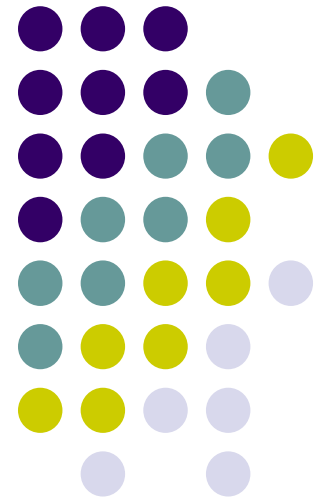


Introduction to C³D

Harris Corporation

May 2014



Introduction

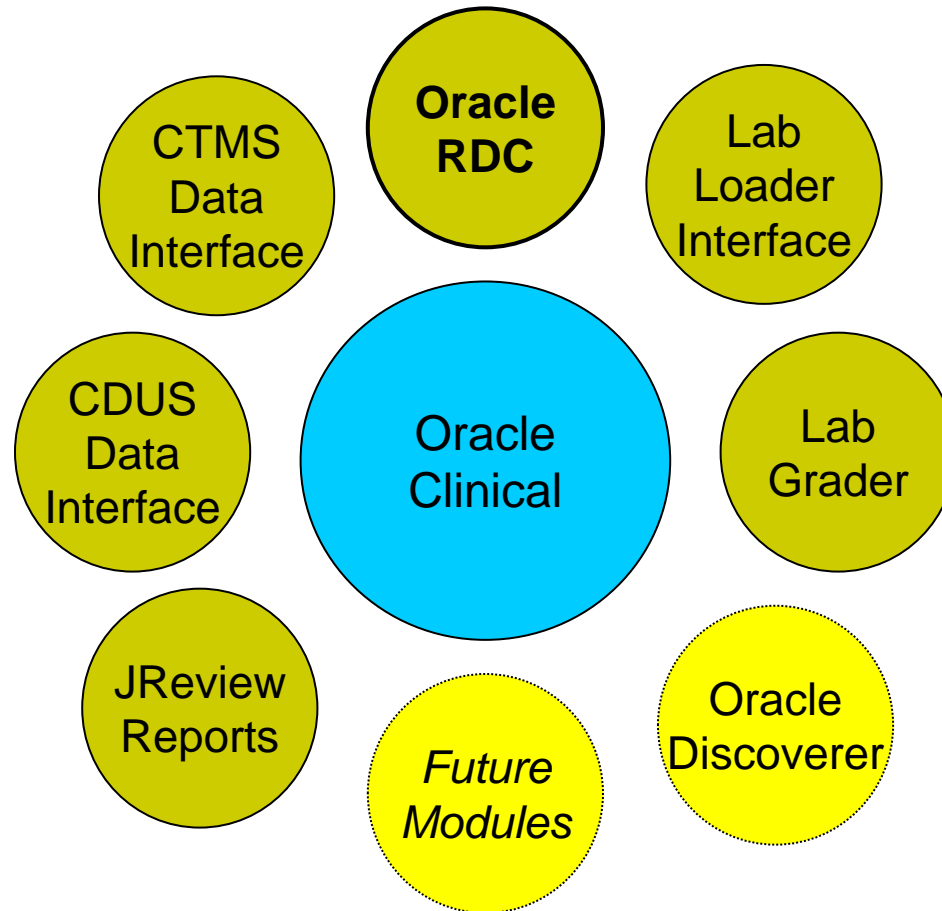
- | C³D - **C**ancer **C**entral **C**linical **D**atabase
- | eCRFs Instructions Manual
- | Support
- | Data Entry
- | Audit-Trail
- | Discrepancy Management
- | Verification
- | Approval
- | Lab Loading

What is C³D

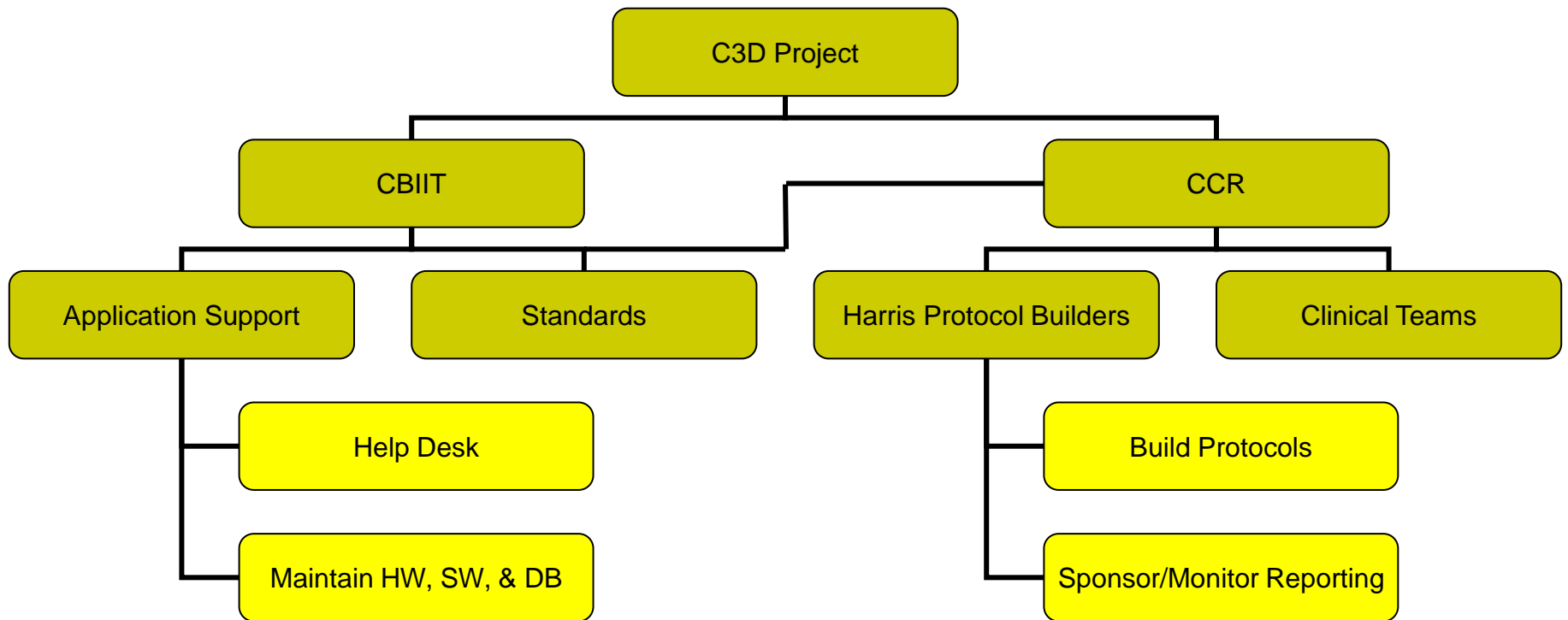


- | Clinical Trials Data Management System
- | RDC (Remote Data Capture) Data Entry
 - q Accessible anywhere in the world (via a Windows computer and Internet Explorer).
- | C³D supports data standardization, reuse, sharing, and interoperability through electronic Case Report Forms (eCRFs) based on Common Data Elements (CDEs)
- | Based on Industry Standard Technologies

