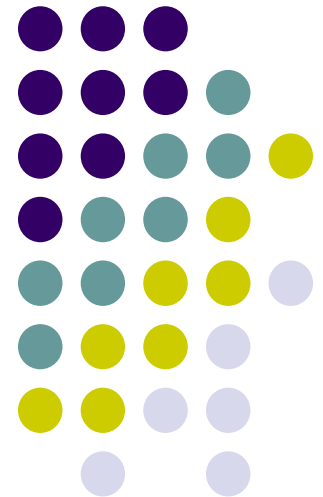


Introduction to C³D

Harris Corporation

May 2017



Introduction

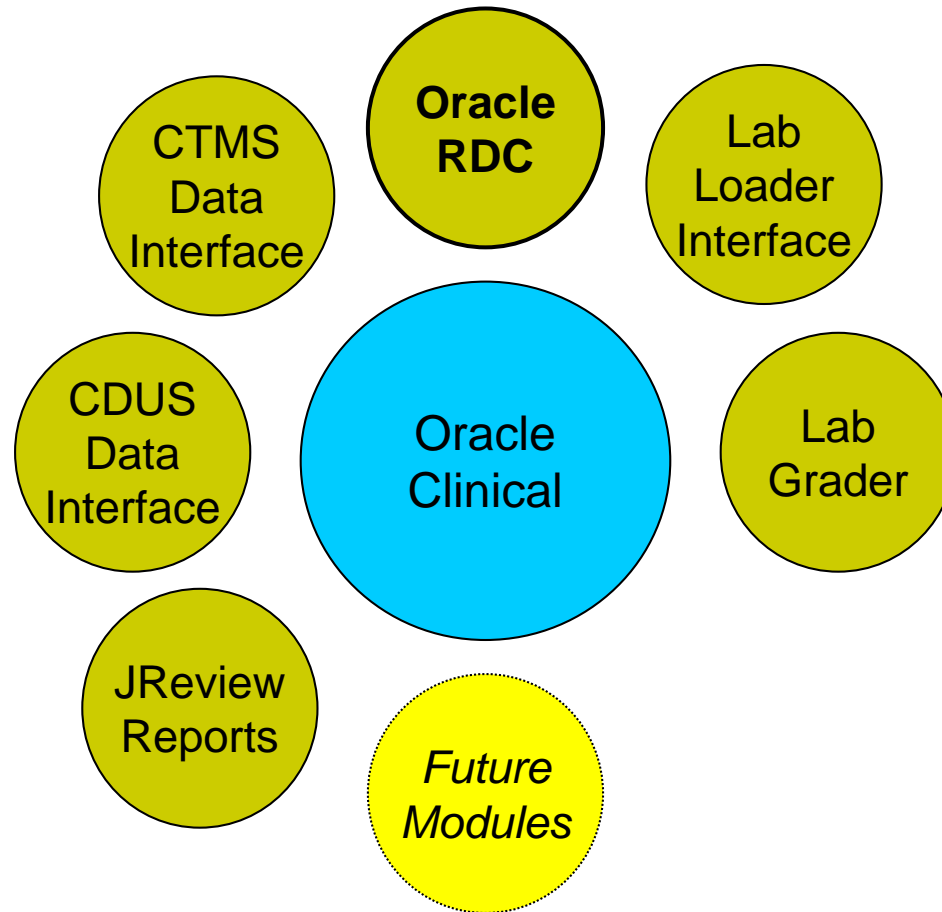
- C³D - **C**ancer **C**entral **C**linical **D**atabase
- eCRFs Instructions Manual
- Support
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval
- Lab Loading

What is C³D

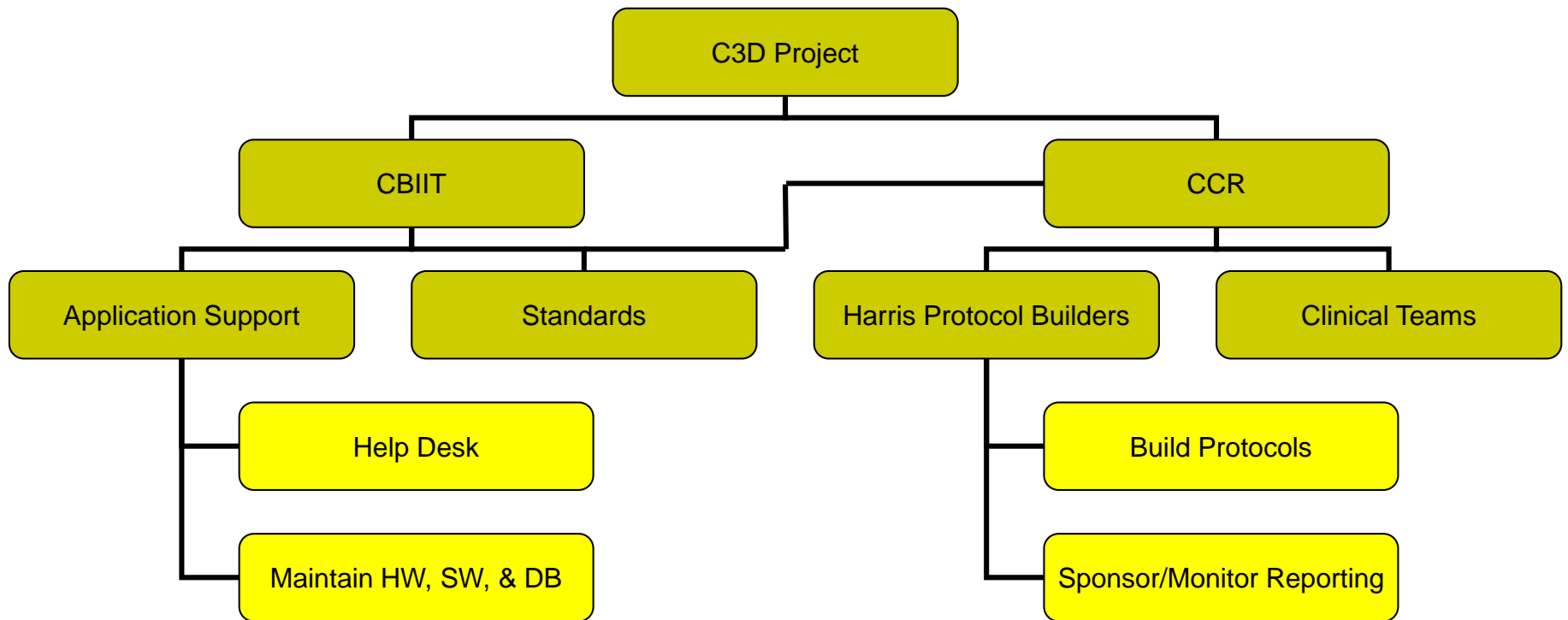


- Clinical Trials Data Management System
- RDC (Remote Data Capture) Data Entry
 - Accessible anywhere in the world (via a Windows computer and Internet Explorer).
- C³D supports data standardization, reuse, sharing, and interoperability through electronic Case Report Forms (eCRFs) based on Common Data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

