, if applicable. i.e. SDV to indicate the eCRF has been reviewed for changes
- To allow the verification comment to be included with all other eCRFs re-verified during the current session, place a check mark in the **Keep comment between verifications** checkbox – if a check mark is placed in the box, the comment will be attached to any eCRFs that have been individually or grouped verified
- Click the **Re-verify** button
- The system will auto-progress to the next available eCRF page. Close the DEW window when complete.
- The *OC RDC Main Spreadsheet* displays with the eCRF cell containing a verified icon

NOTE: Users can select the **Show Changes** button in the *Verification* tab to view the history of a data field that was modified. After opening the Show Changes window, the user can click the **Show** button to view the entire Audit Trail for the data field. Changes to investigator comments or discrepancies without data changes **will not** display in the *Audit Trail* tab.

GROUP VERIFYING eCRFs
OC RDC Classic allows users to group verify those eCRFs that have been "monitored" as part of the overall site visit and not individually source verified.
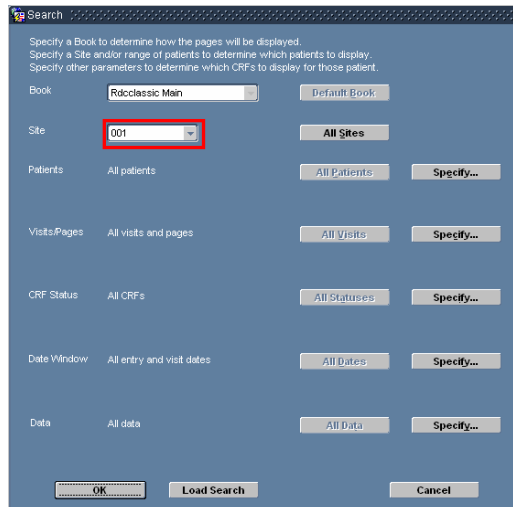
Since the monitoring plan specifies which data needs to be source document verified, it is useful to have a "verified" status which represents the amount of patient information that was processed or group verified at a particular monitoring visit, rather than represent only the individual eCRFs that were verified against the source.

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 Classic will not mark eCRFs saved as Incomplete verified.

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Version 1.0
May 16, 2007
Page 22 of 37

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GROUP VERIFYING eCRFs con't

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

NOTE: 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
- The *OC RDC Main Spreadsheet* displays with the selected dataset

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Version 1.0
May 16, 2007
Page 23 of 37

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GROUP VERIFYING eCRFs con't

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

- 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
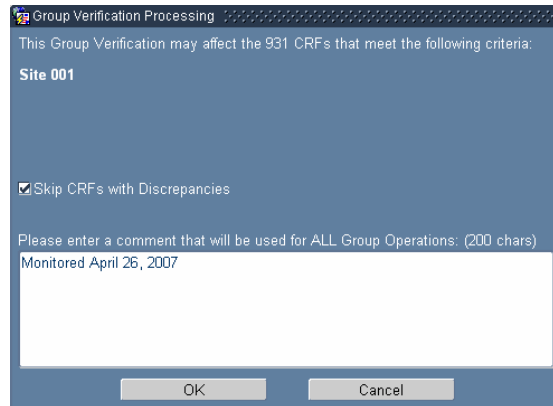
- The **Skip CRFs with Discrepancies** checkbox is automatically checked
- In the text area, enter a comment such as Monitored 8 May, 2007, to attach to any eCRFs group verified
- Click the **OK** button
- The *Group VERIFY Update Completed* window displays indicating how many eCRFs were marked as group verified

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

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AUDIT TRAIL TAB

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 a DEW that has been saved as **Complete or Incomplete**.

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.

To view the history of a data field:
- Open the eCRF containing the data field with the audit history
- Click the **Audit Trail** tab at the bottom of the screen
- If an eCRF has more than one DEW, select the appropriate tab on the far left side of the window to view the audit information from each Data Entry Window tab

- The most recent audit history is viewable on the main screen, however, by clicking the **Show** button associated with individual fields, and entire history for the field can be viewed.
- Click **OK** to exit the *Audit history* window

VIEWING AN INVESTIGATOR COMMENT

If an **Investigator Comment** has been added, the data field will appear with a yellow background and green text. If there is a discrepancy on the data field, adding an investigator comment will change the text color to red.

