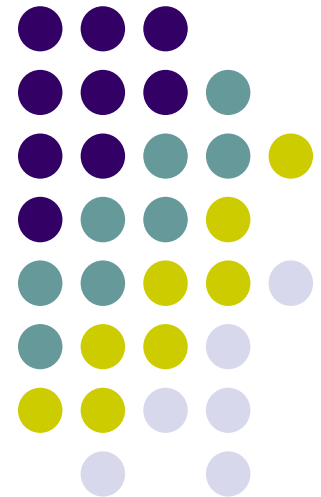


Introduction to C³D

Harris IT Services

Rev June/2012



Introduction

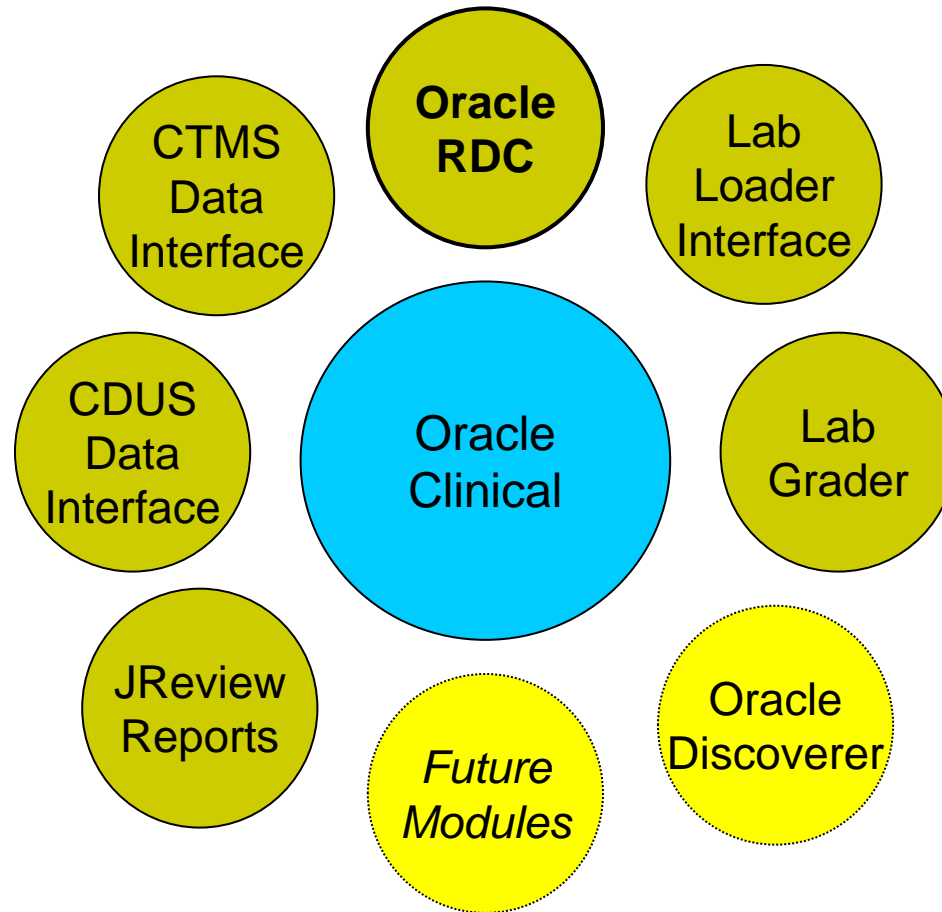
- C³D - **C**ancer **C**entral **C**linical **D**atabase
- Support
- eCRFs Instructions Manual
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval

What is C³D

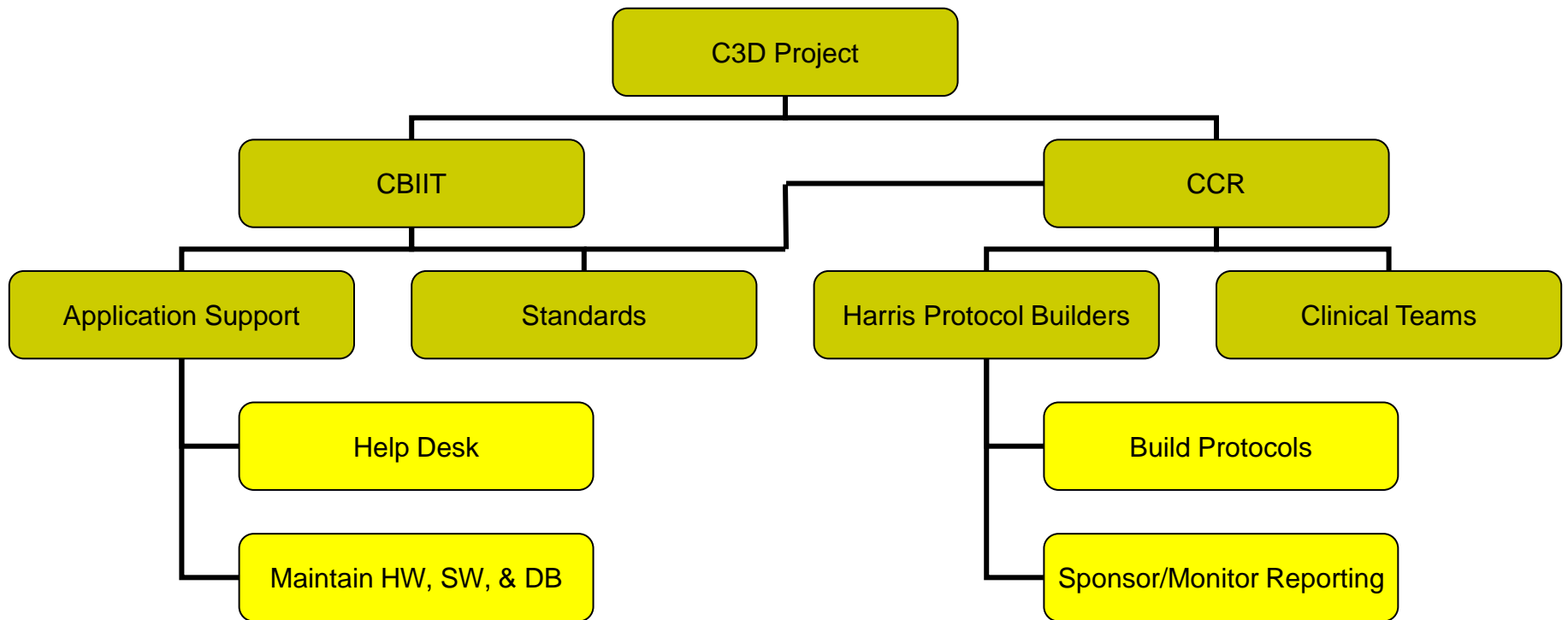


- Web-based Clinical Trials Data Management System
- RDC (Remote Data Capture) On-site
 - Web Based Data Entry
- C³D supports data standardization, reuse, sharing, and interoperability through electronic Case Report Forms (eCRFs) based on Common Data Elements (CDEs)
- Based on Industry Standard Technologies