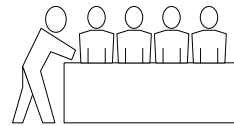
Cancer Central Clinical Database C³D



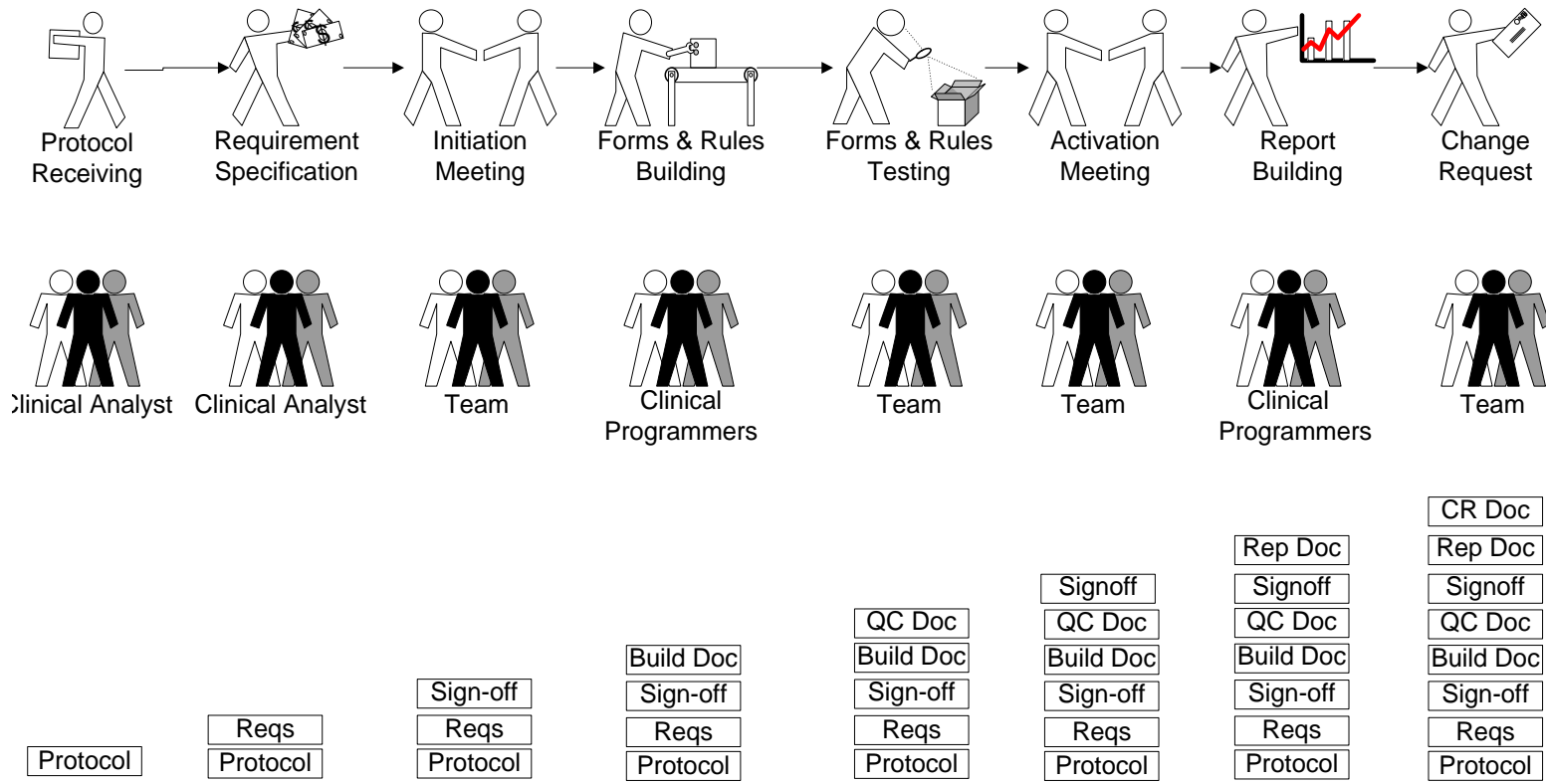
C³D Organization



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

eCRF Instructions Manual

Course Initiation

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

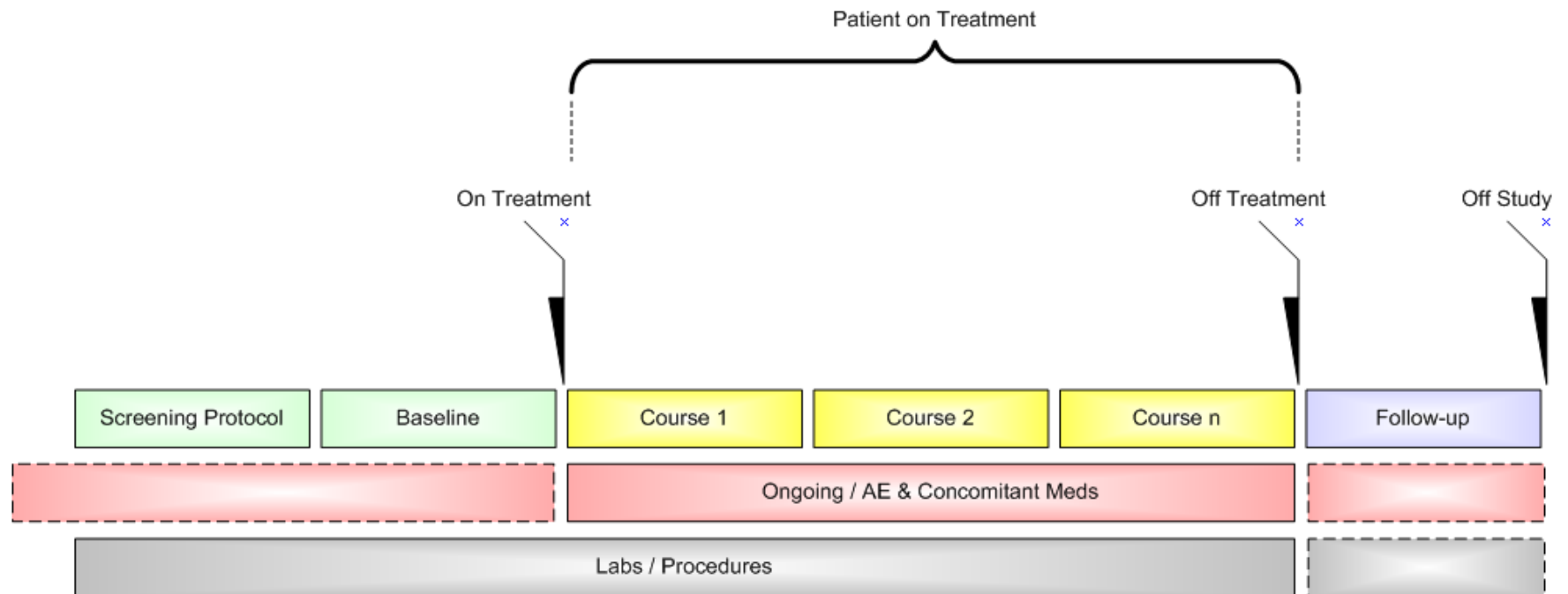
Field Name	Description / Instructions	Format
Visit Date ^(m)	Enter the date the course started.	DD-MMM-YYYY
Course # ^(d)	Sequential number of this course of treatment: first course = 1, second course = 2, etc.	5 digits
Start Date of Course ^(m)	Enter the date on which the course was started. This is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

CCR Standard Case Report Forms

- Screening/Baseline Forms
 - Eligibility, Enrollment, PE, Vitals, Baseline Symptoms, Prior Therapies, ...
- Courses/Cycles
 - Course Initiation, Study Medication Administration, PK, Course Assessment, PE, ...
- Labs
 - Blood Chemistry, Hematology, ...
- Ongoing
 - 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

NCI/CCR Confidentiality Agreement – Training Certificate

- At the end of the Training session, print, sign and fax the CCR Confidentiality Agreement to 240-541-4435. You can also scan and e-mail it back to the Trainer.
- Upon receipt of the CCR Confidentiality Agreement:
 - The request for your C3D account, password and access will be submitted. The C3D Help Desk will provision your C3D account within 2 business days.
 - The Certificate you attended the training will e-mailed to you.
 - Keep your signed CCR Confidentiality Agreement and the Training Certificate in your Study's regulatory binder.

