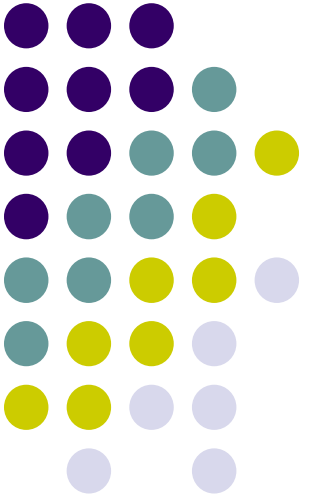
Introduction to C^{3}D

Harris Corporation

Jan 2015



Introduction

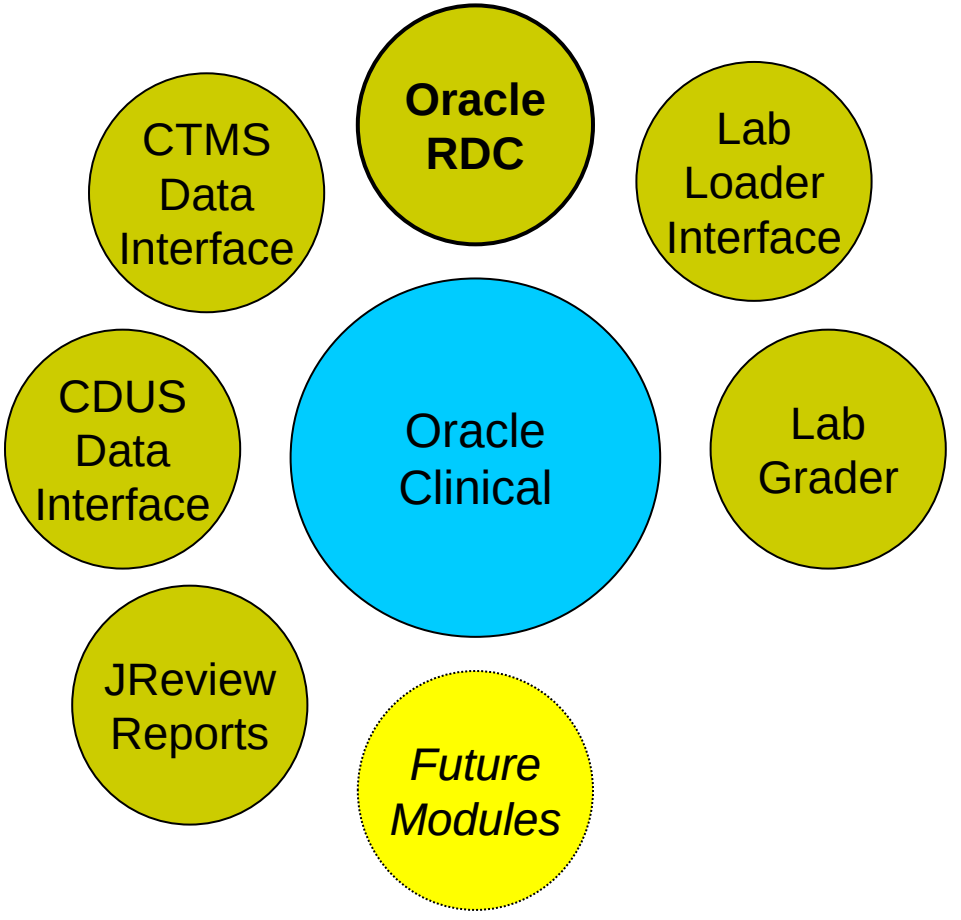
- C^3D - **C**ancer **C**entral **C**linical **D**atabase
- eCRFs Instructions Manual
- Support
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval
- Lab Loading