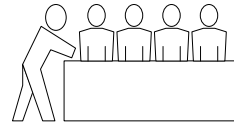
Cancer Central Clinical Database C³D



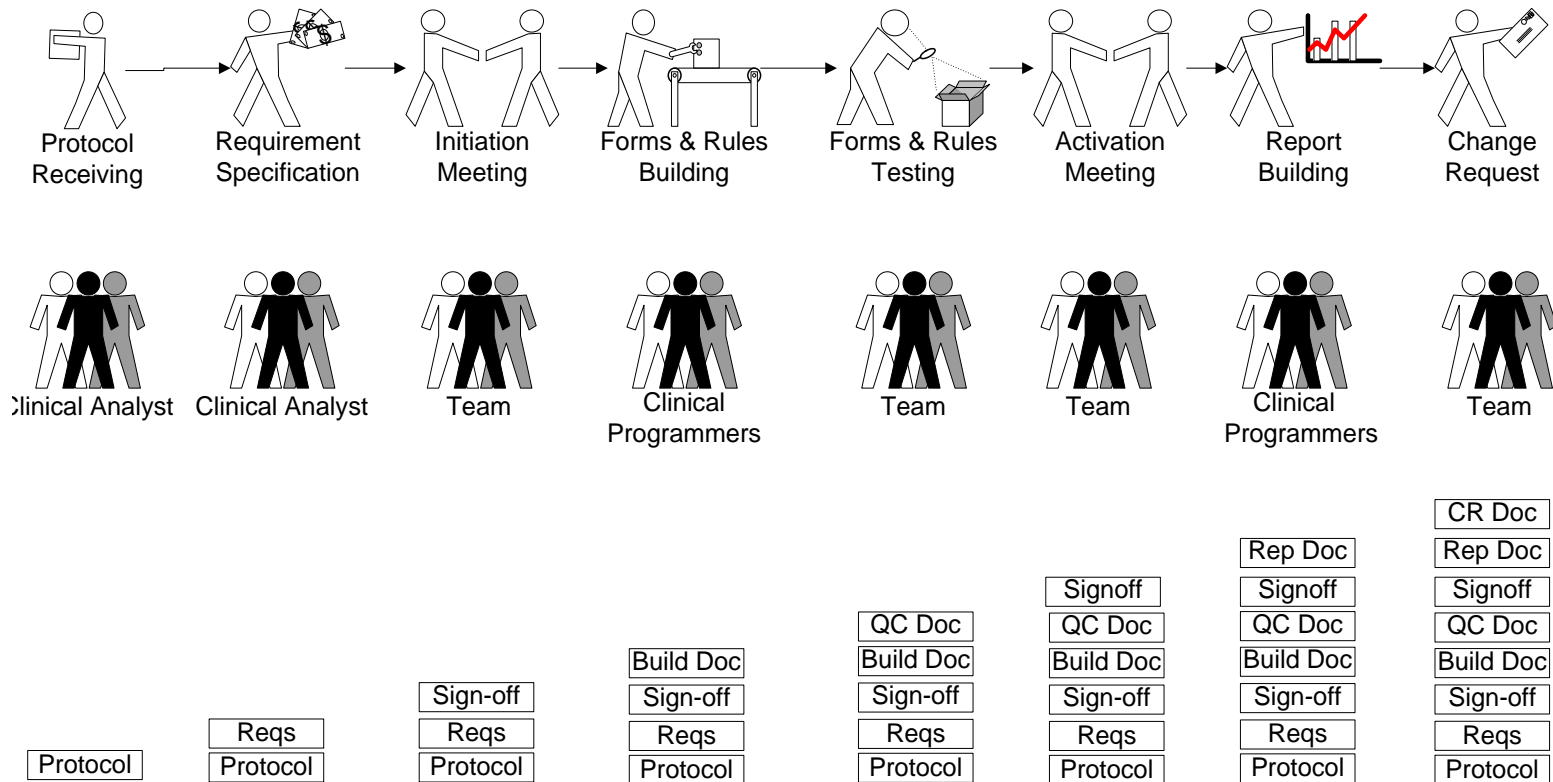
C³D Organization



Designing Protocols in C³D



Control & Configurations Management Group (CCMG)



CCR Standard Case Report Forms

- Library of Standard Forms & Rules is available as a starting point to build protocol specific forms & rules
- Detailed Instructions are available for each Standard Form <https://ccrod.cancer.gov/confluence/x/9QiJAw>
- Each Instructions includes
 - eCRF Screen Shot
 - General Description
 - Field Specific Description (Mandatory, Derived, etc.)
 - Validation/Derivation Rules

eCRF Instructions Manual

Contents
<ul style="list-style-type: none"> • Purpose • Procedures eCRF • Validations • Derivations

Purpose

Record the results of the procedures that are performed as part of the protocol. All laboratory results are to be recorded on the appropriate lab CRF. All procedures that are done as a result of an adverse event are to be recorded on the concomitant measures CRF

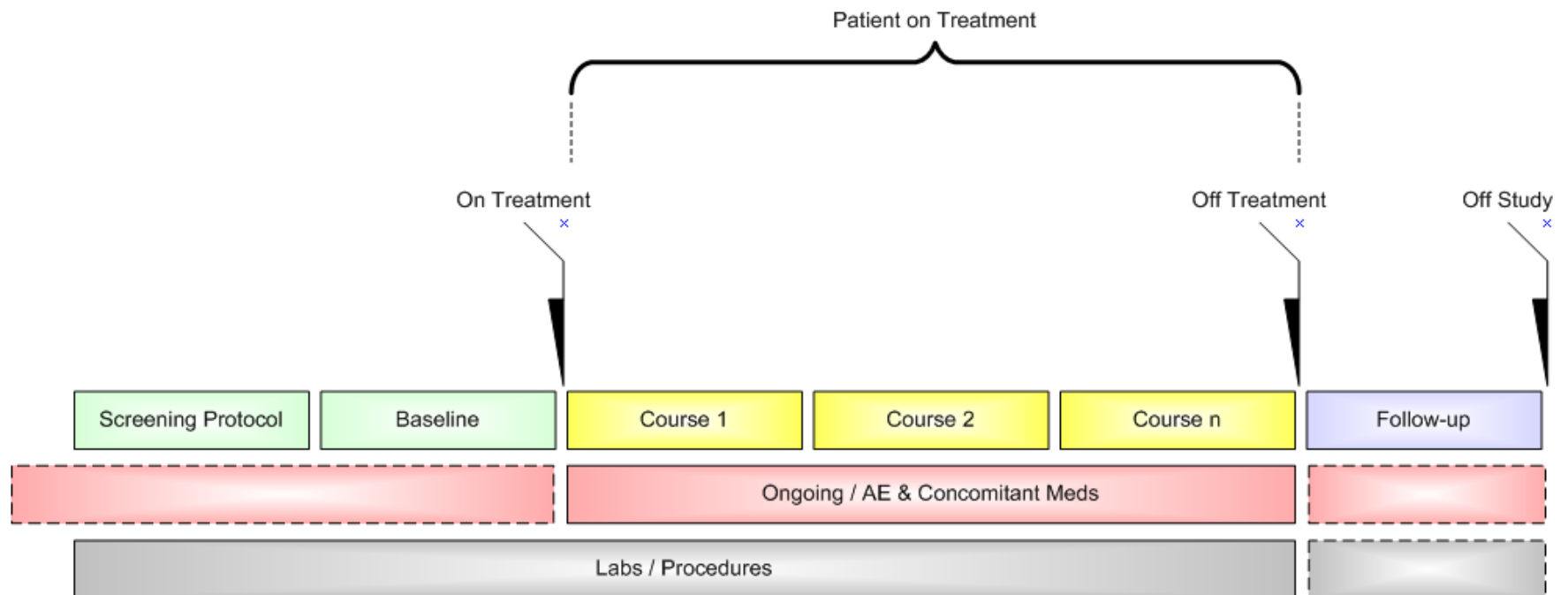
Procedures eCRF

The left screenshot shows a table with columns: VISIT, PROCEDURE, DATE, and a dropdown menu. The right screenshot shows a detailed form with a grid for recording procedure results, including columns for PROCEDURE, DATE, and a dropdown menu.

Field Name	Description / Instructions	Format
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date field.	DD-MMM-YYYY
Course # ^(d)	Indicates the course number the procedure is related to based on their date and time.	5 digits

C³D Protocol Phases

C3D Study Phases



Role Based Access

Access => Role	Browse	Enter Data	Manage Discrepancy	Verify eCRF	Approve eCRF
PI	Yes	No	No	No	No
Research Nurse	Yes	Yes	Yes	Yes	No
Data Manager	Yes	Yes	Yes	No	No
Monitor	Yes	No	Yes	No	Yes
QA	Yes	No	No	No	No
Protocol Builders	Yes	Yes	Yes	No	No

C³D Login Web Pages

- C³D is Accessible Worldwide
- C³D Production Login page:
<https://octrials.nci.nih.gov/opa45/rdclaunch.htm>
- C³D provides a separate Data Entry environment to test protocol design
 - Test Login page:
<https://octrials.nci.nih.gov/opa45/rdclauncht.htm>

RDC Onsite

Launch Oracle Clinical RDC 4.5 - Windows Internet Explorer

https://occlinical.nci.nih.gov/opa45/rddlaunch.htm

File Edit View Favorites Tools Help

Launch Oracle Clinical RDC 4.5

Oracle Pharmaceutical Applications

RDC 4.5

Login

RDC Onsite

[Change Password](#)

[Clear Cache](#)

[Login help](#)

For supported browsers and operating systems check with your system administrator.

*****WARNING*****

- You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.
- Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

Click on RDC Onsite button

Oracle Clinical Task Work Flow

[Downloads](#)

[Life Sciences](#)

[OCUG](#)

RDC Online Documentation

Plugin download page

Oracle Life Sciences

Oracle Clinical User Group

Login

RDC Onsite: Login - Windows Internet Explorer

ORACLE® RDC Onsite Help

Enter User Name, Password and click on Login button

*User Name

*Password

Login

WARNING

- You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage

Username & Password

- Username is of the format **ops\$smiths**
- Password has to be 8 characters starting with a letter and containing **at least one number and one special characters** (e.g. ! #)
- About C³D Password
 - **Do not share the password with others!**
 - Password needs to be changed the first time you login
 - Password expires every 3 months and needs to be changed
 - Account gets locked upon three unsuccessful attempts

C³D Support

- CBIIT provides the first line of support for C³D related issues
- Contact
 - Email: ncicbiit@mail.nih.gov
 - Phone: 240-276-5541
- Protocol specific issues are escalated to the Protocol Builder by CBIIT
- Changes to Standards are escalated to Controls & Configuration Management Group (CCMG)

C³D Support

ORACLE[®] RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Logged in as Ramesh Kanagaraja(Site user, OCPROD); Last Refresh 26-Oct-2011 15:43:58

Study and Site CCR_ROS_2011_V1 NCI Go Study and Site Summary

News
No Records Found

Activities
[Review 1 Active Discrepancies](#)
[Review Investigator comments](#)

My Study Information
[App Support Tickets](#)
[C3D Enhancement Form](#)
[OCUG - Oracle Clin Users Group](#)
[21 CFR Part 11](#)
[eCRF Instructions Manual](#)
[Search on web](#)

Patient Selection List

+ Patient Search **Support Contact**

Patients

Select Patients and... Open Patient Casebooks Go **Change Password**

Select All Select None

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	X1		Unassigned
<input type="checkbox"/>	X2		Unassigned
<input type="checkbox"/>	X3		Unassigned
<input type="checkbox"/>	X4		Unassigned
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>	X7		Unassigned
<input type="checkbox"/>	X8		Unassigned
<input type="checkbox"/>	X9		Unassigned
<input type="checkbox"/>	X10		Unassigned

Select Patients and... Open Patient Casebooks Go

About RDC 4.5.3 Home Casebooks Review Reports Logout Preferences Change Password Help Copyright © 2000, 2007, Oracle. All rights reserved.

