Introduction to C^{3}D

Harris Corporation

January 2019

Introduction

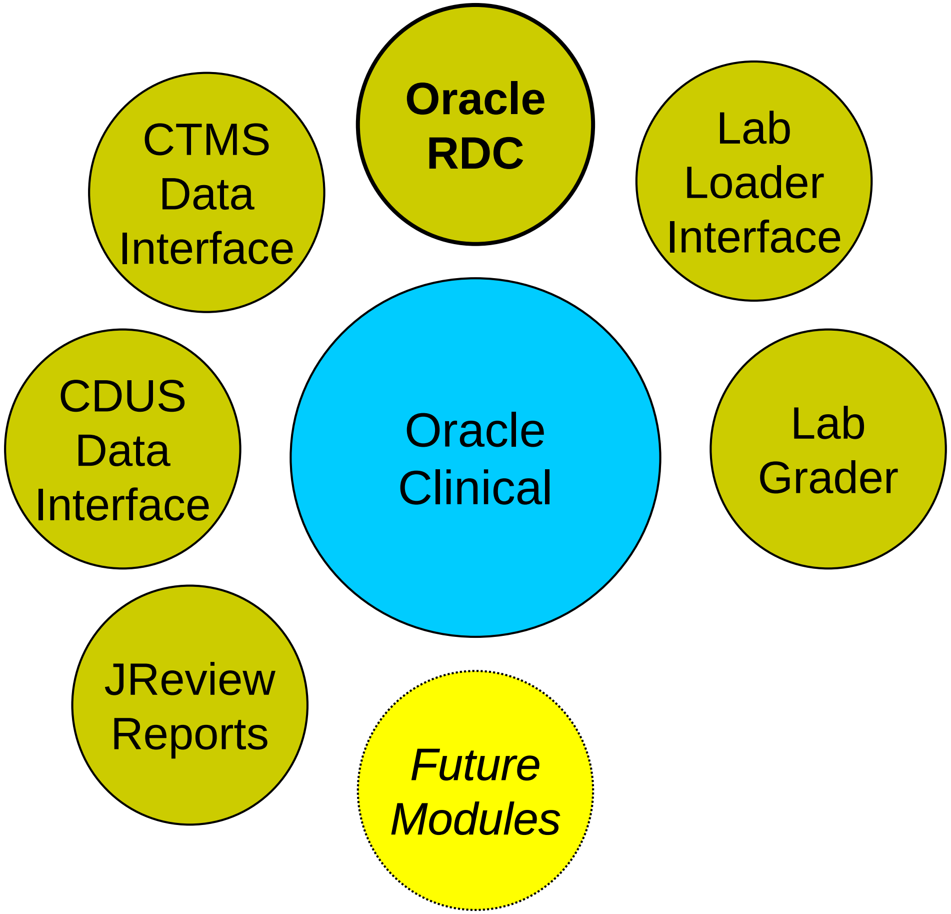
- C^{3}D - **C**ancer **C**entral **C**linical **D**atabase
- eCRFs Instructions Manual
- Support
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval
- Lab Loading

What is C^{3}D

C^{3}D
Cancer Central Clinical Database

- Clinical Trials Data Management System
- RDC (Remote Data Capture) Data Entry
  - Accessible anywhere in the world (via a Windows computer and Internet Explorer).
- C^{3}D 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 C^{3}D



Oracle RDC

CTMS Data Interface

Lab Loader Interface

CDUS Data Interface

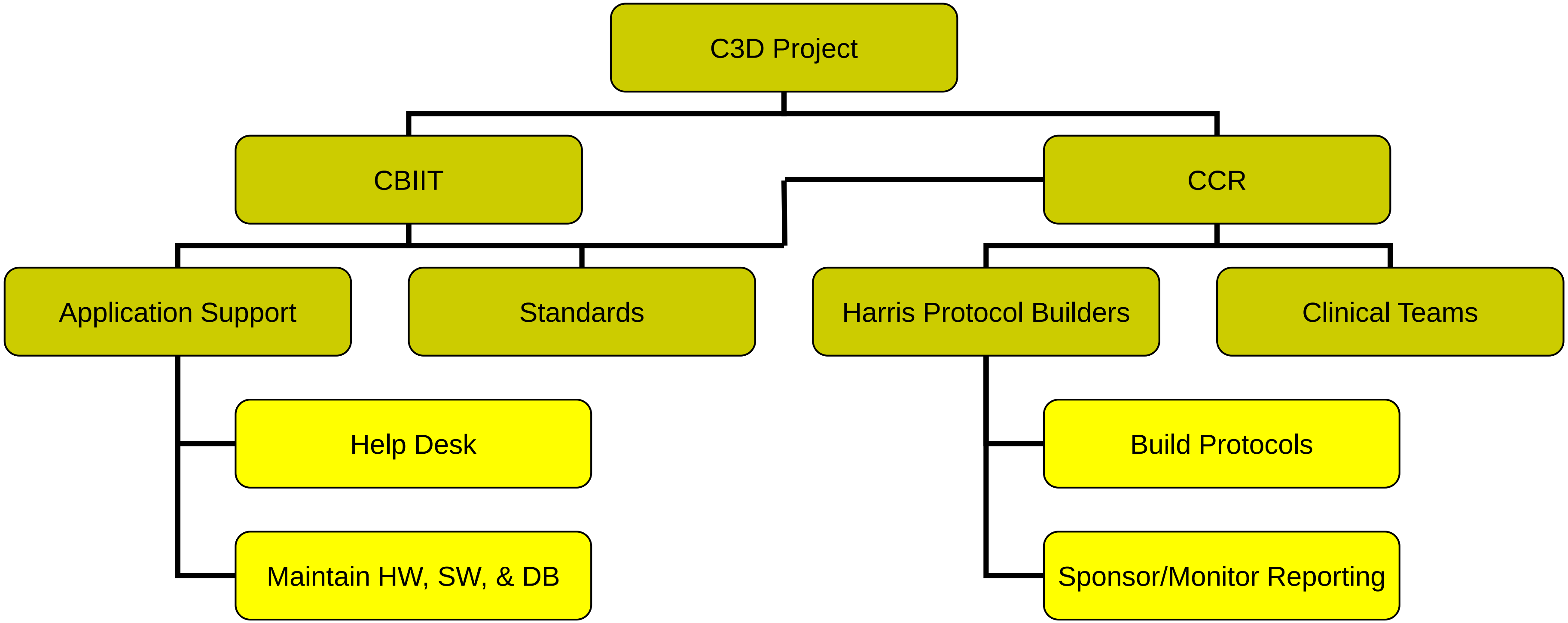
Oracle Clinical

Lab Grader

JReview Reports

Future Modules

C^3D Organization



C3D Project

CBIIT

CCR

Application Support

Standards

Harris Protocol Builders

Clinical Teams

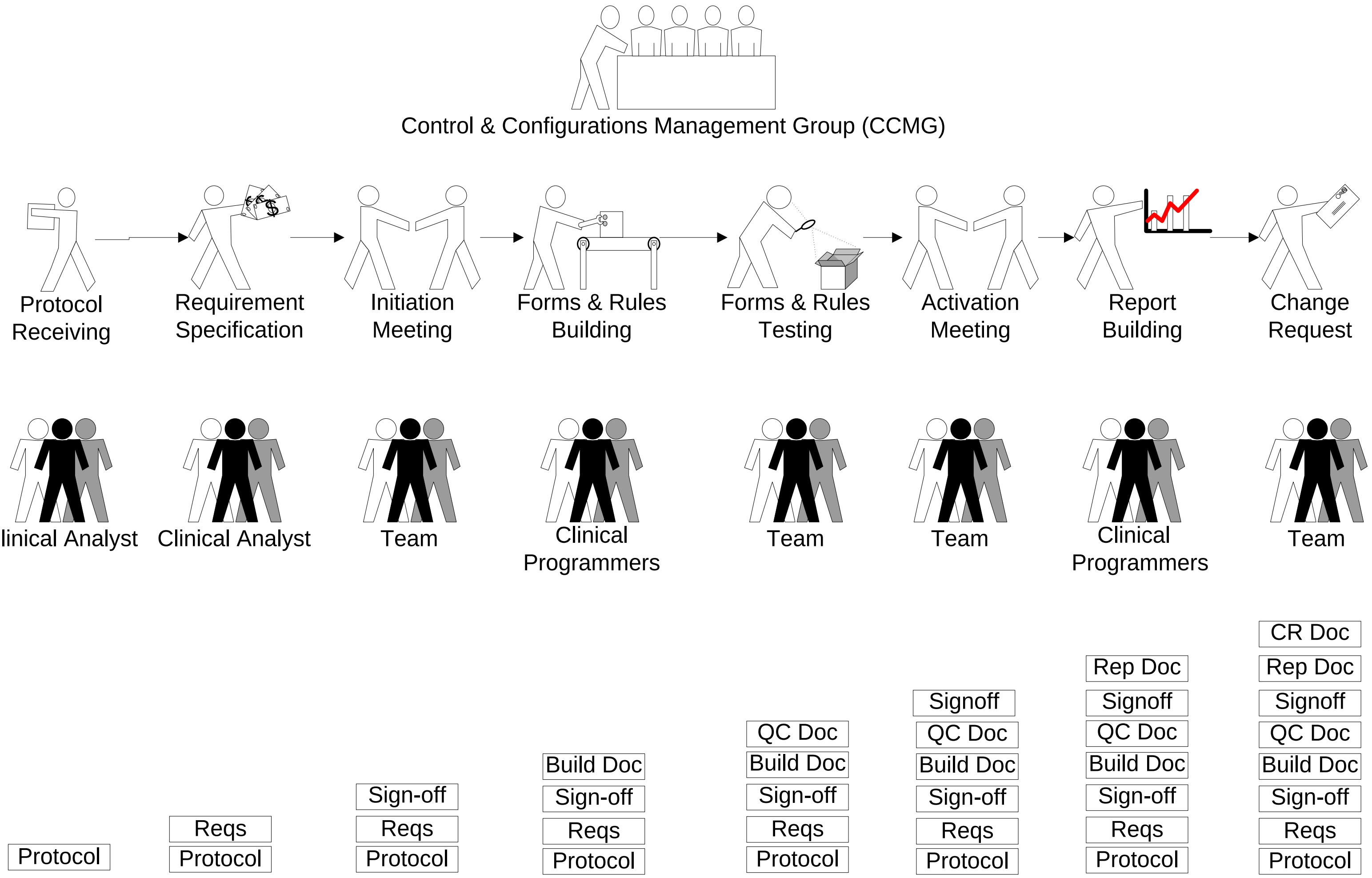
Help Desk

Maintain HW, SW, & DB

Build Protocols

Sponsor/Monitor Reporting

Designing Protocols in C^{3}D



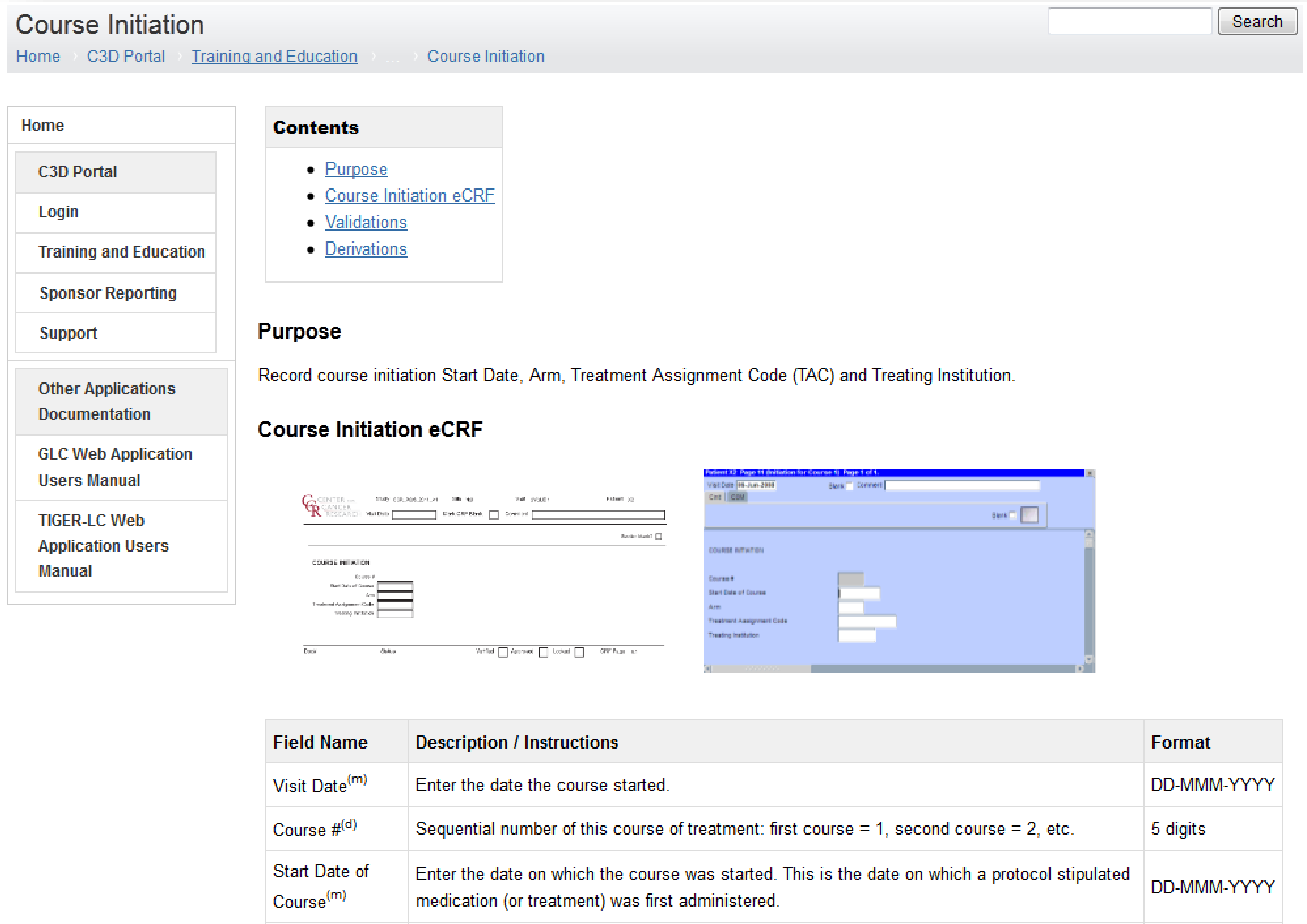
Control & Configurations Management Group (CCMG)

Protocol Receiving	Requirement Specification	Initiation Meeting	Forms & Rules Building	Forms & Rules Testing	Activation Meeting	Report Building	Change Request
Clinical Analyst	Clinical Analyst	Team	Clinical Programmers	Team	Team	Clinical Programmers	Team
Protocol	Reqs Protocol	Sign-off Reqs Protocol	Build Doc Sign-off Reqs Protocol	QC Doc Build Doc Sign-off Reqs Protocol	Signoff QC Doc Build Doc Sign-off Reqs Protocol	Rep Doc Signoff QC Doc Build Doc Sign-off Reqs Protocol	CR Doc Rep Doc Signoff QC Doc Build Doc Sign-off Reqs Protocol

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


Search
Home
C3D Portal
Login
Training and Education
Sponsor Reporting
Support
Other Applications Documentation
GLC Web Application Users Manual
TIGER-LC Web Application Users Manual

Course Initiation

Home › C3D Portal › Training and Education › ... › Course Initiation

Contents

- Purpose
- Course Initiation eCRF
- Validations
- Derivations

Purpose

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

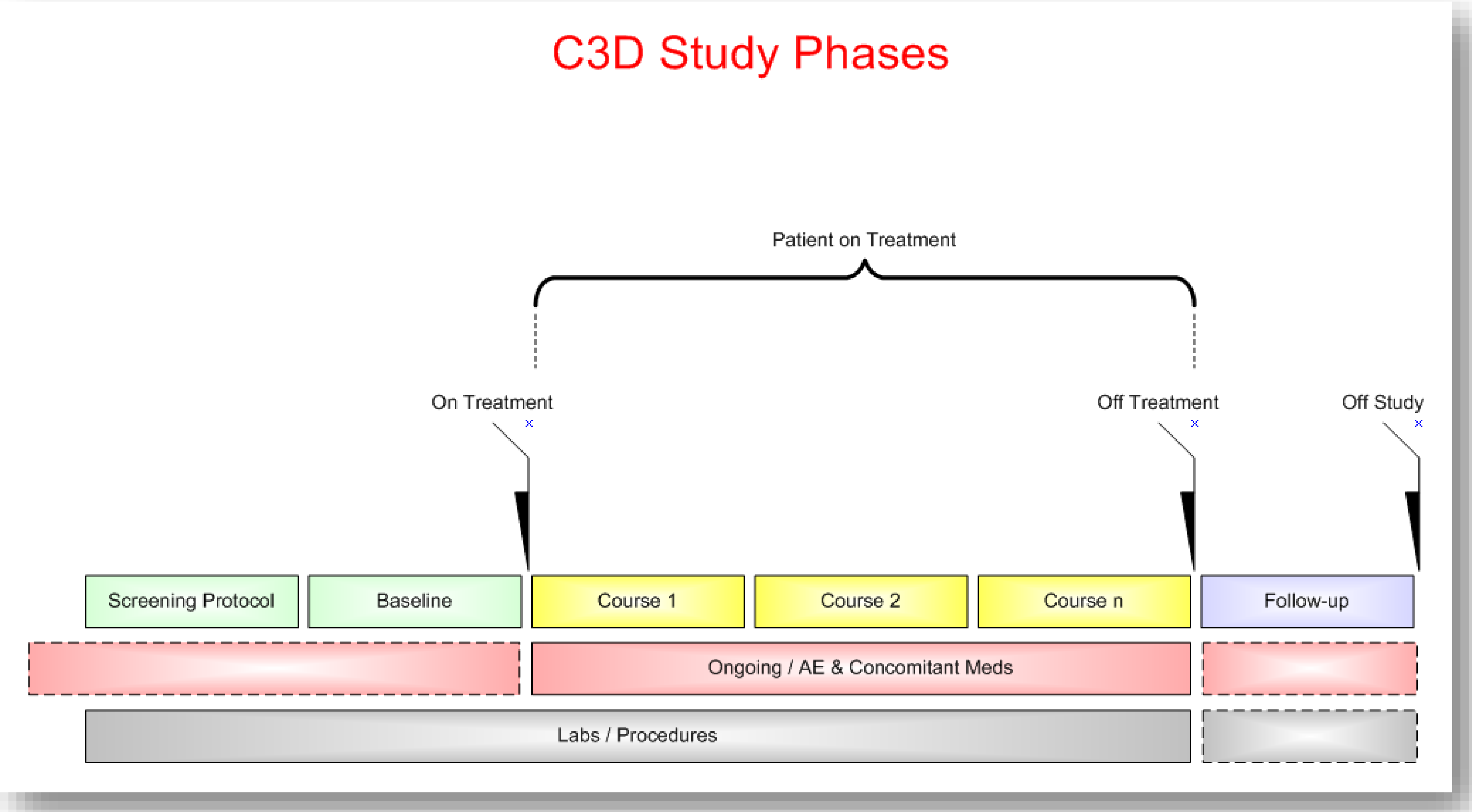
Course Initiation eCRF

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

C^{3}D Protocol Phases


C3D Study Phases
Patient on Treatment
On Treatment
Off Treatment
Off Study
Screening Protocol
Baseline
Course 1
Course 2
Course n
Follow-up
Ongoing / AE & Concomitant Meds
Labs / Procedures

Role Based Access

Access => Role	Browse	Enter Data	Manage Discrepancy	Verify eCRF	Approve eCRF
PI	Yes	No	No	Yes	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.

C^{3}D Support

- CBIIT provides the first line of support for C^{3}D related issues
- Contact
  - Email: NCIAppSupport@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 C^{3}D 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 C^{3}D Help Desk to unlock account and/or get new password.