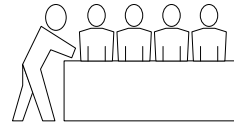
Cancer Central Clinical Database C³D



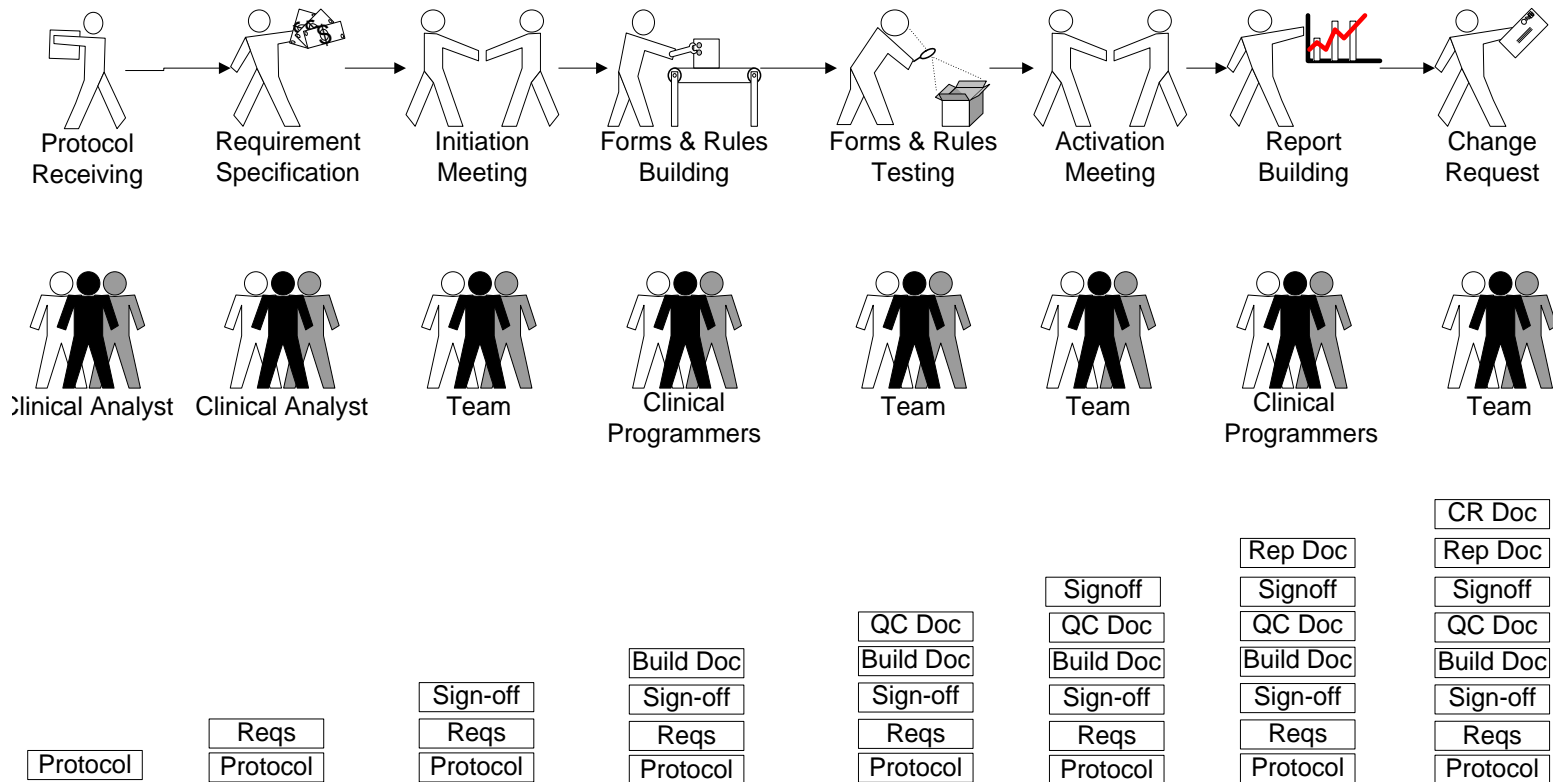
C³D Organization



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:
 - q General Description
 - q eCRF Screenshot
 - q Field Specific Description (Mandatory, Derived, etc.)
 - q Validation/Derivation Rules

eCRF Instructions Manual

Course Initiation

Search

[Home](#) > [C3D Portal](#) > [Training and Education](#) > [Course Initiation](#)

Home

- C3D Portal
- Login
- Training and Education
- Sponsor Reporting
- Support

Other Applications Documentation

- GLC Web Application Users Manual
- TIGER-LC Web Application Users Manual


Contents


- [Purpose](#)
- [Course Initiation eCRF](#)
- [Validations](#)
- [Derivations](#)

Purpose

Record course initiation Start Date, Arm, Treatment Assignment Code (TAC) and Treating Institution.

Course Initiation eCRF





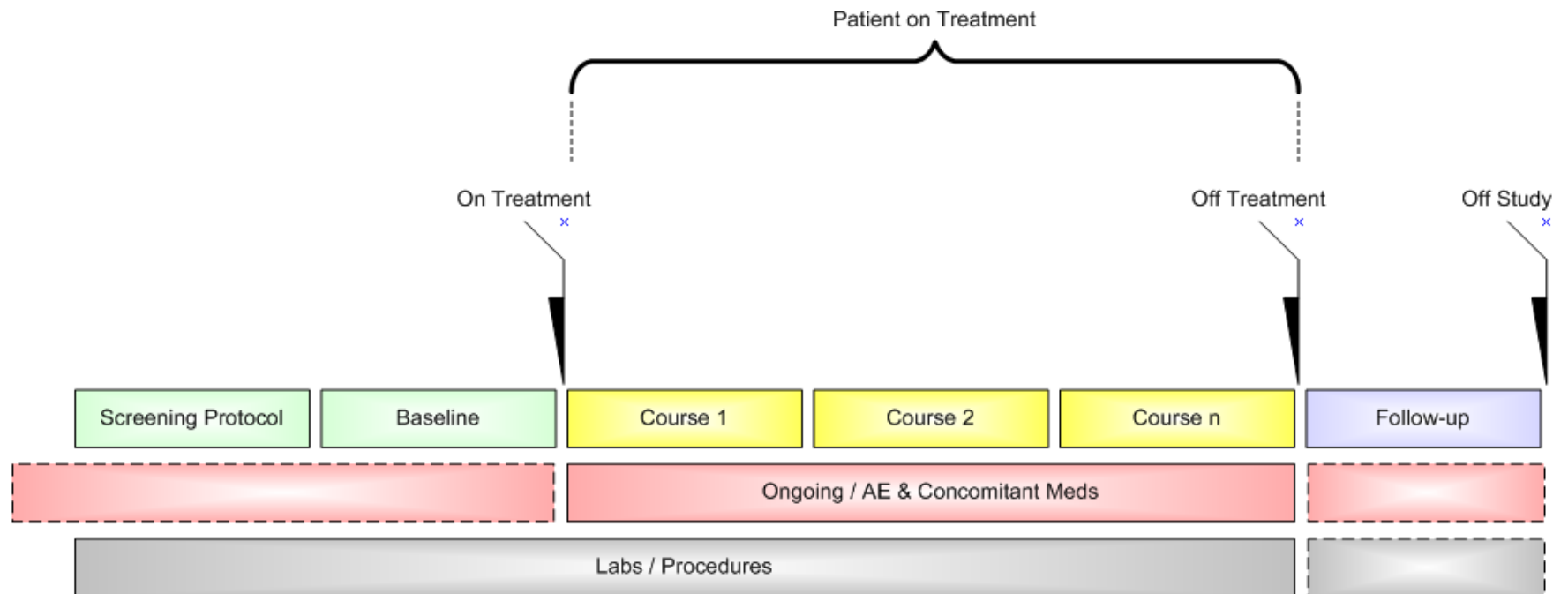
Field Name	Description / Instructions	Format
Visit Date ^(m)	Enter the date the course started.	DD-MMM-YYYY
Course # ^(d)	Sequential number of this course of treatment: first course = 1, second course = 2, etc.	5 digits
Start Date of Course ^(m)	Enter the date on which the course was started. This is the date on which a protocol stipulated medication (or treatment) was first administered.	DD-MMM-YYYY