Home Page Activities

- Choose a Different Study / Site
 - Access to studies is controlled by user role
 - C3D remembers that last study used in prior login
 - Select Study and Site from dropdown and click **Go**
- Activity Links
 - Review ##,### Active Discrepancies
 - Review Investigator Comments
- Specify Patient Search Criteria
 - Enter a range of patient positions and/or
 - Enter a patient reference
(ex: %123% to search for patients with 123 in their MRN) and/or
 - Casebook and/or
 - Discrepancy Status and/or
 - Patients with data entered or without data entered
- Select Patient(s) and Action
 - Review Casebook
 - Review Discrepancies
 - Review Investigator Comments
 - Generate Patient Data Report
 - Generate Blank Casebook Report

Home Page Activities


The screenshot shows the Oracle RDC Onsite Home page. The browser title is "RDC Onsite: Home - Windows Internet Explorer". The page header includes the Oracle logo and navigation links: Home, Casebooks, Review, Reports. A user is logged in as Marcelo Fontinha. The page is for Study and Site CCR_ROS_2011_V1. Key activities are highlighted with yellow callout boxes:

- Choose Different Study / Site**: Points to the "Study and Site" dropdown menu.
- Specify Patient Search Criteria**: Points to the search filters including "Assigned Book" and "Discrepancy Status".
- Activity Links**: Points to the "Activities" section with links like "Review 279 Active Discrepancies".
- Select Specific Patients**: Points to the "Select" column in the patient table.
- Specify Action:**
 - Open Casebook;
 - Review Discrepancies, etc.Points to the "Select Patients and..." dropdown menu.

The "Patients" table contains the following data:

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	1010001	14-Nov-2011 08:39:03	Unassigned
<input type="checkbox"/>	1010002	10-Nov-2011 11:17:54	Unassigned
<input type="checkbox"/>	1010003		Unassigned
<input type="checkbox"/>	1010004	08-Nov-2011 18:04:27	Unassigned
<input type="checkbox"/>	1010005		Unassigned
<input type="checkbox"/>	1010006	04-Nov-2011 12:49:31	Unassigned
<input type="checkbox"/>	1010007		Unassigned
<input type="checkbox"/>	1010008	04-Nov-2011 12:50:55	Unassigned
<input type="checkbox"/>	1010009		Unassigned
<input type="checkbox"/>	1010010		Unassigned

Patient Search Criteria and Selection

- Specify Patient Search Criteria
 - Patient Position range
 - Patient Reference (MRN)
 - Assigned Book (common for Donor / recipient Studies)
 - Discrepancy Status (All, Active, Other, Open, Clean)
 - Patients with data entered or patient with no data entered
- Click on Go button to search and list Patients matching criteria
- Select Patients by placing checkmark next to person icon/patient position
- Select one of the dropdown options:
 - Open Patient Casebooks
 - Review Discrepancies
 - Review Entered CRFs
 - Review Investigator Comments
 - Generate Patient Data Report
 - Generate Blank Casebook Report
- Click on the **Go** button next to the dropdown
- Entering data for a new patient:
 - Place a checkmark next to the appropriate patient position (the icon indicates that the patient position has no data.
 - Click on the Go button next to the dropdown 
- **Quick Tip:**
 - Protocol Amendments may require different DCI Book. Use Search option to pick the appropriate book.

Navigating Casebook

- Casebook List
 - Lists available Casebooks
 - Click on dropdown list to select a different Casebook
- Visit List
 - Lists Casebooks Visits
 - Click on dropdown list to select a different Visit
- Casebook Visit Layout
 - Patients along Rows with identifier on the left
 - Visit's eCRFS along Columns; pull down for additional visits
- Use the CRFs dropdown to view the additional Visit CRFs
- Click on a Casebook eCRF icon to open it

RDC Casebook

Casebook List

Visits List

eCRF within a visit

Patients listed on the left

Select	Patient Number	Elig	Enroll	MRN	Medhist	Prior Rad	Visit	Prior Tx	Symptom	Phys Scrn
<input type="checkbox"/>	1010001						SCREENING			
<input type="checkbox"/>	1010002						SCREENING			
<input type="checkbox"/>	1010003						SCREENING			
<input type="checkbox"/>	1010004						SCREENING			
<input type="checkbox"/>	1010005						SCREENING			

Patient Casebook Search Criteria

- Allows for additional Casebook Search Criteria not found in the Home Page Patient Search
 - CRF Status
 - Data Entry
 - Discrepancy
 - Verification
 - Approval
 - CRF
 - Casebook
 - Visit
 - CRF Name
- Specify the Criteria and Click on **Go** button

Patient Casebook Search Criteria

RDC Onsite: Patient Casebooks [T] - Windows Internet Explorer

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Logged in as Ramesh Kanagaraja(Data management role, OCPRD); Last Refresh 19-Oct-2011 17:04:04

Study and Site CCR_ROS_2011_V1 NCI Go

Patient Casebook Search Criteria

Study and Site Summary

Patient Casebooks

✓ TIP Perform search to retrieve patient data

Search

Patient: Range [] - [] Assigned Book Any Show All

CRF Status: Entry All Discrepancy All Approval All Verification All

CRF Source: Casebook All Visit All CRF Name All

Clear Go

Casebook Spreadsheet

Patients: Previous Next Casebook View: RDCONSITE_BOOK Visit: Screening CRFs: Previous Next

Select	Number	Patient									

Home Casebooks Review Reports Logout Preferences Change Password Help

About RDC 4.5.3 Copyright © 2000, 2007, Oracle. All rights reserved.



Important eCRF Icons

- Square icon represents manual entry
- Round icon represents automated entry (batch loaded lab data or data migrated from legacy system)
- An eCRF just created, but without data has no lines within the icon (Created Status)
- Partially entered eCRF has lines across half of the icon (Entry Started Status)
- Completed eCRF have lines across the whole icon (Entry Complete Status)
- Blank Square icon indicates eCRF has been marked blank
- Red icon indicates one or more open discrepancies

eCRF Icons

RDC Icon Explanation								
	Entry expected	Marked Blank	Created	Entry started	Entry complete	Pass 2 started	Pass 2 complete	Batch Loaded
Entry Status:								
Discrepancies:		Active		Other				
Verification:		Requires Re-verification		Verified				
Approval:		Requires Re-Approval		Approved				
Locking:		Locked						
Unplanned:		Unplanned CRF						

Entering New Patient Data

- A. From the C³D Home Page, place a checkmark next to a patient position with this icon  and click on the **Go** button to go to the Casebook or;
 - B. From the Casebook Page, expand the Search section, click on the **Clear** button, select **Patients with no Data Entered** from the **Show** dropdown list and click on the **Go** button.
- On the row for the desired patient position, click on an empty eCRF icon with a green arrow  to begin data entry in a new eCRF.
 - **Quick Tips:**
 - The total number of Patients available for entry are governed by protocol accrual ceiling. Request additional patient numbers if protocol is amended and accrual ceiling increased.
 - It is a good practice to use the patient numbers in sync with those assigned by Central Registration Office (CRO).

Entering New Patient Data

The screenshot displays the ORACLE RDC Onsite web application. At the top, there is a navigation bar with 'Home', 'Casebooks', 'Review', and 'Reports' tabs. A search bar is present with a dropdown menu set to 'Patients with no data entered'. Below the search bar, there are several filter options for Patient, CRF Status, and CRF Source. The main content area is titled 'Casebook Spreadsheet' and shows a table of patient data for the 'SCREENING' visit. The table has columns for Patient Number, Eligibility, Enrollment, and various data points like Prior Surg, Prior Thrp, Prior Tx, Symptom, and Phys Scrn. A yellow callout box points to the 'Patients with no data entered' dropdown, and another yellow callout box points to the eCRF icons in the table.

Search for Patient Positions with no data entered

Click on eCRF icon to begin data entry

Select	Patient Number	Elig	Enroll	Prior Surg	Prior Thrp	Prior Tx	Symptom	Phys Scrn
<input type="checkbox"/>	1010005							
<input type="checkbox"/>	1010007							
<input type="checkbox"/>	1010009							

Entering New Patient Data

- Visit Date is mandatory for most forms:
 - Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc. Refer to the eCRFs Instructions Manual.
 - Partial dates are not acceptable when a visit date is mandatory
 - In Lab CRFs, Visit Date is the Lab Sample Collection Date.