To view a comment:
- On an open eCRF, click in the field that contains an Investigator Comment
- Click the **Investigator Comment** tool to open the Investigator Comment window
- Review the comment in the text area
- Click **OK** to close the window
- History of the Investigator Comment can be viewed in the Audit Trail tab.

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.

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Version 1.0
May 16, 2007
Page 25 of 37

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VALIDATING A SITE OR A PATIENT

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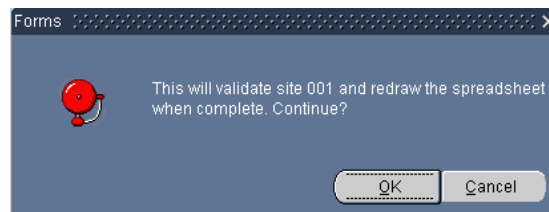
3) In the *Forms* window:
      a. Click the **OK** button to proceed with the validation
      b. Click the **Cancel** button to discontinue the validation

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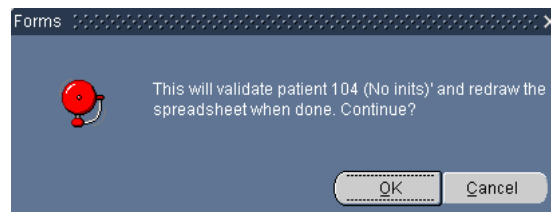
    3) In the *Forms* window:
        a. Click the **OK** button to proceed with the validation
        b. Click the **Cancel** button to discontinue the validation

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Version 1.0
May 16, 2007
Page 26 of 37

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MARKING AN eCRF AS BLANK

If an entire eCRF or a DEW tab within an eCRF will not be completed for a particular patient, or if a patient misses a protocol defined visit, the eCRF or DEW tab should be marked as blank.

Marking a DEW tab as blank alerts the study team that the DEW has not been inadvertently left blank. If an entire DEW is marked as blank, users will not see any data. Also, if data is not entered in all DEW tabs, the system will automatically save the eCRF as incomplete.

1) The following message will display in the DEW tab if the *Blank* checkbox has been checked in the individual DEW tab and will only mark the selected tab as blank.

2) On an eCRF with multiple tabs, if the *Blank* checkbox in the **header** section is selected, all tabs within the eCRF will be marked as blank.

3) When you click the *Blank* checkbox in the DEW tab that has only one eCRF, the system will automatically check the *Blank* checkbox in the header section of the eCRF. If the entire DEW tab is marked as blank, the following message will display.

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

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Version 1.0
May 16, 2007
Page 27 of 37

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MARKING AN eCRF AS BLANK con't

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

- From the *OC RDC Main Spreadsheet*, open the DEW tab which you want to mark as *Blank*
- Check the *Blank* checkbox that is available for the DEW tab
- A *Forms* window appears stating: **Mark the CRF as blank and Save?**
- Click **OK**
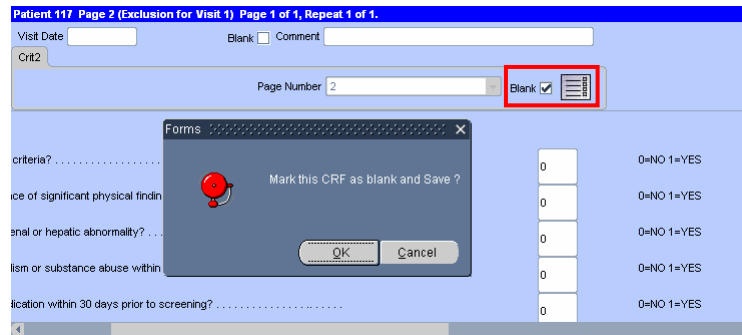
- The *Audit Information for CRF Change* window appears
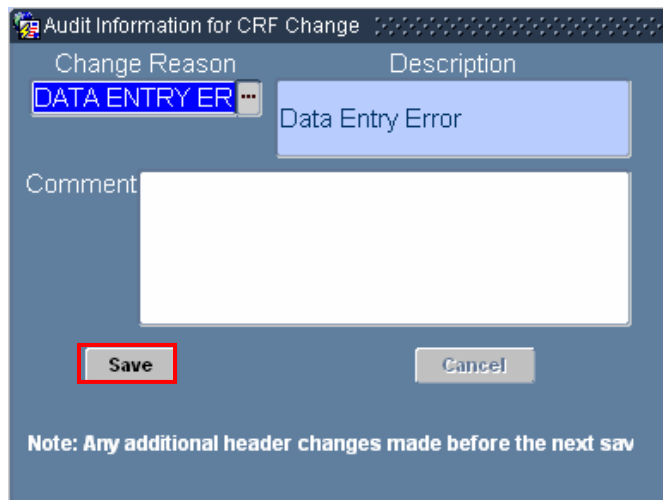
- Click **Save**
- Click the **X** in the upper right of the DEW to close the window