CCR Standard Case Report Forms

- | Screening/Baseline Forms
 - q Eligibility, Enrollment, PE, Vitals, Baseline Symptoms, Prior Therapies, ...
- | Courses/Cycles
 - q Course Initiation, Study Medication Administration, PK, Course Assessment, PE, ...
- | Labs
 - q Blood Chemistry, Hematology, ...
- | Ongoing
 - q AE, Concomitant Measures, Extent of Disease, ...
- | Off Tx / Follow-Up / Off Study

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 Support

- | CBIIT provides the first line of support for C³D related issues
- | Contact
 - q Email: ncicbiit@mail.nih.gov
 - q Phone: 240-276-5541
 - q Additional Information at:
<https://ccrod.cancer.gov/confluence/x/KwBYB>
- | Protocol specific issues are escalated to the Protocol Builder by CBIIT
- | Changes to Standards are escalated to Controls & Configuration Management Group (CCMG)

Username & Password

- | Username is typically your last name and first name initial.
Ex: **smiths**
- | Password rules:
 - q Start with a letter;
 - q Must containing **at least one number and one special characters** (Ex:! #);
 - q Has to be at least 8 characters long;
 - q The following special character could cause problems if used: \$ % & ' ''.
- | About C³D Password:
 - q **Do not share the password with others!**
 - q Password needs to be changed the first time you login
 - q Password expires every 3 months and needs to be changed
 - q **Account gets locked upon three unsuccessful attempts. Contact C³D Help Desk to unlock account and/or get new password.**

C³D Login Web Pages

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

C³D Login Web Page

https://octrials.nci.nih.gov/opa45/rdclaunch.ht Launch Oracle Clinical RDC... x

Oracle Pharmaceutical Applications

RDC 4.5

Login

RDC Onsite

[Change Password](#)

[Clear Cache](#)

[Login help](#)

For supported browsers and operating systems check with your administrator or Oracle Support

WARNING

- You are accessing a U.S. Government information system, which

Click on RDC Onsite button

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

C³D RDC Home Page

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

I Choose a Different Study / Site

- q Access to studies is controlled by user role
- q C³D remembers that last study used in prior login
- q Select Study and Site from dropdown and click **Go**

I Activity Links (optional)

- q Review ##,### Active Discrepancies
- q Review Investigator Comments

I Specify Patient Search Criteria (optional)

- q Enter a range of patient positions
- q Enter a patient reference (if field available)
(ex: %123% to search for patients with 123 in their MRN)
- q Select Casebook form the Assigned Book dropdown list
- q Discrepancy Status
- q From the Show dropdown list, select Patients with data entered or without data entered

I Select Patient(s) and Action

- q Place checkmarks for the desired patients to work on
- q Select an Action:
 - o Review Casebook (this is the default and most common action)
 - o Review Discrepancies
 - o Review Investigator Comments
 - o Generate Patient Data Report
 - o Generate Blank Casebook Report

Home Page Activities

The screenshot shows the RDC Onsite Home page in a Windows Internet Explorer browser. The page has a blue header with the Oracle logo and 'RDC Onsite' text. Below the header are navigation tabs for 'Home', 'Casebooks', 'Review', and 'Reports'. A user is logged in as 'Marcelo Fontinha' with a 'Data management role, OCPRD'. The page is titled 'Study and Site' with dropdown menus for 'CCR_ROS_2011_V1' and 'NCI', and a 'Go' button. A 'Study and Site Summary' link is also present.

Annotations highlight key features:

- Choose Different Study / Site**: Points to the 'Study and Site' dropdown menus.
- Activity Links**: Points to the 'Activities' section, which includes links for 'Review 279 Active Discrepancies' and 'Review Investigator comments'.
- Patient Search Criteria**: Points to the 'Patient Search' form, which includes fields for 'Range', 'Show', 'Assigned Book', and 'Discrepancy Status', along with 'Clear' and 'Go' buttons.
- Select Specific Patients**: Points to the 'Patients' table, which has a 'Select' column with checkboxes and icons.
- Specify Action:**: Points to the 'Select Patients and...' dropdown menu, which is currently set to 'Open Patient Casebooks'. The dropdown options are 'Open Patient Casebooks' and 'Review Discrepancies, etc.'.

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

At the bottom of the page, there is a footer with 'About RDC 4.5.3' on the left and 'Copyright © 2000, 2007, Oracle. All rights reserved.' on the right.

Navigating Casebook

I Casebook List

- q Click on Casebook View dropdown list to select one of the available Casebooks (latest casebook is the default one)

I Visit List

- q Click on Visit dropdown list to switch to another Visits (Screening is the first visit)

I Casebook Visit Layout

- q One row per Patient with identifier on the left
- q Visit's eCRFs along Columns.
 - o Use the CRFs dropdown list (or links) to view the additional Visit CRFs

I Click on an eCRF icon to open it

RDC Casebook

RDC Onsite: Patient Casebooks - Windows Internet Explorer

ORACLE® RDC Onsite

Logout Preferences Change Password Help

Home Casebooks Review Reports

Home > Logged in as Marcelo Fontinha(Data management role, OCPROD); Last Refresh 14-Nov-2011 15:00:12

Study and Site CCR_ROS_2011_V1 NCI Go

Study and Site Summary

Patient Casebooks

Search : 5 Patients Selected From Home Page

Casebook Spreadsheet

Patients: Previous 1-5 of 5 Next Casebook View: BOOK_0_26OCT2011 Visit: SCREENING CRFs: Previous 1-10 of 10 Next

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

Select All Select None

Select	Patient Number	Elig	Enroll	MRN	Medhist	Prior Rad	Visit	CRFs
<input type="checkbox"/>	1010001						SCREENING	BLOODCHEMISTRY
<input type="checkbox"/>	1010002						SCREENING	HEMATOLOGY
<input type="checkbox"/>	1010003						SCREENING	URINALYSIS
<input type="checkbox"/>	1010004						SCREENING	BONE MARROW
<input type="checkbox"/>	1010005						SCREENING	SEROLOGY

Visit dropdown menu:

- SCREENING
- COURSE 1
- COURSE 2
- COURSE 3
- COURSE 4
- COURSE 5
- COURSE 6
- BLOODCHEMISTRY
- HEMATOLOGY
- URINALYSIS
- BONE MARROW
- SEROLOGY
- OTHER SERUM
- BLOOD GAS
- RESPIRATORY
- OTHER URINE
- SERUM ELECTROPH
- URINE ELECTROPH
- COAGULATION
- CSF
- LYMPHOCYTE PHENO
- HLA
- CHIMERISM
- ONGOING
- OFFTREATMENT
- FOLLOWUP
- OFFSTUDY

CRFs table:

Prior Tx	Symptom	Phys Scrn

Home Casebooks Review Reports Logout Preferences

About RDC 4.5.3

Copyright © 2000, 2007, Oracle. All rights reserved.