Electronic CRF (eCRF)

ORACLE RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: RDCONSITE_BOOK- (Ramesh Kanagaraja - Site user) Previous CRF Next CRF

Highlight: All Discrepancies Page 1/2

CENTER FOR CANCER RESEARCH Study: CCR_ROS_2011_V1 Site: NCI Visit: SCREENING Patient: X1

Visit Date: Mark CRF Blank: Comment:

Section blank?

ENROLLMENT

DEMOGRAPHY

Gender: Date of Birth: Age at Entry:

Race: Choose all races that apply

Race 1:
Race 2:
Race 3:
Race 4:
Race 5:
Ethnicity:

Registering Institute:
Patient Subgroup:
Country Code:
Method of Payment:

DISEASE AND CONSENT

Primary Disease Site:
Disease Term:
Date of Diagnosis:
Histology/Cytopathology:
Date Informed Consent Signed:
Treatment Assignment Code:
Date from which to Start Including labs:

Disease Stage at Entry: **II A**
T Stage: N Stage: M Stage:
Date of Confirmation of Histology:
Grade of Histology:
Date of Informed Consent Version:

Doc# R210649401 Status Created Verified Approved Locked CRF Page 34.1

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Annotations:

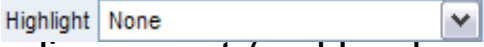









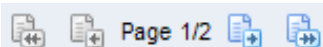

- Toolbar:** Located at the top right of the application window.
- Enterable field:** Points to the Gender input field in the Demography section.
- Non-enterable/Derived field:** Points to the Age at Entry input field in the Demography section.
- Red background indicates a Discrepancy:** Points to the Disease Stage at Entry field, which contains the value "II A" on a red background.
- eCRF Scrollbar:** Points to the vertical scrollbar on the right side of the form.

Electronic CRF (eCRF)

- eCRF may contain multiple pages or sections. Use scrollbars or toolbar page navigation icons.
- eCRF Header and Footer display eCRF identification information
- Visit Date is mandatory for most forms:
 - Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc. Refer to the eCRFs Instructions Manual.
 - Partial dates are not acceptable when a visit date is mandatory.
- **Quick Tip:**
 - Up to 3 eCRFs can be open for simultaneous data entry. Additional eCRFs are open in read-only mode.

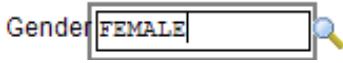

Electronic CRF (eCRF)

- Toolbar features:



-  Use Highlight dropdown list to highlight fields that are discrepant (red background), investigator comments (Purple), or changed since last verification or approval or have audit-trail (Blue)
-  Add Manual Discrepancy to selected field
-  Add Investigator Comments to selected field
-  Delete Selected Row
-  Blank Flag Tool (Blank / un-blank eCRF's section(s) or entire eCRF)
-  Verify, Un-verify and Review Verification History
-  Approve, Un-approve and Review Approval History
-  Delete eCRF
-  Print eCRF
-  Save eCRF
-  Navigate eCRF's Pages (First, Previous, Next, Last)
-  Use Close box to close eCRF

- Navigate to another eCRF by clicking on the Next or Previous CRF icons on the top right corner.

Electronic CRF (eCRF)

- Navigate within eCRF by:
 - Use Tab, Shift-Tab, Left Mouse click or scrollbars to navigate within eCRF.
 - Toolbar page navigation icons.
- Fields with magnifying glass  have a pick list of acceptable values. Use the Pick List!
 - With the pick list shown, press **CTRL + F** to search the pick list.
 - An entered value that is not on the pick list will create a discrepancy. If a value needs to be added to the pick list, contact your DM Supervisor.
- Enter Dates as:
 - MMDDYYYY for Current Information
 - MMYYYY for Prior Information is acceptable when complete date cannot be obtained
 - Click on the calendar icon  to display a popup calendar and click on a date.

Tabular eCRF

- Fields shown in a grid layout.
- Normally have multiple pages. Use the Window vertical scrollbar to navigate to another page or use the Toolbar page navigation icons. The image shows a toolbar with four icons: a left arrow with a plus sign, a right arrow with a plus sign, the text 'Page 1/2', and a right arrow with a double plus sign.
- Click on the  Toolbar icon to delete the selected row.

Tabular eCRF

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: BOOK_0_26OCT2011- (Ramesh Kanagaraja - Site user)

Highlight All Discrepancies

Page 1/6

Center for Cancer Research

Study: CCR_ROS_2011_V1
Visit Name: ONGOING
Site: NCI
Patient: X1
Mark CRF Blank
Comment:

Type: AE1 Section b

To Delete a Single Row

ADVERSE EVENT

Num	Course	AE?	Onset	Resolved	CTCAE Term	SOC	Description	Grade	Research	IND	Attribution to							Unexp.			Expedited Report to													
											IDE	Comm.	Rad.	Surg.	Dis.	Other	Other, Specify	AE	DLT	Serious	Action	Therapy	Outcome	IRB	Sponsor	FDA	OBA							
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Doc# R210656001 Status Created Verified Approved Locked CRF Page 75.1

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CRF and Section Blank Checkboxes


- Entire eCRF can be marked Blank.
- Individual sections of eCRF can be marked Blank.
- **Checking Blank Flag will erase any entered information from the eCRF/Section when saving the eCRFs.**
- Blank Flag can be unchecked to enter information.

CRF and Section Blank Checkboxes

ORACLE RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: BOOK_0_26OCT2011- (Ramesh Kanagaraja - Site user) Previous CRF Next CRF

Highlight All Discrepancies Page 6/6

 Study CCR_ROS_2011_V1 Site NCI Patient X1
Visit Name ONGOING Mark CRF Blank Comment

Marking entire eCRF Blank

Section blank?

Marking Section Blank

COMMENTS

Date	Notes
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

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Entering/Viewing Laboratory Data

- Laboratory Data eCRFs are designed with dedicated Visits (Hematology, Urinalysis, etc.) and only one eCRF is planned initially per Visit.
- Additional eCRFs can be added by selecting a Patient and clicking on Add Visit Page.

The screenshot shows the ORACLE RDC Onsite web application interface. The browser title is "RDC Onsite: Patient Casebooks - Windows Internet Explorer". The page header includes the ORACLE RDC Onsite logo and navigation links: Home, Casebooks, Review, Reports. The user is logged in as Marcelo Fontinha (Data management role, OCPROD) with a last refresh time of 15-Nov-2011 08:22:42. The Study and Site is CCR_ROS_2011_V1, NCI. The page title is "Patient Casebooks".

The main content area shows a "Casebook Spreadsheet" with the following controls:

- Patients: 1-6 of 6
- Casebook View: BOOK_0_26OCT2011
- Visit: URINALYSIS
- CRFs: 1-1 of 1

Buttons include: Generate Patient Data Report, Go, Add Visit Page, Add Other Page, Refresh.

The table below shows the patient data:

Select	Patient Number	Urinalysis
<input type="checkbox"/>	1010001	61
<input type="checkbox"/>	1010002	61

Two yellow callout boxes highlight the steps:

1. Select Patient (pointing to the first patient row)
2. Click Add Visit Page (pointing to the "Add Visit Page" button)

Entering/Viewing Laboratory Data

- Click on Continue to confirm the eCRF Page to add.

RDC Onsite: Add Visit Page -- Webpage Dialog

Add Visit Page

Study CCR_ROS_2011_V1 Site NCI

Visit URINALYSIS Patient 1010001

CRFs

Select CRF and

Select CRF Name

Urinalysis

- Select the Sub-visit from the dropdown and click on Apply.

RDC Onsite: Add Visit Page -- Webpage Dialog

Add Visit Page

Study CCR_ROS_2011_V1 Site NCI

Visit URINALYSIS Patient 1010001

Selected CRF Urinalysis

Select Sub-visit 1

https://oconsite.nci.nih.gov/olsa/oc/rdcMod Local intranet

Entering/Viewing Laboratory Data

- Enter the Lab Date (Sample Collection Date).
- Optionally, choose a Lab Source from the Lab dropdown list.
 - **Outside** option is normally to indicate panel was done in a location other than the site.
 - If Units of Measurement and Normal Ranges have been predefined for your site, select it from the list and C³D will automatically populate the UOM and Normal Range.
- Enter the lab Sample Collection Time using military time.

Entering/Viewing Laboratory Data


RDC Onsite DE: 1010001, URINALYSIS, URINALYSIS - Windows Internet Explorer

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)

Highlight: None

page 1



Study CCR_ROS_2011_V1 Patient 1010001

Visit URINALYSIS Site NCI

Comment

Lab Date Mark CRF Blank


Lab Time Section blank?

