



OC RDC 4.6 Read-Only User Guide

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User Hame Password Login
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ACCESSING OC RDC

Steps for Obtaining Access

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

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

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

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

NOTES:

- PPD OC RDC 4.6 Training is only required to be performed once, regardless of the number of PPD OC RDC 4.6 studies you participate in.
- A PPD RDC Account Access Request Form must be completed for each study you require access to.
- If you will be participating in User Acceptance Testing (UAT) for your study, you must complete training and submit all required forms prior to test access being granted.
- Add your study URL to your Internet Explorer Favorites folder list for rapid access to your study website.



Getting Started	Support Center	Resources	About Us		
elcome to the RDC 4 If you are a first time v account and complete t	.6 Web Portal isitor to the site, please mak raining in order to gain acces	e sure you follow the ste ss to your trial.	ps below to request your	RDC 4.6	
News				User Reference Mat	erials
Welcome to n	ew RDC 4.6 web portal.	Click Log the	gin button to acces Logon window	S E-mail the Support	Center
				Call the Support Ce	nter
ETTING STARTED	for FIRST TIME VISITO	RS			
Submit Account Request Form	Complete Online Training	Bookmark This Page		REGISTERED USER LO	GIN

Logging On

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

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

'User Hame	
'Password	
Login	



Password Changes

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

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

To change your password:

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



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

Computer System and Security

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

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



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



VIEWING DATA IN OC RDC

Study and Site

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

Home	Easebooks	Review	Reports	1923			
						Lo	ogged in as Site Train(Site user, OCDB01T); Last Refresh 27-05-2010 11:21:02
-							Study and Site RDCTRAIN - 102 - Study and Site Summary
News				Patient Selectio	n List		
No Rec	ords Found						
Activi	ties		j	+ Patient Sea	arch		
Revie	w 234 Active Disc	repancies		Patients			
Revie	w 9 Other Discrep	<u>pancies</u>					
Revie	w Investigator co	mments		Select Patients	and Open Patient Ca	SEDOOKSGO	S Previous 1-50 of 300 Next 50 3
Linke				Select All Select	t None		
RDCF	Reports (New)			Select 🖧 🔄	Patient Number	Last Modified	Casebook
RDC C	Onsite 4.6 Online	Training			1021001	28-08-2009 18:40:40	RDC TRAIN PAGES 1-16
EDC S	Support				1021002	09-11-2009 18:16:51	RDC TRAIN PAGES 1-16
Dearc	11 011 1900				1021003	28-07-2009 22:30:42	RDC TRAIN PAGES 1-16

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

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

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



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





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

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

Selecting and Opening a Casebook Spreadsheet

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

Patient Selection List	Study and Site Summary
Range 1021017 Q	Assigned Book Any Discrepancy Status All Clear Go

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

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

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Patie	nts								
Select Patients and Open Patient Casebooks Go									
Select All Select None									
Select	8	Patient Number	Last Modified	Casebook					
•	2	1021017		Unassigned					

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

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

Patient	Patient Selection List										
+ Pat	ient s	Search									
Patien	its										
Select	Select Patients and Open Patient Casebooks 🔽 Go 📿 Previous 1-50 of 300 💌 Next 50 🔊										
Select A	<u>ul se</u>	elect None									
Select	8	Patient Number	Last Modified	Casebook							
	۸	1021001	05-Mar-2008 11:18:32	Unassigned	I						
	۸	1021002	29-Feb-2008 11:50:30	Unassigned	I						
	۵	1021003	29-Feb-2008 09:01:03	Unassigned	I						
	8	1021004	05-Mar-2008 16:26:53	Unassigned	I						
		1001005									

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

Patie	nt Case	ebooks	8										
	+ Se	earch :	1 Patients Se	elected From He	ome Page								
	Casebook Spreadsheet												
	Set Visit Focus: Patient: All 🔽 Casebook: RDC453V1 💽 Visit: ADVERSE EVENTS 💽												
	Patie	ents: 🤅	Previous 1-1	of 1 💌 Next 👽							CRFs: 🔇	Previous 1-3 of	3 🔹 Next 🔊
	Select	: Patie	nts and Ge	nerate Patient Da	ta Report 💌	Go Add V	isit Page	Add Other Pa	je				
	Select a	All Se	elect None										
			Patient					ADVERSE	EVENTS				
	Select	: 🛆	Number	Ae Yn	Ae Data	Ae Data.1							
		۸	1101001	1	2	2 U1							