C³D Support

- CBIIT provides the first line of support for C³D related issues
- Contact
 - ❑ Email: ncicbiit@mail.nih.gov
 - ❑ Phone: 240-276-5541 (**Toll free**: 888-478-4423)
 - Telephone support is available Monday to Friday, 9:00 a.m. to 5:00 p.m. Eastern Time, excluding government holidays.
 - ❑ 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:
 - ❑ Start with a letter;
 - ❑ Must containing **at least one number and one special characters** (Ex:! #);
 - ❑ Has to be at least 8 characters long;
 - ❑ The following special character could cause problems if used: \$ % & ' " /.
- About C³D Password:
 - ❑ **Do not share the password with others!**
 - ❑ Password needs to be changed the first time you login
 - ❑ Password expires every 4 months and needs to be changed
 - ❑ **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/opa51/rdclaunch.htm>
- C³D provides a separate Data Entry environment to test protocol design
 - Test Login page:
<https://octrials.nci.nih.gov/opa51/rdclauncht.htm>

C³D Login Web Page

ORACLE[®] RDC Onsite Help

Enter User Name, Password and click on Login button

* User Name

* Password

Help

Copyright

C³D RDC Home Page

The screenshot shows the Oracle RDC Onsite interface. At the top, it says "ORACLE RDC Onsite" and "Logged in as Marcelo Fontinha(DM, OCPR0D); Last Refresh 11-Apr-2017 13:57:09". Below this is a navigation bar with tabs for "Home", "Patient Casebooks", "Review", "Reports", and "Source Data Verification Plan". On the right of the navigation bar are links for "Logout", "Preferences", "Change Password", and "Help".

Below the navigation bar, there are dropdown menus for "Study" (set to "CCR_ROS_2011_V1") and "Site" (set to "NCI"). Below these is a link for "Study and Site Summary".

On the left side, there is a sidebar with sections: "News", "Activities" (with links to "Review 550 Active Discrepancies", "Review 5 Other Discrepancies", and "Review Investigator comments"), and "Links" (with links to "App Support Ticket", "C3D Enhancement Form", "OCUG - Oracle Clin Users Group", "21 CFR Part 11", "eCRF Instructions Manual", and "Search on web").

The main content area is titled "Patient Search" and contains a table of patients. A yellow box labeled "Support Contact" points to the top of the table. Another yellow box labeled "Change Password" points to the top right of the table. A third yellow box labeled "eCRFs Instructions Manual" points to the "eCRF Instructions Manual" link in the sidebar.

Action	Patient Number	Last Modified	Casebook
	1010001	11-Apr-2017 12:2...	BOOK_0_26OCT2011
	1010002	11-Apr-2017 10:3...	BOOK_0_26OCT2011
	1010003	09-Nov-2016 16:3...	BOOK_0_26OCT2011
	1010004	12-Oct-2016 16:3...	BOOK_0_26OCT2011
	1010005	12-Oct-2016 17:0...	BOOK_0_26OCT2011
	1010006	10-Aug-2016 15:4...	BOOK_0_26OCT2011
	1010007		
	1010008		
	1010009	07-Dec-2016 13:2...	BOOK_0_26OCT2011
	1010010	09-Nov-2016 16:3...	BOOK_0_26OCT2011
	1010011	11-May-2015 12:5...	BOOK_0_26OCT2011
	1010012	10-Mar-2015 17:4...	BOOK_0_26OCT2011
	1010013	24-Jul-2014 09:49...	BOOK_0_26OCT2011
	1010014	24-Jul-2014 09:49...	BOOK_0_26OCT2011
	1010015	28-Mar-2016 13:5...	BOOK_0_26OCT2011
	1010016	09-Sep-2015 16:2...	BOOK_0_26OCT2011

At the bottom of the page, there is a footer with "About RDC 5.1.0" on the left and "Home Patient Casebooks Review Reports Logout Preferences Change Password Help" on the right. Below the footer is the copyright notice: "Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved."

Home Page Activities

1. Select a Study and a Site
 - Access to studies is controlled by user role
 - C³D remembers that last study used in prior login
2. Select a Patient
 - Click on a patient position to select it (row background turns yellow).
It is recommended to work one patient at time.
 - To select multiple patients, use control + click on multiple patient positions.
3. Select an Action:
 - Multi-patient View (**Recommended**)
 - Single-patient View
 - Review Discrepancies
 - Review CRFs
 - Review Investigator Comments
 - Generate Patient Data Report
- Specify Patient Search Criteria (optional)
 - Enter a range of patient positions
 - Enter a patient reference (if field available)
(ex: %123% to search for patients with 123 in their MRN)
 - Select Casebook form the Assigned Book dropdown list
 - Discrepancy Status
 - From the Show dropdown list, select Patients with data entered or without data entered
- Activity Links (optional)
 - Review ##,### Active Discrepancies
 - Review Investigator Comments

Home Page Activities

The screenshot shows the Oracle RDC Onsite interface. At the top, it says "ORACLE RDC Onsite" and "Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 11-Apr-2017 13:59:53". The navigation bar includes "Home", "Patient Casebooks", "Review", "Reports", "Logout", "Preferences", "Change Password", and "Help".

Annotations and activities:

- 1 – Select a Study and a Site:** Points to the "Study" dropdown (set to "CCR_ROS_2011_V1") and the "Site" dropdown (set to "NCI").
- Activity Links:** Points to the left sidebar menu containing "News", "Activities", and "Links".
- Patient Search Criteria:** Points to the "Patient Search" section, which includes fields for "Range", "Assigned Book", "Show for Status", and "Discrepancy", along with "Search" and "Reset" buttons.
- 2 - Select Patient:** Points to the "Patients" table, where the row for patient ID "1010013" is highlighted.
- 3 – Select an Action:** Points to the "Action" dropdown menu, which is open and shows options like "Multi-Patient View", "Single Patient View", "Review Discrepancies", "Review CRFs", "Review Investigator Comments", and "Generate Patient Data Report".

The "Patients" table contains the following data:

Action	Multi-Patient View	Single Patient View	Review Discrepancies	Review CRFs	Review Investigator Comments	Generate Patient Data Report		
	1010007	1010008	1010009	1010010	1010011	1010012	1010013	1010014

At the bottom, it says "About RDC 5.1.0" and "Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved."