UNMARKING AN eCRF AS BLANK

The eCRF or DEW tabs marked as blank can be unmarked as blank to allow data to be entered on the eCRF. This is helpful if an eCRF or a DEW tab was marked blank in error or if it was marked blank to allow the system to save the eCRF as complete.

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Version 1.0
May 16, 2007
Page 28 of 37

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UNMARKING AN eCRF AS BLANK con't

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 Data Entry Window displays
- Click in the **Blank** Checkbox to remove the check
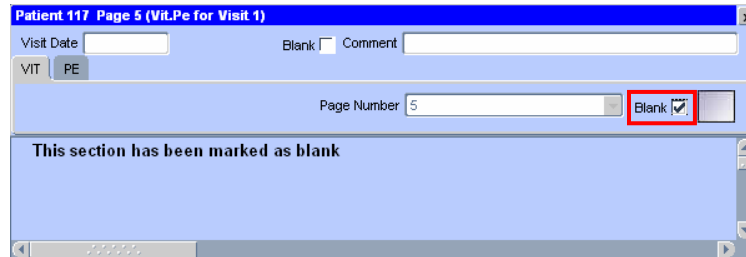
- The *Audit Information for CRF Change* window appears
- Click the drop down arrow in the **Reason** field and select a reason for change from the list
- Add a comment if desired
- Click the **OK** button
- **Enter** Data in the DEW tab
- **Save** data when complete

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 Events visit will be added.
1. From the *OC RDC Main Spreadsheet*, select the correct visit tab
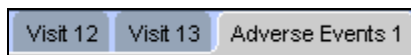
NOTE: Click the column header **"Show Unplanned Pages"** if additional pages have already been added.

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.

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Version 1.0
May 16, 2007
Page 29 of 37
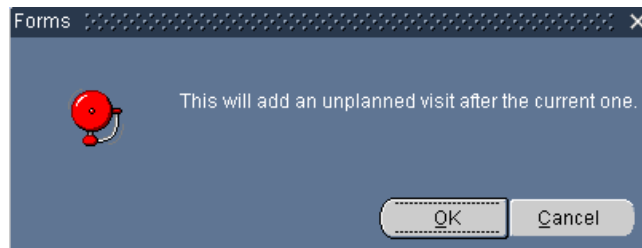Oracle is a registered trademark of Oracle Corporation.

INSERTING ADDITIONAL VISITS con't

4. Select **Insert >Visit** from the Menu Bar
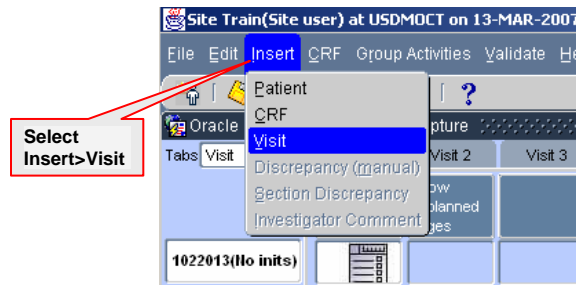
NOTE: ONLY choose INSERT >VISIT. Do not choose Insert>Patient or Insert >CRF from this menu.