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

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



Icons for eCRFs

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

Selecting and Opening an eCRF

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

s											
1 Dationte Se	Jactad From Ho	me Dage									
Casebook Spreadsheet											
us: Patient:	All Case	a Report	3V1 Visit:	ADVERSE EVENTS - ADVERSE EVENTS CON MEDS VISIT 1 VISIT 2	r Page		CRFs: ⓒ) Previous 1-2 of 2 💌 Ne	ext 🕟		
				VISIT 3	ruge						
Select None				VI511 4							
Patient				TERMINATION	ERSE EVENTS						
Number	Ae Yn	Ae Data									
1105020	1	1 2									
	I Patients Se Spreadsheet us: Patient: Previous 1-1 ents and Gee Select None Patient Number 1105020	s s 1 Patients Selected From Ho Spreadsheet us: Patient: All Casel Previous 1-1 of 1 Next (*) ents and Generate Patient Dat Select None Patient Number Ae Yn 1105020 mp 1	select None Patient I 105020 I 1 05020 I 1 050	sets Spreadsheet Spreadsheet Us: Patient: All Casebook: RDC453V1 Visit: OPrevious 1-1 of 1 Next O ents and Generate Patient Data Report Co Add Vi Select None Patient Number Ae Yn Ae Data 1105020 up 1 up 2	select None Patient All Casebook: RDC453V1 Visiti ADVERSE EVENTS CON MEDS VISIT 1 VISIT 1 VISIT 2 VISIT 3 VISIT 4 VISIT 3 VISIT 4 VISI	select None Patient Al	select None Patient All Patient Ae Yn Ae Data Patient Ae Yn Ae Data Patient Ae Patient A Patie	setected From Home Page Spreadsheet Us: Patient: All Casebook: RDC453VI Visit: ADVERSE EVENTS CON MEDS CON MEDS VISIT 2 Patient Generate Patient Data Report V Go Add Vi VISIT 2 Patient AE Yn Ae Data 1105020 up 1 up 2	selected From Home Page Spreadsheet us: Patient: All Casebook: RDC453VI Visit: ADVERSE EVENTS CON MEDS CON MED		

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

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

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NOTES:

- The patient drop-down list in the Set Visit Focus area of the Casebook Spreadsheet is present for all studies, but only enabled for flexible study designs (see later section).
- You will notice a *Browse Mode* watermark on the eCRF indicating that you do not have entry / update access:

						8 (3)
S	itudy Name	RDC46	iV1	DCI Name	IP ACCOU	INTABILITY
	Study Site	102		Status	Entry Con	nplete
	Subject	102100)1	Doc#	R103205	D1
	Visit Name	VISIT 1	11 ⁹⁸ 2	Visit#	100	0
	IP Accou First Study	intabil Drug D	ity IoseDate 06-	APR-2010		
			(dd	/mon/yyyy)		
	Dispensed 06–APR–2 (dd/mon/y	Date 2010 yyy)	Returned Date (dd/mon/yyy	e Numberl 1 79)	Dispensed]	Number Return

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

8	ror	
	annot open the CRF as you do not have access to the DCI.	

Navigation Buttons

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

🚟 Previous CRF | Next CRF 🚟

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



Opening Multiple eCRFs

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

To open up to 3 pages simultaneously in OC RDC:

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

🗿 RDC Onsite DE: 1022004, ADVERSE EVENTS, ADVERSE EVENT DETAIL - Microsoft Internet Explorer provided by PPD INC	
ORACLE' RDC Onsite: Data Entry	Preferences Minimize
Study: RDC453V1, Site: 102, Patient: 1022004, Casebook: RDC453V1- (Read Train - CRA role)	RF Next CRF
Highlight All Discrepancies 🗾 🚍 🖾 🔛 🔛 🛍 🎥 🔚 🔂 🛱 Page 1/2 🔥 🔂	×
page 1	-
Study Name FDC453V1 DCI Name ADVERSE EVENT DETAIL / AE DATA PPD Study Site 102 Status Entry Complete Subject 1022004 Doc# R8739401 Check if Entire Page Blank Visit Name ADVERSE EVENTS Visit# 10 0 0 Adverse Events Visit# 10 0 0 0 Adverse Event Adverse Event 0 0 0 0 Stat Date Stop Date Frequency Outcome 0 0 Stat Date Stop Date Frequency Outcome 0 0 0	
dd/mon/yyyy dd/mon/yyyy	