Casebook List

Visits List

eCRFs within a visit

Patients listed on the left

Patient Casebook Search Criteria

- | Allows for additional Casebook Search Criteria not found in the Home Page Patient Search. Click on the + icon then specify the criteria:
 - q CRF Status:
 - o Data Entry
 - o Discrepancy
 - o Verification
 - o Approval
 - q CRF Source:
 - o Casebook
 - o Visit
 - o CRF Name
- | Then click on **Go** button to search.

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

[Study and Site Summary](#)

Patient Casebook Search Criteria

✓ 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	⌨	Patient	Number																	

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)
-  | A Blank Square icon with a green arrow indicates CRF has not been used. Click on it to begin data entry!
-  | An eCRF just created, but without data has no lines within the icon (Created Status)
-  | eCRF 'Saved as Incomplete' has lines across half of the icon (Entry Started Status)
-  | eCRF 'Saved as Complete' has 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

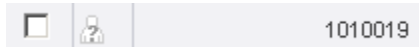
eCRF Icons

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

I From the C³D Home Page: place a checkmark next to the desired patient position icon and click on the **Go** button to go to the Casebook first Visit or;

q A question mark is shown inside the icon of a patient position that has not been used:



I 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.

I 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.

I **Quick Tips:**

q Use the patient positions numbers according to those assigned by Central Registration Office (CRO).

q The total number of Patients available for entry are governed by protocol accrual ceiling. Request additional patient positions if protocol has been amended and accrual ceiling increased.

Entering New Patient Data

The screenshot displays the ORACLE RDC Onsite web application interface. At the top, there are navigation tabs for Home, Casebooks, Review, and Reports. A search bar is present with filters for Study and Site (CCR_ROS_2011_V1, NCI) and a Go button. A yellow callout box points to the search filters with the text: "Search for Patient Positions with no data entered".

Below the search bar is the "Casebook Spreadsheet" section. It includes filters for Patients (1-10 of 14), Casebook View (BOOK_0_26OCT2011), Visit (SCREENING), and CRFs (1-10 of 10). There are buttons for "Generate Patient Data Report", "Go", "Add Visit Page", "Add Other Page", and "Refresh".

The main data table is titled "SCREENING" and has columns for Patient Number, Elig, Enroll, MRN, Medhist, Prior Rad, Prior Surg, Prior Thrp, Prior Tx, Symptom, and Phys Scrn. The table contains three rows of patient data:

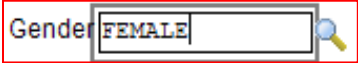
Select	Patient Number	Elig	Enroll	MRN	Medhist	Prior Rad	Prior Surg	Prior Thrp	Prior Tx	Symptom	Phys Scrn
<input type="checkbox"/>	1010005										
<input type="checkbox"/>	1010007										
<input type="checkbox"/>	1010009										

A yellow callout box points to the eCRF icons in the table with the text: "Click on eCRF icon to begin data entry".

Electronic CRF (eCRF)

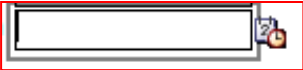
- | eCRF Header and Footer display eCRF identification information
- | Visit Date is mandatory for most forms:
 - q In Lab eCRFs, Visit Date is the Lab Sample Collection Date
 - q Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc. Refer to the eCRFs Instructions Manual.
 - q Visit Date is not needed on eCRFs on Ongoing Visit, but required everywhere else.
- | Navigate within eCRF by:
 - q Using Tab and Shift-Tab keys or left Mouse click to place the cursor on a field.
 - q Use the scrollbars or the Toolbar page navigation icons to go to a different page.
 - o The last page of an eCRFs is the comment page.
- | **Quick Tip:**
 - q Up to 3 eCRFs can be open for simultaneously for data entry. An additional 2 eCRFs can be opened in read-only mode.
 - q It is strongly recommended to only have one eCRF open for data entry to avoid entering data in the wrong patient. Close the eCRF when no longer using it.

Electronic CRF (eCRF)

I Fields with magnifying glass  have a pick list of acceptable values.

- q With the pick list shown, press **CTRL + F** to search the pick list.
- q A typed in 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 Team Lead.
- q **Using the Pick List is particularly important in these two fields below because the MedDRA code is derived 'behind-the-scenes'.**
 - o Enrollment Disease Term
 - o Baseline Symptoms and Adverse Events CTCAE Term.

I Enter Dates as:

- q Complete dates for Current Information (ex: 5/23/2014, 5-23-2014 or 05232014)
- q MMYYYY for Prior Information is acceptable when complete date cannot be obtained (ex: 05-00-2014, 05/00/2014, 05002014)
- q Click on the calendar icon  to display a popup calendar and click on a date.

Electronic CRF (eCRF)

ORACLE RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: RDONSITE_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

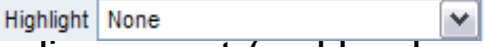









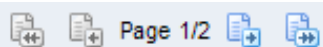

Copyright © 2000, 2007, Oracle. All rights reserved.

Annotations:

- Toolbar**: Points to the top navigation and utility icons.
- Enterable field**: Points to the Gender input field.
- Non-enterable/Derived field**: Points to the Age at Entry input field.
- Red background indicates a Discrepancy**: Points to the Disease Stage at Entry field, which has a red background.
- eCRF Scrollbar**: Points to the vertical scrollbar on the right side of the form.



Electronic CRF (eCRF)

I Toolbar features:

- q  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)
- q  Add Manual Discrepancy to selected field
- q  Add Investigator Comments to selected field
- q  Delete Selected Row
- q  Blank Flag Tool (Blank / un-blank eCRF's section(s) or entire eCRF)
- q  Verify, Un-verify and Review Verification History
- q  Approve, Un-approve and Review Approval History
- q  Delete eCRF
- q  Print eCRF
- q  Save eCRF
- q  Navigate eCRF's Pages (First, Previous, Next, Last)
- q  Use Close box to close eCRF

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

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. A toolbar showing page navigation icons: a left arrow, a right arrow, the text 'Page 1/2', and another right arrow.
- | Click on the  Toolbar icon to delete the selected row. **Do not blank the contents of the entire row, delete the row instead.**

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, Site: NCI, Patient: X1, Visit Name: ONGOING

Mark CRF Blank:

Comment:

Type: AE Section blank?

ADVERSE EVENTS

To Delete selected Row

Course	Dy in Course	Prior Course	Date of Onset	Resolved	CTCAE Term	SOC	AE Description	Grade	Research	IND	IDE	Comm.	Rad.	Surg.	Dis.	Other	Other, Specify	Unexp. 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="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="text"/>	<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="text"/>	<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="text"/>	<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="text"/>	<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="text"/>	<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"/>

Doc# R210656001 Status Created Verified Approved Locked CRF Page 75.1

Copyright © 2000, 2007, Oracle. All rights reserved.

eCRF and Section Blank Checkboxes


- | Entire eCRF can be marked Blank.
 - q Use the 'Mark CRF Blank' checkbox.
- | Individual sections of eCRF can be marked Blank.
 - q Use the 'Section Blank?' checkbox.
- | **Checking Blank Flag will erase any entered information from the eCRF/Section when saving the eCRFs.**
- | Blank Flag can be unchecked later on 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

Section blank?