What is C³D

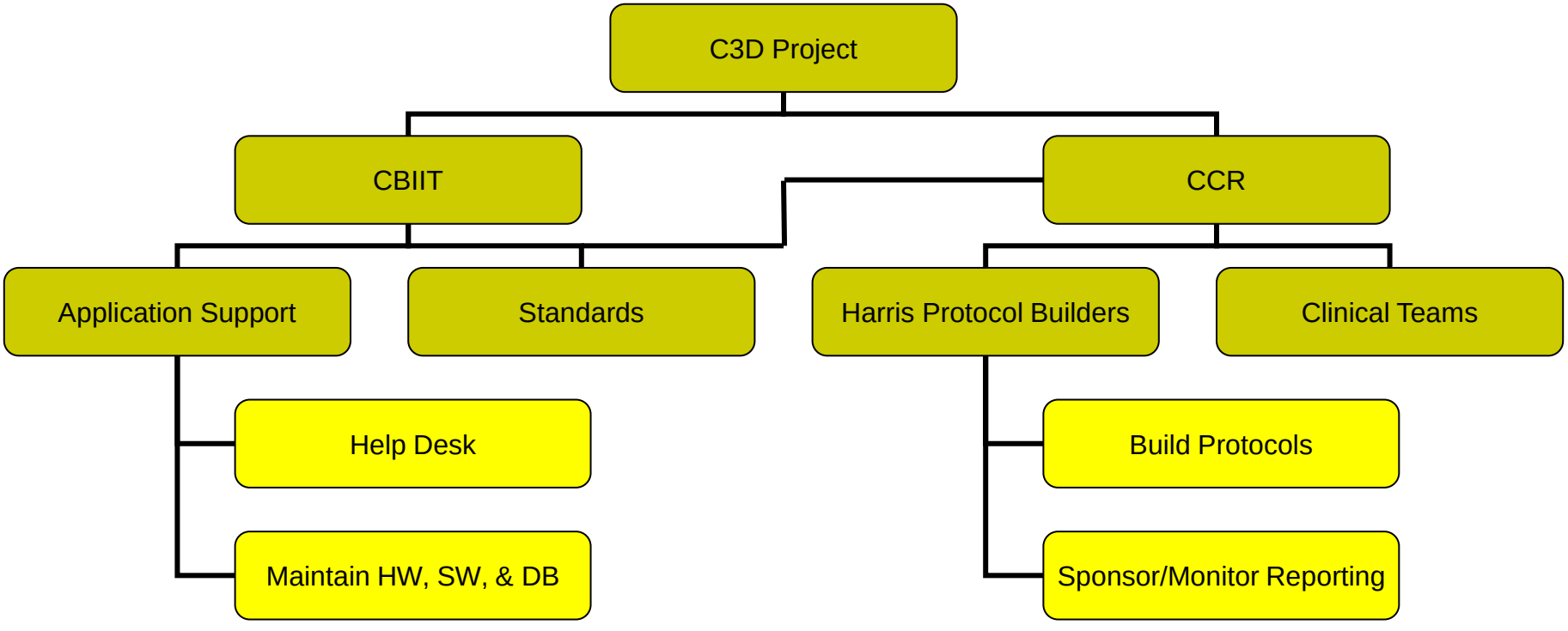
Cancer Central Clinical Database

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

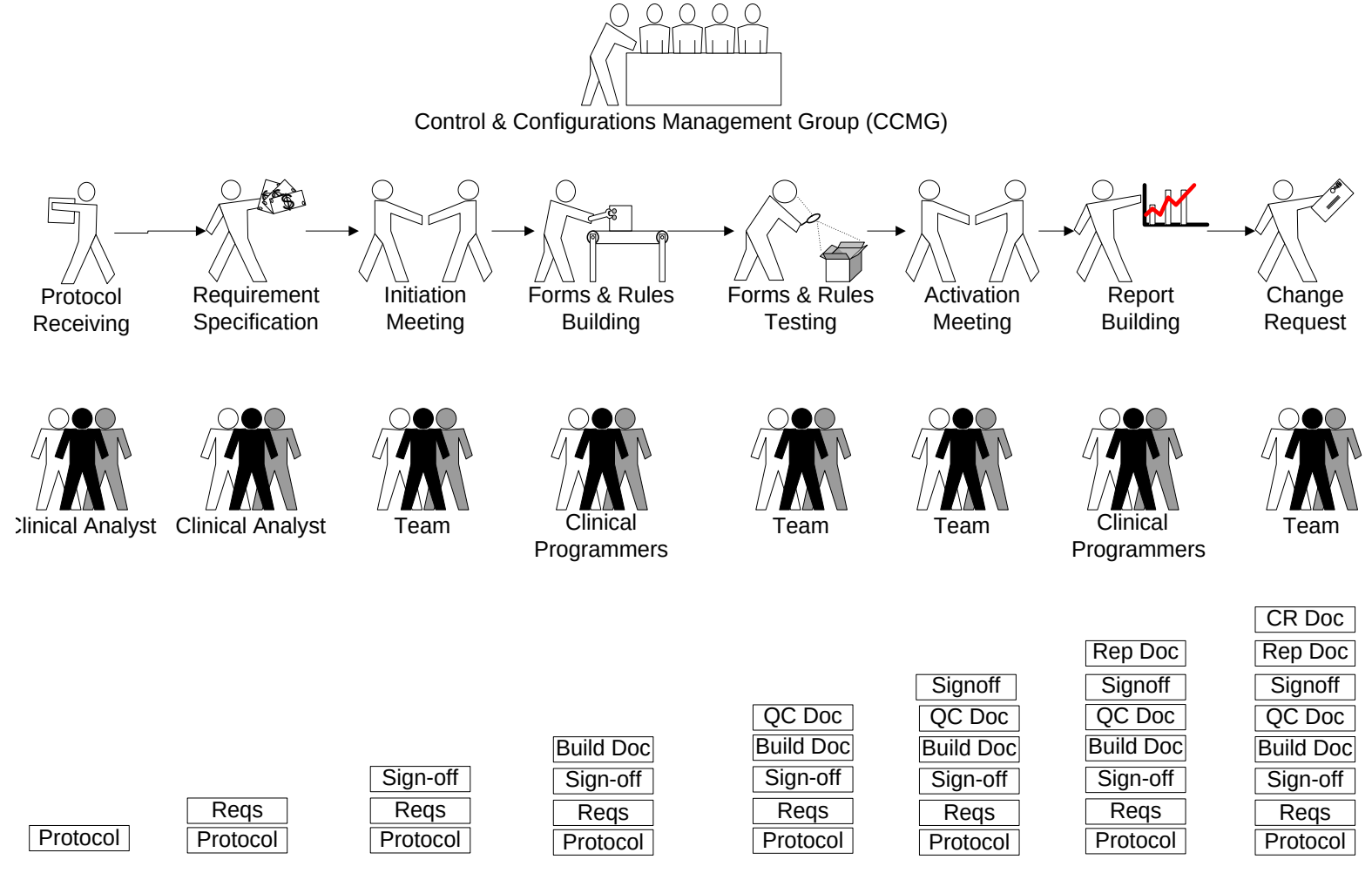
Cancer Central Clinical Database C^{3}D



C3D Organization



Designing Protocols in C³D



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

Search

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

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

Contents

- Purpose
- Course Initiation eCRF
- Validations
- Derivations

Purpose

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

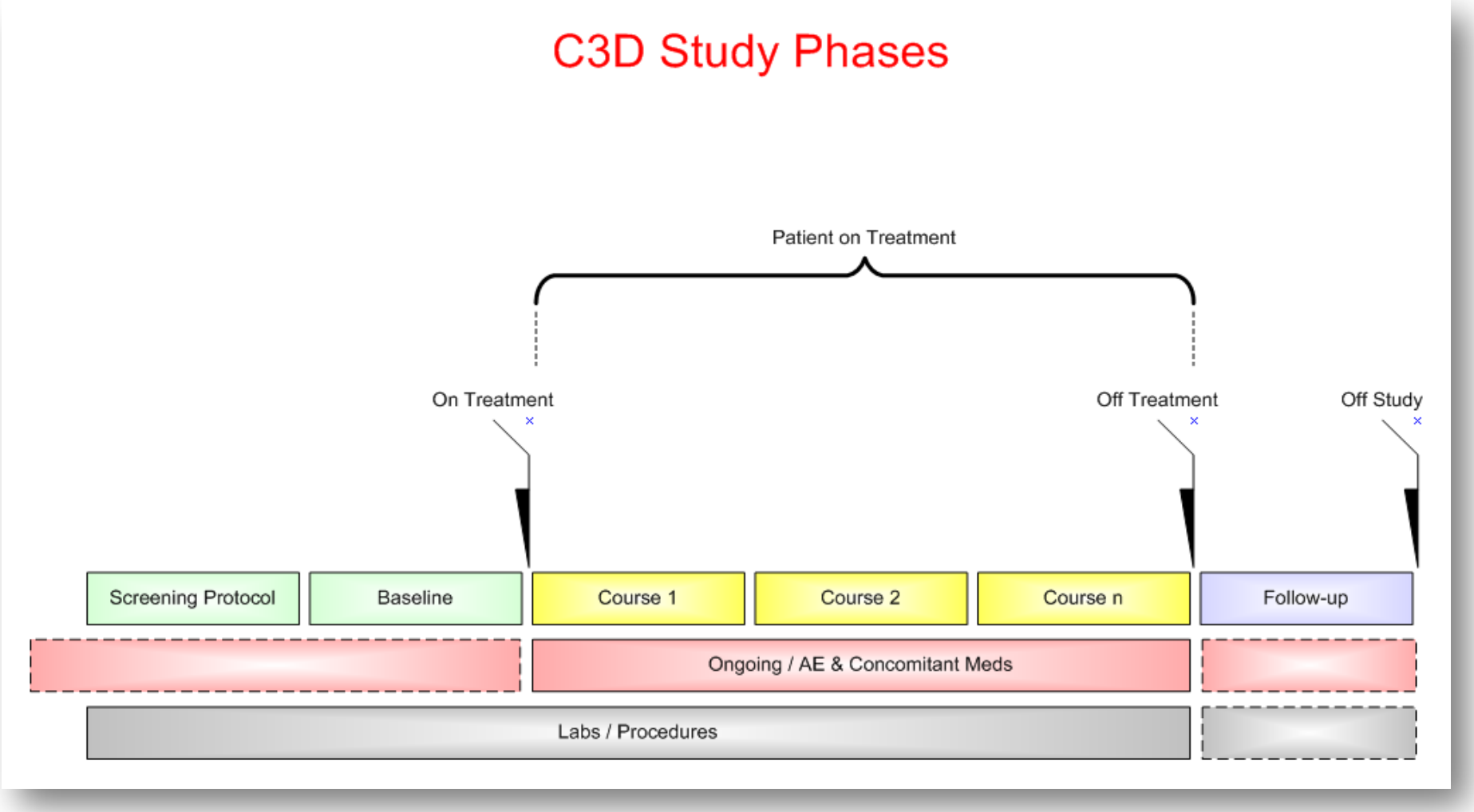
Course Initiation eCRF

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

CCR Standard Case Report Forms

- Screening/Baseline Forms
  - 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



Role Based Access

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

C³D Support

- CBIIT provides the first line of support for C³D related issues
- Contact
  - Email: ncicbiit@mail.nih.gov
  - Phone: 240-276-5541 (**Toll free**: 888-478-4423)
  - 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