Navigating Casebook

- Casebook List
 - Click on Casebook dropdown list to select one of the available Casebooks (latest casebook is the default one)
- Visit List
 - Click on Visit dropdown list to switch to another Visits (Screening is the first visit)
- Casebook Multiple Patient Visit Layout
 - One row per Patient with identifier on the left
 - Visit's eCRFs along Columns
- Click on an eCRF icon to open it

RDC Casebook

The screenshot shows the Oracle RDC Onsite interface. At the top, the header includes the Oracle logo, 'RDC Onsite', and user information: 'Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 08:46:32'. Below the header is a navigation bar with tabs for 'Home', 'Patient Casebooks', 'Review', 'Reports', and 'Source Data Verification Plan'. On the right of the navigation bar are links for 'Logout', 'Preferences', 'Change Password', and 'Help'. Below the navigation bar, there are filters for 'Study' (CCR_ROS_2011_V1), 'Site' (NCI), and 'View' (Multiple). A 'Study and Site Summary' link is also present.

The main content area is titled 'Patient Casebooks' and includes a search bar showing '1 Patients Selected From Home Page'. Below the search bar are dropdowns for 'Casebook' (BOOK_0_26OCT2011) and 'Visit' (SCREENING_BASE). There are buttons for 'Add Visit Page' and 'Add Other Page', and a 'View' dropdown set to 'Multiple'. A table below shows patient data for the 'SCREENING_BASE' visit. The table has columns for Patient Number, Elig, Enroll, MRN, Medhist, Prior_Rad, Prior_Surg, and Prior_Thrp. The first row shows patient 1010013 with status icons for each column. Annotations with yellow boxes and arrows point to various elements: 'Casebook List' points to the Casebook dropdown, 'Visits List' points to the Visit dropdown, 'eCRFs within a visit' points to the Prior_Rad icon, and 'Patients listed on the left' points to the patient number 1010013.

SCREENING_BASE								
Icon	Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp
	1010013							

Columns Frozen 2

Footer: About RDC 5.1.0 Home Patient Casebooks Review Reports Logout Preferences Change Password Help Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

Patient Casebook Search Criteria

- Allows for additional Casebook Search Criteria not found in the Home Page Patient Search. Click on the > icon to open the Search area and then specify the desired criteria:
 - Patient:
 - Patient Position range
 - Assigned Casebook
 - Status
 - CRF Status:
 - Data Entry
 - Discrepancy
 - Verification
 - Approval
 - CRF Source:
 - Casebook
 - Visit
 - CRF Name
- Then click on **Search** button.
- Note that the search result only lists CRFs that have been created and saved. Planned CRFs that have not yet been used, are not displayed.

Patient Casebook Search Criteria

ORACLE® RDC Onsite Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 08:55:41

Home **Patient Casebooks** Review Reports Source Data Verification Plan Logout Preferences Change Password Help

Study CCR_ROS_2011_V1 Site NCI View Multiple

Study and Site Summary
Home >

Patient Casebook Search Criteria

Search : 1 Patients Selected From Home Page

Patient: Range Assigned Book Any Status All

CRF Status: Entry All Discrepancy All Approval All Verification All

CRF Source: Casebook All Visit All CRF Name All

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE









Action View Multiple

SCREENING_BASE								
	Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp
	1010013	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input checked="" type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7

Columns Frozen 2

About RDC 5.1.0 Home Patient Casebooks Review Reports Logout Preferences Change Password Help
Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

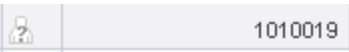

Important eCRF Icons

-  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 and saved 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

- From the C³D Home Page: click on a patient position that has the question mark inside the pers 
 - Then click on the Action dropdown and select “Multi-Patient View”
- From the Casebook Page: expand the Search section, click on the **Reset** button, select **Patients with no Data Entered** from the **Status** dropdown list and click on the **Search** 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:**
 - Use the patient positions numbers according to those assigned by Central Registration Office (CRO).
 - 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

ORACLE® RDC Onsite Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 09:11:47

Home **Patient Casebooks** Review Reports Logout Preferences Change Password Help

Study Site View

Study and Site Summary
Home >

Search for Patient Positions with no data entered

TIP Perform search to retrieve patient data.

Search

Patient: Range Assigned Book Status

CRF Status: Entry Discrepancy Approval

CRF Source: Casebook Visit CRF Name

Patient Casebooks

Casebook: Visit:

Action View

SCREENING								
	Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp
	1010019	<input type="button" value="eCRF"/> 1	<input type="button" value="eCRF"/> 2	<input type="button" value="eCRF"/> 3	<input type="button" value="eCRF"/> 4	<input type="button" value="eCRF"/> 5	<input type="button" value="eCRF"/> 6	<input type="button" value="eCRF"/> 7

Click on eCRF icon to begin data entry

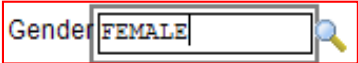
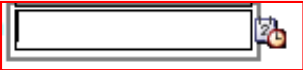
Columns Frozen 2

About RDC 5.1.0 Home Patient Casebooks Review Reports Logout Preferences Change Password Help
Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

Electronic CRF (eCRF)

- eCRF Header and Footer display eCRF identification information
- Visit Date is mandatory for most forms:
 - ❑ **In Lab eCRFs, Visit Date is the Lab Sample Collection Date**
 - ❑ Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc. Refer to the eCRFs Instructions Manual.
 - ❑ Visit Date is not needed on eCRFs on Ongoing Visit, but required everywhere else.
- Navigate within eCRF by:
 - ❑ Using Tab and Shift-Tab keys or left Mouse click to place the cursor on a field.
 - ❑ Use the scrollbars or the Toolbar page navigation icons to go to a different page.
 - The last page of an eCRFs is a general comments page.
- **Quick Tip:**
 - ❑ Up to 3 eCRFs can be open for simultaneously for data entry. An additional 2 eCRFs can be opened in read-only mode.
 - ❑ **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)

- Fields with magnifying glass  have a pick list of acceptable values.
 - ❑ With the pick list shown, press **CTRL + F** to search the pick list.
 - ❑ 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.
 - ❑ **Using the Pick List is particularly important in these two fields below because the MedDRA code is derived 'behind-the-scenes'.**
 - Enrollment Disease Term
 - Baseline Symptoms and Adverse Events CTCAE Term.
- Enter Dates as:
 - ❑ Complete dates for Current Information (ex: 5/23/2014, 5-23-2014 or 05232014)
 - ❑ MMYYYY for Prior Information is acceptable when complete date cannot be obtained (ex: 05-00-2014, 05/00/2014, 05002014)
 - ❑ 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: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile

Previous CRF | Next CRF

Highlight: Active and Other Discrepancies

Page 1/2

ENROLLMENT

Study: CCR_ROS_2011_V1 Site: NCI Visit: SCREENING_BASE Patient: 1010013

Visit Date: Mark CRF Blank: Comment:

Section blank?

DEMOGRAPHY

Gender: Date of Birth: Age at Entry: Patient Initials:

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:

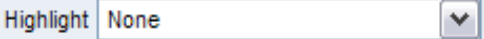










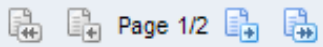

Disease Stage at Entry: **II A**
T Stage: N Stage: M Stage:
Date of Confirmation of Histology:
Grade of Histology:
Date of Informed Consent Version:

Doc# R403709001 Status Created Verified Approved Locked CRF Page 2.1

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.