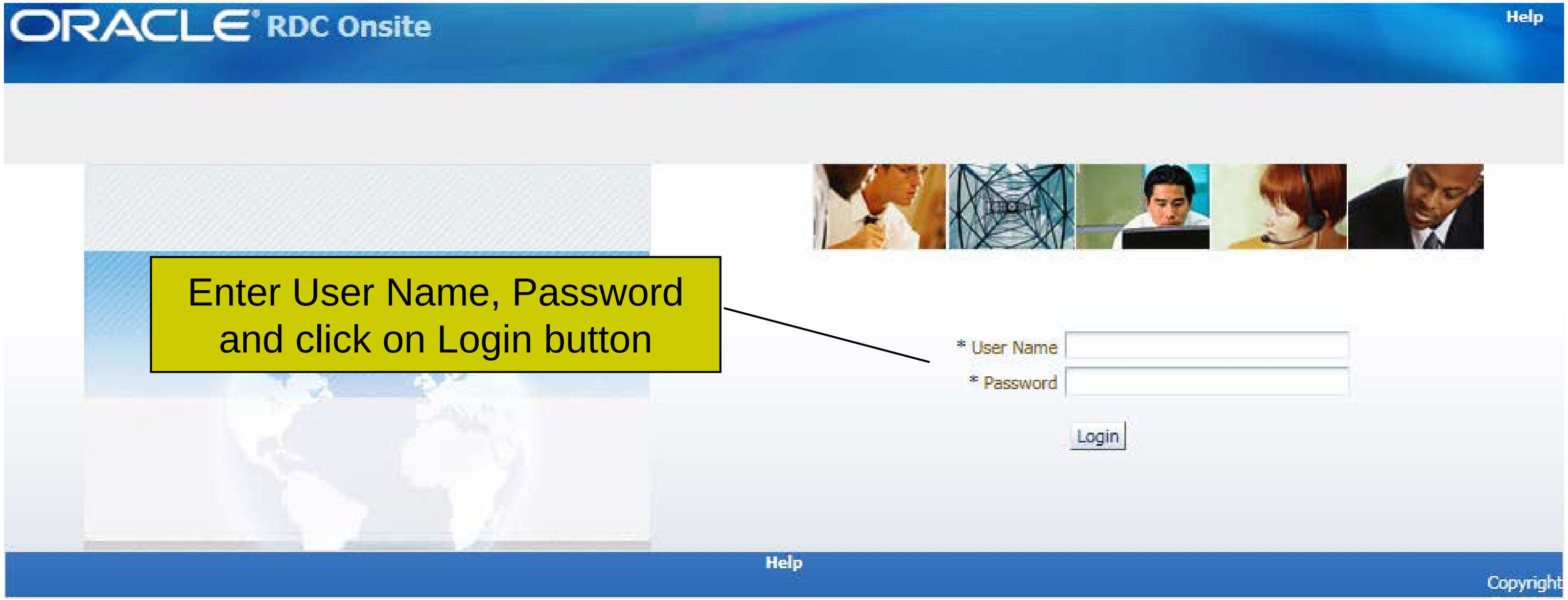
C^{3}D Login Web Pages

- C^{3}D is Accessible Worldwide

- C^{3}D Production Login page: https://octrials.nci.nih.gov/opa52/rdclaunch.htm

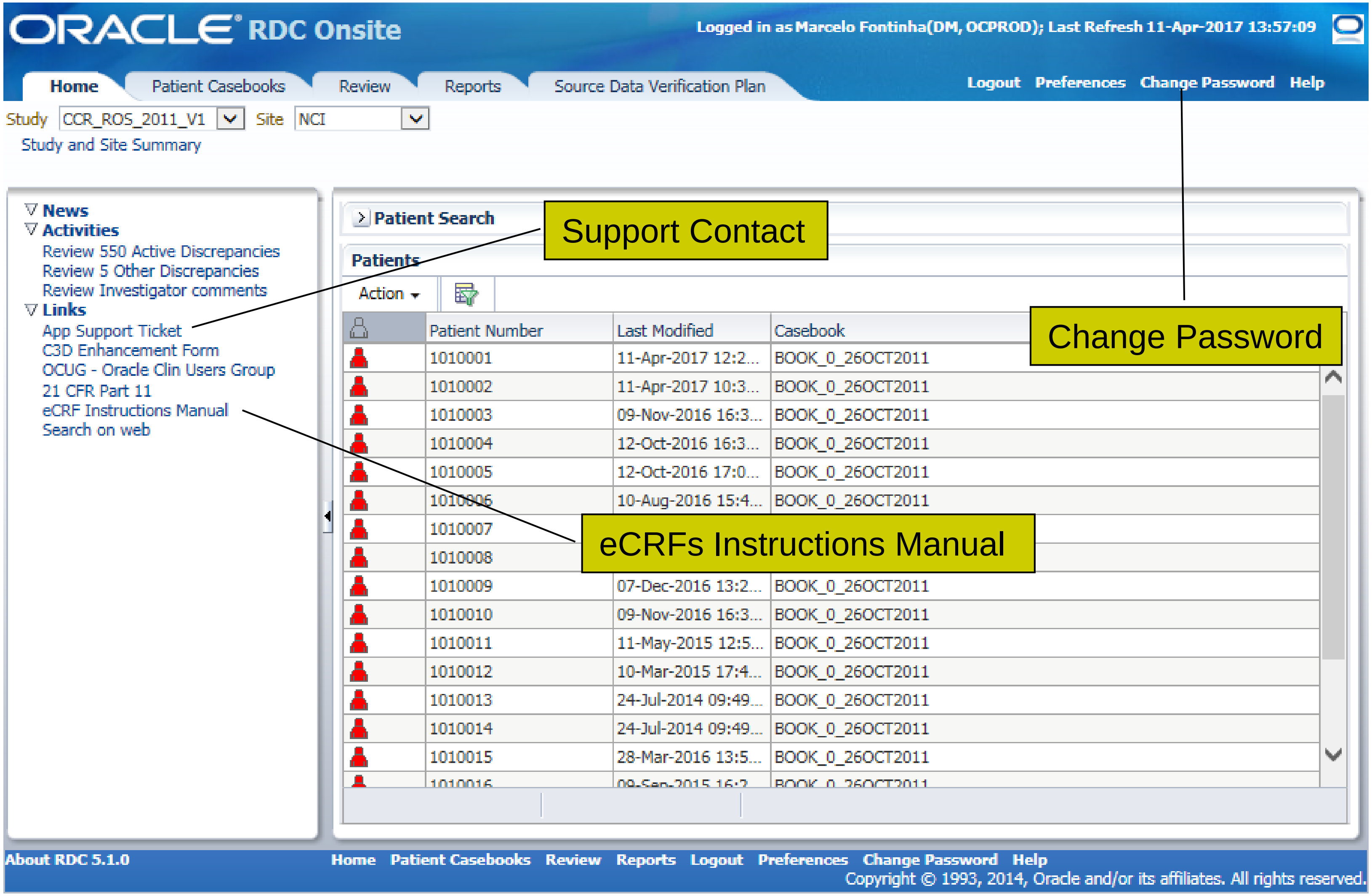
- C^{3}D provides a separate Data Entry environment to test protocol design
  - ☐ Test Login page: https://octrials.nci.nih.gov/opa52/rdclauncht.htm

C^{3}D Login Web Page


ORACLE RDC Onsite
Help
* User Name
* Password
Login
Help
Copyright

Enter User Name, Password and click on Login button

C^{3}D RDC Home Page



ORACLE RDC Onsite

Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 11-Apr-2017 13:57:09

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

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

	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

Support Contact

Change Password

eCRFs Instructions Manual

About RDC 5.1.0

Home Patient Casebooks Review Reports Logout Preferences Change Password Help

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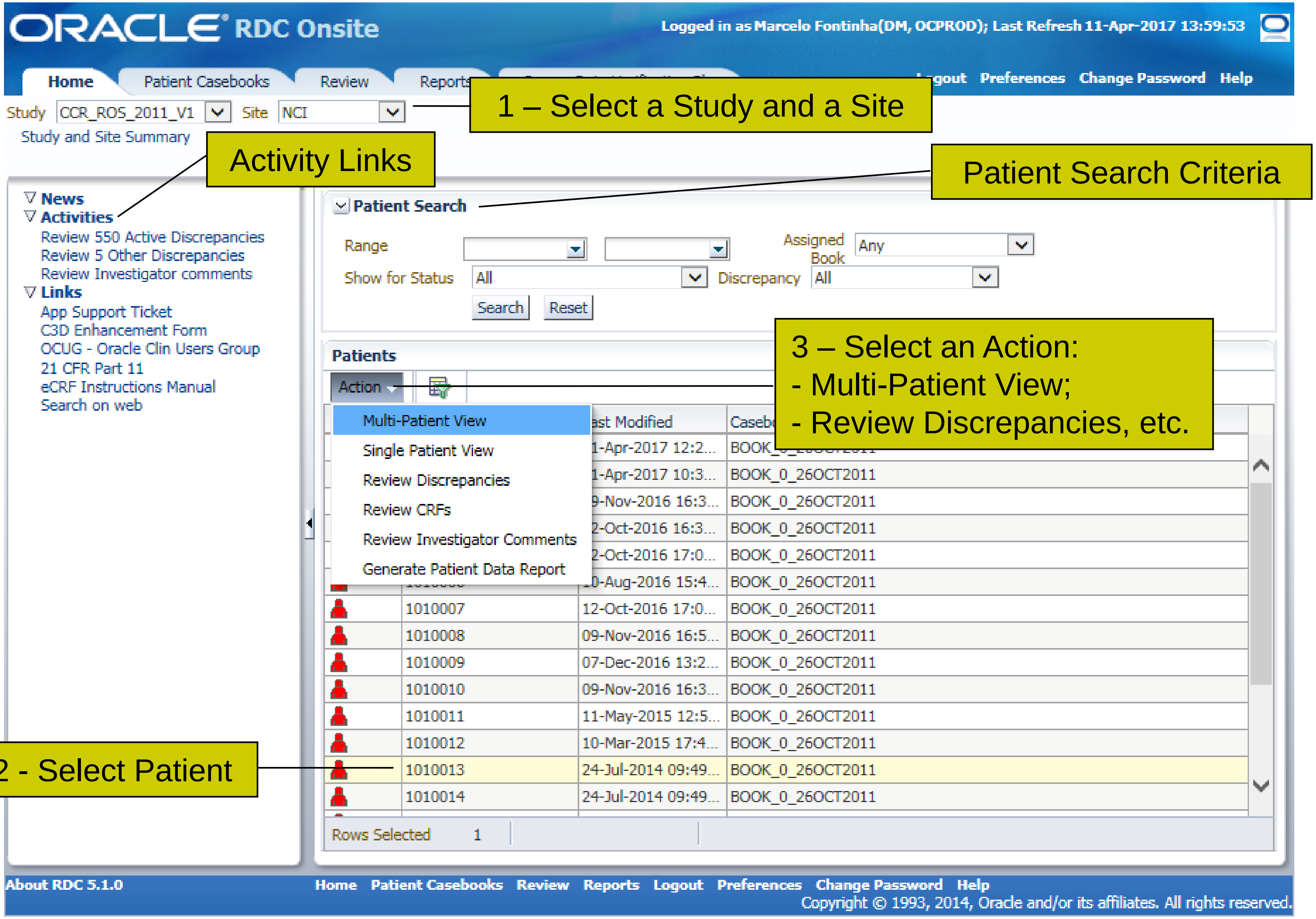
Home Page Activities

1. Select a Study and a Site
    - Access to studies is controlled by user role
    - C^{3}D 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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Reset
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Study: CCR_ROS_2011_V1 Site: NCI

Study and Site Summary

Review 550 Active Discrepancies
Review 5 Other Discrepancies
Review Investigator comments

App Support Ticket
C3D Enhancement Form
OCUG - Oracle Clin Users Group
21 CFR Part 11
eCRF Instructions Manual
Search on web

Range
Show for Status: All
Assigned Book: Any
Discrepancy: All

		ast Modified	Caseb
		1-Apr-2017 12:2...	BOOK
		1-Apr-2017 10:3...	BOOK_0_26OCT2011
		9-Nov-2016 16:3...	BOOK_0_26OCT2011
		2-Oct-2016 16:3...	BOOK_0_26OCT2011
		2-Oct-2016 17:0...	BOOK_0_26OCT2011
		0-Aug-2016 15:4...	BOOK_0_26OCT2011
	1010007	12-Oct-2016 17:0...	BOOK_0_26OCT2011
	1010008	09-Nov-2016 16:5...	BOOK_0_26OCT2011
	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

Rows Selected 1

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1 – Select a Study and a Site

Activity Links

Patient Search Criteria

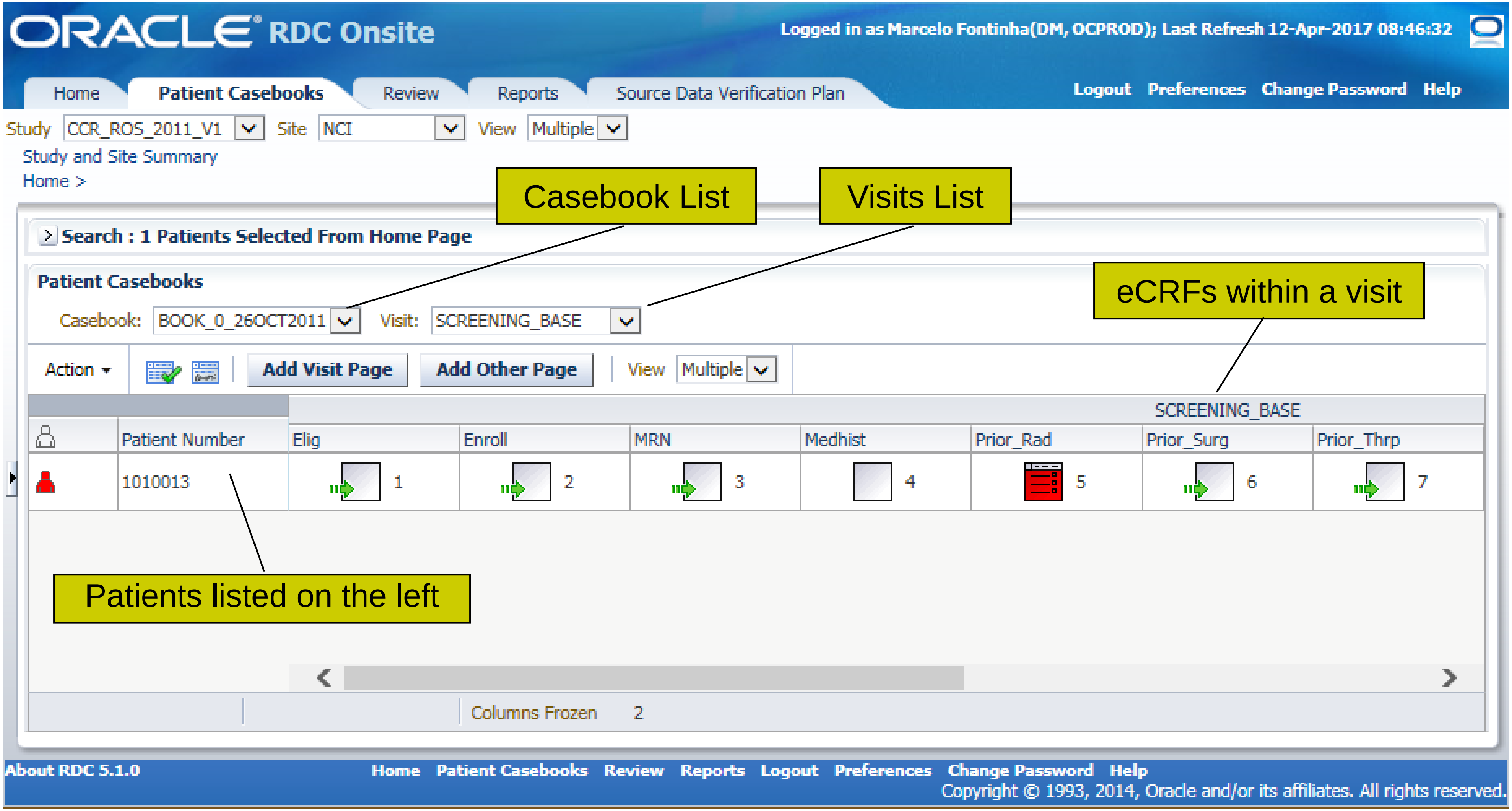
3 – Select an Action:
- Multi-Patient View;
- Review Discrepancies, etc.

2 - Select Patient

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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Study and Site Summary
Home >
Action
Add Visit Page
Add Other Page
About RDC 5.1.0

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Study CCR_ROS_2011_V1 Site NCI View Multiple

Search : 1 Patients Selected From Home Page

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE

View Multiple

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

Columns Frozen 2

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Casebook List

Visits List

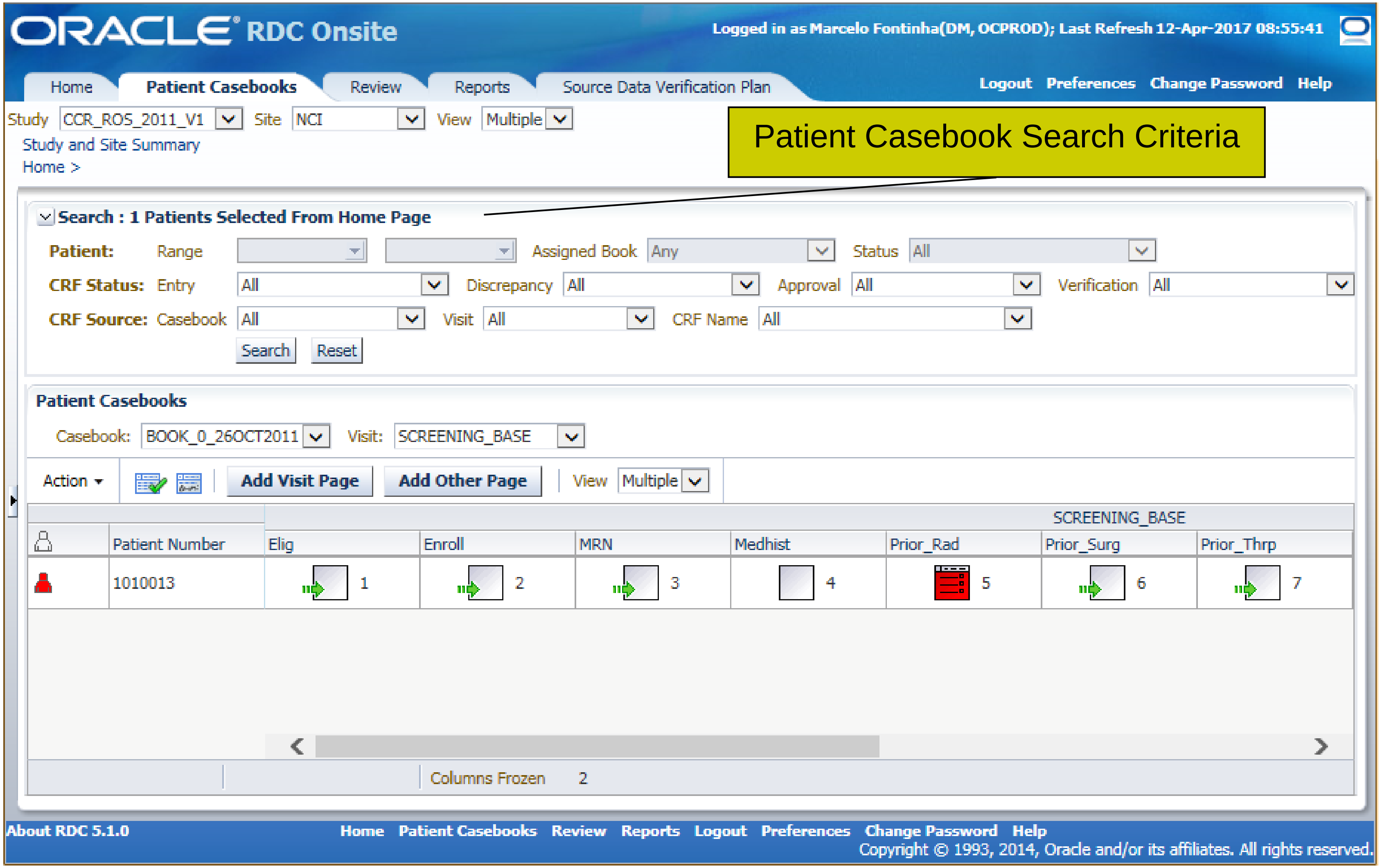
eCRFs within a visit

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 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