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 others can be created by single clicking in the empty cell.   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.
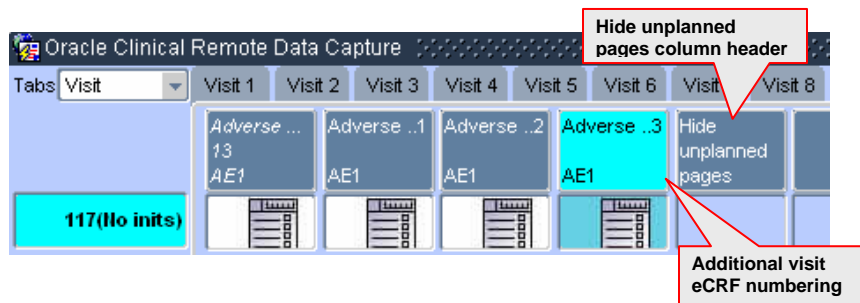
Upon subsequent log-ins, users will need to click on the **"Show unplanned pages"** column header to access the added visits.
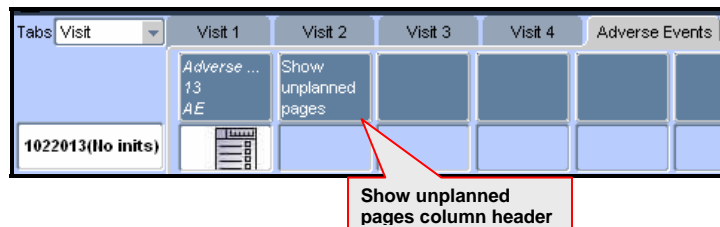
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Version 1.0
May 16, 2007
Page 30 of 37

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## *TIPS FOR INSERTING ADDITIONAL VISITS*

- Do not insert visits until you need them
- Do not create eCRFs in visits that you have added if you do not 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 below)
- 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
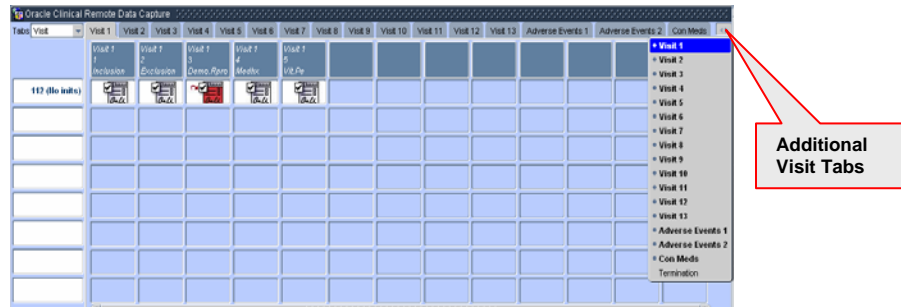
DELETING AN eCRF

OC RDC allows for an eCRF to be deleted. Possible examples for deleting and eCRF include incorrect data being entered on the wrong patient or if an incorrect visit was selected and completed. Any discrepancies and investigator comments will also be deleted along with the data. When deleting data that has been saved as **Complete**, the system prompts users for a deletion reason.

- From the *OC RDC Main Spreadsheet*, tab to the cell that contains the eCRF to be deleted. The background will be highlighted in aqua.
- Click the **Edit > Delete CRF** menu command and the following *Forms* window displays
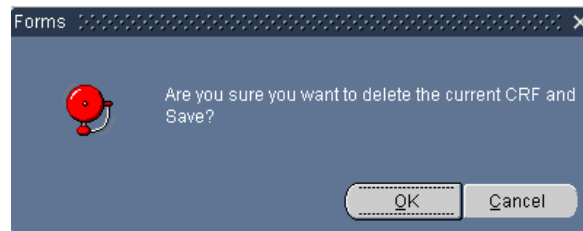
- Click **OK** to continue with deletion
- The *Audit Information for CRF Delete* window appears
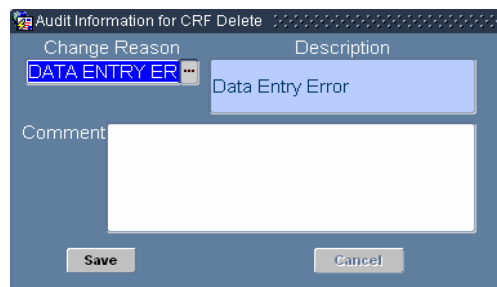
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DELETING AN eCRF con't