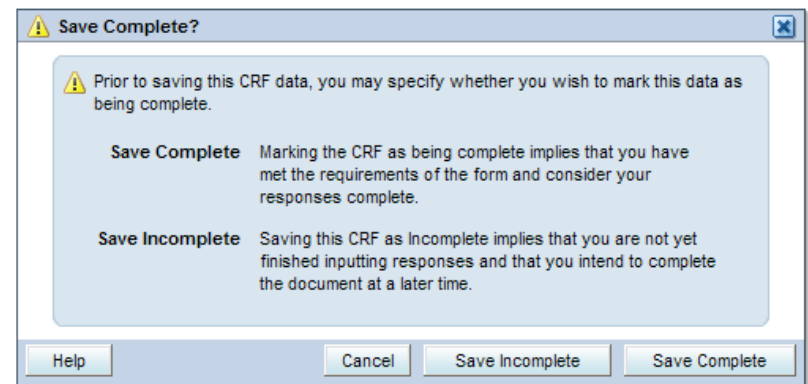
URINALYSIS

Course # Day in Course

Lab Test	Value	UOM	Normal Range (e.g. 1.5-5)	Range Indicator	Grade (Numeric)	Value in	
						Preferred UOM	Preferred UOM
GLUCOSE_UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
PROTEIN_QUAL_UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
UROBILINOGEN_UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Saving eCRF

- Click on the  green floppy disk icon to save the eCRF data.
 - Save Often!! Especially while entering Ongoing Information such as Adverse Events and Concomitant Medications.
- Choose how to save the eCRF:
 - **Save Incomplete**
 - Discrepancies are not created for mandatory fields that have not been touched (cursor no place in field).
 - Batch Validation Discrepancies are not created as well as derived values
 - Verification and Approval cannot be done.
 - **Save Complete**
 - eCRF Status changes to Entry Complete and all Discrepancies and derived values are created.
 - Verification and Approval can be done.
- Audit-trail is always enabled!



- **Quick Tip:**
 - For Ongoing Tabular eCRFs, save as **Complete** once the first row is entered. This will guarantee that batch validation will execute and generate discrepancies related to other eCRFs.

Saving eCRF

The screenshot shows the Oracle RDC Onsite Data Entry interface in a Windows Internet Explorer browser. The browser title is "RDC Onsite DE: 1010001, URINALYSIS, URINALYSIS - Windows Internet Explorer". The page header includes "ORACLE RDC Onsite: Data Entry" and "Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)".

The main content area displays the "CENTER FOR CANCER RESEARCH" logo and patient information: Study CCR_ROS_2011_V1, Patient 1010001, Visit URINALYSIS, Site NCI, and Lab Date 11-NOV-2011. There is a "Mark CRF Blank" checkbox. Below this, there are fields for "Lab" and "Time" (11:11:00) and a "Section blank?" checkbox.

A "Save Complete?" dialog box is open in the foreground. It contains the following text:

Save Complete?

Prior to saving this CRF data, you may specify whether you wish to mark this data as being complete.

Save Complete Marking the CRF as being complete implies that you have met the requirements of the form and consider your responses complete.

Save Incomplete Saving this CRF as Incomplete implies that you are not yet finished inputting responses and that you intend to complete the document at a later time.

The dialog box has buttons for "Help", "Cancel", "Save Incomplete", and "Save Complete".

Two yellow callout boxes are present: one labeled "Save Icon" pointing to the save icon in the browser toolbar, and another labeled "Save Prompt" pointing to the "Save Complete?" dialog box.

Data Entry Change Reason

- Change Reason needs to be specified while changing data on completed eCRF
- Change Reason becomes part of the Audit-Trail along with date of change and user name
- Comments can be provided in the change reason to further explain
- **Quick Tip:**
 - Do not use personnel/patient names or identifiers the comments.

Data Entry Change Reason

The screenshot displays the Oracle RDC Onsite Data Entry interface within a Windows Internet Explorer browser. The browser title bar reads "RDC Onsite DE: X1, OFFSTUDY, SURVIVAL [T] - Windows Internet Explorer". The Oracle logo and "RDC Onsite: Data Entry" are visible in the top left. The page header includes "Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: BOOK_0_26OCT2011- (Ramesh Kanagaraja - Site user)". A navigation bar shows "Page 1/2".

The main content area features the Center for Cancer Research logo and study details: "Study CCR_ROS_2011_V1", "Site NCI", "Visit OFFSTUDY", and "Patient X1". There are input fields for "Visit Date", "Mark CRF Blank" (checkbox), and "Comment". A "Section blank?" checkbox is also present.

The "SURVIVAL" section contains the following fields:

- Date of Death: 19-OCT-2011
- Cause of Death (Presumed): [dropdown]
- Autopsy Results Available?: [dropdown]
- Cause of Death (Autopsy Finding): [dropdown]
- Sites of Disease at Autopsy: [list of 12 empty text boxes]

A "Reason for Change" dialog box is open, showing a dropdown menu with "Data Entry Error" selected and an empty "Comment (optional)" text area. The dialog has "Help", "Cancel", and "OK" buttons. A yellow callout box with the text "Change Reason Prompt" has an arrow pointing to the dialog box.

The footer of the page shows "Doc# R210063701", "Status Entry Complete", "Verified" (checkbox), "Approved" (checkbox), "Locked" (checkbox), and "CRF Page 90.1". The bottom right corner contains the copyright notice: "Copyright © 2000, 2007, Oracle. All rights reserved."

What is a Discrepancy?

- A discrepancy is the failure of entered data to pass a validation check as applied by C³D
- C³D validation checks are defined based on the definition of the fields, logical rules, protocol specifications, and sponsor requirements.

Why Discrepancies?

- Discrepancies are tools to assist teams in programmatically identifying potential data inconsistencies
- Discrepancies facilitate real-time QA of clinical data
- **Quick Tips:**
 - Discrepancies do not cover 100% of possible data inconsistencies.
 - Clinical judgment may supersede discrepancy logic.

C3D Discrepancy Types

- Univariate
 - Generated during data entry/load when data is in some way different from the Question definition (e.g. length, type, range, pick list, etc.)
- Multivariate
 - Based on a condition on one or more fields as defined in a validation rule
 - Generated on-line or when validation rules are run (eCRF must be saved as Complete.)
- Manual
 - Generated by data entry operator seeking clarification on data values

Some Typical Discrepancies

<u>Types</u>	<u>Example:</u>	<u>Resolution</u>
Data Type	Text entered in numeric or date field.	Review Source Document.
Length Problems	Too many characters entered.	Use NIH accepted Abbreviations.
Missing Pick list Values	Generic Agent not present in Concomitant Agent picklist.	Search for alternates, e.g. Generic. Consult Team Lead.
Mandatory Value	Field requires a value, but was left empty.	Refer to Source Document. Design modification.
Partial/Invalid Dates	00-10-2010 entered, but field requires a full data such as 01-01-2010	Refer to Source Documents; Check Day Month Year order; Check that date is not in the future.

Outstanding Discrepancies In a Study

- Total number of Discrepancies in a study are shown in the Home Page Activities section
- Clicking on the **Review ### Active Discrepancies** will present a lists of all discrepancies under the Review Page.
- **Quick Tip:**
 - Data Managers should manage their discrepancies every morning to help ongoing QA of clinical data.

Outstanding Discrepancies In a Study

RDC Onsite: Home - Windows Internet Explorer

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Logged in as Marcelo Fontinha(Data management role, OCPROD); Last Refresh 15-Nov-2011 09:38:00

Study and Site CCR_ROS_2011_V1 NCI Go

Study and Site Summary

News
No Records Found

Activities
[Review 318 Active Discrepancies](#)
[Review Investigator comments](#)


Links
[App Support Ticket](#)
[C3D Enhancement Form](#)
[OCUG - Oracle Clin Users Group](#)
[21 CFR Part 11](#)

Click to view a list of Discrepancies

Patients

Select Patients and... Open

Select All Select None

Select  Patient Number Last Modified Casebook

<input type="checkbox"/>	1010001	15-Nov-2011 09:14:08	Unassigned
--------------------------	---------	----------------------	------------

1-10 of 20 Next 10

Red icon indicates Patient has discrepancies in one or more eCRFs

Home Casebooks Review Reports

CRFs Discrepancies Investigator Comments

Logged in as Marcelo Fontinha(Data management role, OCPROD); Last Refresh 15-Nov-2011 09:40:17

Discrepancies

Study CCR_ROS_2011_V1 Site NCI Patients Selected 6 Total CRFs 26 Total Discrepancies 318





Search

Click to view Discrepancy details

Review Active Discrepancies

Refresh

Previous 1-10 of 318 Next 10

Patient Number	Visit Name	Visit Date	CRF Name	CRF Number	Discr ID	Question / Section	Response	Review Status	Description	Open Detail	Open CRF
1010001	SCREENING	01-Nov-2011	ENROLLMENT	R211026001	328936201	Ethnicity		UNREVIEWED	Value for Ethnicity has not been supplied		
1010001	SCREENING	01-Nov-2011	ENROLLMENT	R211026001					Value for Date of Informed Consent Version not been supplied		

Click to open related eCRF and manage discrepancies

eCRF Containing Discrepancies

- eCRF containing discrepancies are shown in Red icon
- It is a good practice to address discrepant eCRF on an ongoing basis

eCRFs Containing Discrepancies

RDC Onsite: Patient Casebooks [T] - Windows Internet Explorer

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Home > Logged in as Ramesh Kanagaraja(Data management role, OCPROD); Last Refresh 26-Oct-2011 16:40:43