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



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

Microsoft	: Internet Explorer
⚠	Maximum data entry windows (3) are open. Please close at least one data entry window before opening another.
	ОК

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

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

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

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



Visit Handling in Flexible Study Designs

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

	Patient						nterval: SCREE	NING, Visit: Visit	1		
Select	8	Number	Inclusion	Exclusion	Demog	¥itals	Med His	Ip Acct	Sub Study	PK	
	٨	X1	5	н б		8	11	10	11	-	



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

	Casebook Spreadsheet	
$\langle \rangle$	Set Visit Focus: Patient: XI 💌 Casebook: RDC46V1 💌 Visit: Visit 1	
	Patients: O Previous 1-1 of 1 Vext O	CRFs: OPrevious 1-8 of 8 Vext (>

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

CRF Handling in Flexible Study Designs

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

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



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

4.00
- 12
- N -



Example of Flexible Study Design

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

Non-Substudy Pa	tient
------------------------	-------

Patier	tient Casebooks												
	Search : 3 Patients Selected From Home Page												
	Casebook Spreadsheet												
	Set Visit Focus: Patient: XS Casebook: RDC46V1 Visit: Visit 1												
	Patients: Previous 1-3 of 3 Next Patients: Patients: Patients: Previous 1-3 of 3 Next Patients: Patients												B 💌 Next 🕟
	Select	Pati	ents and Ge	nerate Patient D)ata Report	Go Ac	Id Visit 2 Visit 3	ther	Page				
	Select A	AL S	Select None				Visit 4						
			Patient				Incriminau	There and SCRE	ENING, Visit: Visi	t 1			
	Select	8	Number	Inclusion	Exclusion	Demog	Vitals	Med His	Ip Acct	Sub Study	РК		
		۵	X3		1	1		9	10	11	12		
		8	X4			7		9	10	11	12		
		8	X5	5	6	7	в 🛛	н 9	10	11	(-)		

Substudy Patient

ent Case	book	s										
Search : 3 Patients Selected From Home Page												
Case	book	Spreadsheet				\sim						
Set Visit Focus: Patient: X4 Casebook: RDC46V1 Visit:Select Visit-												
Patients: © Previous 1-3 of 3 V Next © CRFs: © Previous 1-8 of 8 V Ne											B 🔽 Next 📎	
Select	Patie	ents and Ge	enerate Patient D	ata Report 👻	Go A	dd Visi Visit 1 Visit 1a	ther	Page				
Select A	<u>all s</u>	Select None				Visit 2						
		Patient				Visit Za Visit 3	5 CRE	ENING, Visit: Vis	it 1			
Select	8	Number	Inclusion	Exclusion	Demog	Visit 3a	is	Ip Acct	Sub Study	PK		
	8	X3		1 6	n 7	Visit 4		10	11	12		
	8	X4		6	7		9	10	11	(🗐 🖻		
	8	X5	5	1 6	n 7		9	10	11	\bigcirc		
	8	X5	n 5	n 6	n 7	8	9	10	11	<u> </u>		

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



OC RDC Features

CRF Navigator

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

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



Viewing Discrepancy Details

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

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



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

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

<u> </u>	Discrepancy Investigator Comment
	Show All Discrepancies Image: Second state Image: Second state <t< td=""></t<>
DCI Name MEDICAL HISTORY / MED HIS PI Status Entry Complete	Month of Con Med Stop Date (row 1) Other Text (row 3) Year of Con Med Stop Date (row 3)
ne nically significant medical conditions	Details
etabolic 11=Hepatic e,Throat 7=Genitourinary 12=Allergic logical 13=Psycholigical/Psychiatric ood/Lymphatic 99=Other	Related Values History Description Value of AUGU for Month of Con Med Stop Date exceeds expected length of 3
Musculoskeletal Ong Date Started Date Stopped Ch (dd/mann/yyyy) (dd/mann/yyyy) If ? 20 a0060 2007	Type UNIVARIATE Review Status Discrepancy not reviewed by user Reason Length Comment TESTING By Site Train Date PENDING
	Action 🖉 💇