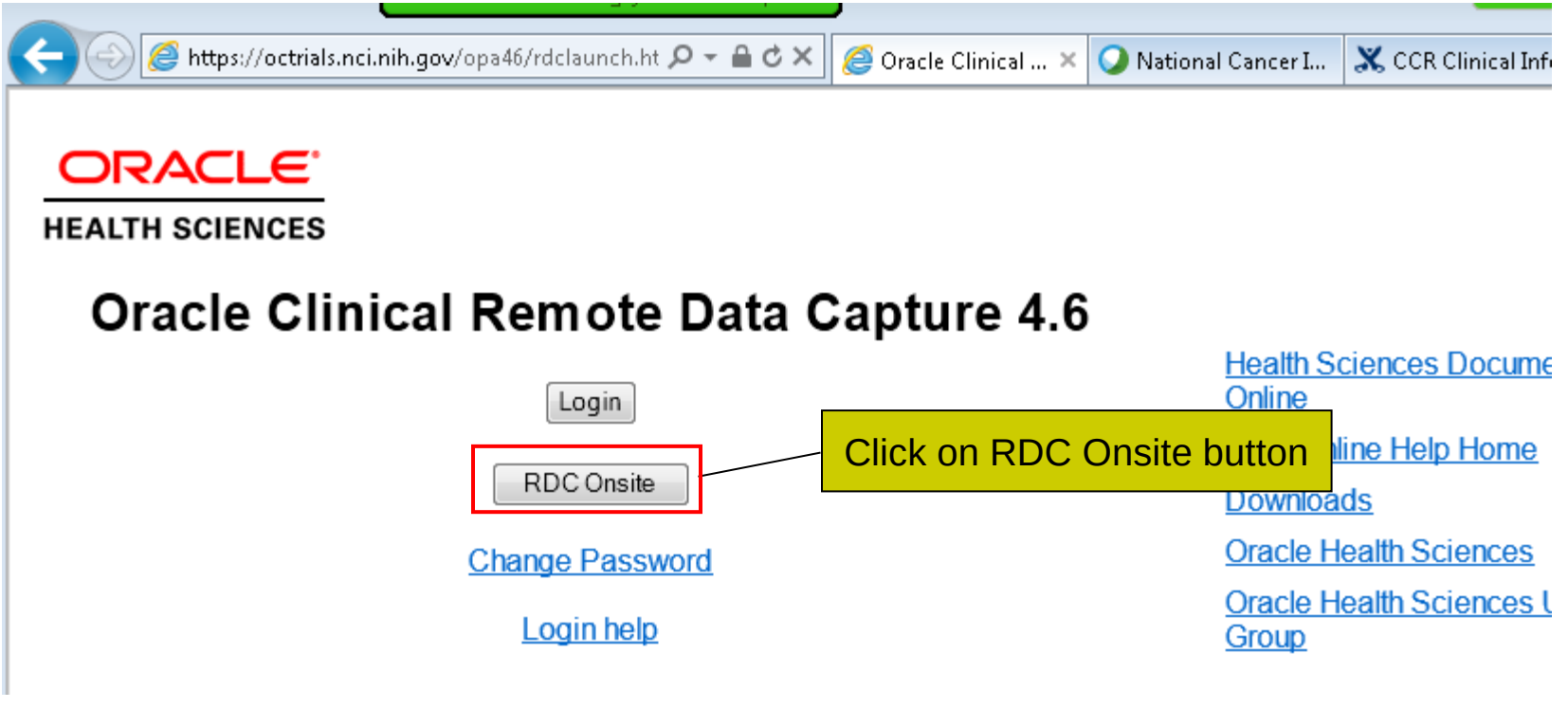
- Username is typically your last name and first name initial.
  Ex: **smiths**
- Password rules:
  - Start with a letter;
  - Must containing **at least one number and one special characters** (Ex:! #);
  - Has to be at least 8 characters long;
  - The following special character could cause problems 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 3 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.

C³D Login Web Pages

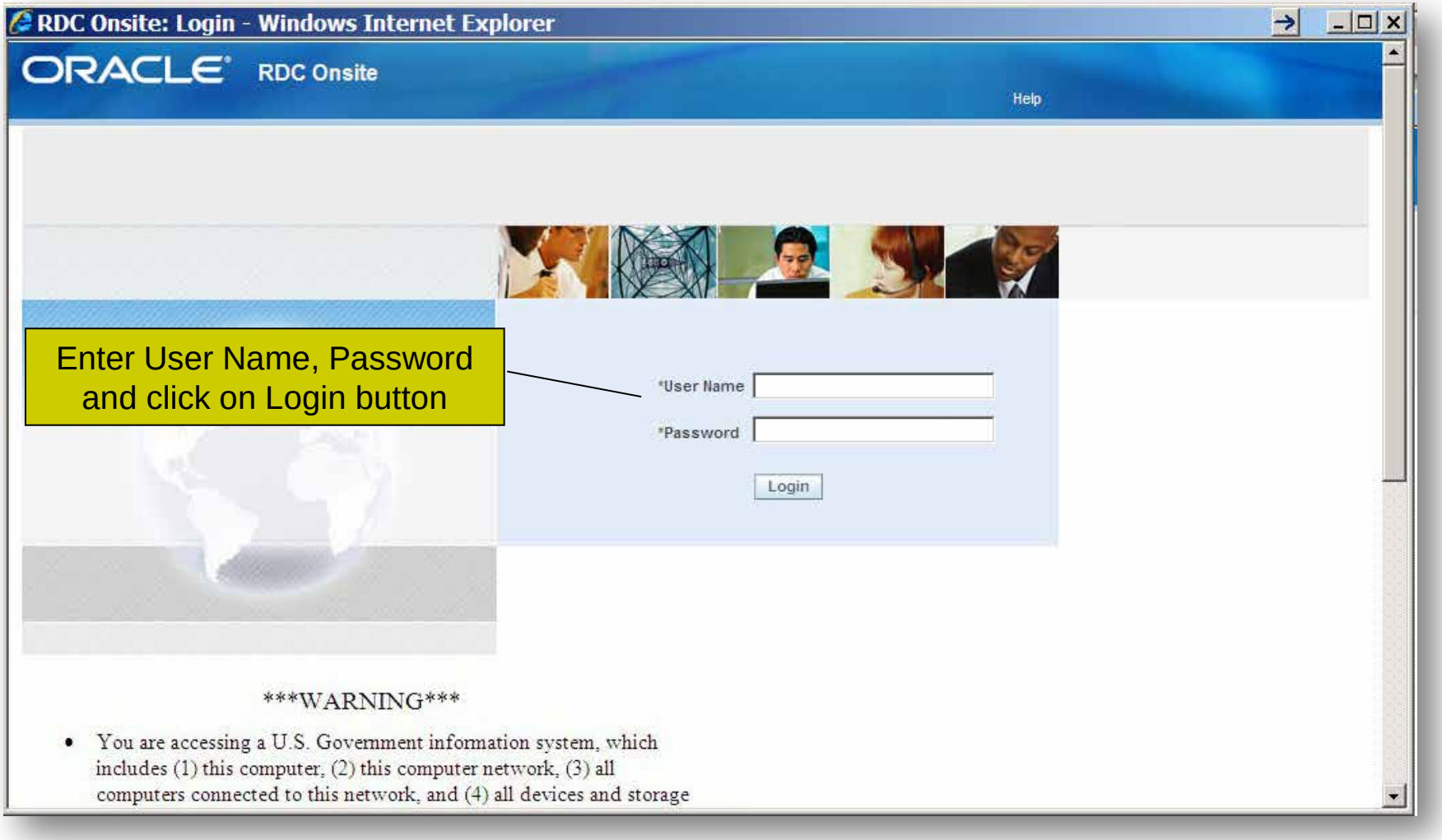
- C³D is Accessible Worldwide
- C³D Production Login page: https://octrials.nci.nih.gov/opa46/rdclaunch.htm
- C³D provides a separate Data Entry environment to test protocol design
  - Test Login page: https://octrials.nci.nih.gov/opa46/rdclauncht.htm

C³D Login Web Page

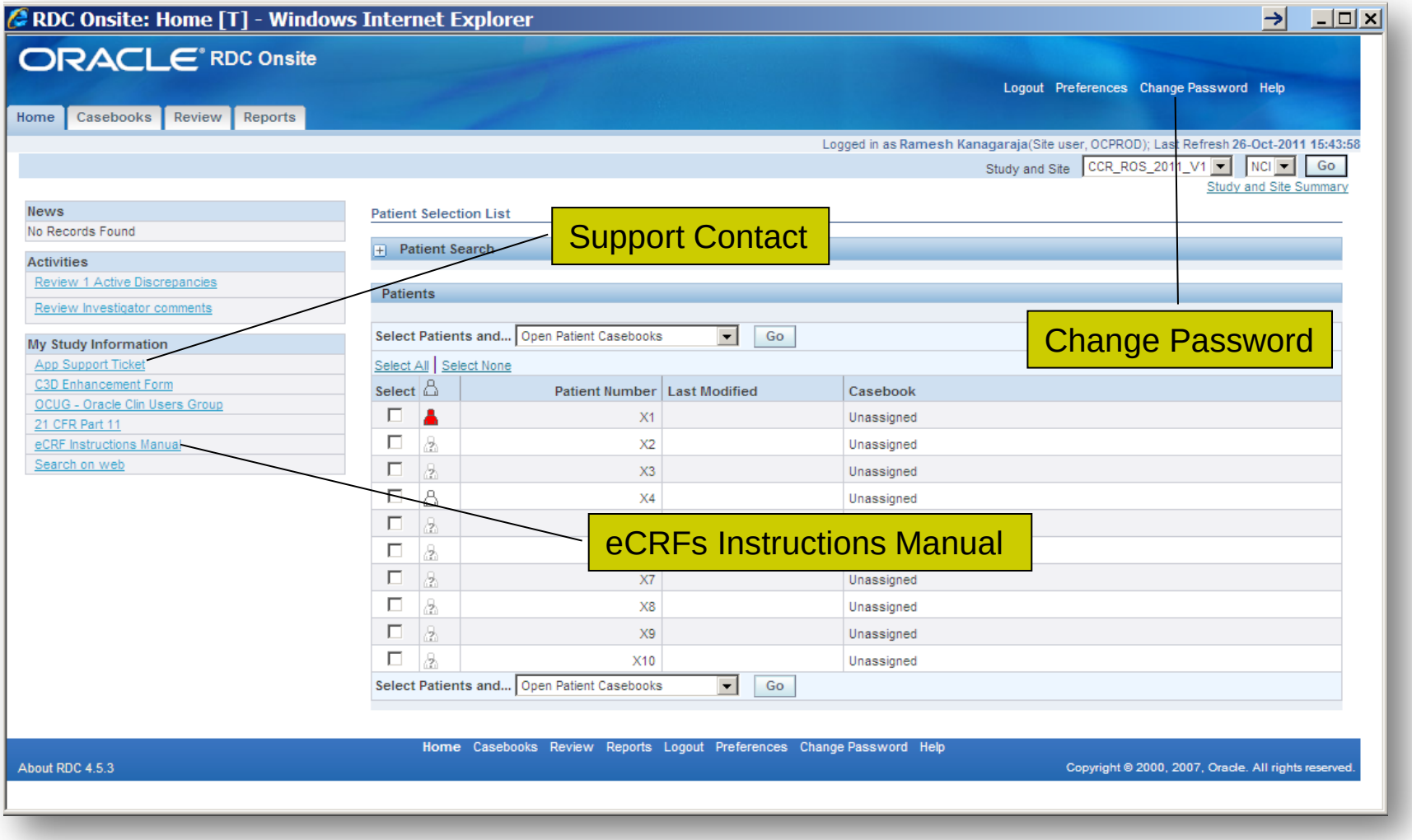
For studies with NCI Clinical Center Number 2012 onwards or Surgery Branch Immunotherapy studies, (ex: 12_C_0001, 15_C_0002), click on the RDC Onsite button.