Study and Site 09_C_0214 1190901 Go Study and Site Summary

Patient Casebooks

Search : 10 Patients Selected From Home Page

Casebook Spreadsheet

Patients: Previous 1-10 of 10 Next Casebook View: BOOK_E_30AUG2011 Visit: SCREENING CRFs: Previous 1-10 of 11 Next

Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page Refresh

Select All Select None

Select	Patient	SCREENING									
	Number	Elig_E	Enroll	MRN	Medhist	Prior Rad	Prior Surg	Prior Thrp	Prior Tx	Phys Scrn	Symptom
<input type="checkbox"/>	X1	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X2	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X3	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X4	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X5	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X6	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X7	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X8	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X9	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	X10	1	2	3	4	5	6	7	8	9	10

Select Patients and... Generate Patient Data Report Go Add Visit Page Add Other Page Refresh

About RDC 4.5.3 Home Casebooks Review Reports Logout Preferences Change Password Help Copyright © 2000, 2007, Oracle. All rights reserved.

eCRF Containing Unreviewed Discrepancies are displayed as Red

Discrepancies Tab

- While viewing an eCRF, click on the vertical handle on the right side of the eCRF to open the Discrepancies panel.
- Click on the **Show** dropdown list and select which discrepancies to show.
- Click on one of the discrepancies to view details and highlight / select the related field.
- Click on the discrepancy details **Related Values** button to view the data points involved.
- Click on the **History** button to view the discrepancy history.
- Click on the **Action** dropdown list to route discrepancy to another user/role or to manually close a discrepancy.
 - Manually closing discrepancies is highly undesirable.

Discrepancies Tab

2. Enumerates all discrepancies

Date of Onset	Date Resolved	System Organ Class	CTCAE Term	Symptom Description	Related To Disease
03-NOV-2011	17-NOV-2011		Disseminated intravascular co	Desc03-01	
10-NOV-2011			OTHER		

Discrepant field is selected

1. Click on this handle to open/close the Discrepancy and Investigator Comments Panel

Details of selected Discrepancy

- Description OTHER for CTCAE Term is not in the lookup thesaurus
- Type UNIVARIATE
- Review Status Discrepancy not reviewed by user
- Reason Thesaurus
- Comment By Ramesh Kanagaraja Date 09-NOV-2011 16:54:30

Route or Manually close Discrepancy

How are Univariate Disc. Created?

- Univariate Discrepancies pop-up is presented during data entry when the entered value does not match the field definition.
- Data Entry operator can:
 - Cancel the pop-up and fix the value
 - Or accept the discrepancy
- **Quick Tip:**
 - Univariate Discrepancies are reassessed during Batch Validation for Design Changes.

How are Univariate Disc. Created?

The screenshot shows the Oracle RDC Onsite Data Entry application. The browser title is "RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - Windows Internet Explorer". The application header includes the Oracle logo and "RDC Onsite: Data Entry". Below the header, the study information is displayed: "Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)". A navigation bar shows "Highlight Audit History" and various icons. The main content area features the Center for Cancer Research logo and the following information: "Study CCR_ROS_2011_V1 Site NCI Visit SCREENING", "Visit Date 01-NOV-2011", and "Mark CRF Blank". A yellow box labeled "Univariate Discrepancy Prompt" points to the "Mark CRF Blank" text. Below this is a "Section blank?" checkbox. A "PATIENT IDENTIFICATION" table is visible, with the first row containing "NCIABC" and "414141411". A "Validation Error and Reason for Change" dialog box is open, showing a "Reason Thesaurus" with the description "NCIABC for Institution is not in the lookup thesaurus". The dialog also includes a "Comment (optional)" field, an "Action" dropdown, and a "Review Status" of "Discrepancy not reviewed by user". A "Change Reason" section has a "*Reason" dropdown set to "Data Entry Error" and another "Comment (optional)" field. The dialog has "Help", "Cancel", and "OK" buttons.

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)

Highlight Audit History

CENTER FOR CANCER RESEARCH

Study CCR_ROS_2011_V1 Site NCI Visit SCREENING

Visit Date 01-NOV-2011 Mark CRF Blank

Section blank?

Univariate Discrepancy Prompt

Institution	Patient Medical Reco
NCIABC	414141411

Validation Error and Reason for Change

Reason Thesaurus

Description NCIABC for Institution is not in the lookup thesaurus

Comment (optional)

Action

Review Status Discrepancy not reviewed by user

Change Reason

*Reason Data Entry Error

Comment (optional)

Help Cancel OK

How is are Discrepancies Displayed?

- Discrepant data background is highlighted in red when one of the following eCRF's Highlight dropdown options is selected:
 - All Discrepancies
 - Closed Discrepancies
 - Active Discrepancies
 - Active and Other Discrepancies
- Click on the vertical handle on the right side of the eCRF to open the Discrepancies panel and view the Discrepancy details.

How is are Discrepancies Displayed?

The screenshot displays the Oracle RDC Onsite Data Entry interface within a Windows Internet Explorer browser window. The browser title is "RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS". The page header includes "ORACLE RDC Onsite: Data Entry" and navigation links for "Previous CRF" and "Next CRF". The breadcrumb trail shows "Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)".

A dropdown menu at the top left is set to "All Discrepancies". A yellow callout box labeled "Highlight Discrepancies Options" points to this dropdown. Below the header, the "CENTER FOR CANCER RESEARCH" logo is visible, along with fields for "Study CCR_ROS_2011_V1", "Site NCI", and "Visit SC". A "Visit Date" field contains "01-NOV-2011".

The "PATIENT IDENTIFICATION" section contains a table with two columns: "Institution" and "Patient Medical Record Number". The first row shows "NCIDTC" and "1234567". The value "1234567" is highlighted in red, with a yellow callout box labeled "Discrepant Data Value is highlighted" pointing to it.

On the right side, a "Discrepancy" panel is open, showing a "List" of one item: "Multi". Below it, the "Details" section provides information about the discrepancy:

- Description:** The format for NIH MRN '1234567' is not valid. Please verify.
- Type:** MULTIVARIATE
- Review Status:** Discrepancy not reviewed by user
- Comment:** By Marcelo Fontinha, Date 15-NOV-2011 11:25:49

A yellow callout box labeled "Discrepancy Details" points to the details section. At the bottom of the discrepancy panel, there is an "Action" dropdown and a "Go" button. The footer of the browser window contains the copyright notice: "Copyright © 2000, 2007, Oracle. All rights reserved."

How are Multivariate Disc. Created?

- Multivariate Discrepancies are created based on validation rules programmed in a study
 - Example 1: Create Discrepancy if the entered BSA is not within 10% of the calculated BSA
 - Example 2: Create Discrepancy if Date of Histological Confirmation is before Date of Diagnosis
- **Quick Tip:**
 - Rules available as a standard on each eCRF are summarized in the eCRFs Instructions Manual.
 - Though several standard rules are implemented for each eCRF as specified on the eCRFs Instructions Manual, clinical teams can request them to be turned off or modified to comply with the Protocol.

Evaluation of Multivariate Rules

- Validation Rules are evaluated
 - on-line upon completion of a form, or;
 - during an overnight batch validation session (only data in eCRF saved as Complete are evaluated.)
- Multivariate Discrepancies are displayed in the same manner as Univariate Discrepancies. The Discrepancy Details panel indicates the type of Discrepancy.
- **Quick Tip:**
 - Complex rules run overnight

How to Address a Discrepancy

- Review Discrepancy Text
- Resolve the discrepancy by:
 - Modifying incorrect data and specifying change reason
 - Requesting eCRF Design or Validation Rule Change
- **Quick Tip:**
 - System obsoletes univariate discrepancy automatically when data is corrected.
 - Multivariate Discrepancies are only re-evaluated during Batch Validation.

How to Address a Discrepancy

RDC Onsite DE: X1, SCREENING, BASELINE SYMPTOMS [T] - Windows Internet Explorer

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: BOOK_0_26OCT2011- (Ramesh Kanagaraja - Site user)

Highlight: None Page 1/2

CENTER FOR CANCER RESEARCH Study: CCR_ROS_2011_V1 Site: NCI Visit: SCREENING Patient: X1
Visit Date: 10-OCT-2010 Mark CRF Blank Comment:

Section blank?

BASELINE SYMPTOMS

Date of Onset	Date Resolved	System Organ Class	CTCAE Term	Symptom Description	Grade	Related To Disease		
						Yes	No	Unknown
08-NOV-2011	17-NOV-2011	Blood and lymphatic	Disseminated intravascular c	Desc03-01	2	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
02-NOV-2011			OTHER		1	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Doc# R210688201 Status Entry Complete Verified Approved Locked CRF Page 9.1

Discrepancy Investigator Comment

Show: All Discrepancies 1/1

List

- CTCAE Term (row 2)

Details

Related Values History

Description: OTHER for CTCAE Term is not in the lookup thesaurus

Type: UNIVARIATE

Review Status: Discrepancy not reviewed by user

Reason Thesaurus

Comment: By Ramesh Kanagaraja Date: 09-NOV-2011 16:54:30

Action: Go

Send to CRA
Send to Data Mgt
Close - no resolution
Close - resolved

Fix Data as indicated in the Discrepancy Text

Choose Go to Data Field from Pull Down Menu

Audit Trail

- Use the eCRF Highlight dropdown **Audit History** option to highlight, with blue background, the fields that have audit-trail.
- Then right-click on one of the highlighted fields and select the **Show Audit History** option from the pop-up menu.
- Review the Audit-trail details at the **Audit History Panel** opened at the bottom of the eCRF window.
- **Quick Tips:**
 - Auditing begins as soon as the eCRF is saved.
 - Do not share user IDs and passwords!