Marking entire eCRF 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"/>

Copyright © 2000, 2007, Oracle. All rights reserved.

Saving eCRF

- I Click on the  green floppy disk icon to save the eCRF.
 - q Save Often!! Especially while entering Ongoing Information such as Adverse Events and Concomitant Medications.

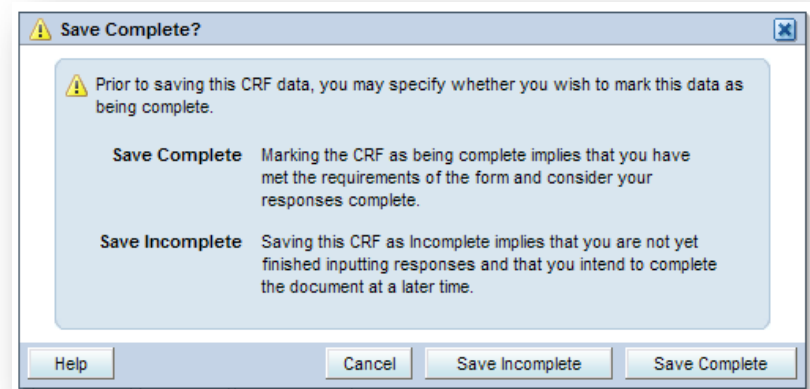
- I Choose how to save the eCRF:

- q **Save Incomplete**

- o Only save CRF as incomplete for a short period of time.
- o Discrepancies are not created for mandatory fields that have not been touched (cursor not placed in field).
- o Overnight validation checks and derivations are not executed.
- o Verification and Approval cannot be done.
- o CRF's Data not available to be submitted via CTMS and CDUS!

- q **Save Complete**

- o eCRF Status changes to Entry Complete.
- o All validation checks and derivations are executed.
- o Verification and Approval can be done.
- o Audit-trail is always enabled!



- I **Quick Tip:**

- q For Ongoing Tabular eCRFs, save as **Complete** once the first row is entered. This will guarantee that validation checks and derivations are executed and eCRF's data are used in checks from other eCRFs and for submissions.

Saving eCRF

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

The main form area includes the Center for Cancer Research logo and the following fields:

- Study: CCR_ROS_2011_V1
- Patient: 1010001
- Visit: URINALYSIS
- Site: NCI
- Comment: [Empty text box]
- Lab Date: 11-NOV-2011
- Mark CRF Blank:

Below the main form, there are fields for "Lab" [Empty], "Time" 11:11:00, and "Section blank?" . A yellow callout box labeled "Save Icon" points to a green floppy disk icon in the toolbar.

The "URINALYSIS" section contains a "Course #" field and a list of lab tests: GLUCOSE_UR, PROTEIN_QUAL_UR, UROBILINOGEN_UR, and PH_UR.

A "Save Complete?" dialog box is open in the foreground, containing 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". A yellow callout box labeled "Save Prompt" points to the dialog box.

Data Entry Change Reason

- | After an eCRF is 'Saved Complete', the audit-trail will prompt the user for a Change Reason whenever data previously saved is being changed.
- | 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:**
 - q Do not use personnel/patient names or identifiers in the comments.

Data Entry Change Reason

RDC Onsite DE: X1, OFFSTUDY, SURVIVAL [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: All Discrepancies

Page 1/2

CENTER FOR CANCER RESEARCH

Study: CCR_ROS_2011_V1 Site: NCI Visit: OFFSTUDY Patient: X1

Visit Date: Mark CRF Blank: Comment:

Section blank?

SURVIVAL

Date of Death: 19-OCT-2011

Cause of Death (Presumed):

Autopsy Results Available?:

Cause of Death (Autopsy Finding):

Sites of Disease at Autopsy

<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"/>

Doc#: R210063701 Status: Entry Complete Verified: Approved: Locked: CRF Page: 90.1

Copyright © 2000, 2007, Oracle. All rights reserved.

Change Reason Prompt

Entering/Viewing Laboratory Data

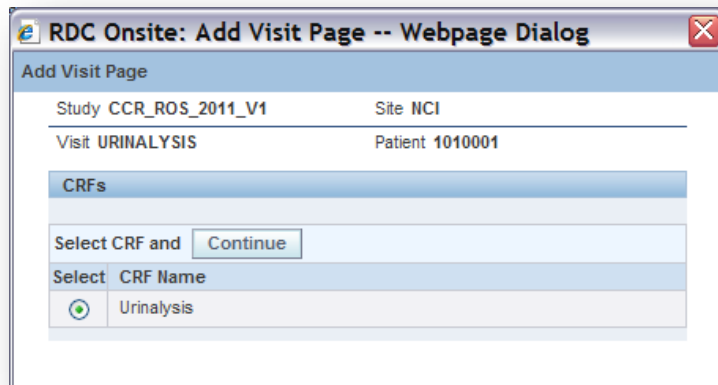
- 1 Laboratory Data eCRFs are designed with dedicated Visits (Hematology, Urinalysis, etc.) and only one eCRF is planned initially per Visit.
- 1 Additional eCRFs can be added by selecting a Patient and clicking on **Add Visit Page**.

The screenshot shows the ORACLE RDC Onsite Patient Casebooks interface. The page title is "RDC Onsite: Patient Casebooks - Windows Internet Explorer". The ORACLE RDC Onsite logo is visible in the top left. 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 are CCR_ROS_2011_V1 and NCI. The page is titled "Patient Casebooks" and shows a "Casebook Spreadsheet" view. The spreadsheet has columns for "Patient Number" and "Urinalysis". Two patients are listed: 1010001 and 1010002. The "Add Visit Page" button is highlighted with a yellow box and labeled "2. Click Add Visit Page". A yellow box labeled "1. Select Patient" points to the first patient row.

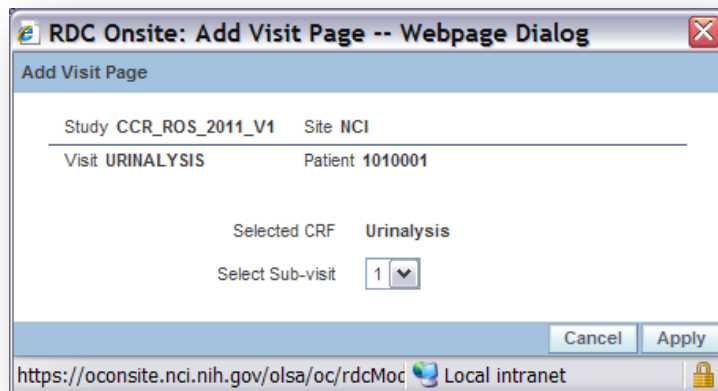
Select	Patient Number	Urinalysis
<input type="checkbox"/>	1010001	61
<input type="checkbox"/>	1010002	61

Entering/Viewing Laboratory Data

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



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



- Click on the new Unplanned Lab eCRF icon  to begin data entry.