Login


RDC Onsite: Login - Windows Internet Explorer
ORACLE
RDC Onsite
Help
Enter User Name, Password and click on Login button
*User Name
*Password
Login
WARNING
You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage

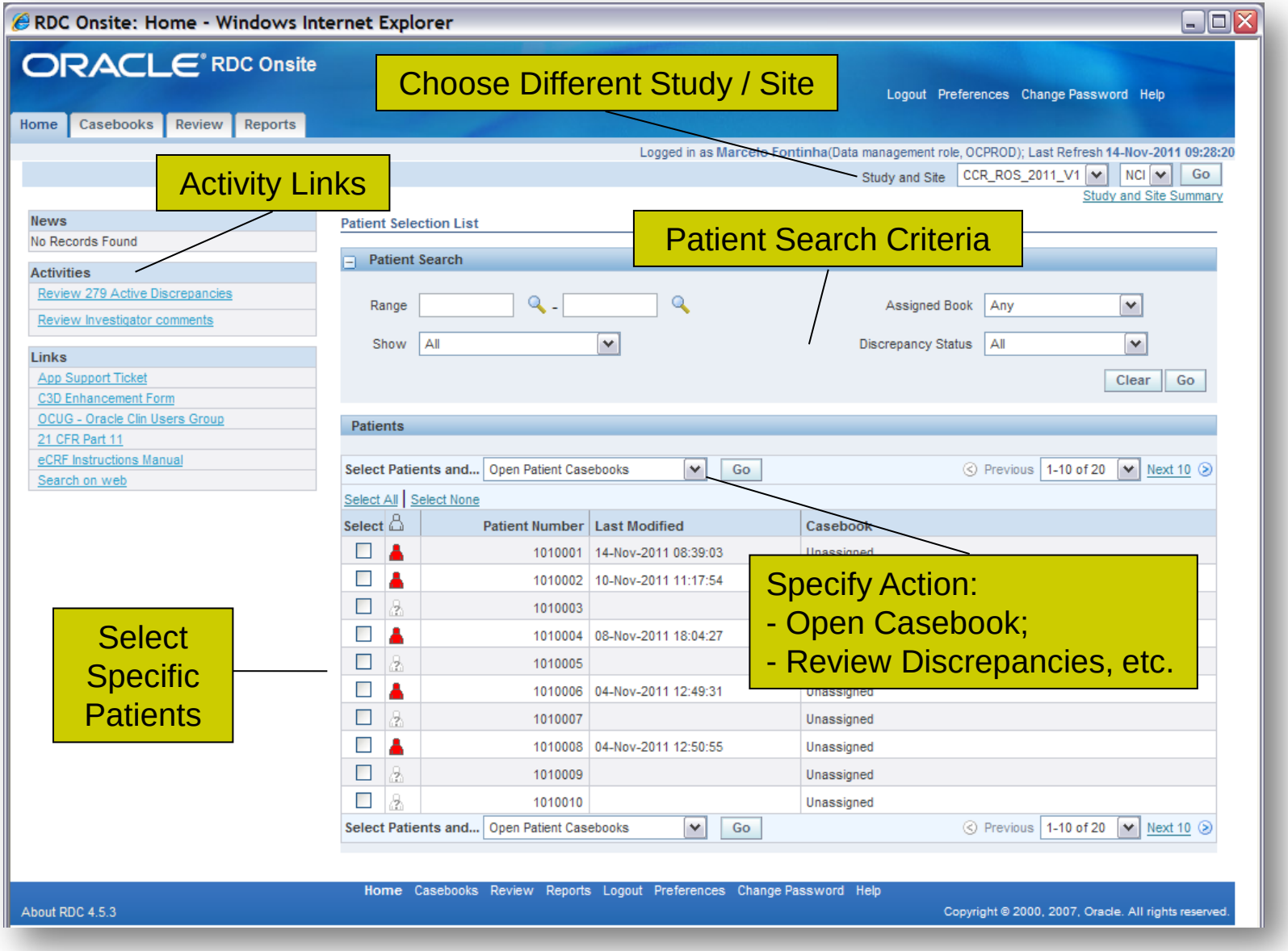
C3D RDC Home Page



Home Page Activities

- Choose a Different Study / Site
  - Access to studies is controlled by user role
  - C^{3}D remembers that last study used in prior login
  - Select Study and Site from dropdown and click **Go**
- Activity Links (optional)
  - Review ##,### Active Discrepancies
  - Review Investigator Comments
- 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
- Select Patient(s) and Action
  - Place checkmarks for the desired patients to work on
  - Select an Action:
    - Review Casebook (this is the default and most common action)
    - Review Discrepancies
    - Review Investigator Comments
    - Generate Patient Data Report
    - Generate Blank Casebook Report