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
-  Generate CRF Report
-  Generate CRF History
-  Delete 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. 

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 Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile Previous CRF Next CRF

Highlight Active and Other Discrepancies

CENTER FOR CANCER RESEARCH

Study CCR_ROS_2011_V1 Site NCI

Visit Name ONGOING Mark CRF Blank

Type AE1 Section blank? **To Delete selected Row**

ADVERSE EVENTS

Course Dy in Num	Prior Course	Date of Onset	Resolved	CTCAE Term	SOC	AE	Attribution to	Other C
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/>
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/>
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/>
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/>
___	___	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			<input type="checkbox"/>

Number of rows per page is fixed.

a) Use the Toolbar Page Navigation icons or;

b) Use the vertical scrollbar to navigate to another page.

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved

eCRF and Section Blank Checkboxes

- Entire eCRF can be marked Blank.
 - Use the 'Mark CRF Blank' checkbox.
- Individual sections of eCRF can be marked Blank.
 - 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: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile Previous CRF Next CRF

Highlight Active and Other Discrepancies Page 6/6

CENTER FOR CANCER RESEARCH

Study CCR_ROS_2011_V1 Site NCI

Visit Name ONGOING Mark CRF Blank

Section blank?

Marking entire eCRF Blank


Marking Section Blank

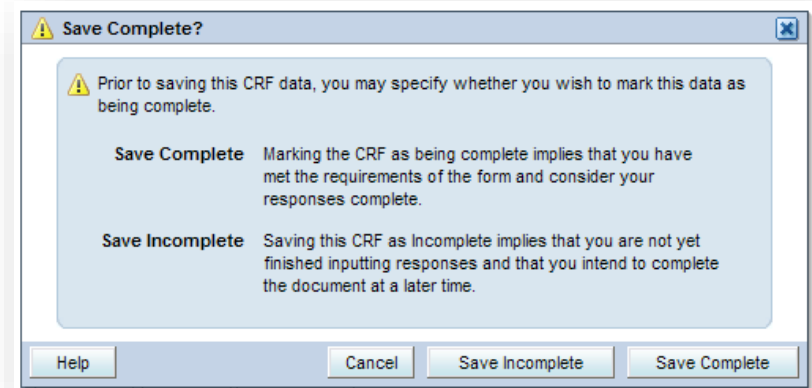
COMMENTS

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

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

Saving eCRF

- Click on the  green floppy disk icon to save the eCRF.
 - Save Often!! Especially while entering Ongoing Information such as Adverse Events and Concomitant Medications.
- Choose how to save the eCRF:
 - **Save Incomplete**
 - Only save CRF as incomplete for a short period of time.
 - Discrepancies are not created for mandatory fields that have not been touched (cursor not placed in field).
 - Overnight validation checks and derivations are not executed.
 - Verification and Approval cannot be done.
 - CRF's Data not available to be submitted via CTMS and CDUS!
 - Audit-trail enabled.
 - **Save Complete**
 - eCRF Status changes to Entry Complete.
 - All validation checks and derivations are executed.
 - Verification and Approval can be done.
 - Audit-trail prompts user for a reason for the change!



- **Quick Tip:**
 - 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

ORACLE RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile Previous CRF Next CRF

Highlight Active and Other Discrepancies Page 1/2

Save Icon

Save Prompt

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.

Help Cancel Save Incomplete Save Complete

Center for Cancer Research

Study CCR_ROS_2011_V1 Patient 1010013

Visit URINALYSIS Site NCI

Comment

Lab Date 11-APR-2017 Mark CRF Blank

Lab Time 14:23:00 Section blank?

URINALYSIS

Course #

Lab Test

GLUCOSE_UR

PROTEIN_QUAL_UR

UROBILINOGEN_UR

PH_UR

HGB_UR

KETONES UR

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

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:**
 - ❑ Do not use personnel/patient names or identifiers in the comments.

Data Entry Change Reason

ORACLE® RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile Previous CRF Next CRF

Highlight Active and Other Discrepancies Page 1/2

CENTER FOR CANCER RESEARCH

Study CCR_ROS_2011_V1 Site NCI Visit OFFSTUDY Patient

Visit Date 11-APR-2017 Mark CRF Blank Comment

Section blank?

SURVIVAL

Date of Death 11-APR-2017

Cause of Death (Presumed) M

Autopsy Results Available? Y

Cause of Death (Autopsy Finding)

Sites of Disease at Autopsy

Reason for Change

*Reason CRA Correction, Src Data consulted


Comment (optional) Autopsy results made available on 4/12/2017

Help Cancel OK

Change Reason Prompt

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

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:**
 - ❑ Auditing begins as soon as the eCRF is 'Saved Complete'.
 - ❑ 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.
 - ❑ **Do not share user IDs and passwords!**

Audit Trail

The screenshot shows the Oracle RDC Onsite: Data Entry interface. At the top, the title bar reads "ORACLE RDC Onsite: Data Entry" and the breadcrumb trail shows "Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011". A "Highlight" dropdown menu is set to "Audit History".

Below the header, the "CENTER FOR CANCER RESEARCH" logo is visible. The main form area includes fields for "Study" (CCR_ROS_2011_V1), "Site" (NCI), "Visit" (OFFSTUDY), and "Patient". A "Visit Date" field is set to "11-APR-2017". A "Section blank?" checkbox is present.

The "SURVIVAL" section contains a "Date of Death" field (11-APR-2017) with a blue background, a "Cause of Death (Presumed)" field, and an "Autopsy Results Available?" field with a blue background. A vertical handle is located between the "Autopsy Results Available?" field and the "Cause of Death (Autopsy Finding)" field.

At the bottom, the "Audit History: Autopsy Results Available?" panel is expanded, showing a table of changes:

Date	Changed To	By	Reason	Comment	Details
12-APR-2017 09:3Y		Marcelo Fontinha (DM)	CRA CORR-SRC	Autopsy results made available on 4/12/2017	[Details]
12-APR-2017 09:3U		Marcelo Fontinha (DM)			[Details]

Yellow callout boxes provide instructions: "Highlight Audit History Option" points to the dropdown menu; "Field with blue background indicates presence of Audit-trail" points to the blue background of the "Date of Death" and "Autopsy Results Available?" fields; "Click on this handle to show/hide the Audit History panel." points to the vertical handle; and "Audit-trail details" points to the audit history table.

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 displays the ORACLE RDC Onsite web application interface. At the top, the user is logged in as Marcelo Fontinha (DM, OCPROD) with a last refresh time of 12-Apr-2017 09:49:55. The navigation menu includes Home, Patient Casebooks, Review, Reports, and Source Data Verification Plan. The current page is 'Patient Casebooks', with filters for Study (CCR_ROS_2011_V1), Site (NCI), and View (Multiple). A search bar indicates '1 Patients Selected From Home Page'. Below the search bar, the 'Patient Casebooks' section shows a Casebook of 'BOOK_0_26OCT2011' and a Visit of 'URINALYSIS'. The 'Action' menu includes 'Add Visit Page' and 'Add Other Page'. A table below shows a list of patients with columns for Patient Number and Urinalysis. The patient with ID 1010013 is selected, and the 'Add Visit Page' button is highlighted with a yellow callout box labeled '2. Click Add Visit Page'. Another yellow callout box labeled '1. Select Patient' points to the patient ID 1010013 in the table.