Patient Casebook Search Criteria

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Study: CCR_ROS_2011_V1 Site: NCI View: Multiple

Study and Site Summary

Home >

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

Search
Reset

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

Columns Frozen 2

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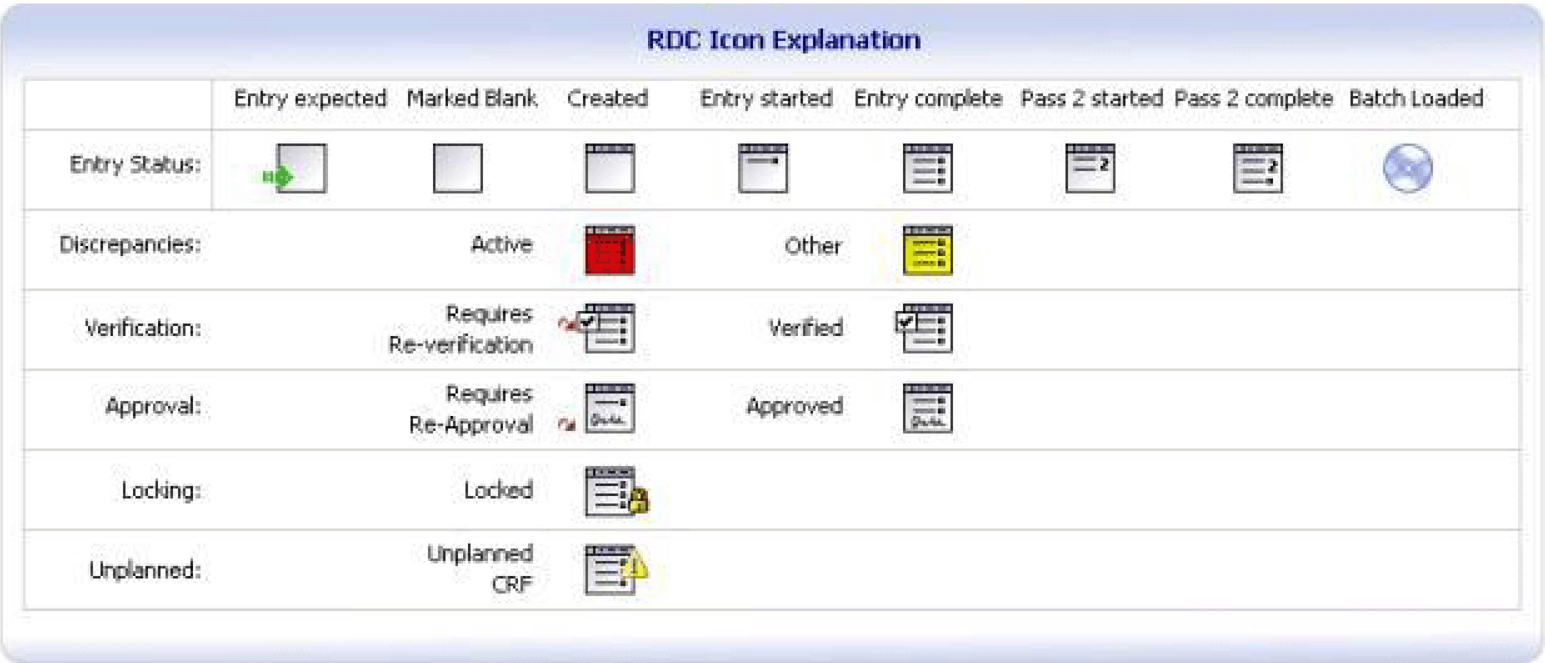
Important eCRF Icons

- 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

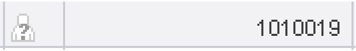


RDC Icon Explanation

	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

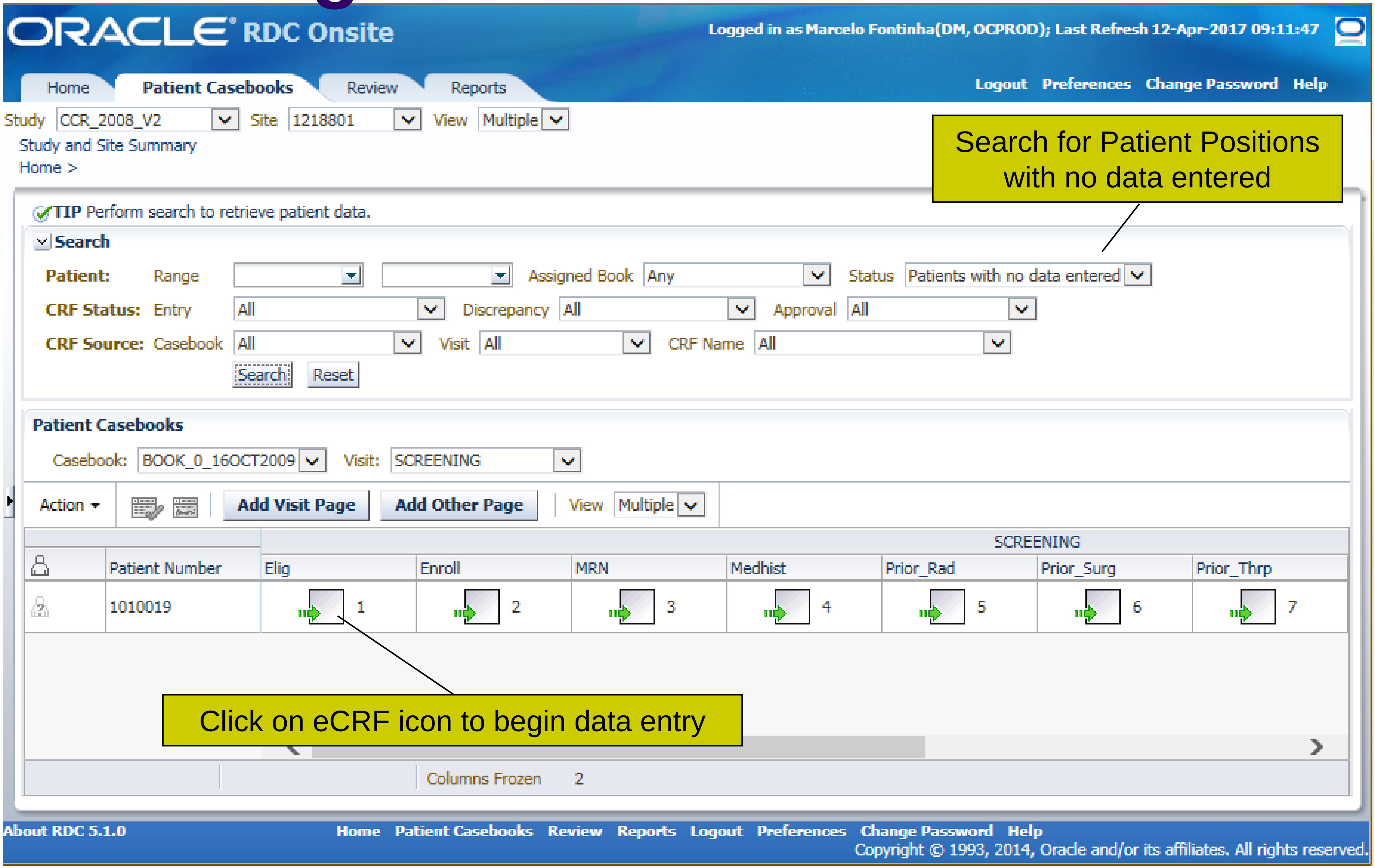
- From the C^{3}D Home Page: click on a patient position that has the question mark inside the pers
    - Then click on the Action dropdown and select “Multi-Patient View”



- 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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Study: CCR_2008_V2 Site: 1218801 View: Multiple

Study and Site Summary
Home >

Search for Patient Positions with no data entered

TIP Perform search to retrieve patient data.

Search

Patient: Range: (blank) (blank) Assigned Book: Any Status: Patients with no data entered

CRF Status: Entry: All Discrepancy: All Approval: All

CRF Source: Casebook: All Visit: All CRF Name: All

Search
Reset

Patient Casebooks

Casebook: BOOK_0_16OCT2009 Visit: SCREENING

Action
Add Visit Page
Add Other Page

View: Multiple

		SCREENING						
	Patient Number	Elig	Enroll	MRN	Medhist	Prior_Rad	Prior_Surg	Prior_Thrp
	1010019	1	2	3	4	5	6	7

Click on eCRF icon to begin data entry

Columns Frozen 2

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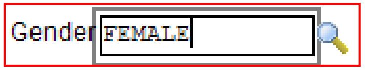
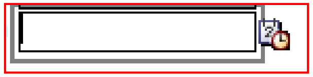
Electronic CRF (eCRF)

- 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.

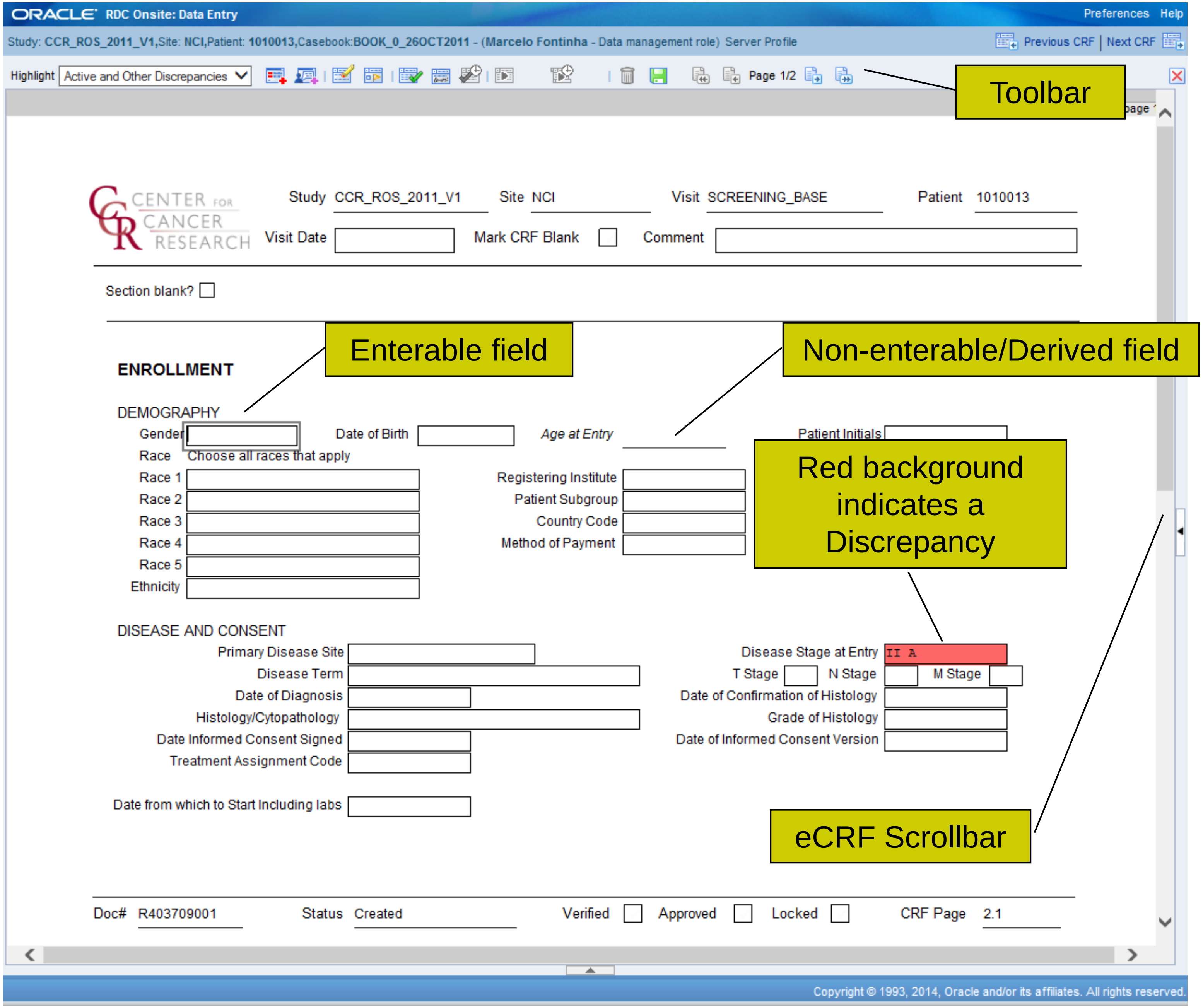
- **Quick Tip:**
  - Up to 3 eCRFs can be open for simultaneously for data entry. An additional 2 eCRFs can be opened in read-only mode.
  - It is strongly recommended to only have one eCRF open for data entry to avoid entering data in the wrong patient. Close the eCRF when no longer using it.

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)



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

Toolbar

CENTER FOR CANCER RESEARCH

Study: CCR_ROS_2011_V1
Site: NCI
Visit: SCREENING_BASE
Patient: 1010013
Visit Date:
Mark CRF Blank ☐
Comment:

Section blank? ☐

Enterable field

Non-enterable/Derived field

ENROLLMENT

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:

Red background indicates a Discrepancy

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:

eCRF Scrollbar

Doc# R403709001
Status: Created
Verified ☐
Approved ☐
Locked ☐
CRF Page 2.1

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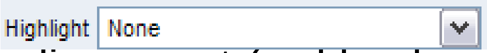
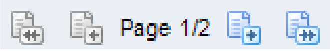
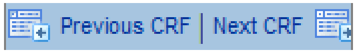
Electronic CRF (eCRF)

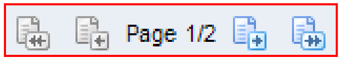
- Toolbar features:
  - 

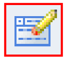
    Use Highlight dropdown list to highlight fields that are discrepant (red background), investigator comments (Purple), or changed since last verification or approval or have audit-trail (Blue)
  - Add Manual Discrepancy to selected field
  - Add Investigator Comments to selected field
  - Delete Selected 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

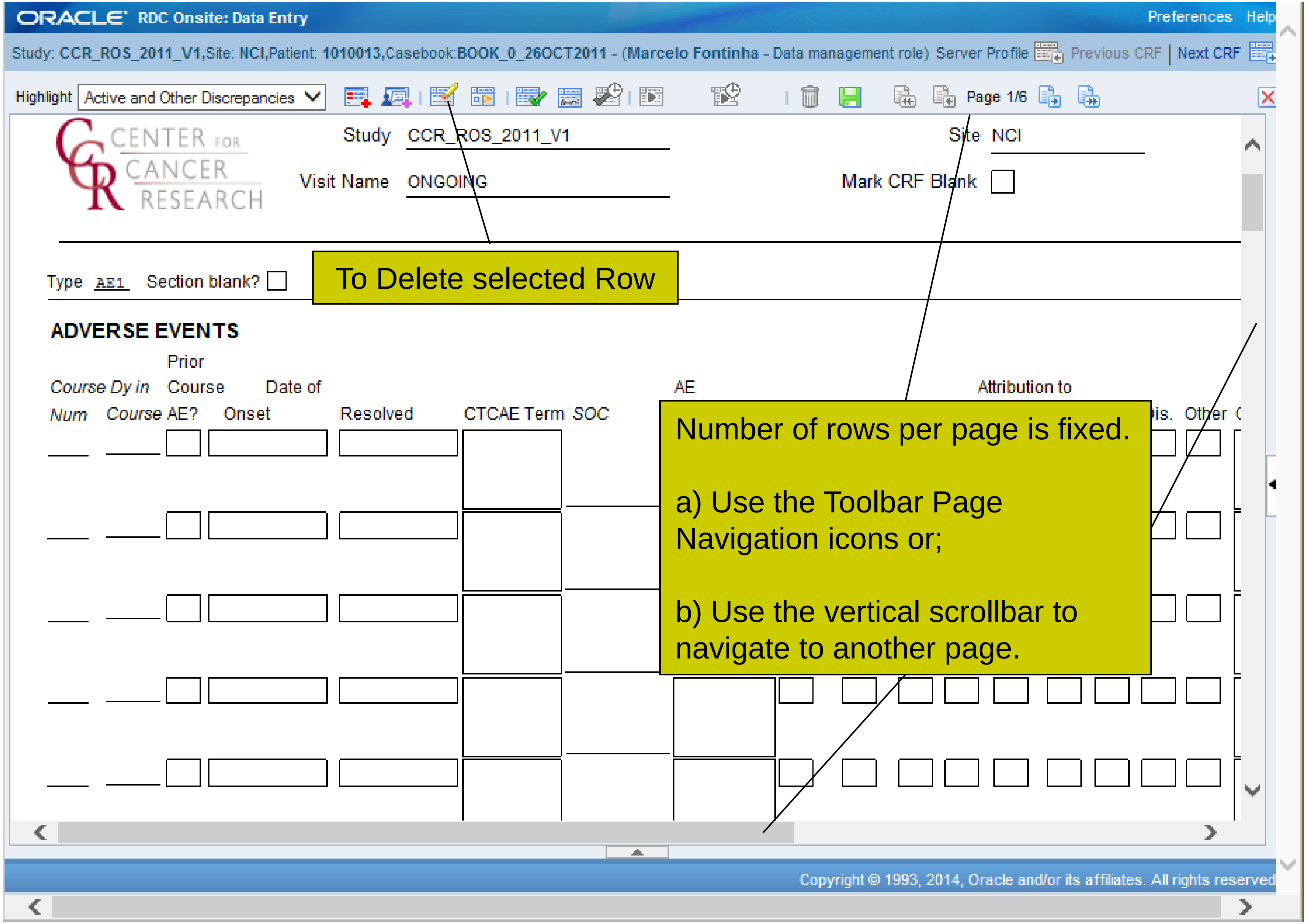
- Navigate to another eCRF by clicking on the Next or Previous CRF icons on the top right corner. 

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. 

- 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: 1010013,Casebook:BOOK_0_26OCT2011 - (Marcelo Fontinha - Data management role)

Highlight: Active and Other Discrepancies

Page 1/6

Study: CCR_ROS_2011_V1

Site: NCI

Visit Name: ONGOING

Mark CRF Blank ☐

Type AE1 Section blank? ☐

ADVERSE EVENTS

Preferences
Help
Server Profile
Previous CRF
Next CRF
CENTER FOR CANCER RESEARCH
Course Num
Dy in Course
Prior Course AE?
Date of Onset
Resolved
CTCAE Term
SOC
AE
Attribution to
Dis.
Other

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To Delete selected Row

Number of rows per page is fixed.