Audit Trail

Highlight Audit History Option

Center for Cancer Research
Visit: SCREENING Patient: 1010001
Visit Date: 01-NOV-2011 Mark CRF Blank Comment:

Section blank?

PATIENT IDENTIFICATION

Institution	Patient Medical Record Number
NCIDTC	1234567

Blue background indicates presence of Audit-trail

Audit-trail details

Date	Changed From	Changed To	By	Reason	Comment	Details
15-NOV-2011 11:20:41	414141411	1234567	Marcelo Fontinha	DATA ENTRY ERR		

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Delete eCRF

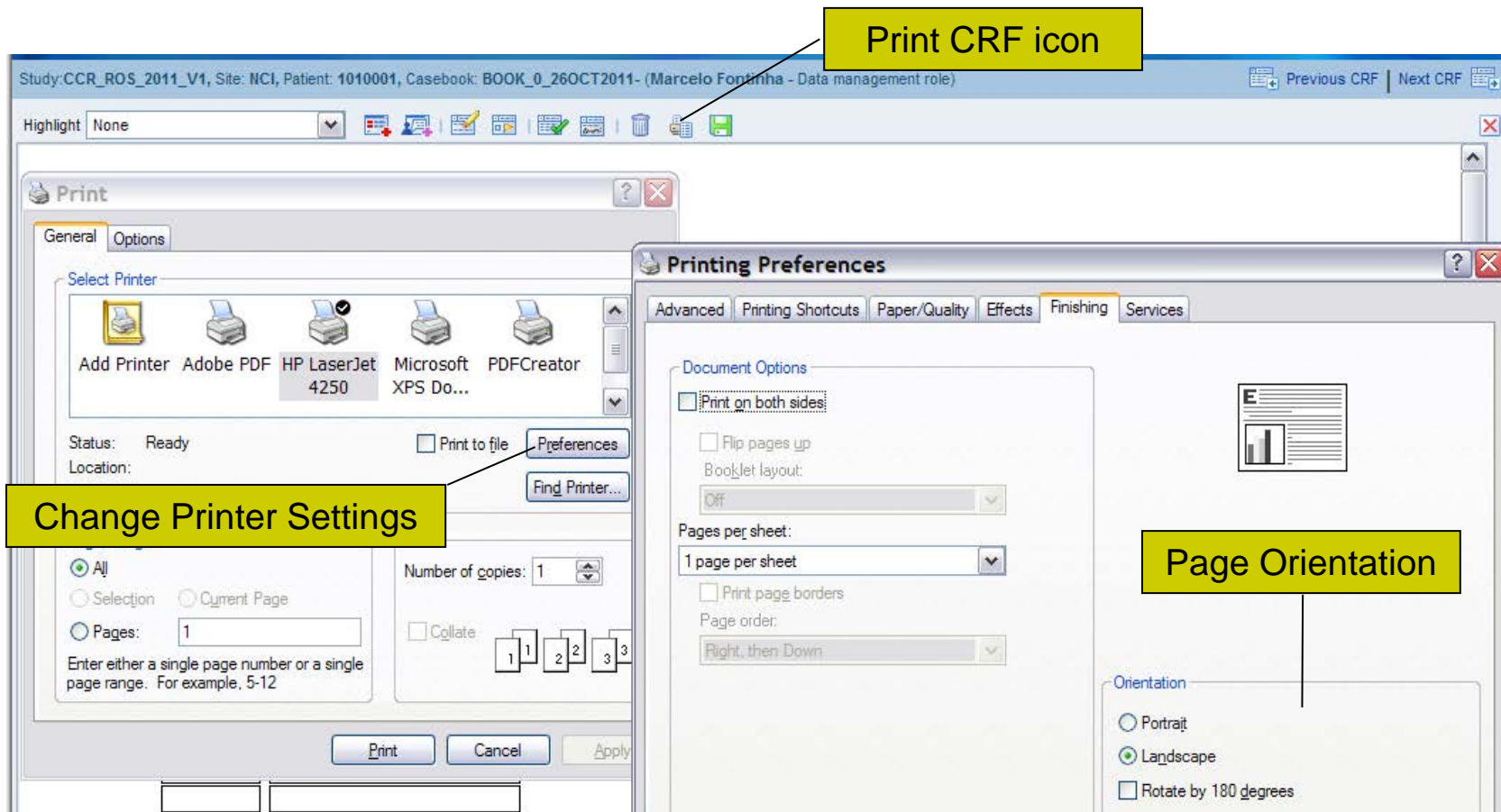
- Click on the **Delete CRF** Toolbar icon to delete the entire eCRF and its data.
- Once deletion is confirmed, eCRF and data cannot be recovered.

The screenshot displays the Oracle RDC Onsite Data Entry application in a Windows Internet Explorer browser window. The browser title is "RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS". The application header shows "ORACLE RDC Onsite: Data Entry" with "Preferences" and "Help" links. The main content area includes the Center for Cancer Research logo, study information (Study: CCR_F, Visit: SCREENING, Patient: 1010001), and a toolbar with various icons. A yellow box labeled "Delete CRF icon" points to the trash can icon in the toolbar. Below the toolbar, there are fields for "Visit Date" (01-NOV-2011), "Mark CRF Blank" (checkbox), and "Comment". A "Section blank?" checkbox is also present. A "Delete CRF" dialog box is open, showing a dropdown menu for "*Change Reason" set to "Data Entry Error", a text area for "Change Comment (optional)", and a checkbox for "Remember comment for subsequent Delete CRF operations". A yellow box labeled "Delete Confirmation" points to the "Delete" button in the dialog. The background shows a "PATIENT IDENTIFICATION" section with a table for "Institution" and "Patient Medical Record Number".

Institution	Patient Medical Record Number
NCIDTC	9999999

Print eCRF

- Click on the **Print CRF** Toolbar icon to print the eCRF and its data.
- Make sure to select the Printer Page Orientation (Portrait or Landscape) that matches the eCRF design.



Verification & Approval

- C³D Verification & Approval functionality offer capabilities to track QA and Monitoring of eCRFs.
- Verification is Associated with the Research Nurse User Role.
- Approval is Associated with the Monitor User Role.

RDC Icon Explanation								
	Entry expected	Marked Blank	Created	Entry started	Entry complete	Pass 2 started	Pass 2 complete	Batch Loaded
Entry Status:								
Discrepancies:		Active		Other				
Verification:		Requires Re-verification		Verified				
Approval:		Requires Re-Approval		Approved				
Locking:		Locked						
Unplanned:		Unplanned CRF						

Verification

- Each eCRF can be verified by clicking on the Toolbar Verify button
- Verified eCRF Icon has a Checkmark
- Editing a verified eCRF changes its icon to a Re-Verify status
- Edited eCRF can be re-verified
- eCRF Verification Change History is maintained in the Verification pop-up Window

Verification

RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - Windows Internet Explorer

ORACLE® RDC Onsite: Data Entry

Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)

Highlight None

CENTER FOR CANCER RESEARCH

Study: NCI Visit: SCREENING Patient: 1010001

Visit Date: 01-NOV-2011 Mark CRF Blank

Section blank?

PATIENT IDENTIFICATION

Institution	Patient Medical Record Number
NCIDTC	9999999

Verify CRF

Verification History

Date	Operation	Changed By	Comment
15-NOV-2011 12:02:27	Verify	Marcelo Fontinha	Verified

Verification Comment

Remember comment for subsequent CRF Verification operations.

Help Undo Verification Cancel

Verify Icon

Verification History

Verify / Undo Verification Button

Approval

- Each eCRF can be approved clicking on the Toolbar Approve button and providing your C3D user name and password.
- Approved eCRF Icon has a Signature
- Editing an approved eCRF changes its icon to a Re-Approve status
- Edited eCRF can be re-approved
- eCRF Approval Change History is maintained in the Approval pop-up Window

Approval

RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - Windows Internet Explorer

ORACLE® RDC Onsite: Data Entry

Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)

Highlight None

Center for Cancer Research

Study CCI Visit SCREENING Patient 1010001

Visit Date 01-NOV-2011 Mark CRF Blank Comment

Section blank?

PATIENT IDENTIFICATION

Institution	Patient Me
NCIDTC	9999999

Approve CRF

Approval History

Date	Operation	Changed By	Comment
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Approval Comment

Remember comment for subsequent CRF Approval operations.