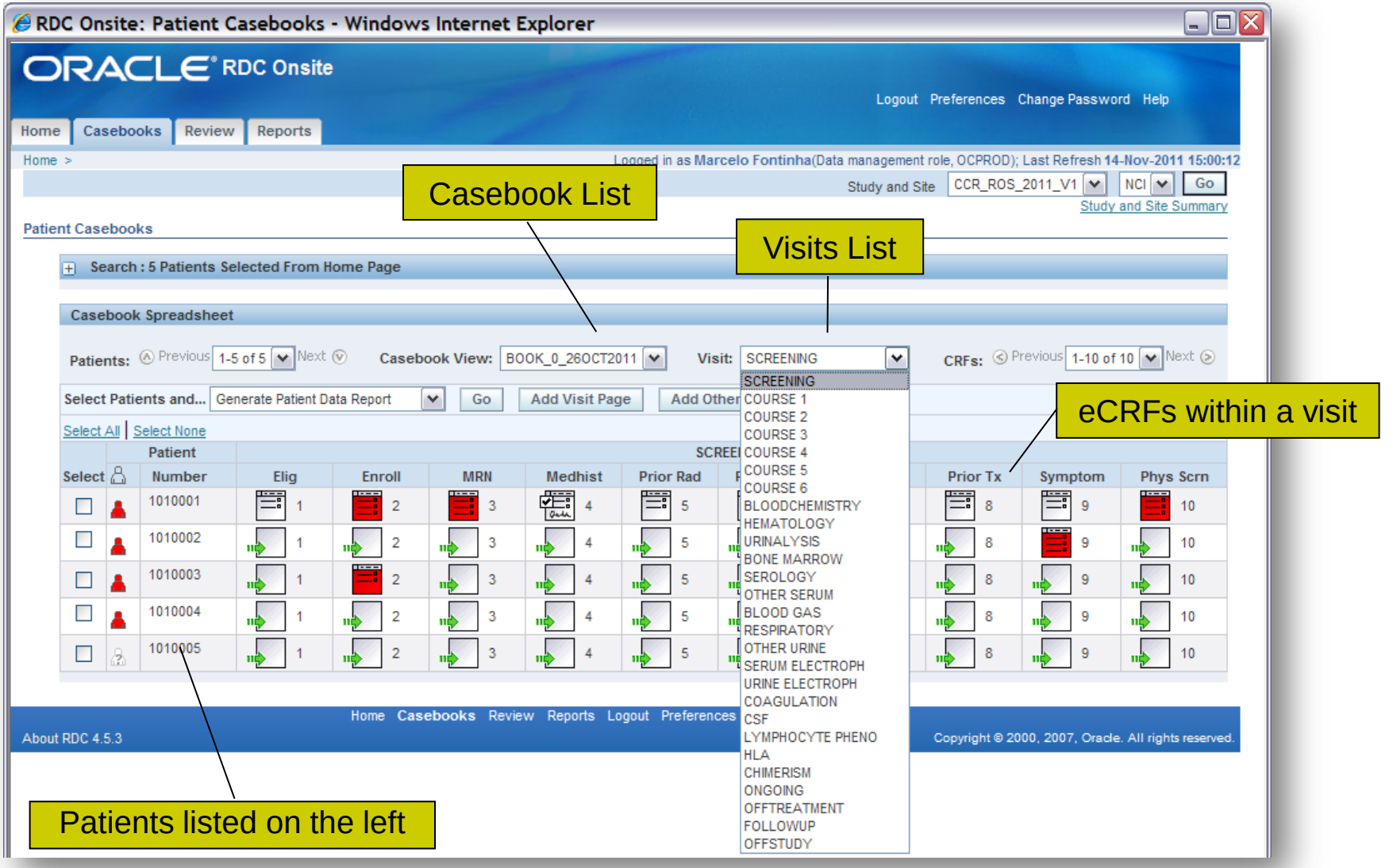
Home Page Activities



Navigating Casebook

- Casebook List
  - Click on Casebook View 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 Visit Layout
  - One row per Patient with identifier on the left
  - Visit's eCRFs along Columns.
    - Use the CRFs dropdown list (or links) to view the additional Visit CRFs
- Click on an eCRF icon to open it