Viewing Discrepancy History

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

To view the discrepancy history:

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

				Rem F	ote Data C Read-Only	Capture v User Gui
		- Details				
			Related Value	History		
screpancy History						
Date	Description	Updated By	Review Status	Comment	Resolution Reason	Resolution Comment
Date 12-MAR-2008 14:31:15	Description Value of 195 for Systolic Blood Pressure in mnHg above expected maximum of 180	Updated By Site Train	Review Status CRA Review	Comment 195 is the patient's systolic blood pressure. Can the patient remain in the study?	Resolution Reason	Resolution Comment
Date 12-MAR-2008 14:31:15 28-JAN-2008 16:19:17	Description Value of 195 for Systolic Blood Pressure in mmHg above expected maximum of 180 Value of 195 for Systolic Blood Pressure in mmHg above expected maximum of 180	Updated By Site Train Train Cra10	Review Status CRA Review INV Review	Comment 195 is the patient's systolic blood pressure. Can the patient remain in the study? Per the protocol, blood pressure must remain within the acceptable limits specified or the subject must be removed from the study.	Resolution Reason	Resolution Comment

• When finished viewing the history, click the Close button

Viewing Investigator Comments

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

Subject	t 1021005 Doc# R7926101	Chack i	Fentire Page	Discrepancy	Investigator Cor	nment
Visit Name	VISIT 1 Visit# 110 . 0	Clieck		⊜ ⊚ ov	1 2 3	R
Medic Please rec	al History None			List Other Tex	xt (row 1)	
Body	Body System Codes: 1-Skin 6=Endocrine/Metabolic 11=Hepatic 2=Head,Eyes,Ears,Nose,Throat 7=Genitourinary 12=Allergic 3=Respiratory 3=Neurological 13=Psycholigical/Psychiatic 4=Cardiovascular 9=Bload/Jumphatic 99=Other 5=Gastrointestinal 10=Musculoskeletal	2				
System Code 1 I	Condition/Disgnosis 3C/ZEMA	Date Started (dd/mmm/yyyy) 12 DEC 2007	Date Stopped (dd/mmn/yyy	▶		History

To view a comment:

• On an open eCRF, select the Investigator Comment **Highlight**, from the dropdown list in the top left corner of the eCRF.





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

History

Viewing Audit History

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

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

To view the history of a data field:

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



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





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

4	Blood Pressure: 1	95 / 80 mm systolic diastolic 65 beats permin	Hg Temperat Wei n Heig	ure 98.6 V 252 11: ght 68	F C CM VIN	•
Audit History: Weigh	ıt		•		≪ < 0/1	> >
Date	Changed From	Changed To	Ву	Reason	Comment	Details
14-JAN-2008 14:04:2	260	252	Site Train	DATA ENTRY ERR		

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

CRF Search Criteria

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

On the Casebook and Review tabs, CRF search criteria fall into two subcategories:

1. CRF Status Criteria

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

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



2. CRF Source Criteria

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

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

tient Casebooks								
Search : 6 Par	tients Selected F	rom Home Page						
Patient:	Range		Assigned Book Any	Show	All	V		
CRF Status:	Entry All	•	Discrepancy All	▼ A;	proval All	•	Verification All	•
CRF Source:	Casebook All	Visit All	CRF Name	1	•			
								Clear Go
Casebook Spre	adsheet							

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

Patient	Retore			Assigned Book	Any P	Show At	V		
r strong	marge	6	-	Mangalou book	enty 🔛	5104 [-1		and the second second	
CRF Status:	Entry	Entry Complete	*	Discrepancy Activ	0	Approval All	-	Verification AI	-
CRF Source:	Casebook	Al	Visit AL	· CRF	Name Al	-	6		