Help Approve Cancel

Approve Icon

Approval History

Approve / Undo Approval Button

Log Out

- Exit C3D before closing the Browser
- Inactivity for more than 30 minutes logs your out automatically

Log Out

RDC Onsite: Home [T] - Windows Internet Explorer

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Logged in as Ramesh Kanagaraja (Site user, OCPROD); Last Refresh 26-Oct-2011 15:28:29

Study and Site CCR_ROS_2011_V1 NCI Go

Study and Site Summary

News
No Records Found

Activities
[Review 1 Active Discrepancies](#)
[Review Investigator comments](#)

My Study Information
[App Support Ticket](#)
[C3D Enhancement Form](#)
[OCUG - Oracle Clin Users Group](#)
[21 CFR Part 11](#)
[eCRF Instructions Manual](#)
[Search on web](#)

Patient Selection List

+ Patient Search

Patients

Select Patients and... Open Patient Casebooks Go

Select All | Select None

Select	Patient Number	Last Modified	Casebook
<input type="checkbox"/>	X1		Unassigned
<input type="checkbox"/>	X2		Unassigned
<input type="checkbox"/>	X3		Unassigned
<input type="checkbox"/>	X4		Unassigned
<input type="checkbox"/>	X5		Unassigned
<input type="checkbox"/>	X6		Unassigned
<input type="checkbox"/>	X7		Unassigned
<input type="checkbox"/>	X8		Unassigned
<input type="checkbox"/>	X9		Unassigned
<input type="checkbox"/>	X10		Unassigned

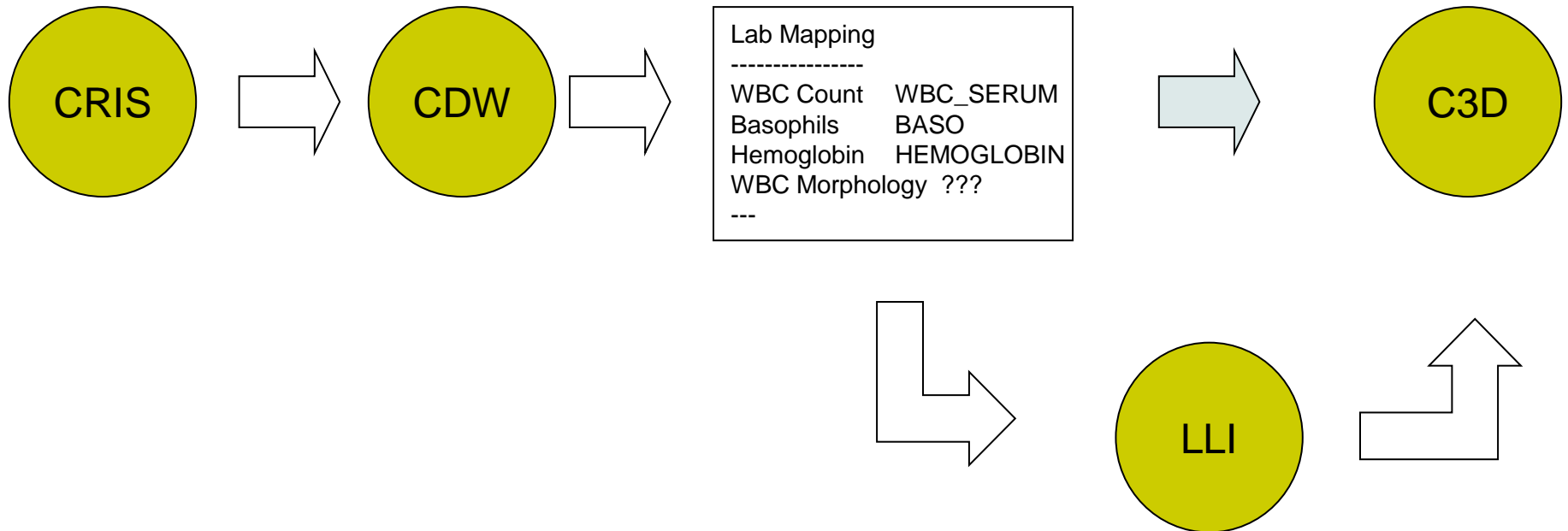
Select Patients and... Open Patient Casebooks Go

Home Casebooks Review Reports Logout Preferences Change Password Help

About RDC 4.5.3

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CRIS to C3D Lab Data Flow



What is LLI?

- LLI is a utility to review and identify specific Lab Test Results to be downloaded from the CRIS/CDW into C3D
- URL:
<http://octrials.nci.nih.gov/opa45/labloadinter.htm>
- Username & Password are same as C3D

LLI Search Screen

Lab Load Interface

Search | Work Cart | Load Cart | All Labs

Lab Load Interface Lab Panel Search

OCTRN

Search Criteria

Study: Pt: Lab Panel: C3D Test Name:

Date Relation: DD: MON: YYYY:

Time Relation: HH24: MI:

Search | New Search

Search Results

Select All | Unselect All

	Study	Pt	Lab Panel	Sample DateTime
<input checked="" type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				

Move Panel(s) to Load Cart

Move Panel(s) to Archive

View All Labs for Panel and Date

Exit

Record: 1/1 | ... | List of Valu... | <OSC>

Workflow

Search Criteria

Selected Panels

Action Buttons

LLI Search Criteria

Search Criteria

Study Pt Lab Panel C3D Test Name

Date Relation DD MON YYYY

Time Relation HH24 MI

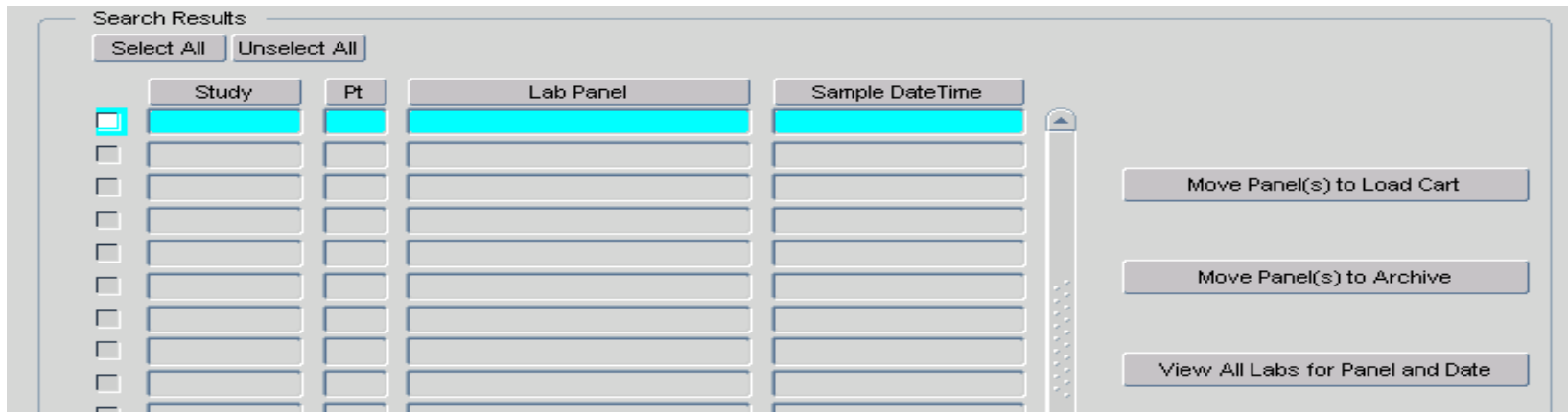
Search

New Search

- **Searching**

- Can search by Study, Patient Number, Lab Panel, OC Lab Question, Date and/or Time
 - Each search field contains Pick List.
 - Date and Time allows the ‘%’ wild card
 - Date and Time provide the additional option of:
 - “On or Before”, “On or After” and “LIKE” comparisons
 - Partial dates can be entered as %NOV%

LLI Search Screen Results



- **Search Results**
 - The result set lists Lab Panels that have at least one lab test available for loading that meet the criteria entered into the search fields.
 - The sort order can be changed using the column headings.
 - Results can be selected/deselected for processing by using the individual select check box or Select Buttons.
 - Entire panels of lab tests can then be moved to the Load Cart or Marked for Archive.
 - Clicking “View All...” button or by double clicking the record presents the Work Cart with specific Lab Test Results for that panel.

LLI Work Cart

The screenshot shows the 'Work Cart' interface. At the top, there are search filters for 'Study', 'Pt', 'Sample Datetime', and 'Lab Panel'. Below these are 'Select All' and 'Unselect All' buttons. The main area is a table with columns: 'R', 'C3D Test Name', 'Result', 'Unit', 'Range', and 'Status'. The first row is highlighted in cyan. To the right of the table is a 'Load Flags' section with radio buttons for 'All', 'Review', 'Missing', 'Loaded', 'Marked', and 'Others'. The 'All' flag is selected.

R	C3D Test Name	Result	Unit	Range	Status
<input checked="" type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					
<input type="checkbox"/>					

- **Work Cart**

- Shows Entire Panel, including previously loaded and missing Lab Tests
- The list can be filtered using the “Load Flag” radio buttons.
- Sort by Lab Test Panel Order (R), Test Name, Results, etc.
- Results can be selected/deselected for processing by using the individual select check box or Select Buttons.
- Once selected, the lab tests can be moved to the Load Cart or Archived

Question & Answer