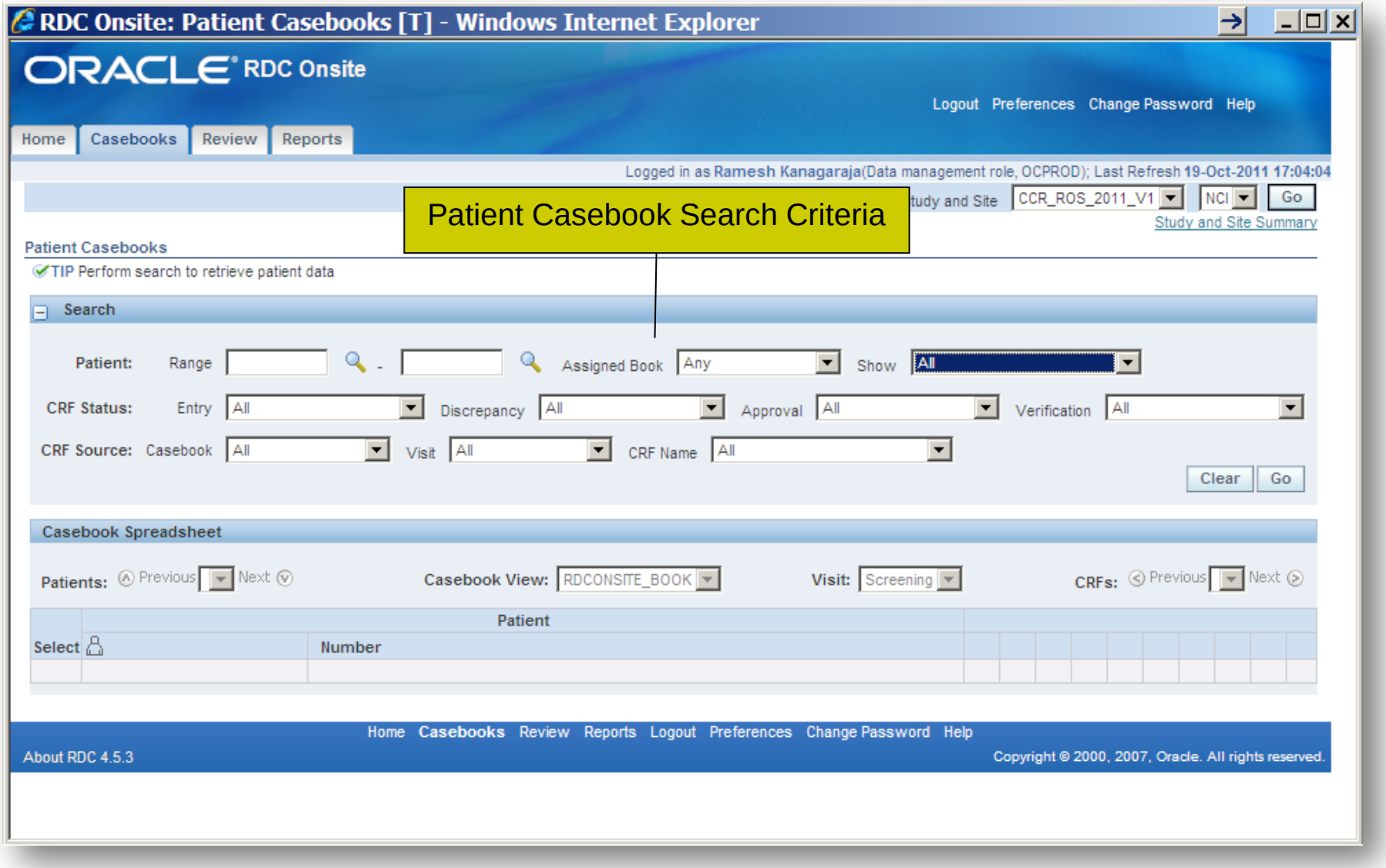
RDC Casebook



Patient Casebook Search Criteria

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

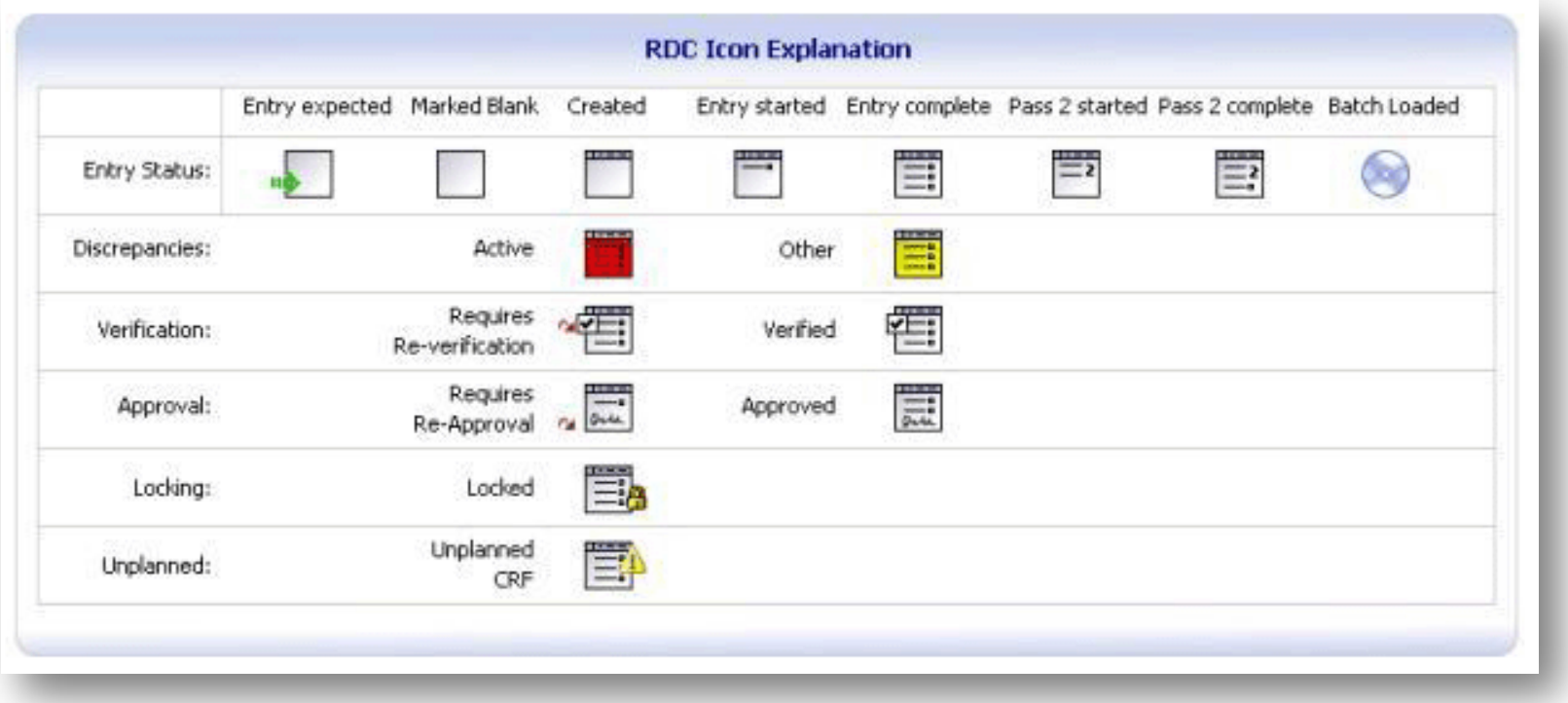
Patient Casebook Search Criteria



Important eCRF Icons

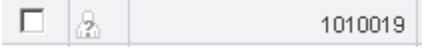
- Square icon: represents manual entry
- Round icon: represents automated entry (batch loaded lab data or data migrated from legacy system)
- A Blank Square icon with a green arrow indicates CRF has not been used. Click on it to begin data entry!
- An eCRF just created, but without data has no lines within the icon (Created Status)
- eCRF ‘Saved as Incomplete’ has lines across half of the icon (Entry Started Status)
- eCRF ‘Saved as Complete’ has lines across the whole icon (Entry Complete Status)
- Blank Square icon indicates eCRF has been marked blank
- Red icon indicates one or more open discrepancies

eCRF Icons


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

Entering New Patient Data

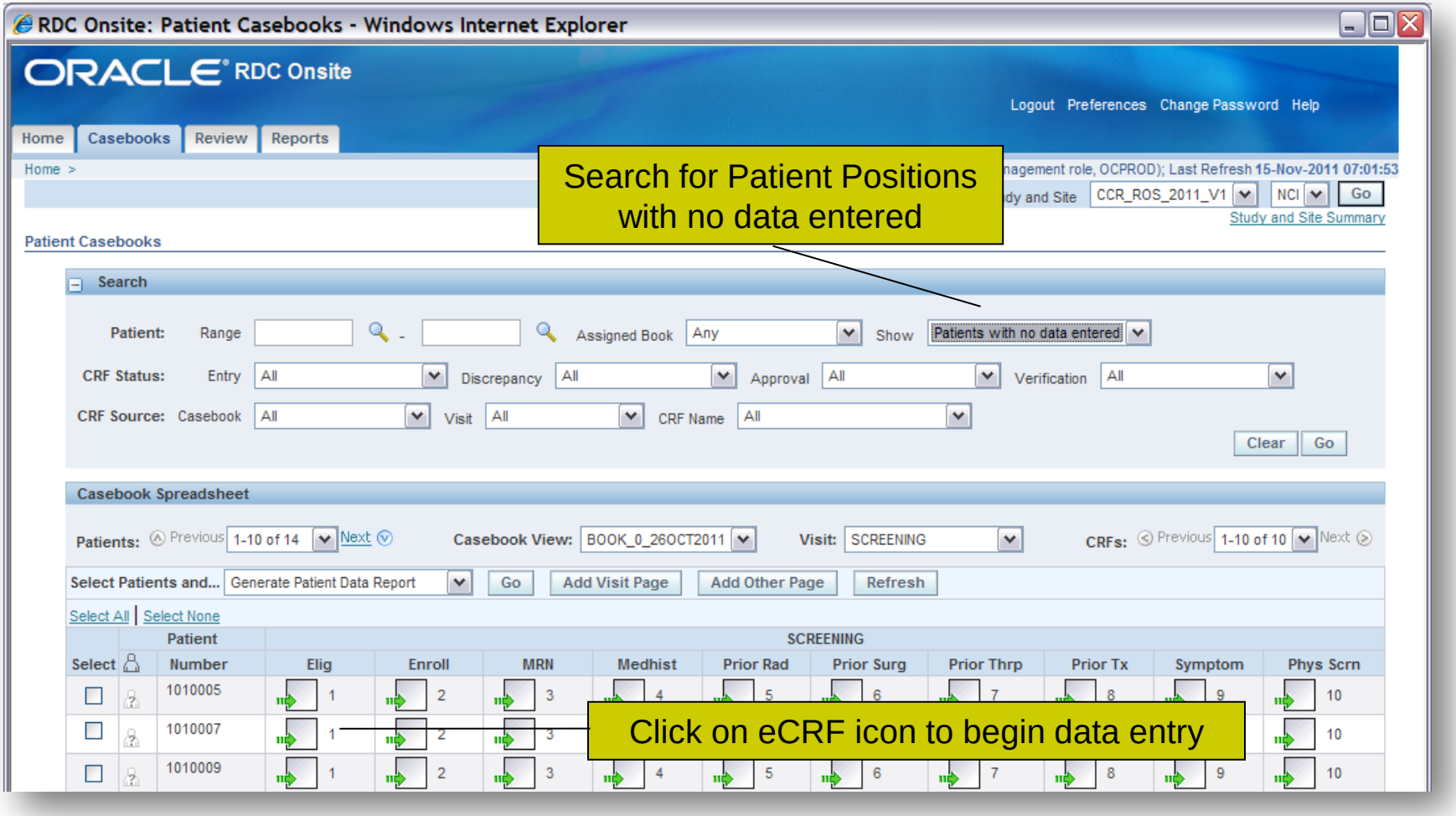
- From the C3D Home Page: place a checkmark next to the desired patient position icon and click on the **Go** button to go to the Casebook first Visit or;
  - A question mark is shown inside the icon of a patient position that has not been used:



- From the Casebook Page: expand the Search section, click on the **Clear** button, select **Patients with no Data Entered** from the **Show** dropdown list and click on the **Go** button.
- On the row for the desired patient position, click on an empty eCRF icon with a green arrow to begin data entry in a new eCRF.

- **Quick Tips:**
  - 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

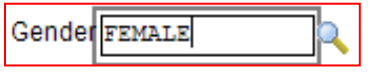


Electronic CRF (eCRF)

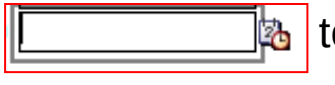
- eCRF Header and Footer display eCRF identification information
- Visit Date is mandatory for most forms:
  - In Lab eCRFs, Visit Date is the Lab Sample Collection Date
  - Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc. Refer to the eCRFs Instructions Manual.
  - 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 the comment 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.