- Select a **Change Reason** from the drop down list
- Enter a *Comment* if applicable
- Click the **Save** button
- The eCRF cell will display as blank. If that page is needed at a later point in time, click in the empty cell to create the eCRF page.
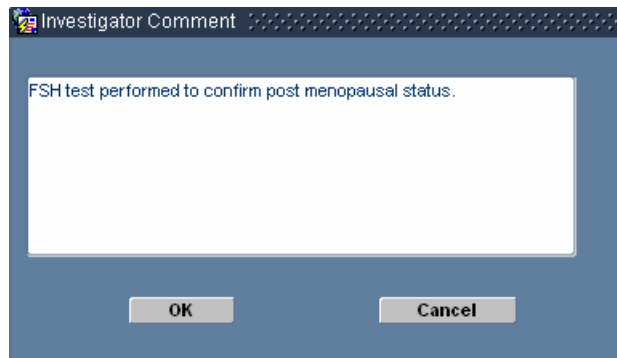
ADDING AN INVESTIGATOR COMMENT

The **Investigator Comment** tool 🖳 can be used by the investigator site to add details to a data field. The comment function is not a communication tool and in no way replaces the normal channels of communication such as e-mails, phone calls or site visits.

Adding an **Investigator Comment** to a data field is useful in explaining why a certain piece of data was entered, however, comments are not collected as part of the data analysis.

Comments should not be added if the issue was already captured in a discrepancy or if a data field can be used to capture the information. Any field containing an **Investigator Comment** appears with a **yellow background and green text.**

- From an open DEW tab, navigate to the desired field
- Click the **Investigator Comment** tool 🖳
- The Investigator Comment window appears, enter comment

- Click the **OK** button
- The *Audit Information for Investigator Comment* window displays
- Select a **Change Reason** from the drop down menu
- Click the **Save** button
- The field will display with a yellow background and green text
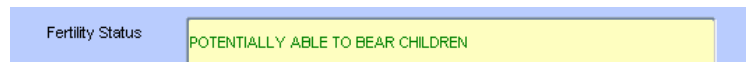
NOTE: It is recommended that sites **DO NOT USE** Investigator Comments. Most protocols will have a comments log page where that information should be captured.
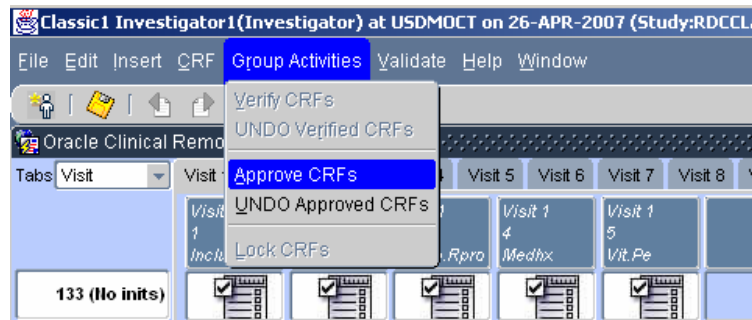
If you experience any problems with OC RDC, contact the EDC Support Center
Toll free numbers and a Support Center email form can be found at http://edc.ppdi.com
Version 1.0
May 16, 2007
Page 32 of 37

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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 **Group Approving eCRFs**.