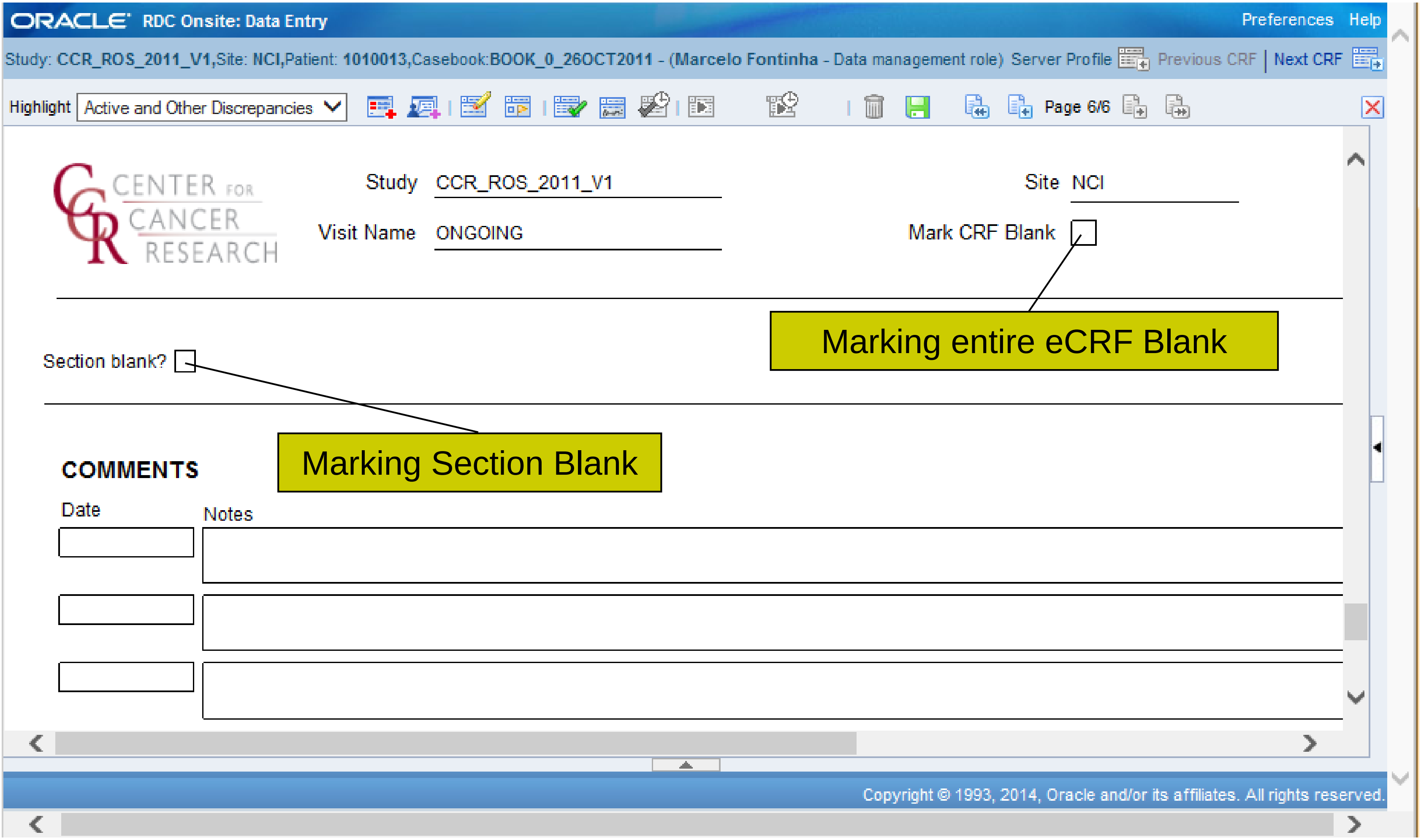
a) Use the Toolbar Page Navigation icons or;

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

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
Previous CRF | Next CRF
Highlight
Page 6/6
CENTER FOR CANCER RESEARCH
COMMENTS
Date
Notes

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

Study: CCR_ROS_2011_V1

Site: NCI

Visit Name: ONGOING

Mark CRF Blank ☐

Section blank? ☐

Marking entire eCRF Blank

Marking Section Blank

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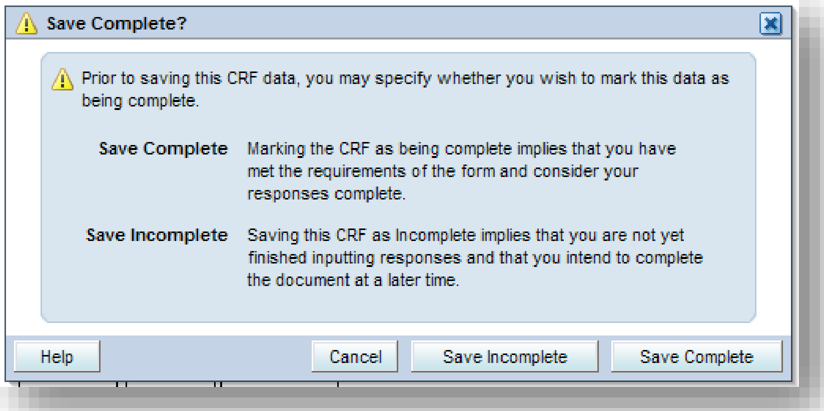
Saving eCRF

- 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!



Save Complete?

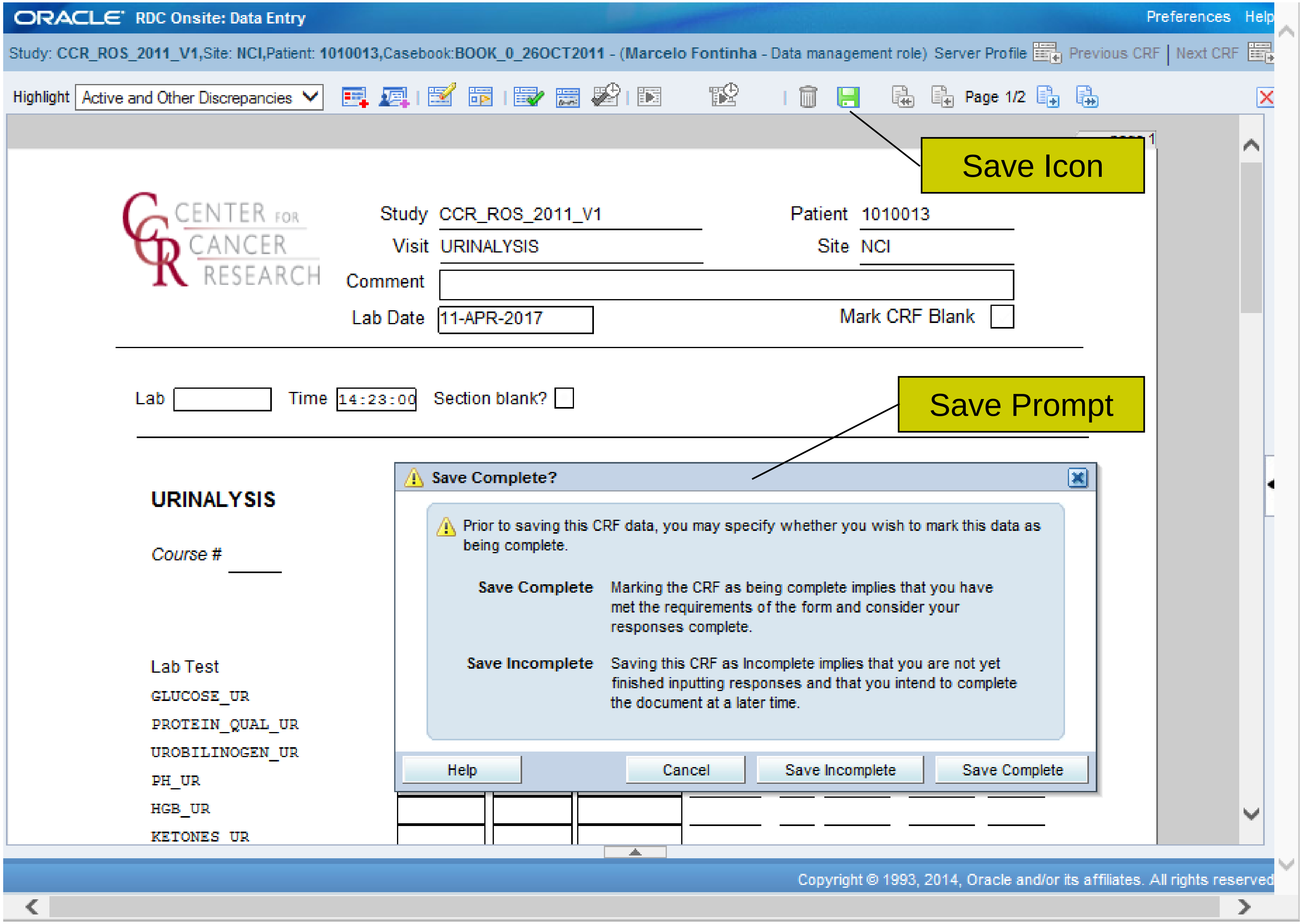
Prior to saving this CRF data, you may specify whether you wish to mark this data as being complete.

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.

- **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
Highlight Active and Other Discrepancies
Page 1/2
Lab Test
GLUCOSE_UR
PROTEIN_QUAL_UR
UROBILINOGEN_UR
PH_UR
HGB_UR
KETONES_UR
Help
Cancel
Save Incomplete
Save Complete

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

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 #

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.

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Save Icon

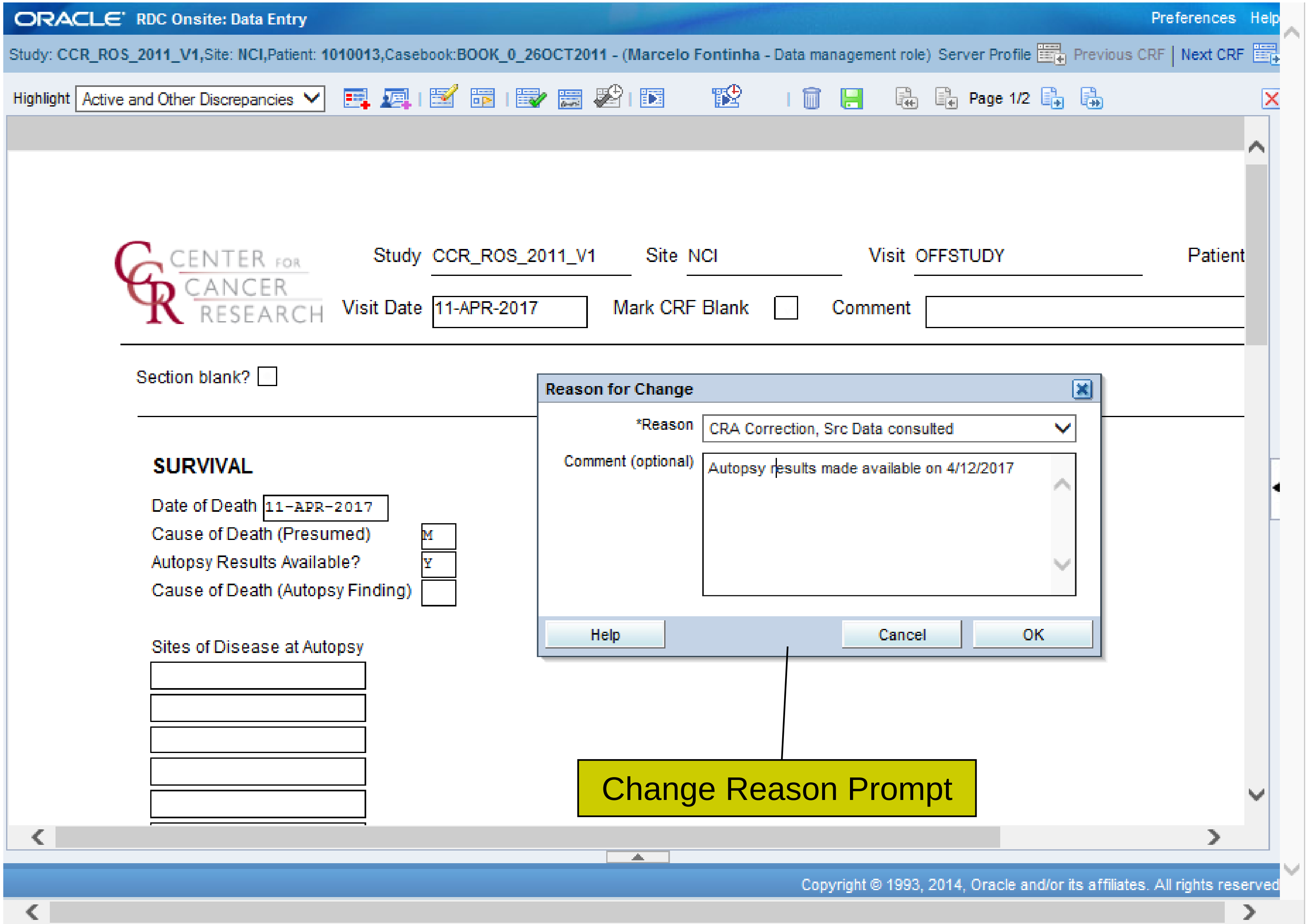
Save Prompt

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

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

Highlight: Active and Other Discrepancies

Study: CCR_ROS_2011_V1
Site: NCI
Visit: OFFSTUDY
Visit Date: 11-APR-2017
Mark CRF Blank ☐
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

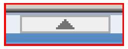
Reason for Change

*Reason: CRA Correction, Src Data consulted
Comment (optional): Autopsy results made available on 4/12/2017

Preferences
Help
Server Profile
Previous CRF
Next CRF
Page 1/2
CENTER FOR CANCER RESEARCH
Patient
Comment
Help
Cancel
OK
Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved

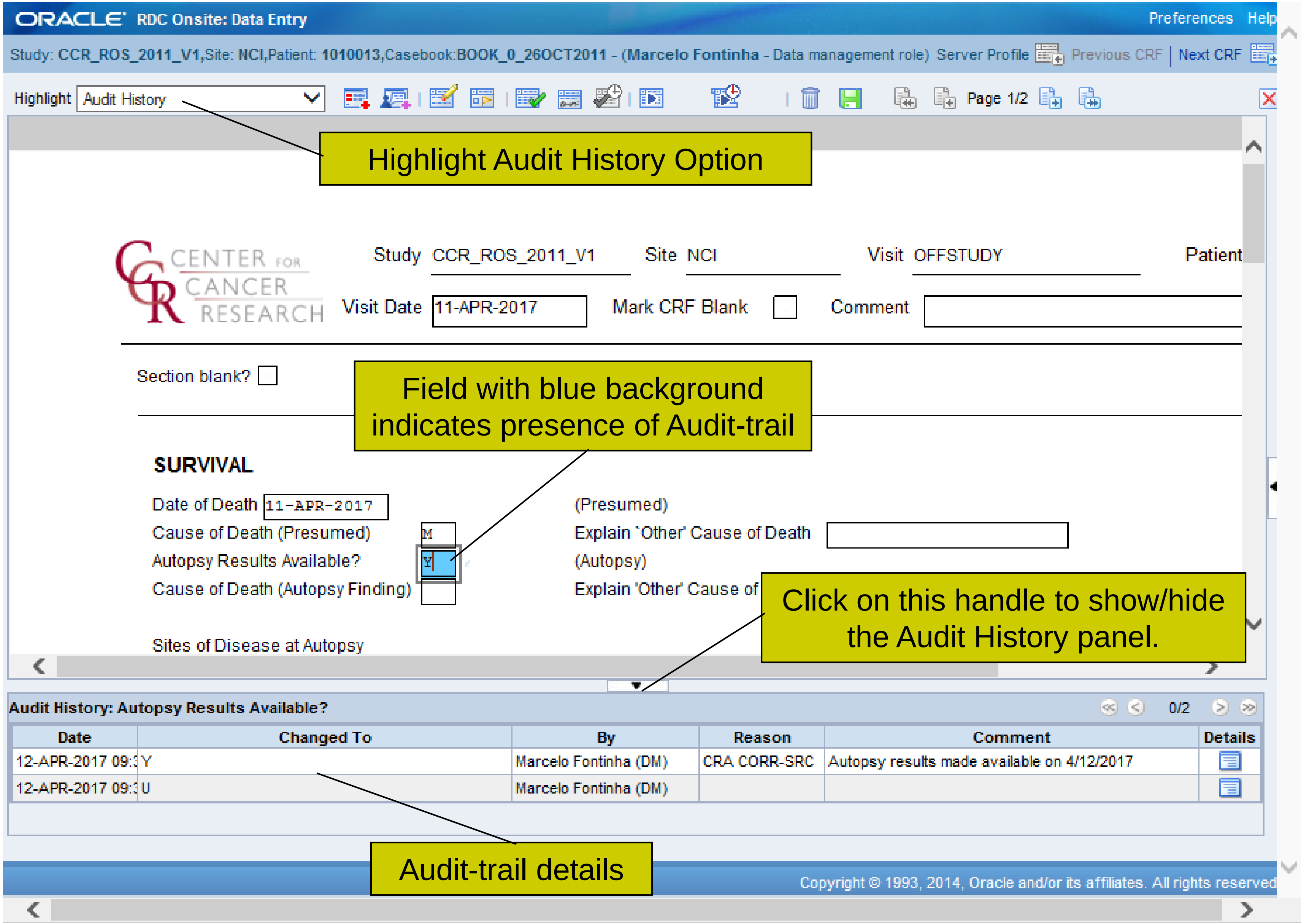
Change Reason Prompt

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



ORACLE RDC Onsite: Data Entry
Preferences Help
Server Profile
Previous CRF
Next CRF
Page 1/2
CENTER FOR CANCER RESEARCH

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

Highlight: Audit History

Highlight Audit History Option

Study: CCR_ROS_2011_V1
Site: NCI
Visit: OFFSTUDY
Patient
Visit Date: 11-APR-2017
Mark CRF Blank ☐
Comment

Section blank? ☐

Field with blue background indicates presence of Audit-trail

SURVIVAL

Date of Death: 11-APR-2017
(Presumed)
Cause of Death (Presumed): M
Explain `Other' Cause of Death
(Autopsy)
Autopsy Results Available?: Y
Cause of Death (Autopsy Finding)
Explain 'Other' Cause of
Sites of Disease at Autopsy

Click on this handle to show/hide the Audit History panel.

Audit History: Autopsy Results Available? 0/2

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

Audit-trail details

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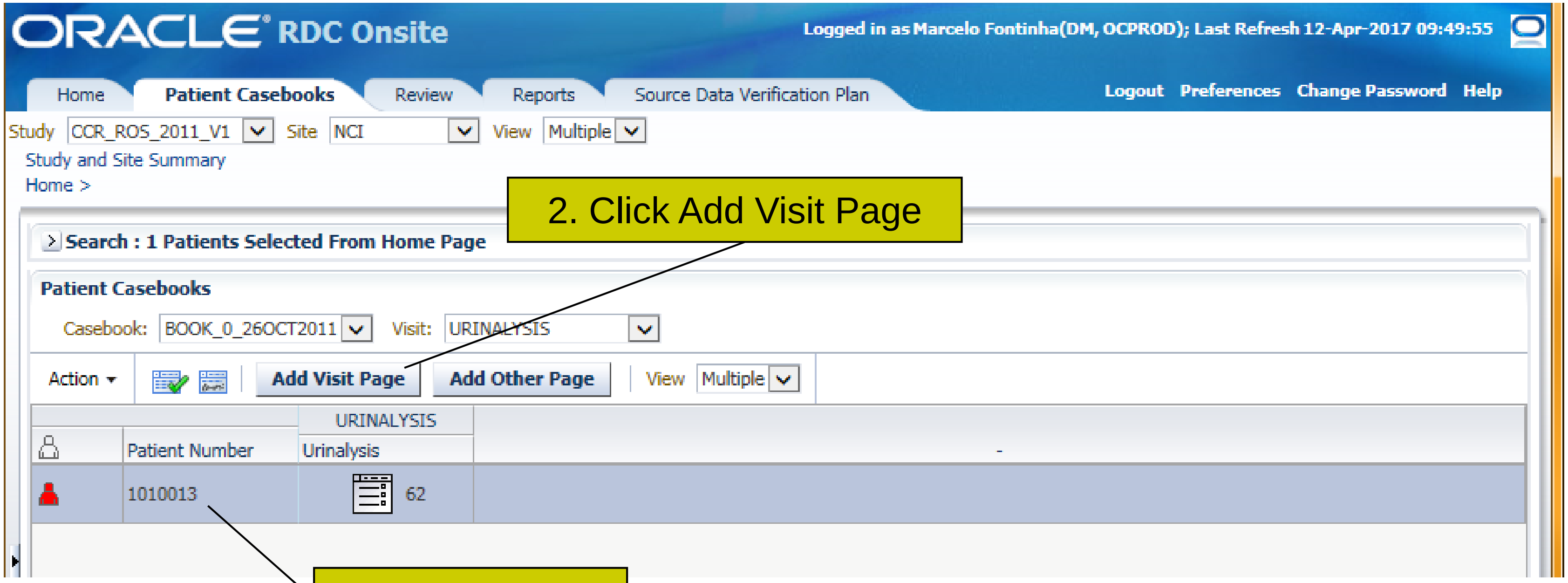
Entering/Viewing Laboratory Data

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


ORACLE RDC Onsite
Home
Patient Casebooks
Review
Reports
Source Data Verification Plan
Logout
Preferences
Change Password
Help
Study and Site Summary
Home >
Action
Add Visit Page
Add Other Page

Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 09:49:55

Study CCR_ROS_2011_V1 Site NCI View Multiple

Search : 1 Patients Selected From Home Page

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: URINALYSIS

View Multiple

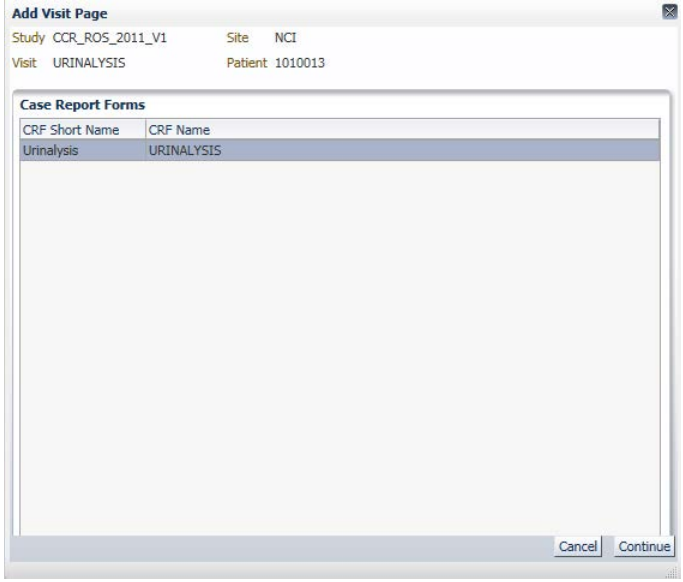
		URINALYSIS
	Patient Number	Urinalysis
	1010013	62

2. Click Add Visit Page

1. Select Patient

Entering/Viewing Laboratory Data

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



Add Visit Page

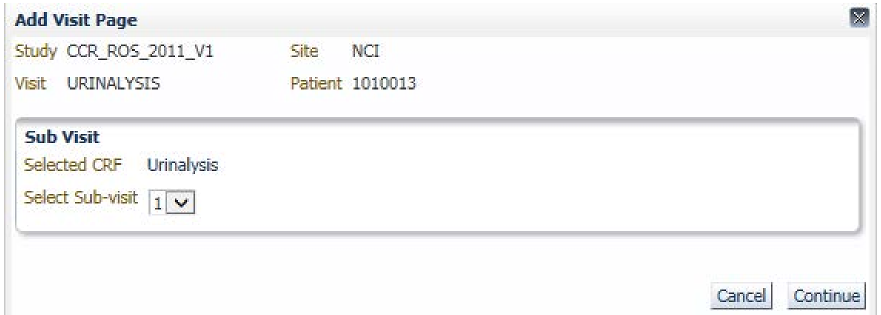
Study CCR_ROS_2011_V1 Site NCI

Visit URINALYSIS Patient 1010013

Case Report Forms

CRF Short Name	CRF Name
Urinalysis	URINALYSIS

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



Add Visit Page

Study CCR_ROS_2011_V1 Site NCI

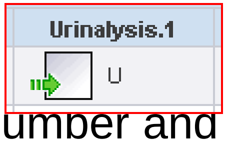
Visit URINALYSIS Patient 1010013

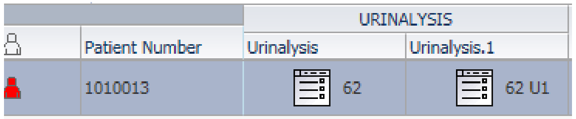
Sub Visit

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



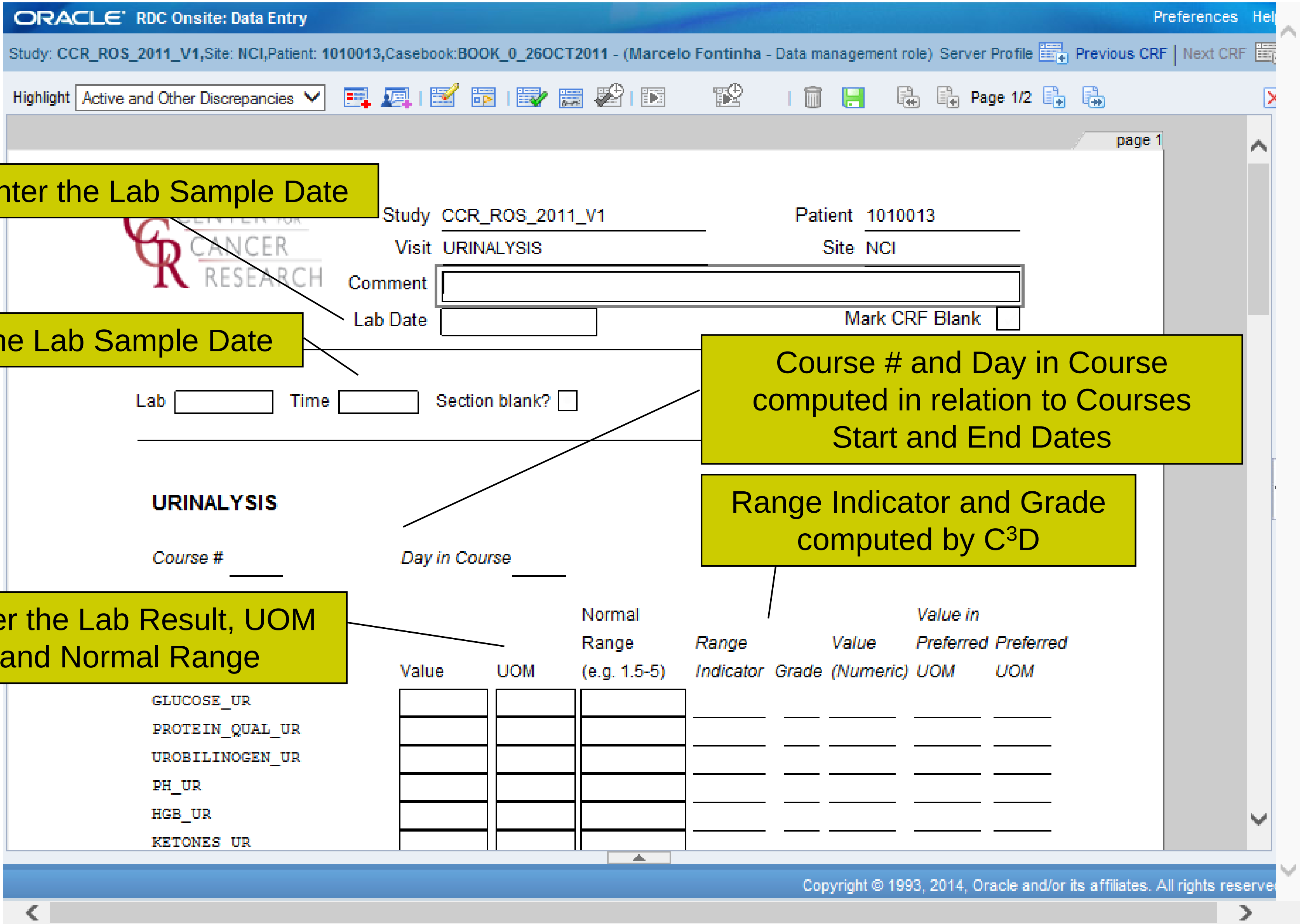


		URINALYSIS	
	Patient Number	Urinalysis	Urinalysis.1
	1010013	62	62 U1

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 C^{3}D will automatically populate the UOM and Normal Range.
- C^{3}D 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 Hel
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
page 1
CENTER FOR CANCER RESEARCH
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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

	Value	UOM	Normal Range (e.g. 1.5-5)	*Range Indicator*	*Grade*	*Value (Numeric)*	*Value in Preferred UOM*	*Preferred UOM*
GLUCOSE_UR								
PROTEIN_QUAL_UR								
UROBILINOGEN_UR								
PH_UR								
HGB_UR								
KETONES_UR								

Enter the Lab Sample Date

Enter the Lab Sample Date

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

Range Indicator and Grade computed by C^3D

Enter the Lab Result, UOM and Normal Range

What is a Discrepancy?

- A discrepancy is the failure of entered data to pass a validation check as applied by C^{3}D.
- C^{3}D 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.

C^{3}D 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

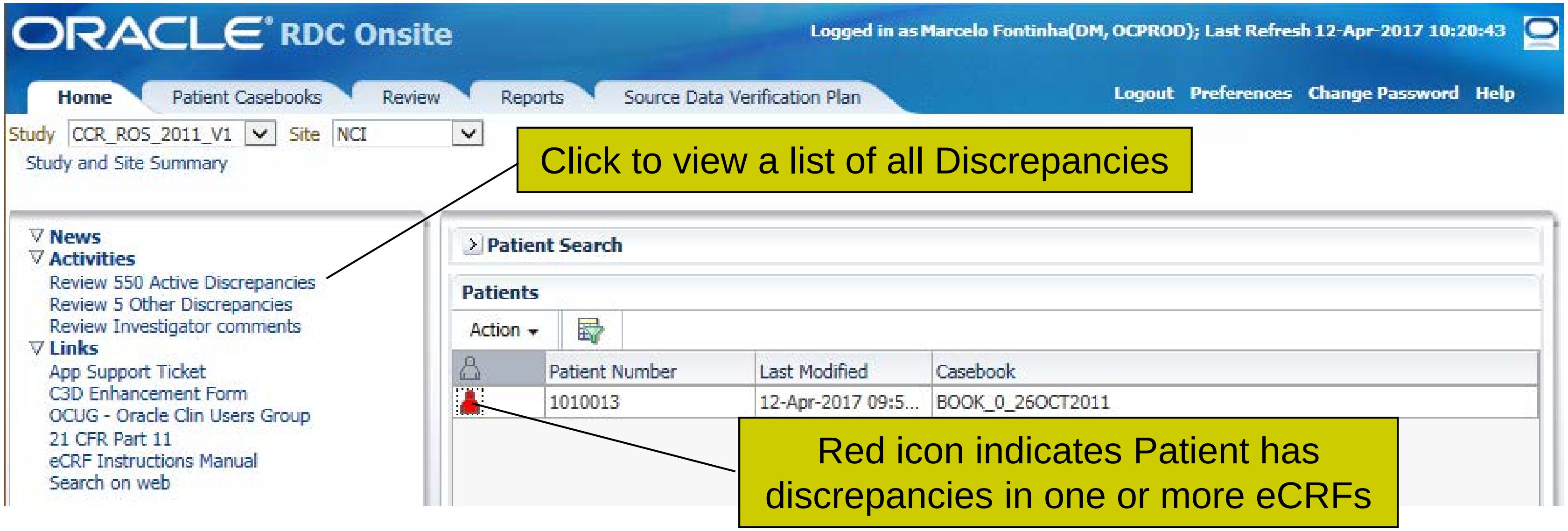
Types	Example:	Resolutions
Data Type	Text entered in numeric or date field.	Review Source Document and enter appropriate data.
Length Problems	Too many characters entered.	Use NIH accepted Abbreviations.
Value not on the Pick List	Generic Agent not present in Concomitant Agent Pick List and user typed 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

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

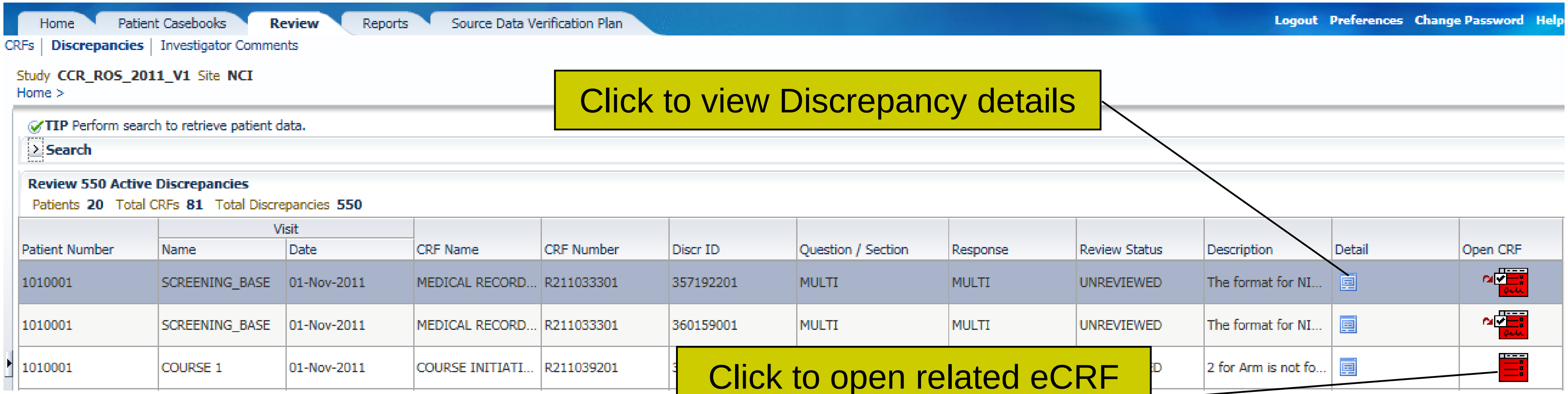
Patient Search

Patients

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

Click to view a list of all Discrepancies

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

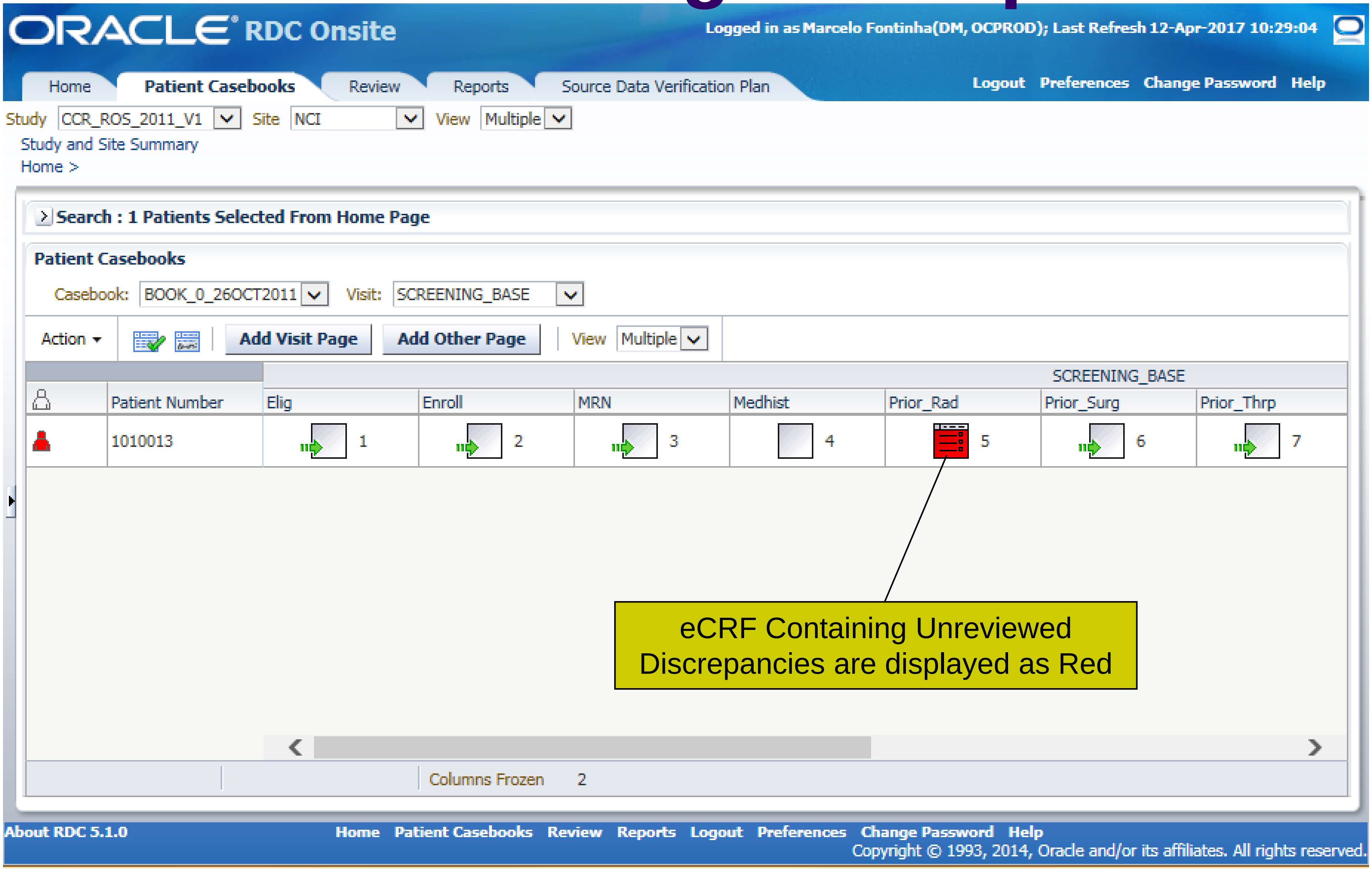
Patients **20** Total CRFs **81** Total Discrepancies **550**

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 NI...	▤	🟥
1010001	SCREENING_BASE	01-Nov-2011	MEDICAL RECORD...	R211033301	360159001	MULTI	MULTI	UNREVIEWED	The format for NI...	▤	🟥
1010001	COURSE 1	01-Nov-2011	COURSE INITIATI...	R211039201	3			D	2 for Arm is not fo...	▤	🟥

Click to view Discrepancy details

Click to open related eCRF and manage discrepancies

eCRFs Containing Discrepancies


ORACLE RDC Onsite
Home
Patient Casebooks
Review
Reports
Source Data Verification Plan
Logout
Preferences
Change Password
Help
Study and Site Summary
Home >
Action
Add Visit Page
Add Other Page
About RDC 5.1.0
Home
Patient Casebooks
Review
Reports
Logout
Preferences
Change Password
Help

Logged in as Marcelo Fontinha(DM, OCPROD); Last Refresh 12-Apr-2017 10:29:04

Study CCR_ROS_2011_V1 Site NCI View Multiple

Search : 1 Patients Selected From Home Page

Patient Casebooks

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE

View Multiple

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

Columns Frozen 2

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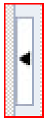
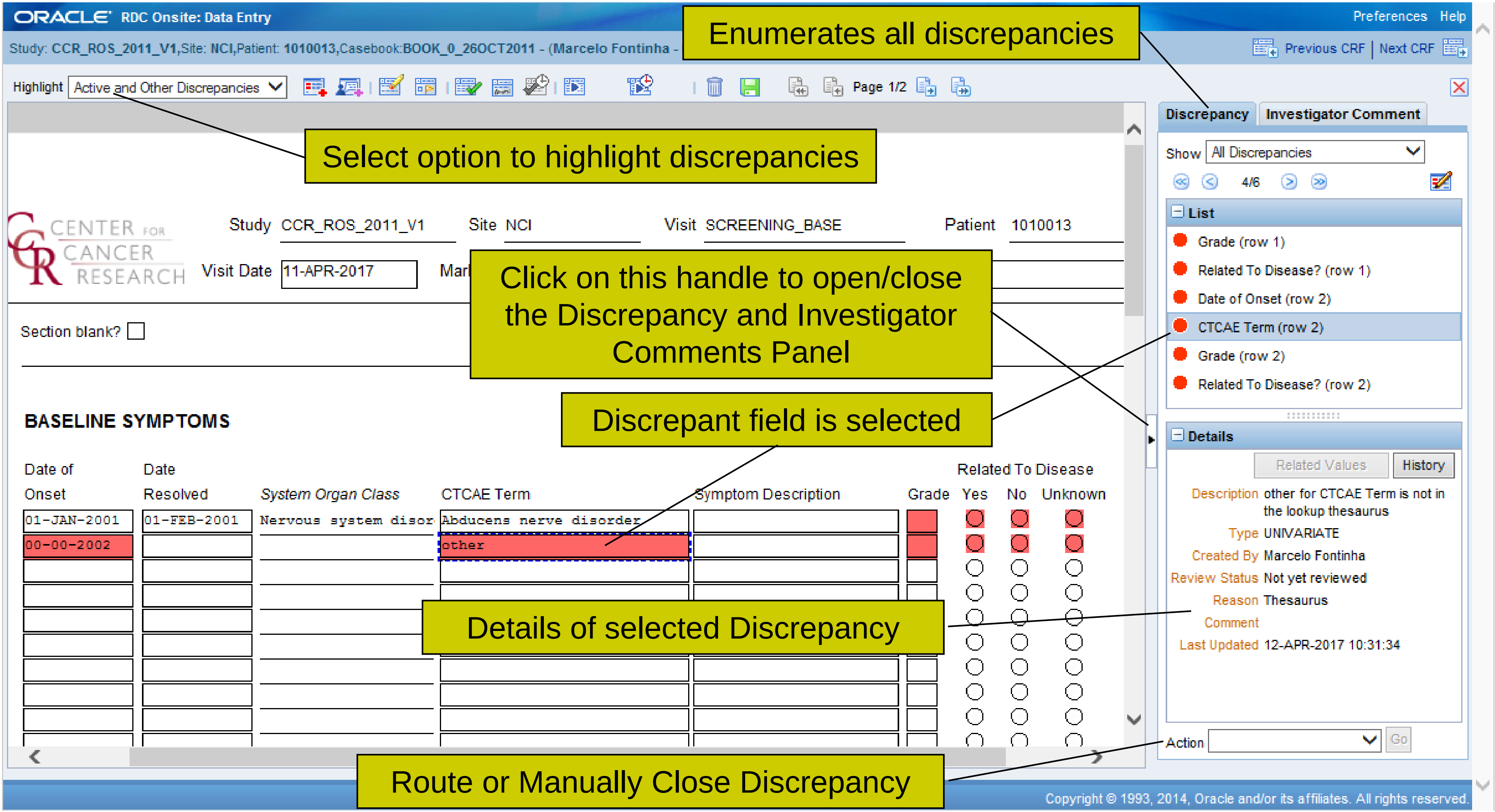
eCRF Containing Unreviewed Discrepancies are displayed as Red