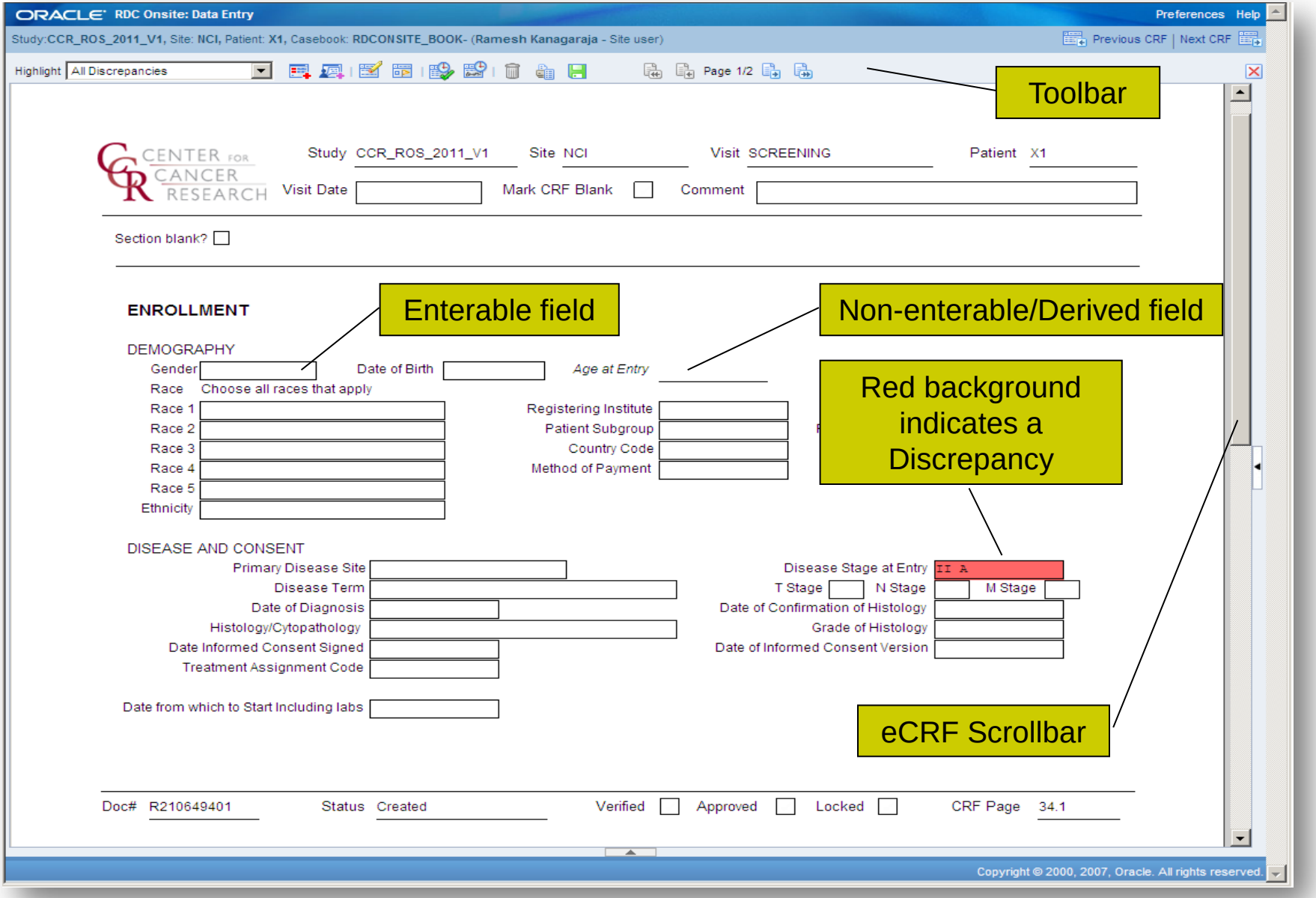
Electronic CRF (eCRF)

- Fields with magnifying glass 

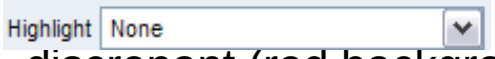
have a pick list of acceptable values.
  - With the pick list shown, press **CTRL + F** to search the pick list.
  - A typed in value that is not on the pick list will create a discrepancy. If a value needs to be added to the pick list, contact your Team Lead.
  - Using the Pick List is particularly 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.

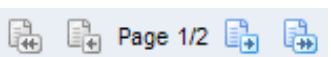
- Enter Dates as:
  - Complete dates for Current Information (ex: 5/23/2014, 5-23-2014 or 05232014)
  - MMYYYY for Prior Information is acceptable when complete date cannot be obtained (ex: 05-00-2014, 05/00/2014, 05002014)
  - Click on the calendar icon  to display a popup calendar and click on a date.

Electronic CRF (eCRF)



Electronic CRF (eCRF)

- Toolbar features:
  - 

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

Navigate eCRF's Pages (First, Previous, Next, Last)
  - Use Close box to close eCRF

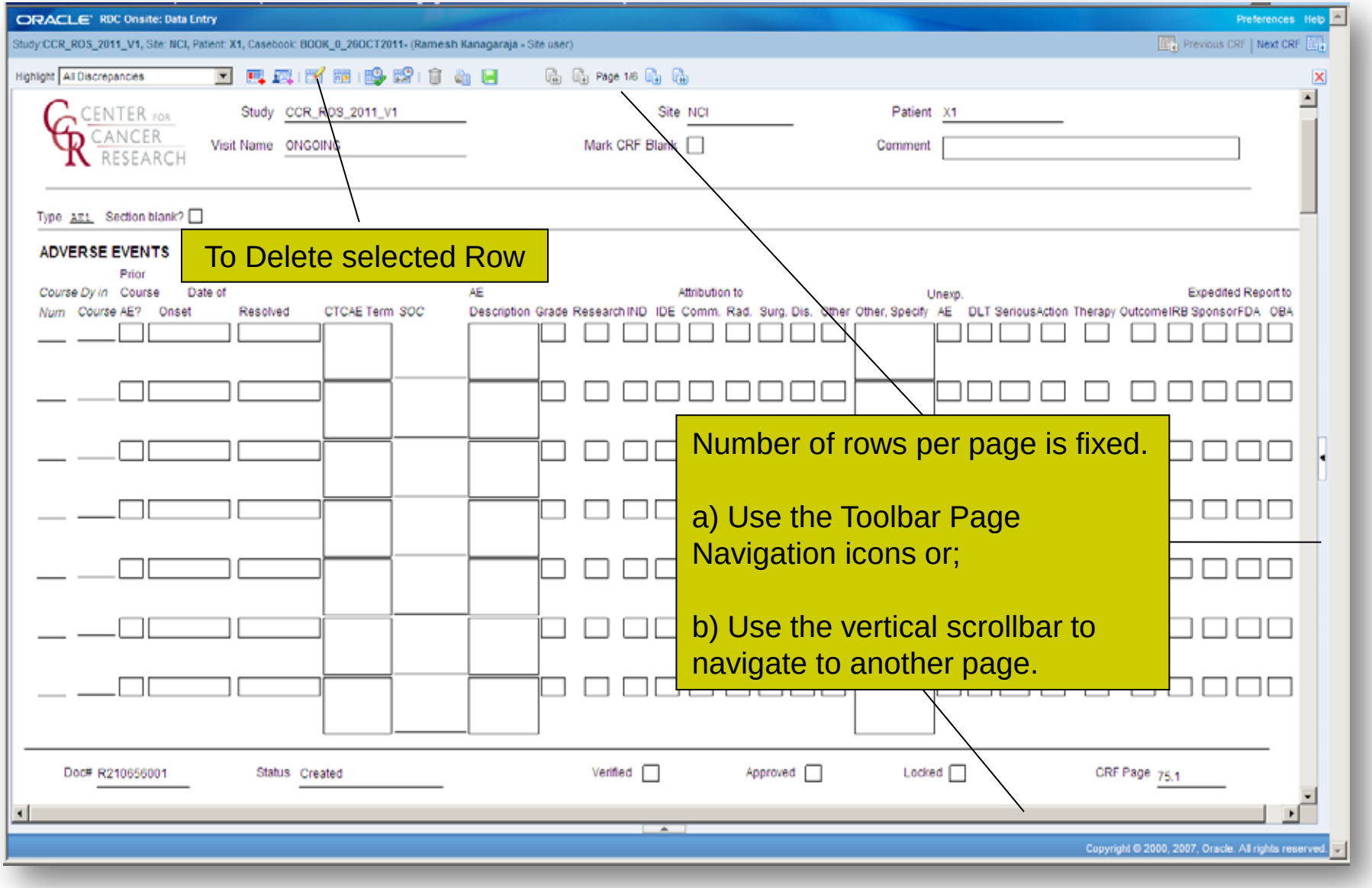
- Navigate to another eCRF by clicking on the Next or Previous CRF icons on the top right corner.

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.