Entering/Viewing Laboratory Data

- | Enter the Lab Date (**Sample Collection Date**).
- | Enter the Lab Time (**Sample Collection Time**) using military time.
- | Optionally, choose a Lab Source from the Lab dropdown list.
 - q **Outside** option is normally used to indicate panel was done in a location other than the patient's site.
 - q If Units of Measurement (UOM) and Normal Ranges have been predefined for your site, select your site from the list and C³D will automatically populate the UOM and Normal Range.
- | C³D will derive the Range Indicator and Grade the lab result according to CTEP's CTCAE Criteria:
 - q http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm

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 1/2

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)	Indicator	Grade (Numeric)	Value in Preferred UOM	Value in 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"/>

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.
- | Discrepancies are tools to assist teams in identifying potential data inconsistencies and facilitate real-time QA of data.

- | **Quick Tips:**
 - q Discrepancies do not cover 100% of possible data inconsistencies.
 - q Clinical judgment may supersede discrepancy logic.

C³D Discrepancy Types

I Univariate

- q Generated during data entry/load when data is in some way different from the Question's definition (e.g. mandatory, length, type, range, pick list, etc.)

I Multivariate

- q Based on a condition on one or more questions as defined in a validation rule
- q Generated on-line or when validation rules are run (eCRF must be saved as Complete.)

I Manual

- q Generated by data entry operator seeking clarification on data values

Some Typical Discrepancies

Types	Example:	Resolutions
Data Type	Text entered in numeric or date field.	Review Source Document and enter appropriate data.
Length Problems	Too many characters entered.	Use NIH accepted Abbreviations.
Value not on the Pick List	Generic Agent not present in Concomitant Agent Pick List and user typed in an Agent not found on the Pick List.	Search for alternates. Consult Team Lead. Request value to be added to Pick List.
Mandatory Value	Required Field 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.
- | eCRF containing discrepancies are shown in Red icon

- | **Quick Tip:**
 - q Data Managers should manage their discrepancies every morning to help ongoing QA of 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 P

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	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

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


Patient		SCREENING									
Select	Number	Elig_E	Enroll	MRN	Medhist	Prior Rad	Prior Surg	Prior Thrp	Prior Tx	Phys Scrn	Symptom
<input type="checkbox"/>	X1										
<input type="checkbox"/>	X2										
<input type="checkbox"/>	X3										
<input type="checkbox"/>	X4										
<input type="checkbox"/>	X5										
<input type="checkbox"/>	X6										
<input type="checkbox"/>	X7										
<input type="checkbox"/>	X8										
<input type="checkbox"/>	X9										
<input type="checkbox"/>	X10										

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

- | Open the eCRF that has discrepancies.
- | Click on the **Highlight** dropdown list and select which discrepancies to show.
- | On the right side of the eCRF, click on the vertical handle  to open the Discrepancies panel.
- | 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.
 - q Manually closing discrepancies is highly undesirable. It should be the exception.

How are Univariate Disc. Created?

- | Univariate Discrepancies pop-up is presented during data entry when the entered value does not match the field definition.
 - q Mandatory field left empty
 - q Text entered in a Date or Numeric Field
 - q Too many characters entered
 - q Value is not on the Pick List
 - q Partial Date entered when a complete date is required
- | Data Entry operator can:
 - q Cancel the pop-up and fix the value
 - q Or accept the discrepancy
- | **Quick Tip:**
 - q Univariate Discrepancies are reassessed during Batch Validation for Design Changes.

How are Multivariate Disc. Created?

- | Multivariate Discrepancies are created based on validation rules programmed in a study
 - q Example 1: Create Discrepancy if the entered BSA is not within 10% of the calculated BSA
 - q Example 2: Create Discrepancy if Date of Histological Confirmation is before Date of Diagnosis

- | **Quick Tip:**
 - q Rules available as a standard on each eCRF are summarized in the eCRFs Instructions Manual.
 - q 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:
 - q on-line validation rules are evaluated upon completion of a CRF **Saved as Complete**
 - q during an overnight batch validation session for CRFs **Saved as Complete**

- | Multivariate Discrepancies are displayed in the same manner as Univariate Discrepancies. The Discrepancy Details panel indicates the type of Discrepancy.

- | **Quick Tip:**
 - q Complex rules run overnight.

How to Address a Discrepancy

- | Review Discrepancy Details
- | Resolve the discrepancy by:
 - q Consulting Source Documentation and;
 - q Modifying incorrect data and specifying change reason;
 - q Requesting eCRF Design and/or Validation Rule Change.

- | **Quick Tip:**
 - q System obsoletes univariate discrepancy automatically when data is corrected and complies with design/rules.
 - q Multivariate Discrepancies are only re-evaluated during overnight Batch Validation.

How to Address a Discrepancy

ORACLE RDC Onsite: Data Entry | Study: CCR_ROS_2011_V1, Site: NCI, Patient: X1, Casebook: BOOK_0_26OCT2011- (Ramesh Kanagaraja - Site user)

Study: CCR_ROS_2011_V1 | Site: NCI | Visit: SCREENING | Patient: X1
Visit Date: 10-OCT-2010 | Mark CRF Blank: | Comment:

Section blank?

BASILINE SYMPTOMS

Date of Onset	Date Resolved	System Organ Class	CTCAE Term	Symptom Description	Grade	Yes	No	Unknown
03-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"/>
						<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"/>
						<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"/>
						<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"/>
						<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

If Data cannot comply with Design/rules, and in rare exceptions, select an Action from Pull Down Menu to Manually Close the Discrepancy.

Audit Trail

- | After an eCRF is 'Saved Complete', audit-trail is kept for any previously saved data that are changed.
- | Use the eCRF Highlight dropdown **Audit History** option to highlight, with a blue background, the fields that have audit-trail.
- | On the bottom part of the eCRF, click on the horizontal handle  to open the Audit History panel.
- | Review the Audit-trail details at the **Audit History Panel** opened at the bottom of the eCRF window.

- | **Quick Tips:**
 - q Auditing begins as soon as the eCRF is 'Saved Complete'.
 - q A newly entered row in an eCRF previously saved as complete will not prompt user for a reason why data is being changed because it is new row. However, changing or entering data in a previously saved row will trigger the audit-trail and prompt the user for a change reason.
 - q **Do not share user IDs and passwords!**

Audit Trail

The screenshot shows the Oracle RDC Onsite Data Entry interface. At the top, the browser title is "RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - 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)".

A dropdown menu labeled "Highlight" is set to "Audit History". A yellow callout box points to this dropdown with the text "Highlight Audit History Option".

Below the header, there is a form with fields for "Study" (CCR_ROS_2011_V1), "Site" (NCI), "Visit" (SCREENING), and "Patient" (1010001). There is also a "Visit Date" field (01-NOV-2011) and a "Mark CRF Blank" checkbox. A yellow callout box points to the "Mark CRF Blank" checkbox area with the text "Field with blue background indicates presence of Audit-trail".

The "PATIENT IDENTIFICATION" section contains a table with columns "Institution" and "Patient Medical Record Number". The "Patient Medical Record Number" field is highlighted in blue and contains the value "1234567". A yellow callout box points to this field with the text "Click on this handle to show/hide the Audit History panel.".