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



= Se	earch	: 6 Patients Sele	ected From Home Pa	ge					
	Pati	ient: Range	·	Assigned I	Book Any	Show All	×		
C	RF Sta	itus: Entry	Entry Complete	Discrepancy	Active	Approval	All	Verification All	•
CF	F Sou	rce: Casebook	All Vis	sit 🛛 🔳	CRF Name All				Clear Go
Case	book	Spreadsheet							
Patie	nts:	Previous 1-3	of 3 🔻 Next 📀	Casebo	ok View: RDC453	8V1 🔽 Vis	it: VISIT 1 💌	CRFs: SPrev	ious 1-1 of 1 💌 Next 🛞
Select	Patie	ents and Gene	erate Patient Data Repo	t 🔽 Go 📝	dd Visit Page	Add Other Page	Refresh		
Select	AI	elect None							
		Patient				VISIT 1			
Select	8	Number	Med His						
		1021001							
		1021002	9						
		1021005	9						

Accessing Special Listings

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

LISTING / AE for	Patient 1023	070				
Visit		CRF		Verbatim		Open
Name	Date	Name	Row	Term	Auxiliary Information	CRF
ADVERSE EVENTS		ADVERSE EVENT DETAIL	1	ACID REFLUX	Day Adverse Event Start Date: 11 Month Adverse Event Start Date: MAR Year Adverse Event Start Date: 2009 Day Adverse Event Stop Date: Month Adverse Event Stop Date: Year Month Event Stop Date: Frequency: 2 Outcome of Adverse Event: 2 Treatment Required: 1 Intensity: 2 Action Taken with Study Treatment: 3 Causality: Termination Due to this AE7: 0 Serious Event: 0 Hospitalization: Hospitalization: Initial or Prolongation: Day of Admission Date: Month of Admission Date: Zear of Admission Date: Day of Discharge Date: Month of Discharge Date: Year of Discharge Date: Life Threatening: Congenital Anomaly: Important Medical Event: Persis or Signif Disability/Incapacity: Results in Death: Other Reason: Day of Death Date: Month of Date: Month Date: Year of Death Date: Was an Autopsy Performed: Was a Death Cettricate Completed: Other Specify: SAE Abate after Study Drug Stopped! SAE Reoccur after Reintroduction of Drug: Day of Lext Date: Year of Drug Restarted Date: Year of Drug Stopped Date: Day of Drug Restarted Date: Denscription of Adverse Event (cont): Umrelated Relationship to Study Drug Stopped Description of Adverse Event Description of Adverse Event (cont): Umrelated Relationship to Study Drug Stopped: Specify Con Med/Disease Wink Caused SAE: Umrelated Relationship Specify:	l 📰
ADVERSE EVENTS.1		ADVERSE EVENT DETAIL	1	ANXIET	Day Adverse Event Start Date: 02 Month Adverse Event Start Date: MAR Year Adverse Event Start Date: 2009 Day Adverse Event Stop Date: Month Adverse Event Stop Date: Year Month Event Stop Date: Frequency: 2 Outcome of Adverse Event 1 Treatment Required: 1 Intensity: 2 Action Taken with Study Treatment Causality: Termination Due to this AE7: 0 Serious Event: 0 Hospitalization: Hospitalization: Initial or Prolongation: Day of Admission Date: Month of Admission Date: Year of Admission Date: Day of Discharge Date: Month of Discharge Date: Year of Discharge Date: Life Threatening: Congenital Anomaly: Important Medical Event: Persit or Signif Disability/Incapacity: Results in Death: Other Reason: Day of Death Date: Month of Death Date: Year of Discharge Date: Vear of Discharge Date: Life Threatening: Congenital Anomaly: Important Medical Event: Persit or Signif Disability/Incapacity: Results in Death: Other Reason: Day of Death Date: Month of Death Date: Year of Dueat Date: Was an Autopsy Performed: Was a Death Certificate Completed: Other Specify: SAE Abate after Study Drug Stopped Date: Day of Drug Restarted Date: Month of Drug Restarted Date: Year of Drug Restarted Date: Month of Date I Date: Was of Date: Month of Drug Restarted Date: Month of Date: Daver of Date I Date: Vear of Drug of Sequelae: Description of Adverse Event: Description of Adverse Event (cont): Unrelated Relationship Socify:	
ADVERSE EVENTS.2		ADVERSE EVENT DETAIL	1	BACK PAIN	Day Adverse Event Start Date: 03 Month Adverse Event Start Date: MAR Year Adverse Event Start Date: 2009 Day Adverse Event Stop Date: Month Adverse Event Stop Date: Year Month Event Stop Date: Frequency: 2 Outcome of Adverse Event 2 Treatment Required: 1 Intensity: 1 Action Taken with Study Treatment: 3 Causality: Termination Due to this AE7: 0 Serious Event: 0 Hospitalization: Hospitalization: Initial or Prolongation: Day of Admission Date: Month of Admission Date: Zev of Date: Date: Day of Discharge Date: Nonth of Event Discharge Date: Year of Discharge Date: Life Threatening: Congenital Anomaly: Important Medical Event: Persis or Signif Disability[Incopacity: Results in Death: Other Reason: Day of Death Date: Month of Death Date: for Signif Disability[Incopacity: Results in Death: Other Reason: Day of Death Date: Month of Date: Year of Drug Stopped! SAE Reoccur after Reinbrduction of Drug: Day or Month of Drug Stopped Date: Year of Drug Stopped Date: Day of Drug Restarted Date: Description of Adverse Event (cont): Umerated Date: Vear Study Drug Stopped: Specify Con Med/Disase Winki Caused SAE: Umerated Relationship Specify: Study Drug Stopped: Specify Con Med/Disase Winki Caused SAE: Umerated Relationship Specify:	l III