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



Enumerates all discrepancies

Select option to highlight discrepancies

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

Discrepant field is selected

Details of selected Discrepancy

Route or Manually Close Discrepancy

ORACLE RDC Onsite: Data Entry

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

Highlight: Active and Other Discrepancies

Page 1/2

Study: CCR_ROS_2011_V1
Site: NCI
Visit: SCREENING_BASE
Patient: 1010013
Visit Date: 11-APR-2017

Section blank? ☐

BASELINE SYMPTOMS

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 disor	Abducens nerve disorder			○	○	○
00-00-2002			other			○	○	○

Discrepancy | Investigator Comment

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

Action:

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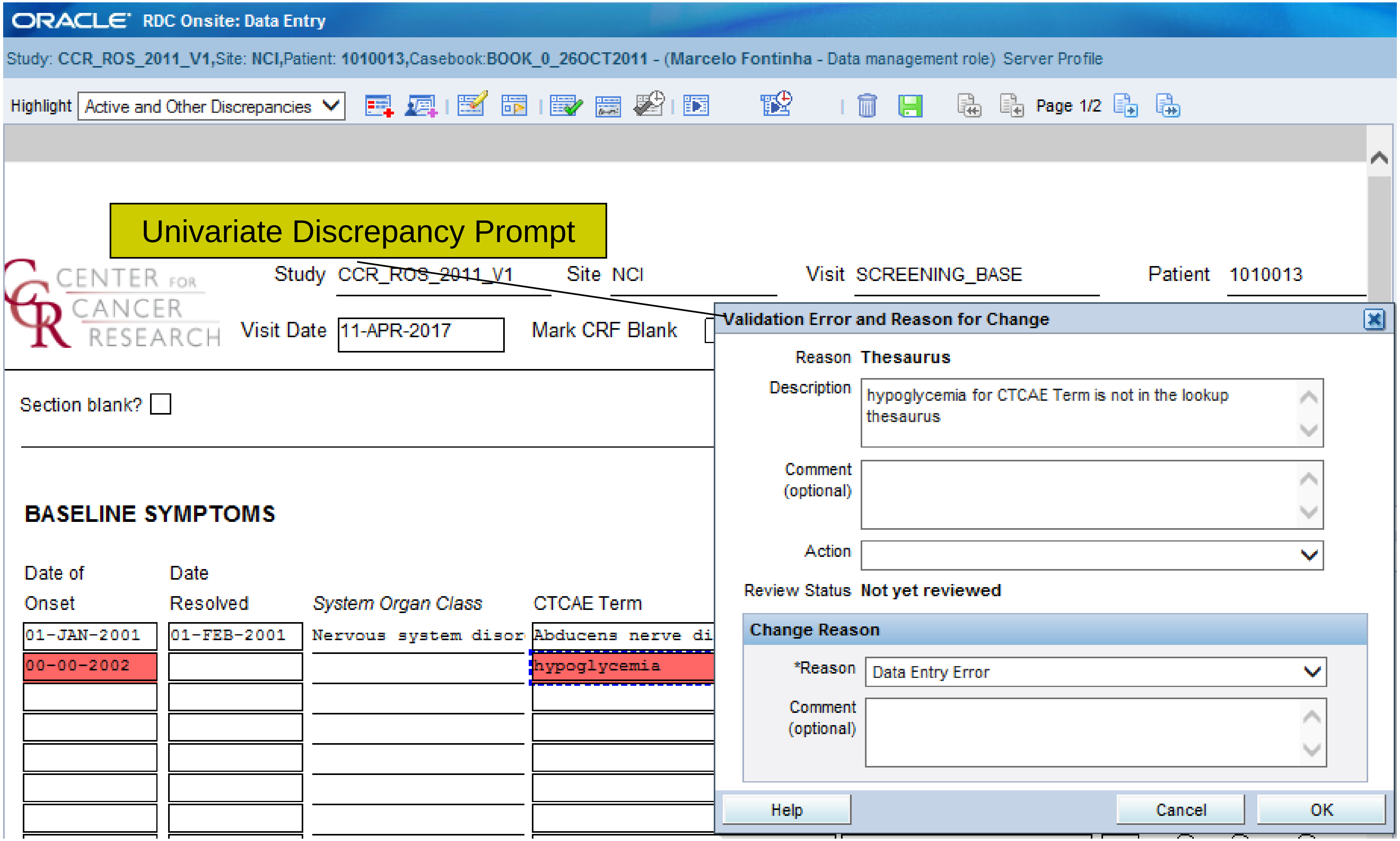
How are Univariate Disc. Created?

- 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
Univariate Discrepancy Prompt
CENTER FOR CANCER RESEARCH
Help
Cancel
OK

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

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 disor	Abducens nerve di
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):

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.

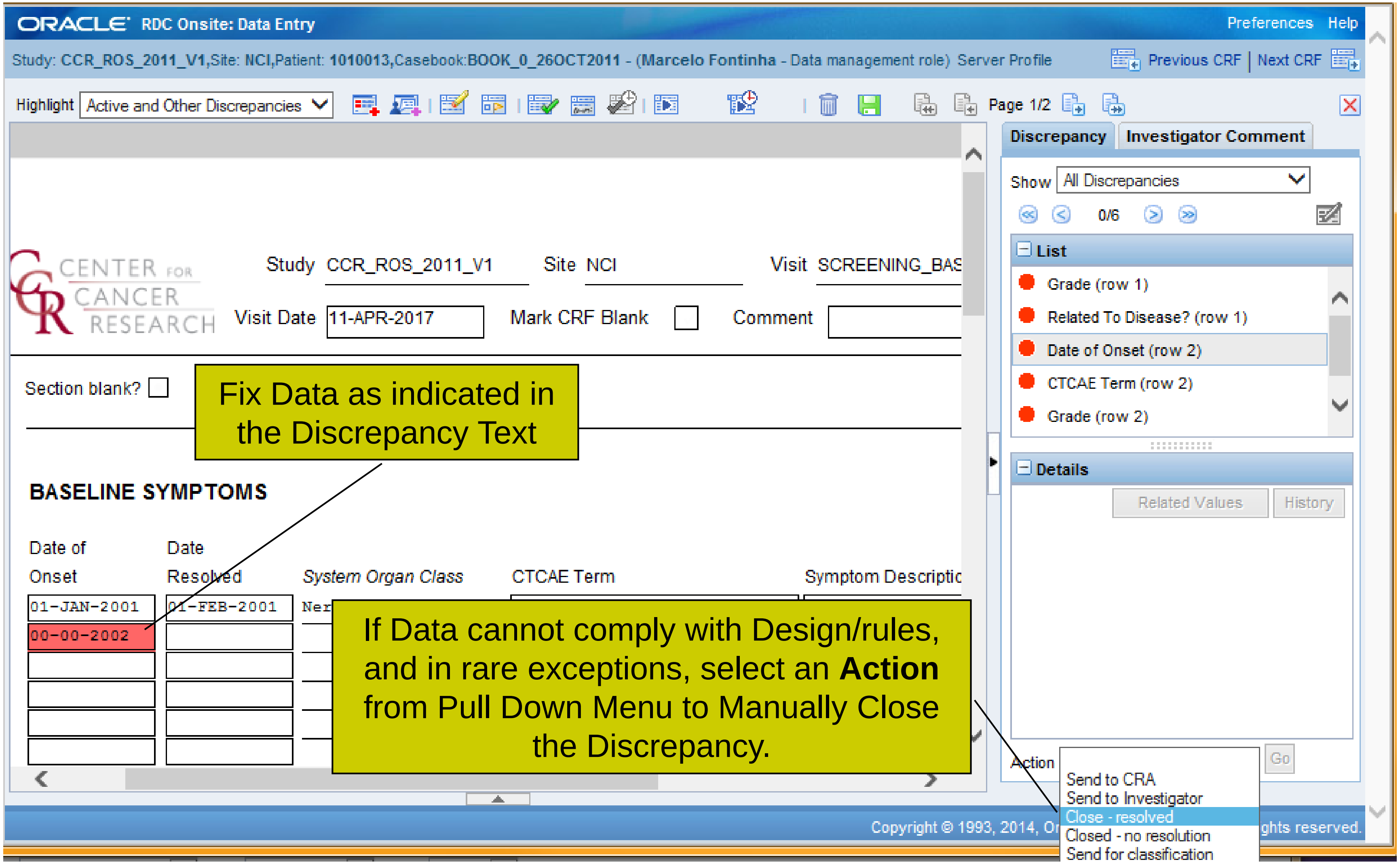
- **Quick Tip:**
  - Complex rules run overnight.

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



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

Study CCR_ROS_2011_V1 Site NCI Visit SCREENING_BAS

Visit Date 11-APR-2017 Mark CRF Blank ☐ Comment

Section blank? ☐

BASELINE SYMPTOMS

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

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)

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.

ORACLE RDC Onsite: Data Entry
Preferences
Help
Previous CRF
Next CRF
Page 1/2
Discrepancy
Investigator Comment
CENTER FOR CANCER RESEARCH
Details
Related Values
History
Action
Send to CRA
Send to Investigator
Close - resolved
Closed - no resolution
Send for classification
Go
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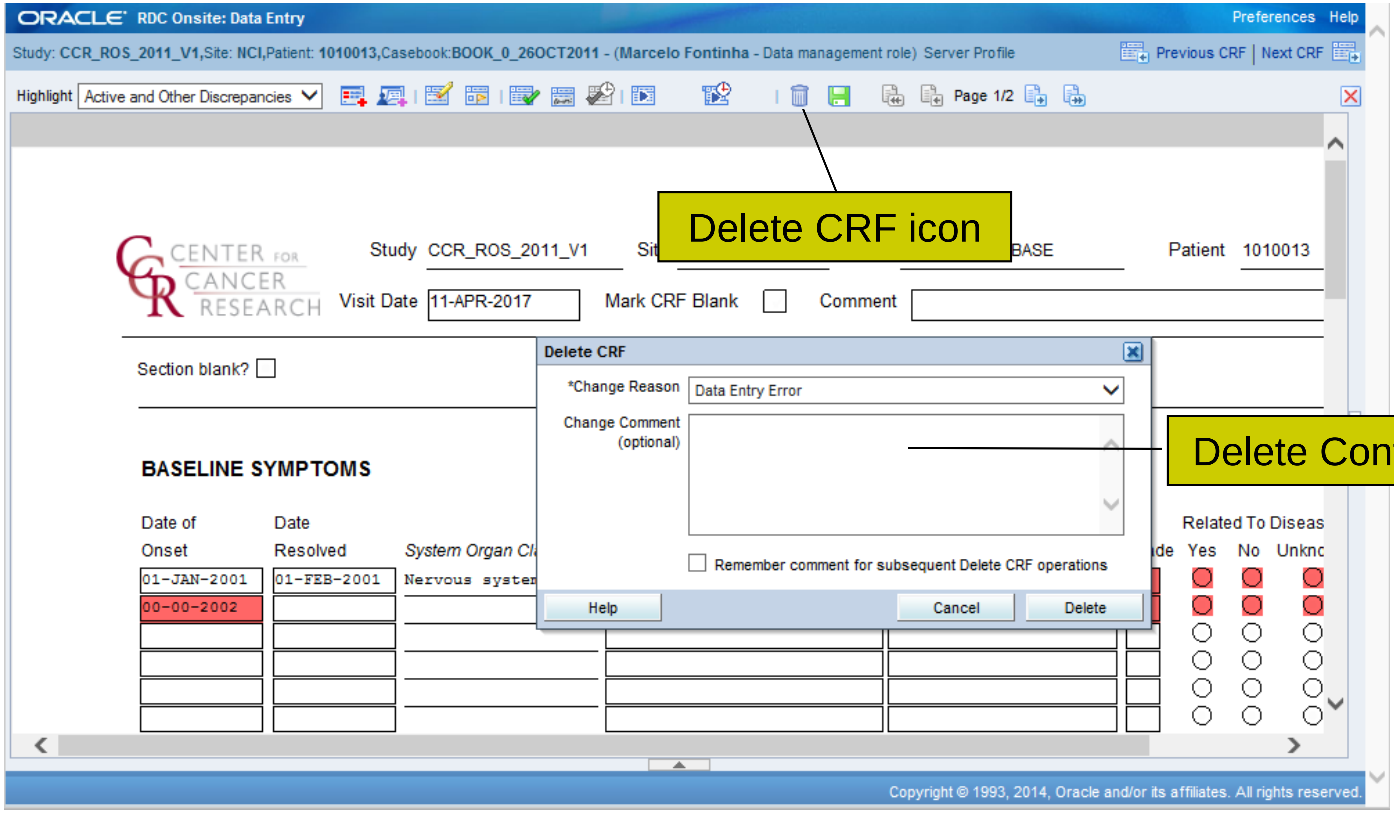
Delete eCRF

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



Delete CRF icon

Delete Confirmation

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

Study: CCR_ROS_2011_V1

Patient: 1010013

Visit Date: 11-APR-2017

Mark CRF Blank ☐

Section blank? ☐

BASELINE SYMPTOMS

Delete CRF

*Change Reason: Data Entry Error

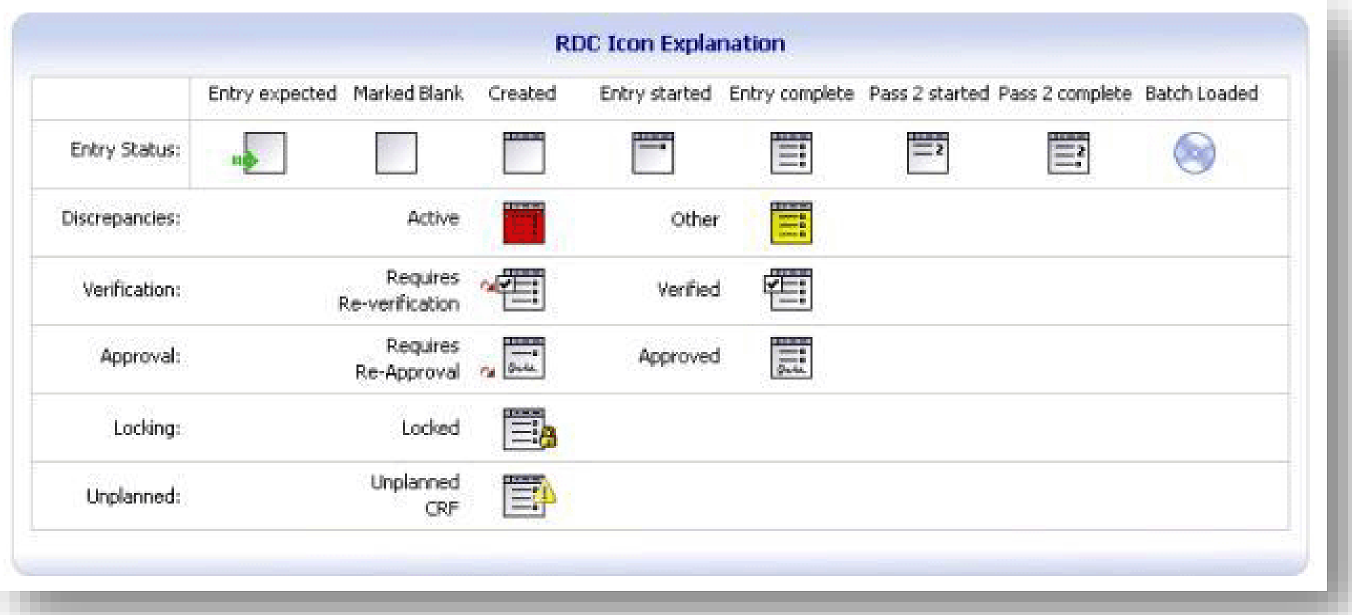
Change Comment (optional):

☐ Remember comment for subsequent Delete CRF operations

Preferences
Help
Previous CRF
Next CRF
Page 1/2
Comment
Date of Onset
Date Resolved
System Organ Cl
Related To Diseas
Yes
No
Unknc
01-JAN-2001
01-FEB-2001
Nervous systen
00-00-2002
Help
Cancel
Delete
Copyright © 1993, 2014, Oracle and/or its affiliates. All rights reserved.

Verification & Approval

- C^{3}D 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.



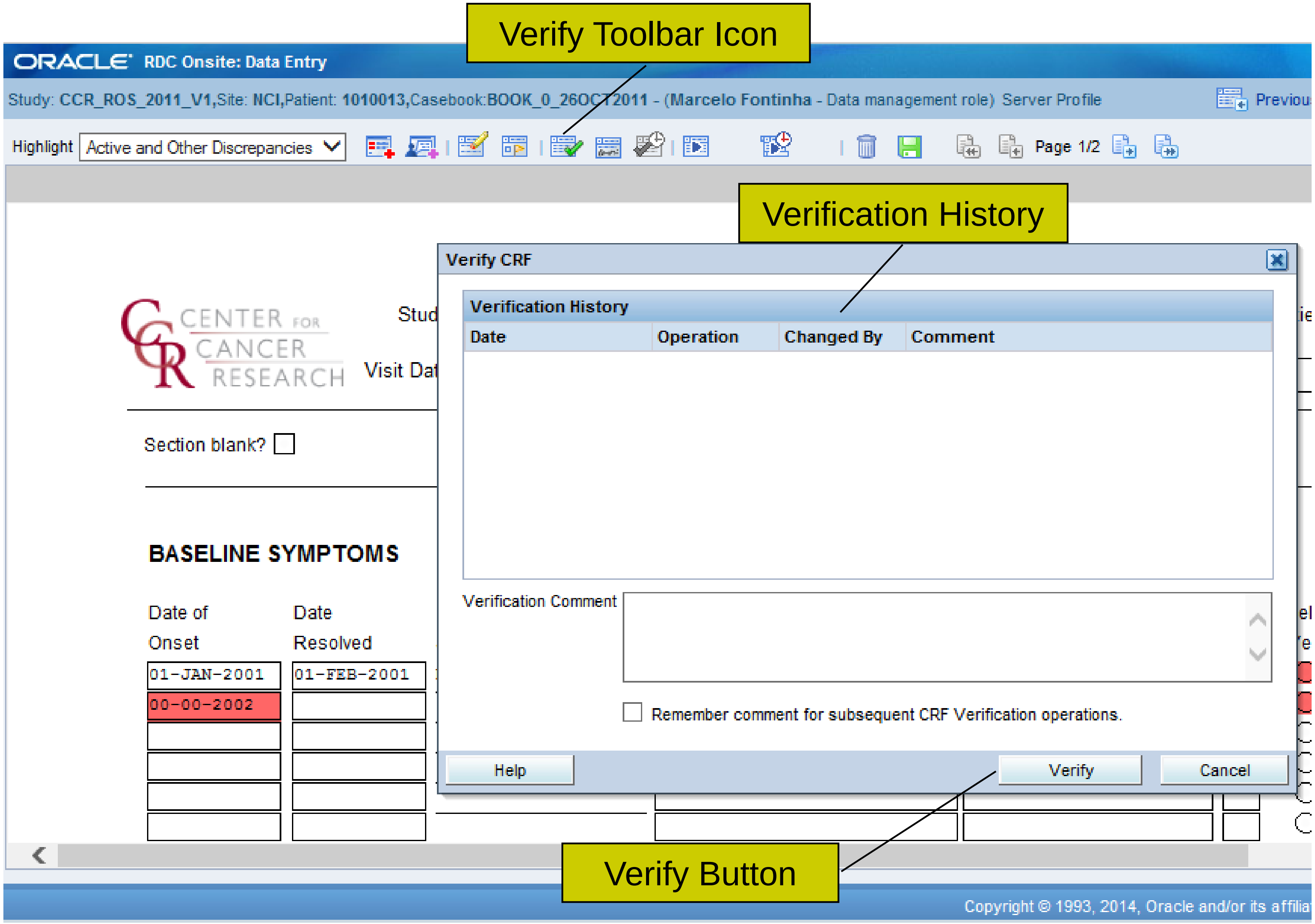
RDC Icon Explanation

	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

Verification History

Verify Button

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

Section blank? ☐

BASELINE SYMPTOMS

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

Verify CRF

Verification History

Date	Operation	Changed By	Comment

Verification Comment

☐ Remember comment for subsequent CRF Verification operations.