Below the patient identification table, an "Audit History" panel is displayed for "Patient Medical Record Number (row 1)". It contains a table with the following data:

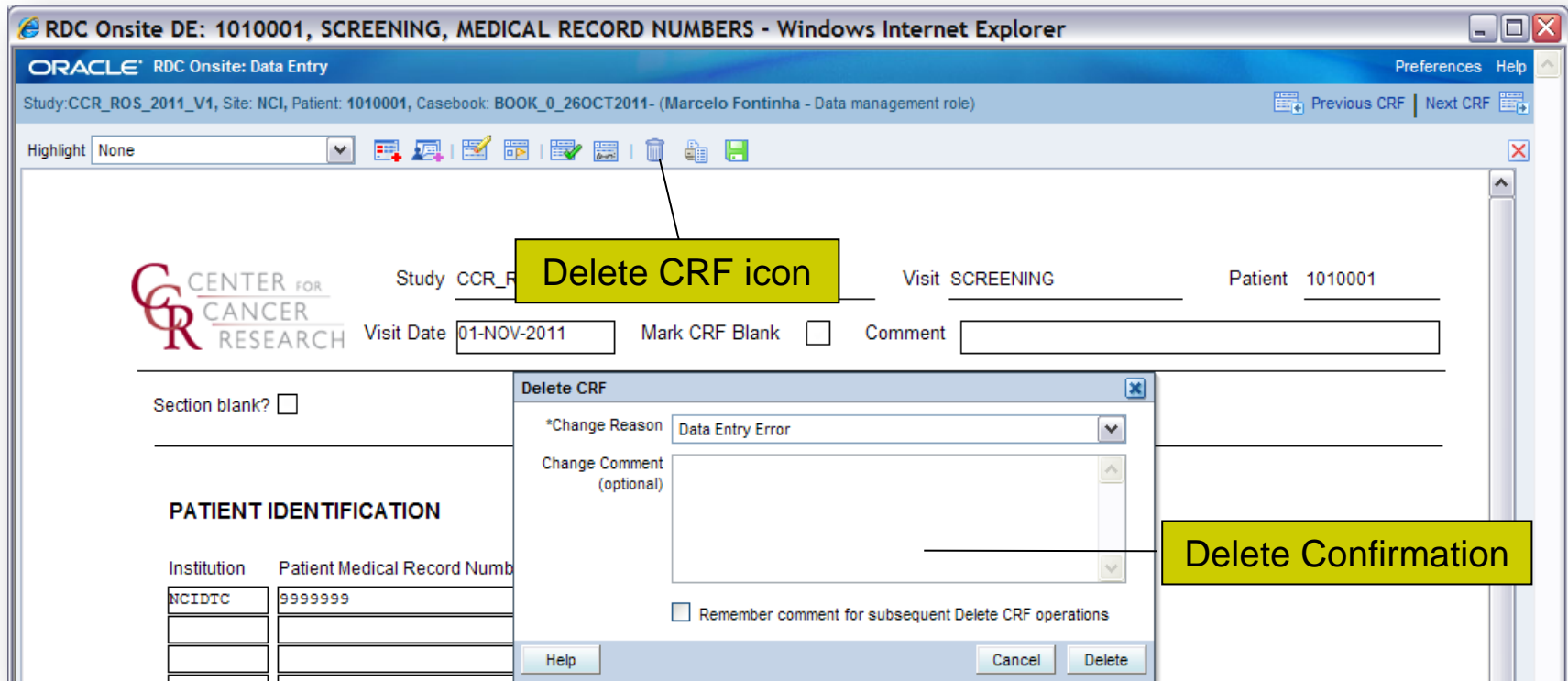
Date	Changed From	Changed To	By	Reason	Comment	Details
15-NOV-2011 11:20:41	414141411	1234567	Marcelo Fontinha	DATA ENTRY ERR		

A yellow callout box points to the "Changed From" field in the audit history table with the text "Audit-trail details".

At the bottom right of the page, there is a copyright notice: "Copyright © 2000, 2007, Oracle. All rights reserved."

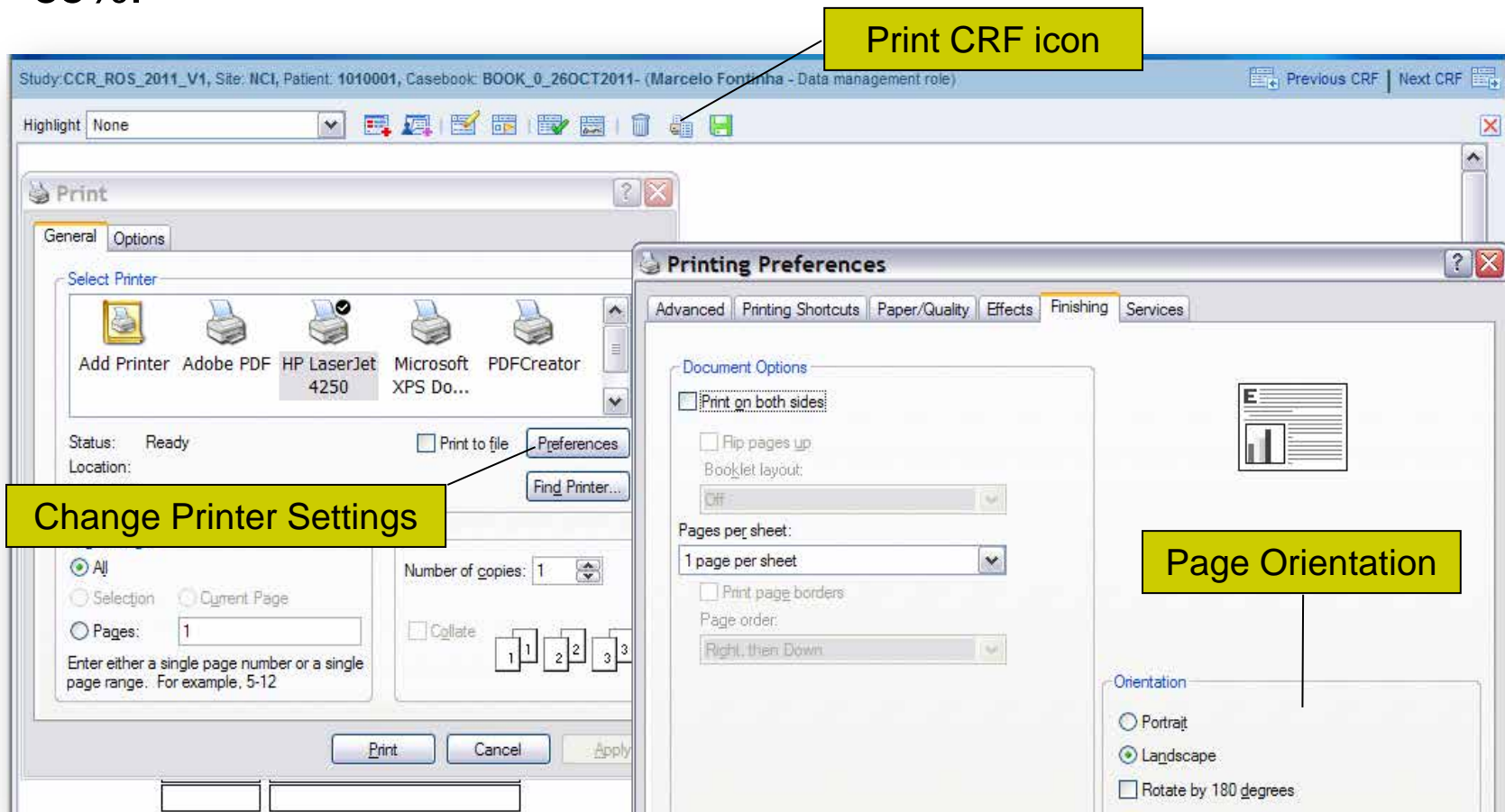
Delete eCRF

- 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.



