1. Log into OC RDC Classic using credentials emailed from PPD.
2. The *Activity List* window displays. Select the 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**
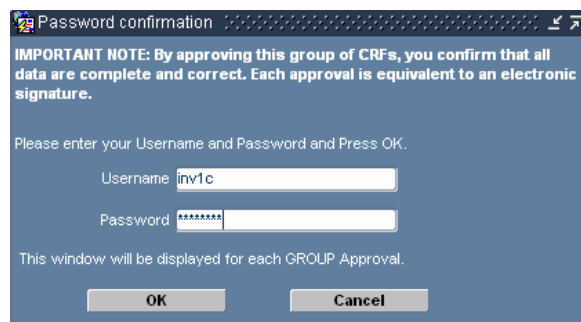
8. The **Group Approval Processing** window displays. Leave default settings checked to Skip CRFs with Discrepancies and Skip Un-verified CRFs.
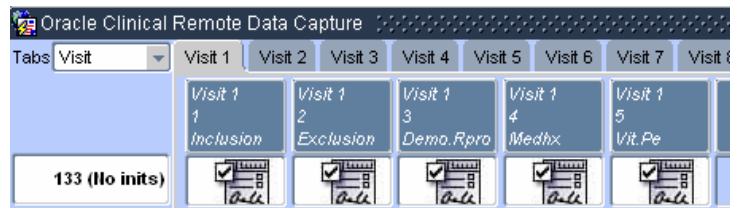9. Click **OK**
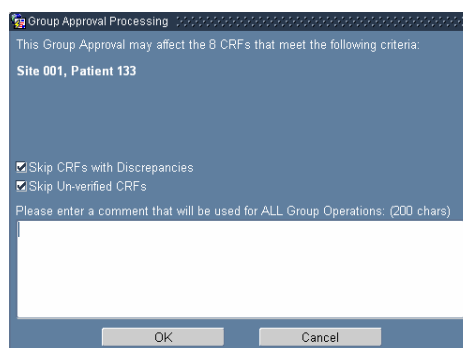
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10. The *Group APPROVAL Update Completed* window displays advising number of CRFs approved. Click **OK**.

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

### Approve, Re-Approve or Undo Approval at the eCRF Page Level
If a data change occurs on a page after Investigator Approval the re-approval icon will appear.

The Investigator would conduct the following steps to approve, re-approve or undo approval at the eCRF page level.
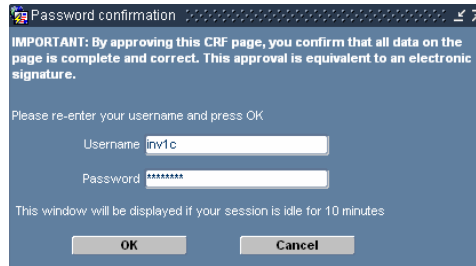
Approving an Individual eCRF
1) Click the eCRF icon that needs approval.
2) Click the **Approval** tab.
3) Review that data captured in the eCRF corresponds to source documents.
4) Type your password and hit **Enter** to approve the eCRF.
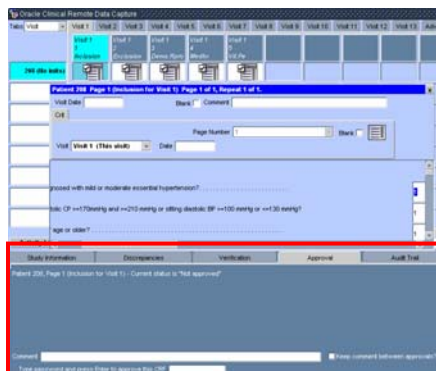
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Version 1.0
May 16, 2007
Page 34 of 37

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PRINCIPAL INVESTIGATOR APPROVAL PROCESS con't

5) The *Password Confirmation* window appears. Enter your Username and Click **OK**. The eCRF icon displays with a signature.

Re-Approving an Individual eCRF
1) Click the eCRF icon that needs **Re-approval**.
2) Click the **Approval** tab.
3) Review data captured in the eCRF corresponds to source documents.
4) Type your password and hit Enter to re-approve the eCRF.
5) The *Password Confirmation* window appears.
6) Enter your Username and Click **OK**. The eCRF icon displays with a signature.

Undo Approval of an Individual eCRF
1) Click the eCRF icon for which you wish to **Undo Approval**.
2) Click the **Undo Approval** button at the bottom of the window.
3) Type your Username and Password in the *Password Confirmation* window.
4) Click **OK**.
5) The eCRF icon displays without a signature.

LOGGING OUT OF OC RDC CLASSIC

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
- From the *OC RDC Main Spreadsheet*, select the **File >Exit** menu command
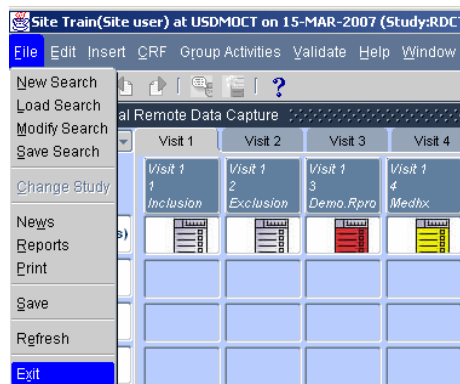
- The *edc.ppdi.com website* window displays
- Close the *edc.ppdi.com* window by clicking the **X** in the upper right corner of the window