2. Click Add Visit Page

1. Select Patient

	Patient Number	Urinalysis
	1010013	62

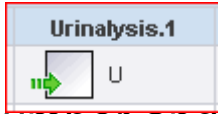
Entering/Viewing Laboratory Data

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

CRF Short Name	CRF Name
Urinalysis	URINALYSIS

- Click on **Continue**
 - Sub-visit indicates the number of the additional unplanned CRF added to the Visit.

Selected CRF: Urinalysis
Select Sub-visit: 1

- Click on the new Unplanned Lab eCRF icon  to begin data entry.
 - Unplanned CRF have the same page number and the planned one followed by the letter U and the sub-visit number

		URINALYSIS	
	Patient Number	Urinalysis	Urinalysis.1
	1010013	62	62 U1

Entering/Viewing Laboratory Data

- Enter the Lab Date (**Sample Collection Date**).
- Enter the Lab Time (**Sample Collection Time**) using military time (seconds are optional and default to 00 if not entered). **Lab Time is required.**
- Optionally, choose a Lab Source from the Lab dropdown list.
 - **Outside** option is normally used to indicate panel was done in a location other than the patient's site.
 - 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:
 - http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm

Entering/Viewing Laboratory Data

ORACLE RDC Onsite: Data Entry Preferences Help

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile Previous CRF Next CRF

Highlight: Active and Other Discrepancies

page 1

Study CCR_ROS_2011_V1 Patient 1010013
 Visit URINALYSIS Site NCI

Comment
 Lab Date Mark CRF Blank

Lab Time Section blank?

URINALYSIS

Course # Day in Course

Enter the Lab Result, UOM and Normal Range

	Value	UOM	Normal Range (e.g. 1.5-5)	Range Indicator	Value 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"/>
PH_UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
HGB_UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
KETONES UR	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Course # and Day in Course computed in relation to Courses Start and End Dates

Range Indicator and Grade computed by C³D

Copyright © 1993, 2014, Oracle and/or its affiliates. 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.
- Discrepancies are tools to assist teams in identifying potential data inconsistencies and facilitate real-time QA of 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's definition (e.g. mandatory, length, type, range, pick list, etc.)
- Multivariate
 - ❑ Based on a condition on one or more questions 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

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:**
 - ❑ Data Managers should manage their discrepancies every morning to help ongoing QA of data.

Outstanding Discrepancies in a Study

ORACLE® RDC Onsite
 Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 10:20:43

Home Patient Casebooks Review Reports Source Data Verification Plan Logout Preferences Change Password Help

Study CCR_ROS_2011_V1 Site NCI
 Study and Site Summary

Click to view a list of all Discrepancies

News
 Activities
 Review 550 Active Discrepancies
 Review 5 Other Discrepancies
 Review Investigator comments
 Links
 App Support Ticket
 C3D Enhancement Form
 OCUG - Oracle Clin Users Group
 21 CFR Part 11
 eCRF Instructions Manual
 Search on web

Patient Search

Patients

Action	Patient Number	Last Modified	Casebook
	1010013	12-Apr-2017 09:5...	BOOK_0_26OCT2011

Red icon indicates Patient has discrepancies in one or more eCRFs

Home Patient Casebooks Review Reports Source Data Verification Plan Logout Preferences Change Password Help

CRFs Discrepancies Investigator Comments

Study CCR_ROS_2011_V1 Site NCI
 Home >

TIP Perform search to retrieve patient data.

Search

Review 550 Active Discrepancies
 Patients 20 Total CRFs 81 Total Discrepancies 550

Patient Number	Visit		CRF Name	CRF Number	Discr ID	Question / Section	Response	Review Status	Description	Detail	Open CRF
	Name	Date									
1010001	SCREENING_BASE	01-Nov-2011	MEDICAL RECORD...	R211033301	357192201	MULTI	MULTI	UNREVIEWED	The format for NL...		
1010001	SCREENING_BASE	01-Nov-2011	MEDICAL RECORD...	R211033301	360159001	MULTI	MULTI	UNREVIEWED	The format for NL...		
1010001	COURSE 1	01-Nov-2011	COURSE INITIATI...	R211039201					2 for Arm is not fo...		

Click to view Discrepancy details

Click to open related eCRF and manage discrepancies

eCRFs Containing Discrepancies



Study CCR_ROS_2011_V1 Site NCI View Multiple

Study and Site Summary

Home >

Search : 1 Patients Selected From Home Page

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE

Action



Add Visit Page


Add Other Page

View Multiple

SCREENING_BASE								
Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp	
1010013	1	2	3	4	5	6	7	

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.
 - ❑ Manually closing discrepancies is highly undesirable. It should be the exception.

Discrepancies Tab

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha)

Enumerates all discrepancies

Select option to highlight discrepancies

Highlight: Active and Other Discrepancies

Center for Cancer Research

Study: CCR_ROS_2011_V1, Site: NCI, Visit: SCREENING_BASE, Patient: 1010013

Visit Date: 11-APR-2017

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

Discrepancy

Show: All Discrepancies

4/6

List

- Grade (row 1)
- Related To Disease? (row 1)
- Date of Onset (row 2)
- CTCAE Term (row 2)
- Grade (row 2)
- Related To Disease? (row 2)

Details

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

Type: UNIVARIATE

Created By: Marcelo Fontinha

Review Status: Not yet reviewed

Reason: Thesaurus

Comment

Last Updated: 12-APR-2017 10:31:34

Details of selected Discrepancy

Date of Onset	Date Resolved	System Organ Class	CTCAE Term	Symptom Description	Grade	Related To Disease		
						Yes	No	Unknown
01-JAN-2001	01-FEB-2001	Nervous system disorder	Abducens nerve disorder			<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
00-00-2002			other			<input checked="" type="radio"/>	<input checked="" 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"/>

Route or Manually Close Discrepancy

Action: [Dropdown] Go

Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

How are Univariate Disc. Created?

- Univariate Discrepancies warning pop-up presented during data entry when the entered value does not match the field definition:
 - Mandatory field left empty
 - Text entered in a Date or Numeric Field
 - Too many characters entered
 - Value is not on the Pick List (**some pick lists are case sensitive!**)
 - A “Lookup Thesaurus” is a non-study specific picklist which the values are “controlled” - they either have all the values needed or a change will require approval.
 - Partial Date entered when a complete date is required; or less than the expected date components entered (ex: Only 2001 entered for year when date field expects also a month)
- Data Entry operator can:
 - Cancel the pop-up and fix the value
 - Or accept the discrepancy and address it later
- **Quick Tip:**
 - Univariate Discrepancies are reassessed when date changes and during Batch Validation when field design or validation check change.

How are Univariate Disc. Created?

ORACLE[®] RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile

Highlight: Active and Other Discrepancies

Univariate Discrepancy Prompt

Study: CCR_ROS_2011_V1 Site: NCI Visit: SCREENING_BASE Patient: 1010013

Visit Date: 11-APR-2017 Mark CRF Blank

Section blank?