Print eCRF

- 1 Click on the **Print CRF** Toolbar icon to print the eCRF and its data.
- 1 Make sure to select the Printer Page Orientation (Portrait for Lab Panels and Landscape for other eCRFs) and shrink contents to about 85%.






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

Verify Toolbar Icon

Visit SCREENING Patient 1010001

Visit Date 01-NOV-2011 Mark CRF Blank

Verification History

Section blank?

PATIENT IDENTIFICATION

Institution	Patient Medical Record Num
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.

Verify / Undo Verification Buttons

Help Undo Verification Cancel

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

The screenshot shows 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 "Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)".

Key elements of the interface include:

- Approve Toolbar Icon:** A toolbar at the top contains several icons, with a green checkmark icon highlighted by a yellow box labeled "Approve Toolbar Icon".
- Approval History:** A yellow box labeled "Approval History" points to the "Approval History" section within the "Approve CRF" dialog box. This section contains a table with the following columns: Date, Operation, Changed By, and Comment.
- Approve / Undo Approval Button:** A yellow box labeled "Approve / Undo Approval Button" points to the "Approve" button at the bottom of the "Approve CRF" dialog box.
- Form Fields:** The main form includes fields for "Visit Date" (01-NOV-2011), "Mark CRF Blank" (checkbox), "Comment", and "Section blank?" (checkbox).
- Patient Identification Table:** A table titled "PATIENT IDENTIFICATION" with columns "Institution" and "Patient Me". The first row contains "NCIDTC" and "99999999".
- Dialog Box:** The "Approve CRF" dialog box includes an "Approval Comment" text area, a checkbox for "Remember comment for subsequent CRF Approval operations.", and buttons for "Help", "Approve", and "Cancel".

Log Out

- | Exit C³D before closing the Browser
- | C³D session times out, without warning, after 30 minutes of Inactivity
- | Unsaved data is lost if session times out or network connection is lost

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, OCPRD); 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

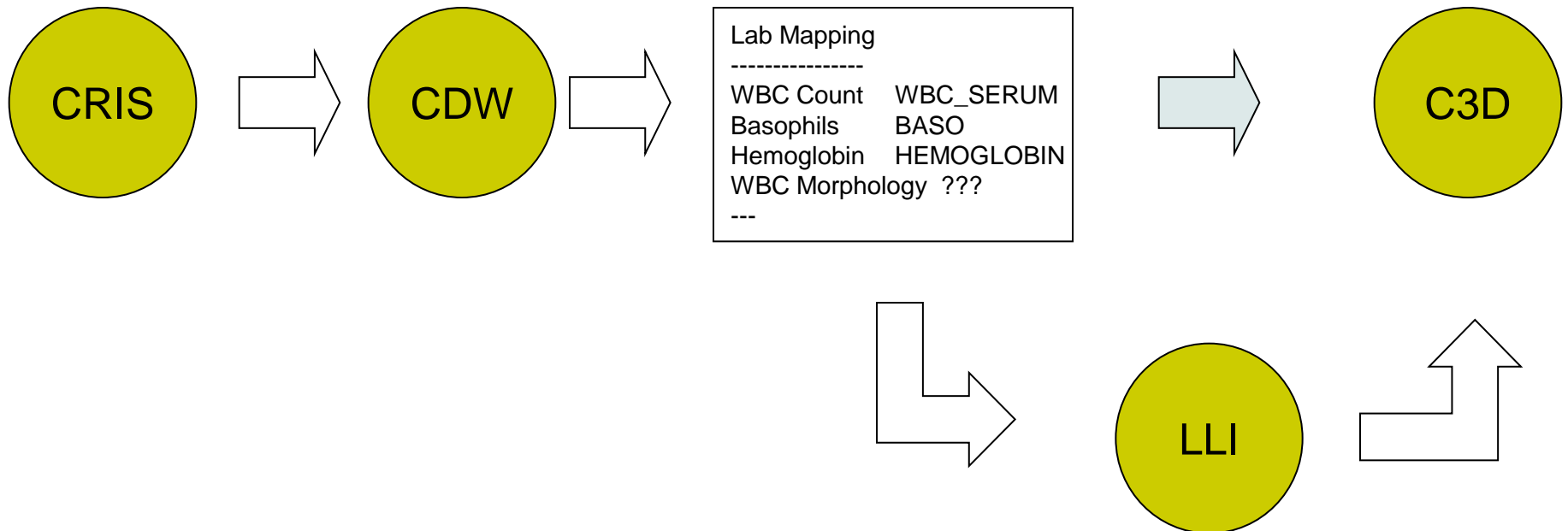
Select Patients and... Open Patient Casebooks Go

Home Casebooks Review Reports Logout Preferences Change Password Help

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

Click to Log out

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 Criteria

Search Criteria

Study Pt Lab Panel C3D Test Name

Date Relation DD MON YYYY

Time Relation HH24 MI

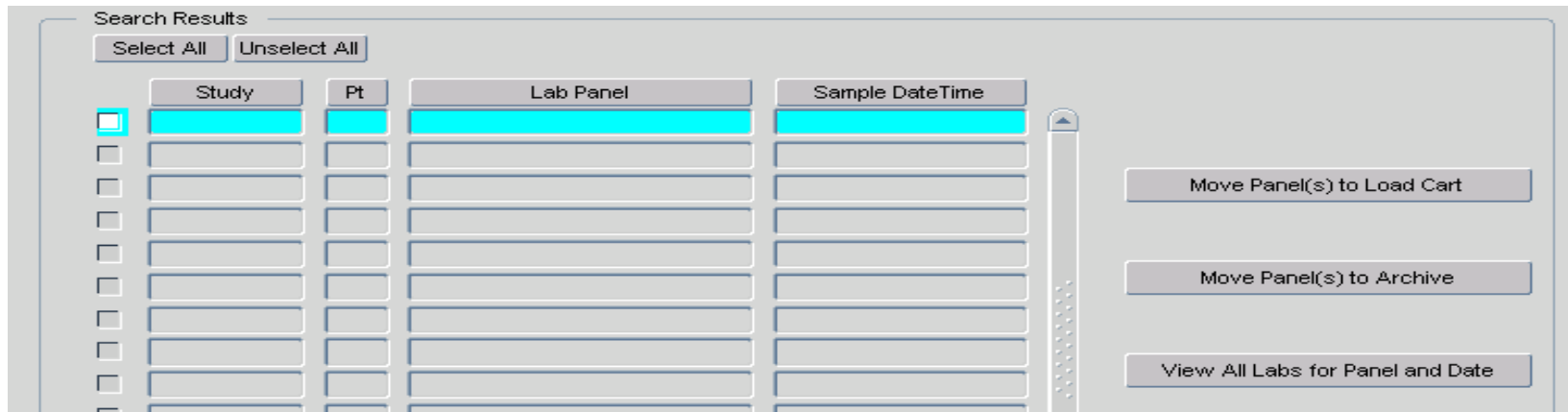
Search

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 is a 'Work Selection' section with input fields for 'Study', 'Pt', 'Sample Datetime', and 'Lab Panel'. Below this is a 'Selection Results' section containing 'Select All' and 'Unselect All' buttons. The main part of the interface 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' radio button 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"/>					
<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

Questions?