Previou
Page 1/2
CENTER FOR CANCER RESEARCH
Stud
Visit Dat
Help
Verify
Cancel

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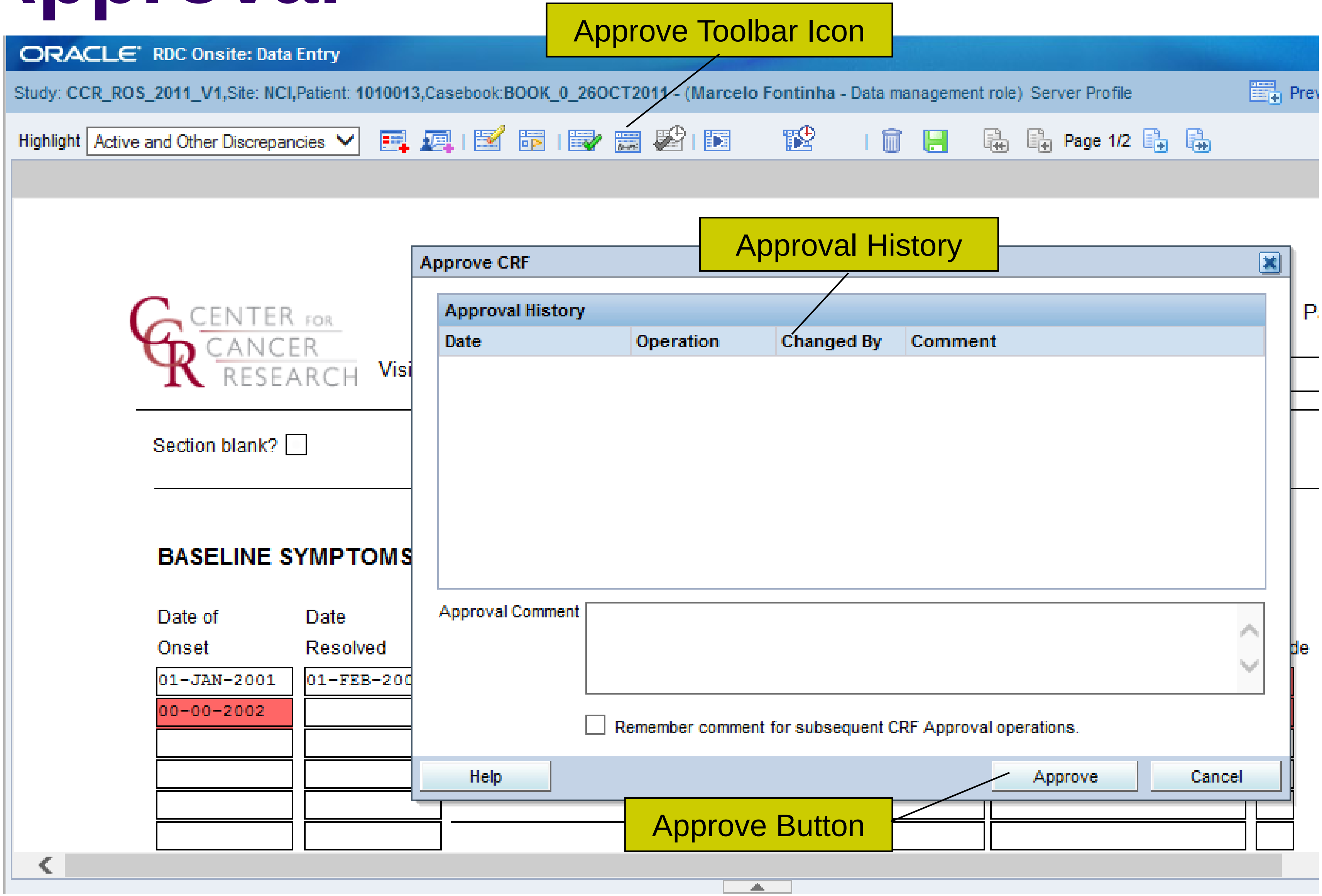
Approval

- Each eCRF can be approved clicking on the Toolbar Approve button and providing your C^{3}D 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


Approve Toolbar Icon

Approval History

Approve Button

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

Section blank? ☐

BASELINE SYMPTOMS

Date of Onset	Date Resolved
01-JAN-2001	01-FEB-200
00-00-2002	

Approve CRF

Approval History

Date	Operation	Changed By	Comment

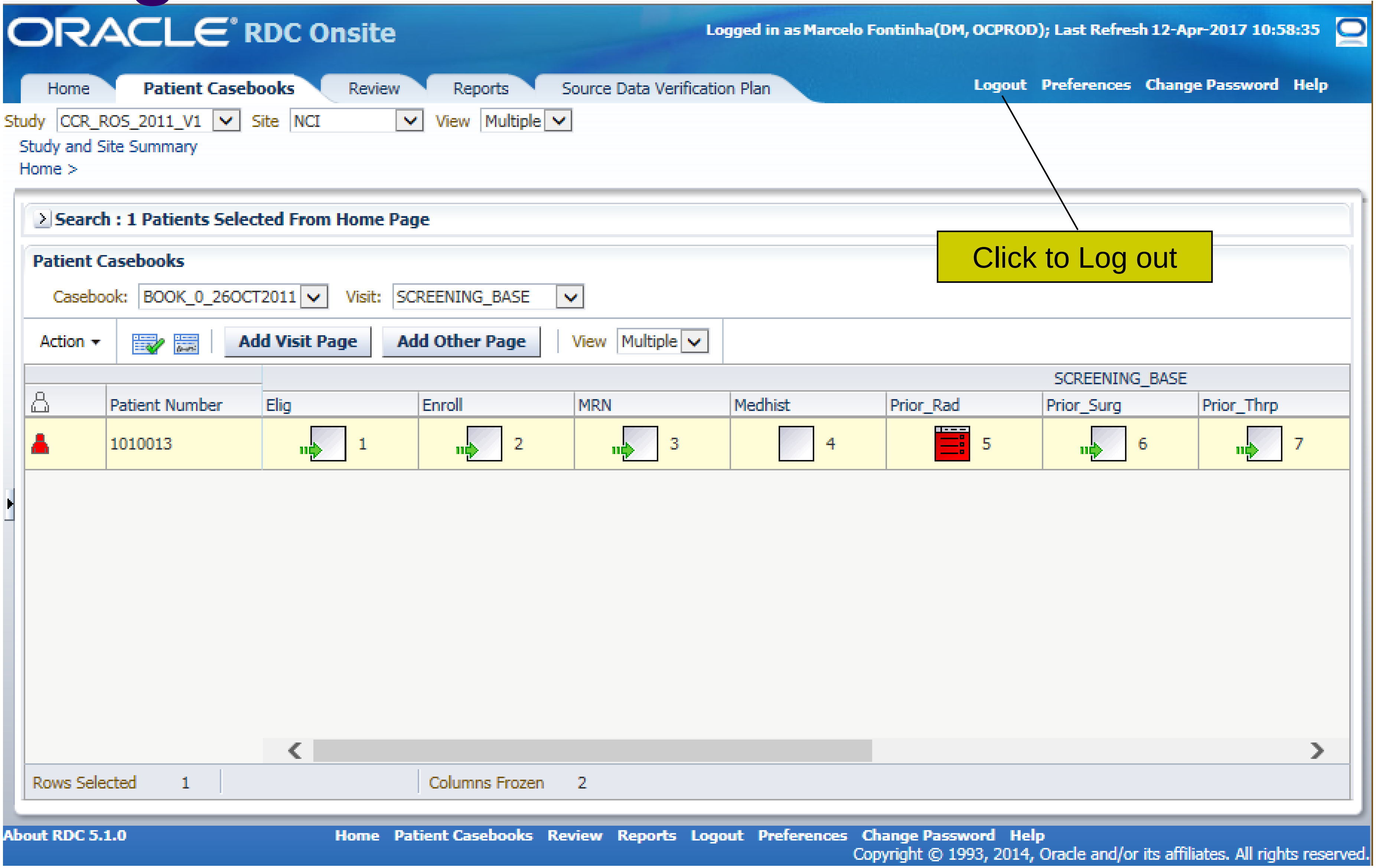
Approval Comment:

☐ Remember comment for subsequent CRF Approval operations.

Log Out

- Exit C^3D before closing the Browser
- C^3D 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



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

Study: CCR_ROS_2011_V1 Site: NCI View: Multiple

Search : 1 Patients Selected From Home Page

Casebook: BOOK_0_26OCT2011 Visit: SCREENING_BASE

View: Multiple

	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

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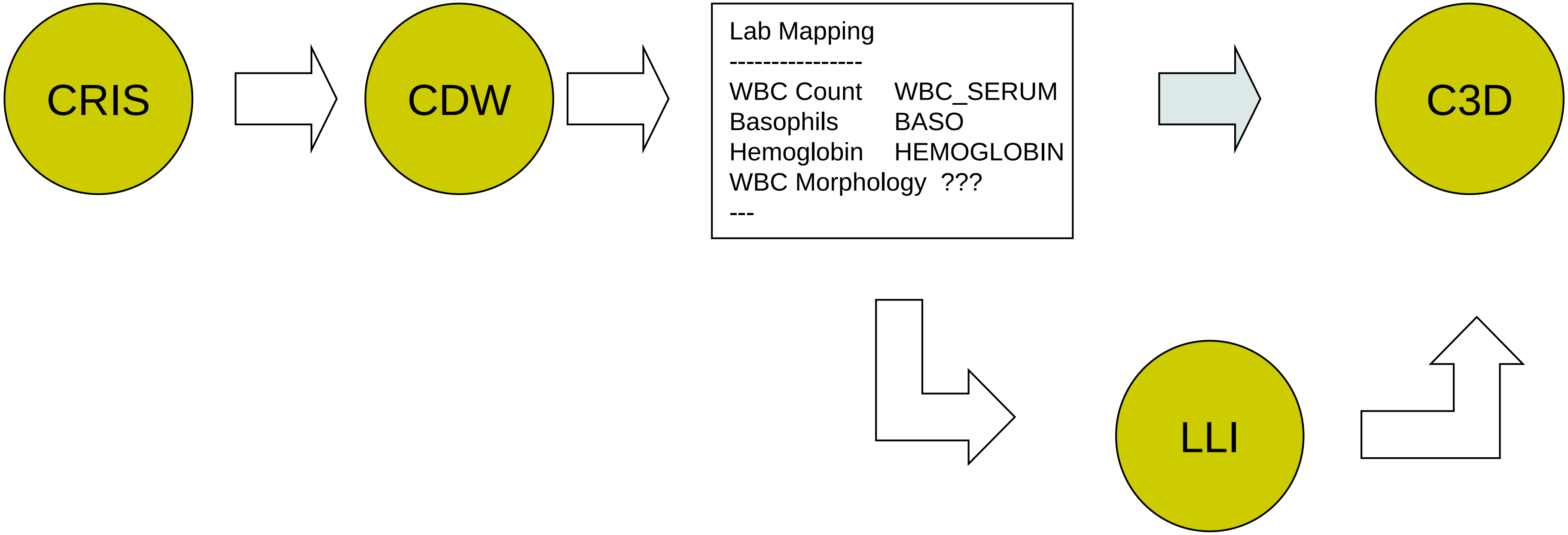
ORACLE RDC Onsite
Home
Patient Casebooks
Review
Reports
Source Data Verification Plan
Logout
Preferences
Change Password
Help
Study and Site Summary
Home >
Patient Casebooks
Action
Add Visit Page
Add Other Page
SCREENING_BASE
About RDC 5.1.0

Click to Log out

CRIS to C^3D Lab Data Flow


CRIS
CDW
C3D
LLI

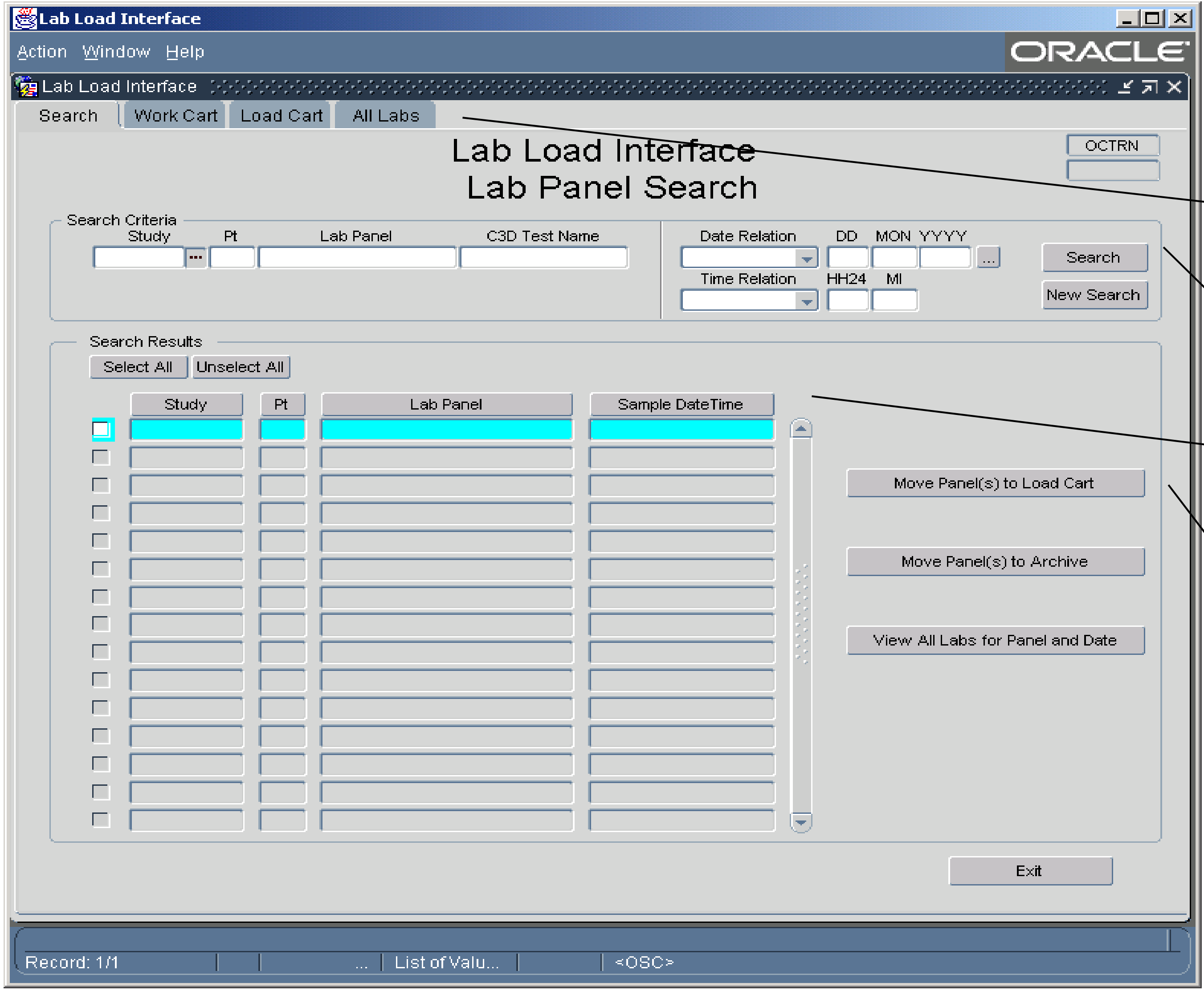
Lab Mapping

WBC Count	WBC_SERUM
Basophils	BASO
Hemoglobin	HEMOGLOBIN
WBC Morphology	???

What is LLI?

- LLI is a utility to review and identify specific Lab Test Results to be downloaded from the CRIS/CDW into C^{3}D
- Login Link: https://octrials.nci.nih.gov/opa52/labloadinter.htm
- Username & Password are same as C^{3}D

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
Time Relation
HH24
MI
Search
New Search
Search Results
Select All
Unselect All
Study
Pt
Lab Panel
Sample DateTime
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>

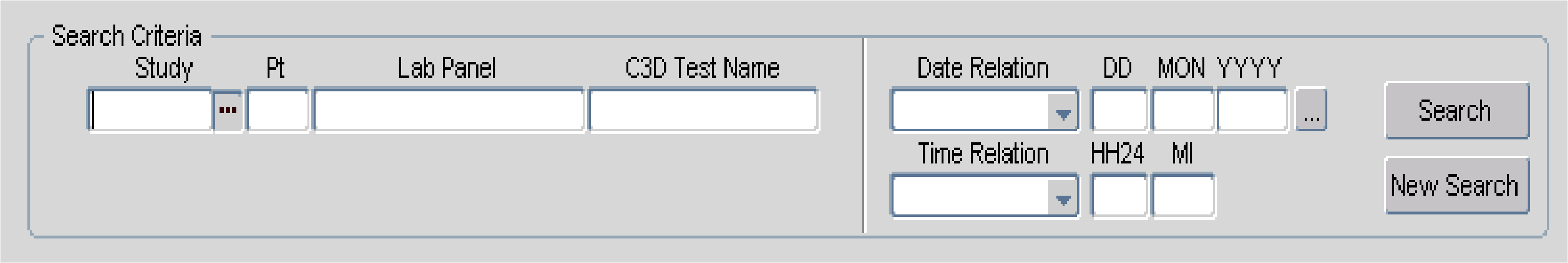
Workflow

Search Criteria

Selected Panels

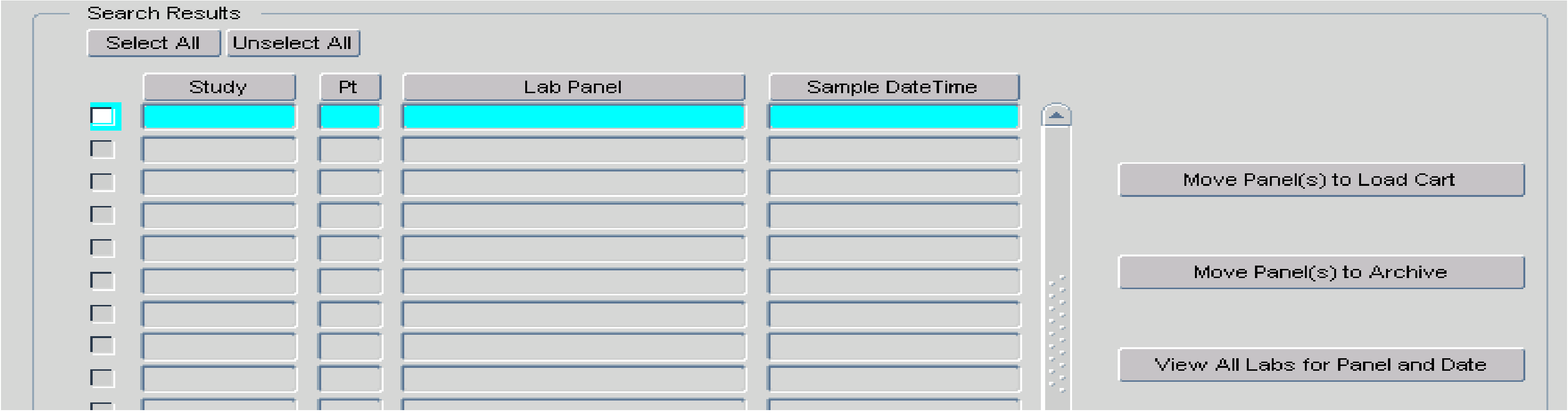
Action Buttons

LLI Search Criteria


Search Criteria
Study
Pt
Lab Panel
C3D Test Name
Date Relation
DD
MON
YYYY
Time Relation
HH24
MI
Search
New Search