BASELINE SYMPTOMS

Date of Onset	Date Resolved	System Organ Class	CTCAE Term
01-JAN-2001	01-FEB-2001	Nervous system disorder	Abducens nerve disorder
00-00-2002			hypoglycemia

Validation Error and Reason for Change

Reason: **Thesaurus**

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

Comment (optional):

Action:

Review Status: **Not yet reviewed**

Change Reason

*Reason: Data Entry Error

Comment (optional):

Buttons: Help, Cancel, OK

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 validation rules are evaluated upon completion of a CRF **Saved as Complete**
 - ❑ 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:**
 - ❑ Complex rules run overnight.

How to Address a Discrepancy

- Review Discrepancy Details
- Resolve the discrepancy by:
 - Consulting Source Documentation and;
 - Modifying incorrect data and specifying change reason;
 - Requesting eCRF Design and/or Validation Rule Change.
 - Include Protocol section reference if request supported by Protocol.
- **Quick Tip:**
 - System obsoletes univariate discrepancy automatically when data is corrected and complies with design/rules.
 - Multivariate Discrepancies are only re-evaluated during overnight Batch Validation.

How to Address a Discrepancy

The screenshot shows the ORACLE RDC Onsite: Data Entry interface. The top navigation bar includes 'ORACLE RDC Onsite: Data Entry', 'Preferences', and 'Help'. The study information is 'Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile'. The 'Highlight' dropdown is set to 'Active and Other Discrepancies'. The main content area shows the 'CENTER FOR CANCER RESEARCH' logo and study details: 'Study CCR_ROS_2011_V1', 'Site NCI', 'Visit SCREENING_BAS', and 'Visit Date 11-APR-2017'. There are checkboxes for 'Section blank?' and 'Mark CRF Blank'. Below this is a table titled 'BASELINE SYMPTOMS' with columns: 'Date of Onset', 'Date Resolved', 'System Organ Class', 'CTCAE Term', and 'Symptom Descriptio'. The first row has '01-JAN-2001' and '01-FEB-2001'. The second row has '00-00-2002' highlighted in red. A yellow callout box points to this row with the text: 'Fix Data as indicated in the Discrepancy Text'. To the right, a 'Discrepancy' panel is open, showing a list of discrepancies: 'Grade (row 1)', 'Related To Disease? (row 1)', 'Date of Onset (row 2)', 'CTCAE Term (row 2)', and 'Grade (row 2)'. Below the list is a 'Details' section with 'Related Values' and 'History' buttons. At the bottom right, an 'Action' dropdown menu is open, showing options: 'Send to CRA', 'Send to Investigator', 'Close - resolved', 'Closed - no resolution', and 'Send for classification'. A yellow callout box points to this menu with the text: 'If Data cannot comply with Design/rules, and in rare exceptions, select an Action from Pull Down Menu to Manually Close the Discrepancy.'

ORACLE RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile

Highlight Active and Other Discrepancies

Page 1/2

CENTER FOR CANCER RESEARCH

Study CCR_ROS_2011_V1 Site NCI Visit SCREENING_BAS

Visit Date 11-APR-2017 Mark CRF Blank Comment

Section blank?

Fix Data as indicated in the Discrepancy Text

BASELINE SYMPTOMS

Date of Onset	Date Resolved	System Organ Class	CTCAE Term	Symptom Descriptio
01-JAN-2001	01-FEB-2001	Neoplasms		
00-00-2002				

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

Discrepancy Investigator Comment

Show All Discrepancies

0/6

List

- Grade (row 1)
- Related To Disease? (row 1)
- Date of Onset (row 2)
- CTCAE Term (row 2)
- Grade (row 2)

Details

Related Values History

Action

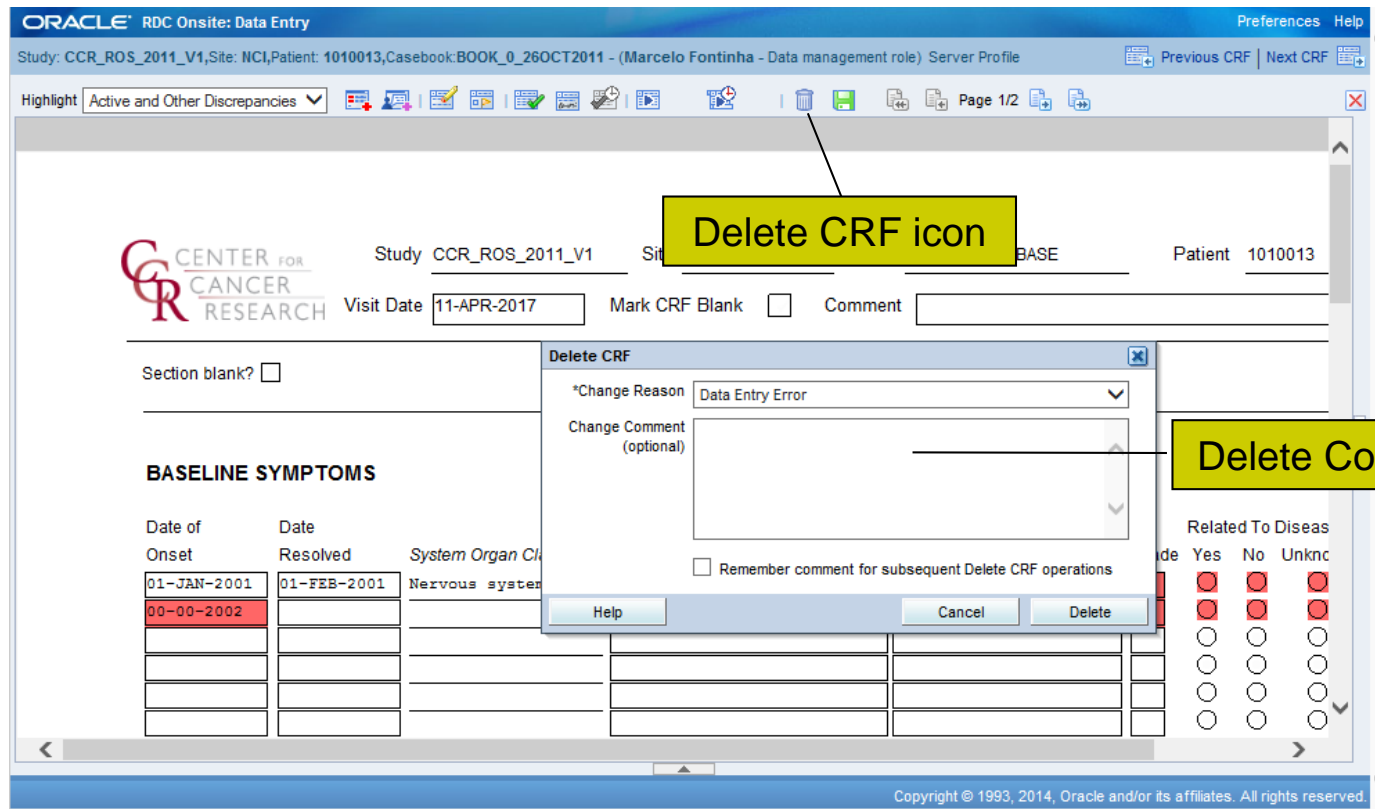
- Send to CRA
- Send to Investigator
- Close - resolved
- Closed - no resolution
- Send for classification

Go

Copyright © 1993, 2014, 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.**






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

ORACLE® RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_260C72011 - (Marcelo Fontinha - Data management role) Server Profile

Highlight: Active and Other Discrepancies

Page 1/2

Verify CRF

Verification History

Date	Operation	Changed By	Comment
------	-----------	------------	---------

Verification Comment

Remember comment for subsequent CRF Verification operations.