OC RDC TRAINING SUPPORT

Training Options & Access Requests

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

- OC RDC Classic is a direct data entry system; source documentation is required.
- All equipment provided to the site should ***ONLY*** be used for OC RDC Classic 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. 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.
- Training can be requested through the Study Team.   All training sessions must be documented before access to a study protocol in the OC RDC Classic application is granted.
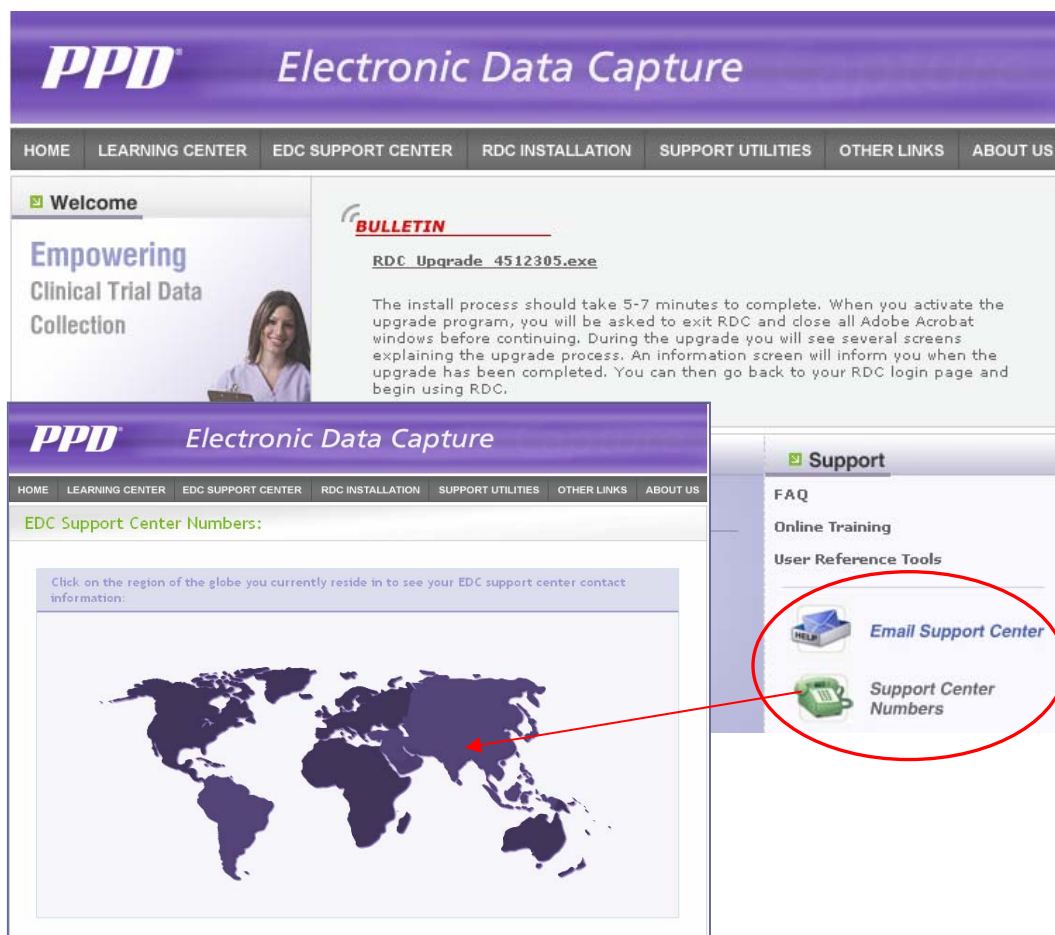
Training Materials

The following OC RDC Classic training materials are available for all site users:
- On-line training
- Quick Reference Guide
- Investigator Site User Guide
- Functionality Guides

If you experience any problems with OC RDC, contact the EDC Support Center
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Version 1.0
May 16, 2007

Page 36 of 37

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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 and
Email support can be found at http://edc.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://edc.ppdi.com

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