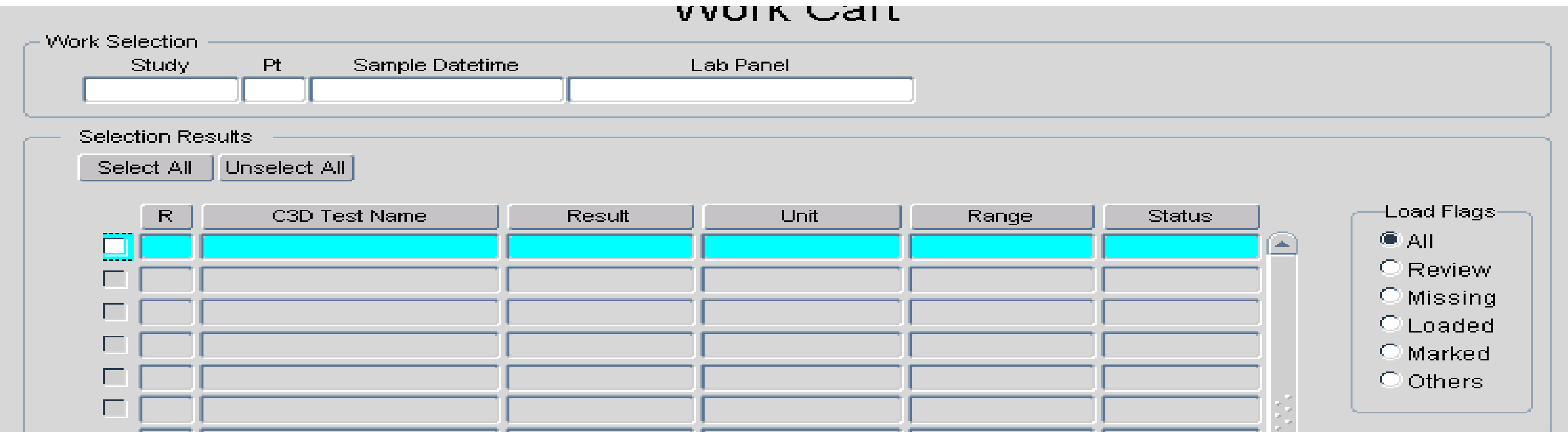
- **Searching**
  - Can search by Study, Patient Number, Lab Panel, OC Lab Question, Date and/or Time
    - Each search field contains Pick List.
    - Date and Time allows the ‘%’ wild card
    - Date and Time provide the additional option of:
      - “On or Before”, “On or After” and “LIKE” comparisons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

LLI Search Screen Results


Search Results
Select All
Unselect All
Study
Pt
Lab Panel
Sample DateTime
Move Panel(s) to Load Cart
Move Panel(s) to Archive
View All Labs for Panel and Date

- **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


Work Cart
Work Selection
Study
Pt
Sample Datetime
Lab Panel
Selection Results
Select All
Unselect All
R
C3D Test Name
Result
Unit
Range
Status

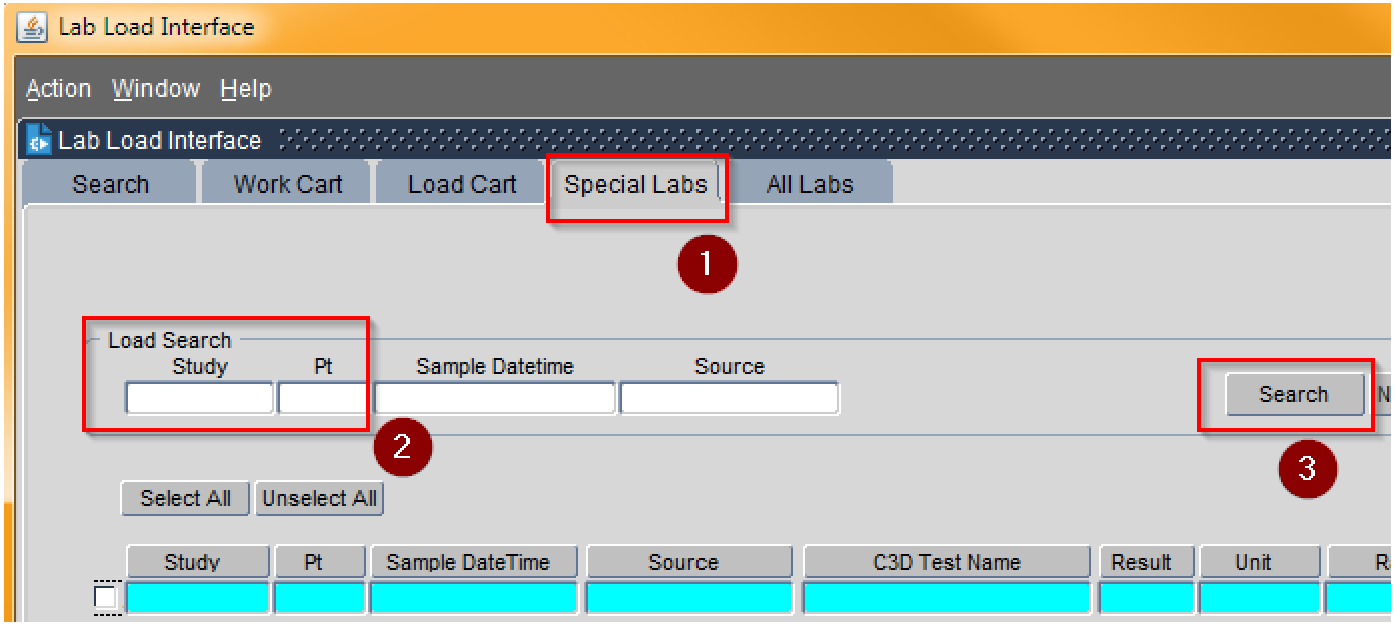
Load Flags
● All
○ Review
○ Missing
○ Loaded
○ Marked
○ Others

- **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

LLI Special Labs

- Some Labs need to handled via the Special Labs tab.
- These are labs which the Source has been manually entered in CRIS and they may have, or not, been mapped to a C3D Test Name.

1. Click on Special Labs tab
2. Select the Study and Patient
3. Click on Search

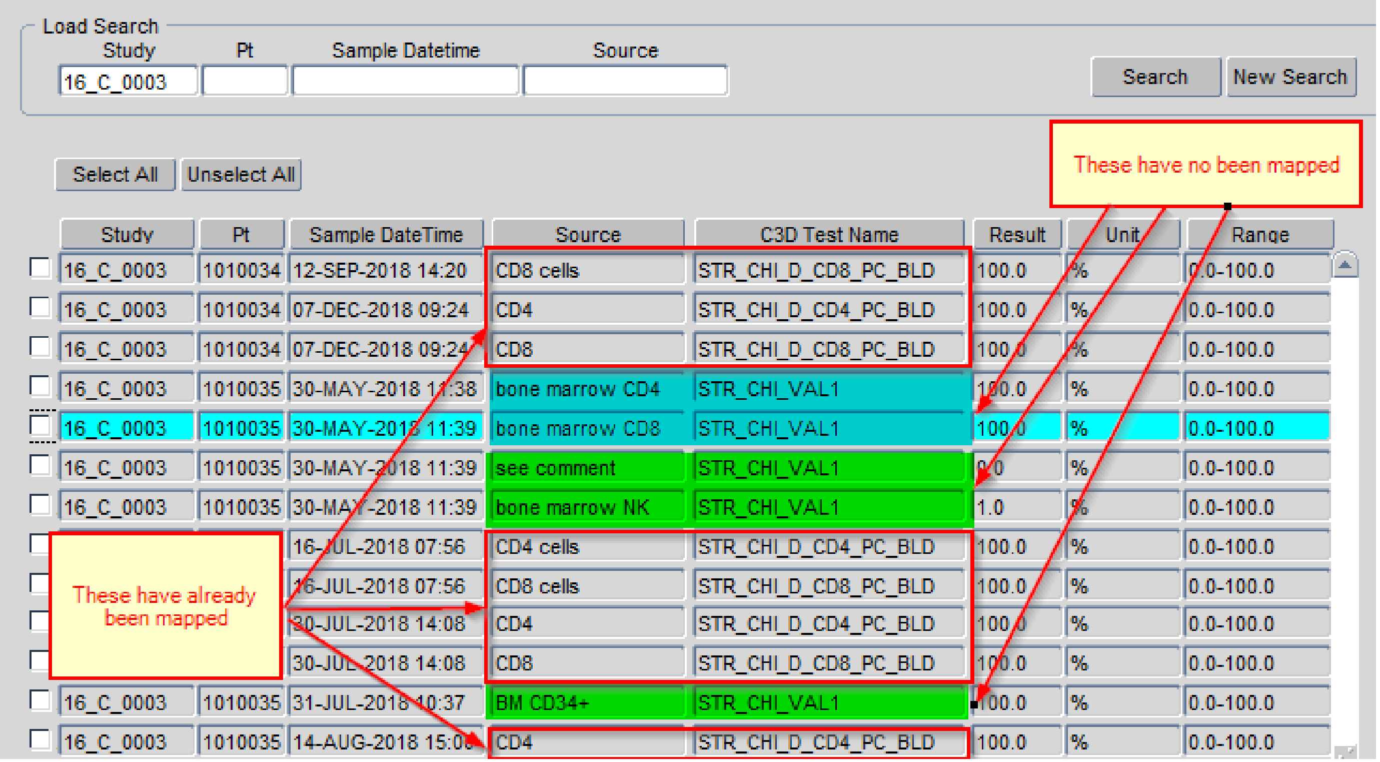

Lab Load Interface
Action
Window
Help
Lab Load Interface
Search
Work Cart
Load Cart
Special Labs
All Labs
1
Load Search
Study
Pt
Sample Datetime
Source
Search
N
2
3
Select All
Unselect All
Study
Pt
Sample DateTime
Source
C3D Test Name
Result
Unit
R

LLI Special Labs

- **Notice that two C3D Test Name have been mapped to two Sources.**

Source	Test Name	Intent
CD4 Cells	STR_CHI_D_CD4_PC_BLD	Short Tandem Repeat Chimerism, Donor, Clusters of Differentiation 4 (CD4), %, Blood
CD8 Cells	STR_CHI_D_CD8_PC_BLD	Short Tandem Repeat Chimerism, Donor, Clusters of Differentiation 8 (CD8), %, Blood

- **However, there are other Sources that have C3D Test Name STR_CHI_VAL1**
  - ***These are not mapped***



Study: 16_C_0003
Pt:
Sample Datetime:
Source:

These have no been mapped

	Study	Pt	Sample DateTime	Source	C3D Test Name	Result	Unit	Range
☐	16_C_0003	1010034	12-SEP-2018 14:20	CD8 cells	STR_CHI_D_CD8_PC_BLD	100.0	%	0.0-100.0
☐	16_C_0003	1010034	07-DEC-2018 09:24	CD4	STR_CHI_D_CD4_PC_BLD	100.0	%	0.0-100.0
☐	16_C_0003	1010034	07-DEC-2018 09:24	CD8	STR_CHI_D_CD8_PC_BLD	100.0	%	0.0-100.0
☐	16_C_0003	1010035	30-MAY-2018 11:38	bone marrow CD4	STR_CHI_VAL1	100.0	%	0.0-100.0
☐	16_C_0003	1010035	30-MAY-2018 11:39	bone marrow CD8	STR_CHI_VAL1	100.0	%	0.0-100.0
☐	16_C_0003	1010035	30-MAY-2018 11:39	see comment	STR_CHI_VAL1	0.0	%	0.0-100.0
☐	16_C_0003	1010035	30-MAY-2018 11:39	bone marrow NK	STR_CHI_VAL1	1.0	%	0.0-100.0
☐			16-JUL-2018 07:56	CD4 cells	STR_CHI_D_CD4_PC_BLD	100.0	%	0.0-100.0
☐			16-JUL-2018 07:56	CD8 cells	STR_CHI_D_CD8_PC_BLD	100.0	%	0.0-100.0
☐			30-JUL-2018 14:08	CD4	STR_CHI_D_CD4_PC_BLD	100.0	%	0.0-100.0
☐			30-JUL-2018 14:08	CD8	STR_CHI_D_CD8_PC_BLD	100.0	%	0.0-100.0
☐	16_C_0003	1010035	31-JUL-2018 10:37	BM CD34+	STR_CHI_VAL1	100.0	%	0.0-100.0
☐	16_C_0003	1010035	14-AUG-2018 15:08	CD4	STR_CHI_D_CD4_PC_BLD	100.0	%	0.0-100.0

These have already been mapped

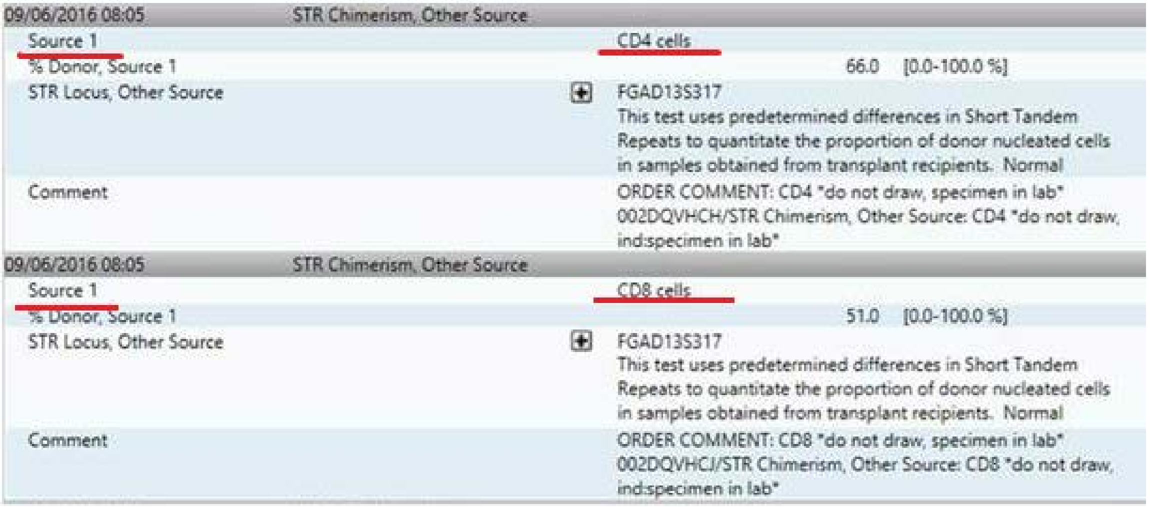
LLI Special Labs

- See Source ‘bone marrow CD4’. It is associated with test STR_CHI_VAL1 – It has not mapped.

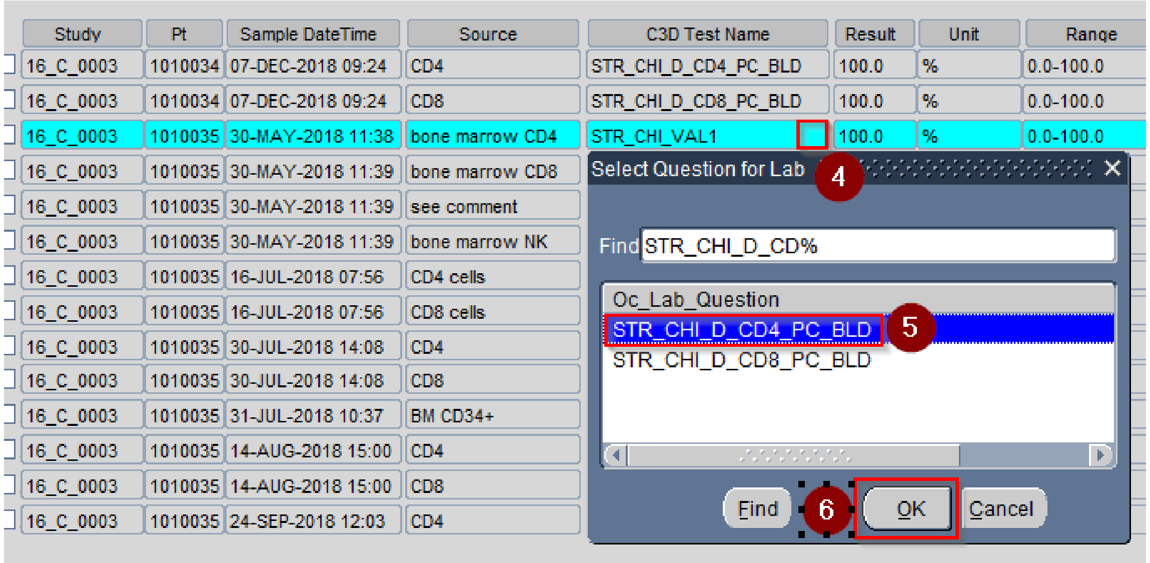
- If this test/result is needed in C3D, check Protocol design/calendar and CRIS order/result.

- If this test has the same intent as STR_CHI_D_CD4_PC_BLD, then click on the ellipsys and select it from the list.
  Also, submit a ticket to the C3D Help Desk requesting the mapping of this source and C3D Test Name.

- If this test has a different intent, then a new C3D Test Name has to be created and mapped to the ‘bone marrow CD4’ source. Submit a ticket to the C3D Help Desk inlcuding a description of the intent of the test and to which Source it should be mapped. Provided Study, Patient, Source and Date/Time.



09/06/2016 08:05	STR Chimerism, Other Source		
Source 1		CD4 cells	
% Donor, Source 1		66.0	[0.0-100.0 %]
STR Locus, Other Source		FGAD13S317 This test uses predetermined differences in Short Tandem Repeats to quantitate the proportion of donor nucleated cells in samples obtained from transplant recipients. Normal	
Comment		ORDER COMMENT: CD4 "do not draw, specimen in lab" 002DQVHCH/STR Chimerism, Other Source: CD4 "do not draw, ind:specimen in lab"	
09/06/2016 08:05	STR Chimerism, Other Source		
Source 1		CD8 cells	
% Donor, Source 1		51.0	[0.0-100.0 %]
STR Locus, Other Source		FGAD13S317 This test uses predetermined differences in Short Tandem Repeats to quantitate the proportion of donor nucleated cells in samples obtained from transplant recipients. Normal	
Comment		ORDER COMMENT: CD8 "do not draw, specimen in lab" 002DQVHCJ/STR Chimerism, Other Source: CD8 "do not draw, ind:specimen in lab"	



Study	Pt	Sample DateTime	Source	C3D Test Name	Result	Unit	Range
16_C_0003	1010034	07-DEC-2018 09:24	CD4	STR_CHI_D_CD4_PC_BLD	100.0	%	0.0-100.0
16_C_0003	1010034	07-DEC-2018 09:24	CD8	STR_CHI_D_CD8_PC_BLD	100.0	%	0.0-100.0
16_C_0003	1010035	30-MAY-2018 11:38	bone marrow CD4	STR_CHI_VAL1	100.0	%	0.0-100.0
16_C_0003	1010035	30-MAY-2018 11:39	bone marrow CD8				
16_C_0003	1010035	30-MAY-2018 11:39	see comment				
16_C_0003	1010035	30-MAY-2018 11:39	bone marrow NK				
16_C_0003	1010035	16-JUL-2018 07:56	CD4 cells				
16_C_0003	1010035	16-JUL-2018 07:56	CD8 cells				
16_C_0003	1010035	30-JUL-2018 14:08	CD4				
16_C_0003	1010035	30-JUL-2018 14:08	CD8				
16_C_0003	1010035	31-JUL-2018 10:37	BM CD34+				
16_C_0003	1010035	14-AUG-2018 15:00	CD4				
16_C_0003	1010035	14-AUG-2018 15:00	CD8				
16_C_0003	1010035	24-SEP-2018 12:03	CD4				

Select Question for Lab

Find STR_CHI_D_CD%

Oc_Lab_Question
STR_CHI_D_CD4_PC_BLD
STR_CHI_D_CD8_PC_BLD

Questions?