Help Verify Cancel

Verify Button

Verify Toolbar Icon

Verification History

Verify Button

Copyright © 1993, 2014, Oracle and/or its affiliates




CENTER FOR CANCER RESEARCH

Section blank?

BASELINE SYMPTOMS

Date of Onset	Date Resolved
01-JAN-2001	01-FEB-2001
00-00-2002	

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

ORACLE® RDC Onsite: Data Entry

Study: CCR_ROS_2011_V1, Site: NCI, Patient: 1010013, Casebook: BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role) Server Profile

Highlight: Active and Other Discrepancies

Approve Toolbar Icon

Approval History

Approve CRF

Approval History			
Date	Operation	Changed By	Comment

Approval Comment

Remember comment for subsequent CRF Approval operations.

Help Approve Cancel

Approve Button

CENTER FOR CANCER RESEARCH

Section blank?

BASELINE SYMPTOMS

Date of Onset	Date Resolved
01-JAN-2001	01-FEB-2001
00-00-2002	

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

ORACLE® RDC Onsite Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 10:58:35

Home Patient Casebooks Review Reports Source Data Verification Plan Logout Preferences Change Password Help



Study CCR_ROS_2011_V1 Site NCI View Multiple










Study and Site Summary
Home >

> Search : 1 Patients Selected From Home Page

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE

Action   Add Visit Page Add Other Page View Multiple

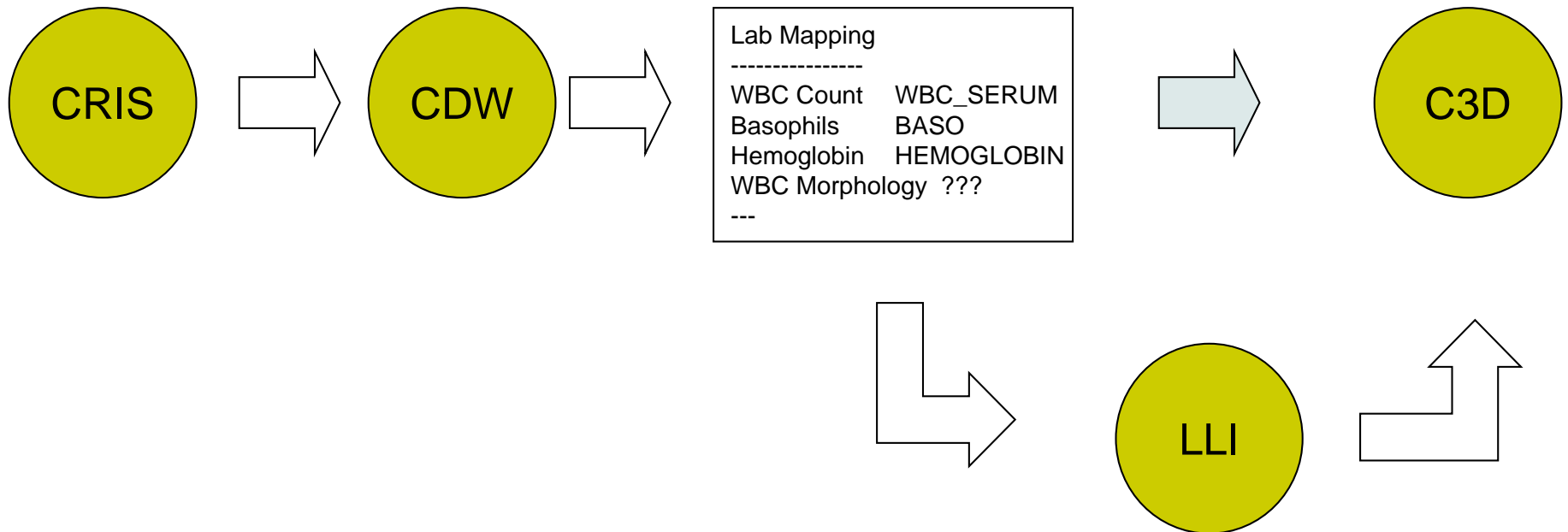
SCREENING_BASE								
	Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp
	1010013	 1	 2	 3	 4	 5	 6	 7

Rows Selected 1 Columns Frozen 2

About RDC 5.1.0 Home Patient Casebooks Review Reports Logout Preferences Change Password Help
Copyright © 1993, 2014, Oracle and/or its affiliates. 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
- Login Link:
<https://octrials.nci.nih.gov/opa51/labloadinter.htm>
- Username & Password are same as C³D

LLI Search Screen

Lab Load Interface
Action Window Help ORACLE

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	Search
				Time Relation	HH24	MI		New Search

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"/>				
<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

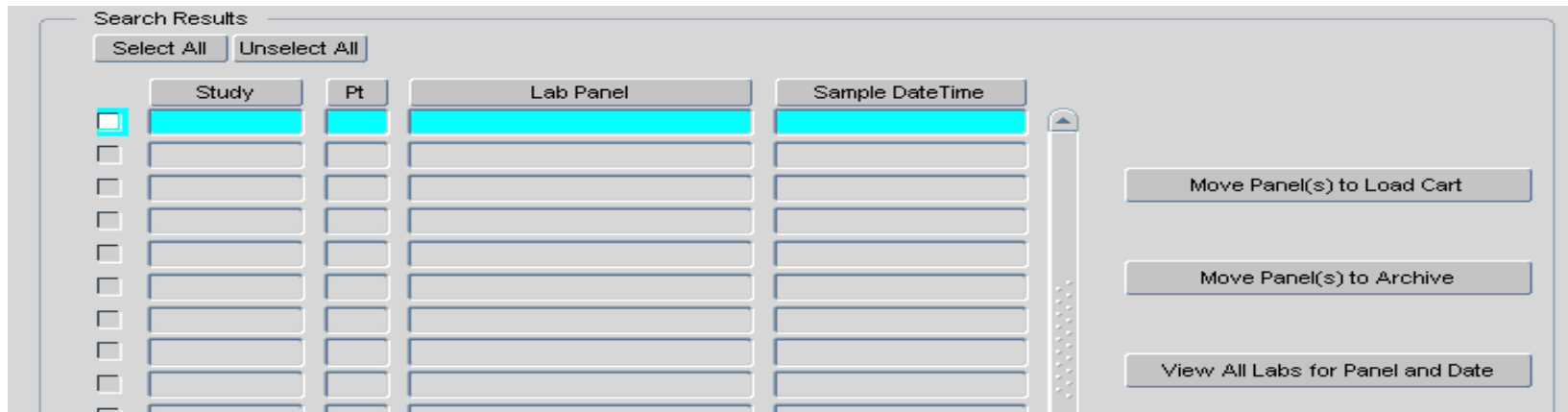
Search

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 displays 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 the 'Selection Results' section, which includes 'Select All' and 'Unselect All' buttons. A table with columns 'R', 'C3D Test Name', 'Result', 'Unit', 'Range', and 'Status' is shown. 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"/>					

- **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?