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



From the Review tab:

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

_ Sear	ch		
Patient	1021001	Listing Type	LISTING / AE LISTING / AE LISTING / CM LISTING / MH

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

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

ial Listings						
Study RDC453V1	Site 102					
Search						
Patient 102307	0 🔍	Listing Typ	pe	LISTING / AE 💌		Go
LISTING / AE for	Patient 1023	070				
			1			
VISI Name	Date	CRF Name	Row	/ Verbatim Term 🔺	Auxiliary Information	Open CRF
ADVERSE EVENTS		ADVERSE EVENT DETAIL	1	ACID REFLUX	Day Adverse Event Start Date: 11 Month Adverse Event Start Date: MAR Year Adverse Event Start Date: 2009 Day Adverse Event Stop Date: Month Adverse Event Stop Date: Year Month Event Stop Date: Frequency: 2 Outcome of Adverse Event: 2 Treatment Required: 1 Intersity: 2 Attion Taken with Study Treatment: 3 Causality: Termination Due to this AE?: 0 Serious Event: 0 Hospitalization: Hospitalization: Day of Admission Date: Month of Admission Date: Vear of Admission Date: Month of Admission Date: Month of Admission Date: Month Adverse Event: 0 Hospitalization: Hospitalization: Day of Discharge Date: Month of Discharge Date: Month of Discharge Date: Month of Discharge Date: Month of Death Date: Year of Admission Date: Day of Death Date: Month of Death Date: Year of Discharge Date: War of Death Date: Other Reason: Day of Death Date: Month of Death Date: Year of Death Date: War of Adverse Event Year of Drug Stopped Date: SAE Reoccur after Reintroduction of Drug: Day o: Month of Drug Stopped Date: Year of Drug Stopped Date: Type of Sequeles: Description of Adverse Event (cont); Unrelated Relationship to Study Drug: Description of Adverse Event Description of Adverse Event (cont); Unrelated Relationship to Study Drug: Description of Durgs Day o: Month of Drug Stopped Date: Year of Drug Stopped Date: Type of Sequeles: Description of Durgs Day o: Drug Date: Type of Sequeles: Description of Durgs Day o: Drug Adverse Event Date: Description of Adverse Event (cont); Unrelated Relationship to Study Drug: Description of Durgs Description of Adverse Event (cont); Unrelated Relationship to Study Drug: Description of Date: Description of Adverse Event (cont); Unrelated Relationship to Study Drug: Description of Date: Description of Date: Des	

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

From the Home or Casebooks tab:

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



LOGGING OUT OF OC RDC

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

To Log out:

O	RACL		DC Onsite		
				Logout references Change Password	Contact U
ome	Casebooks	Review	Reports		
lome ≻				Log	ged in as Si

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





OC RDC TRAINING SUPPORT

Training Options & Access Requests

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

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

Training Materials

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

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



Need Technical Help? CALL THE PPD EDC SUPPORT CENTER



EDC Support Center Phone Numbers

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

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

Version 1.0 20th Jul, 2010