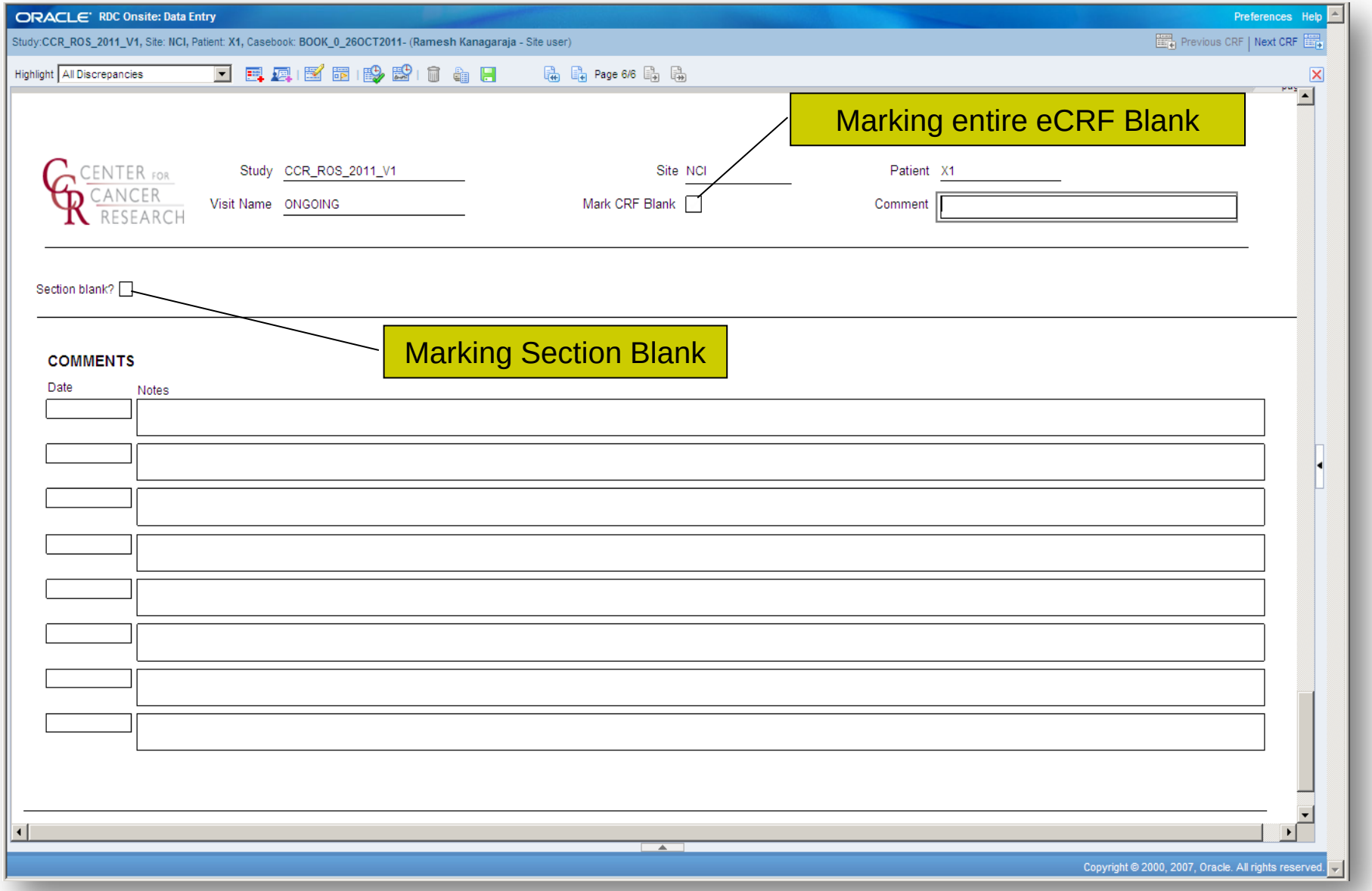
Tabular eCRF



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.

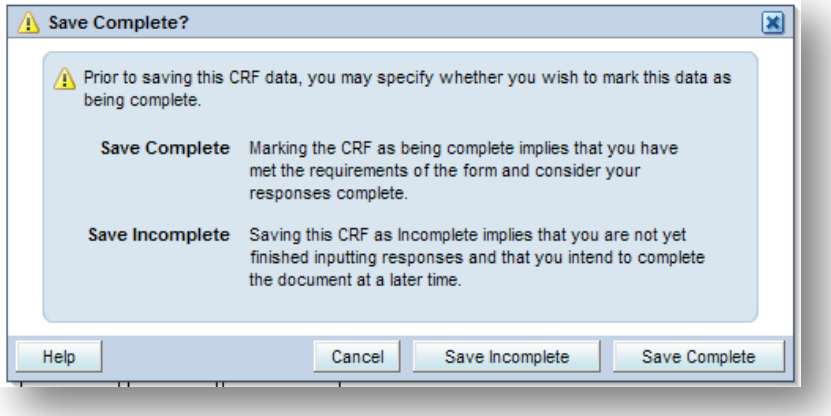
CRF and Section Blank Checkboxes



Saving eCRF

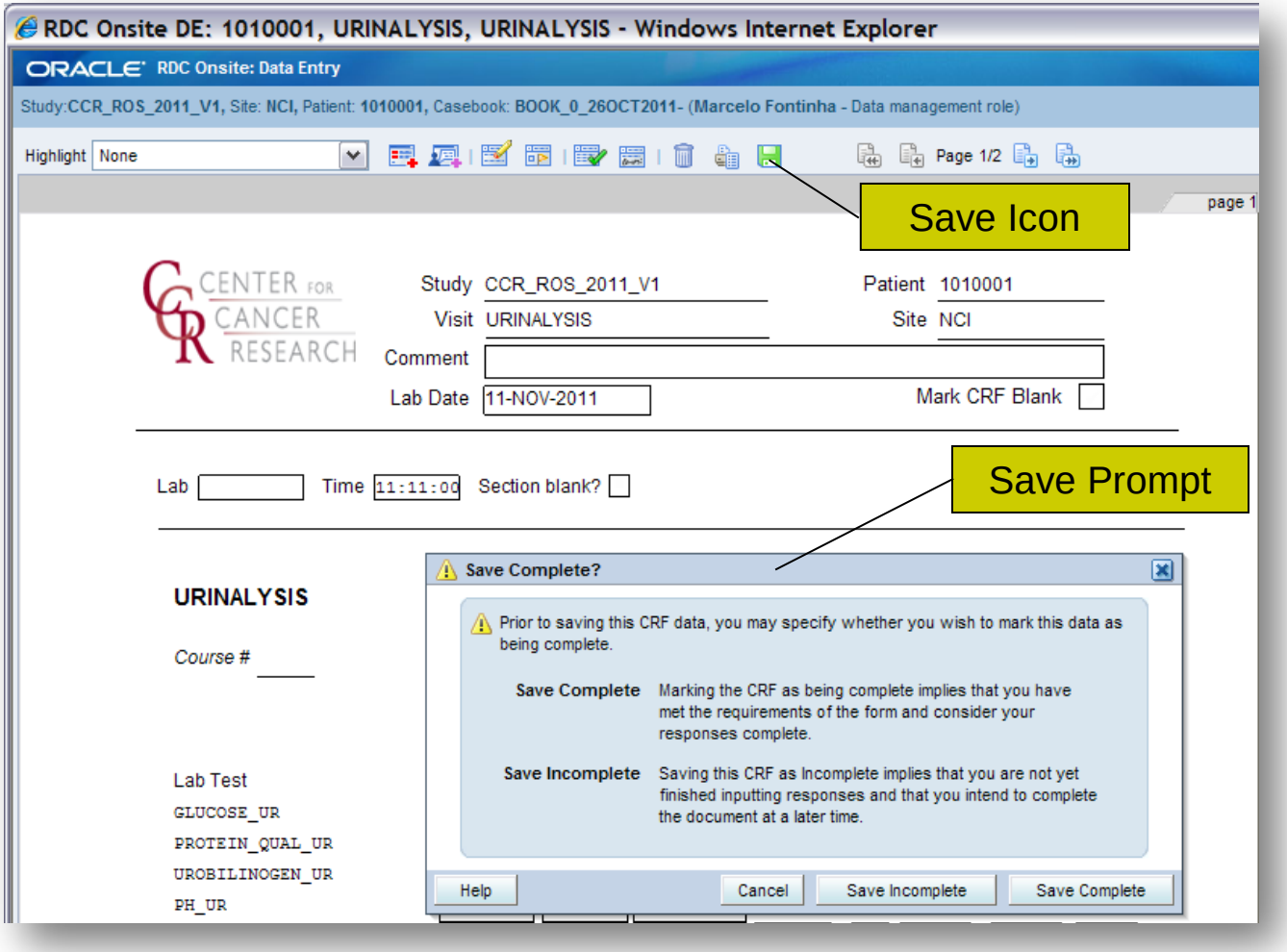
- Click on the green floppy disk icon to save the eCRF.
  - Save Often!! Especially while entering Ongoing Information such as Adverse Events and Concomitant Medications.

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



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

Saving eCRF

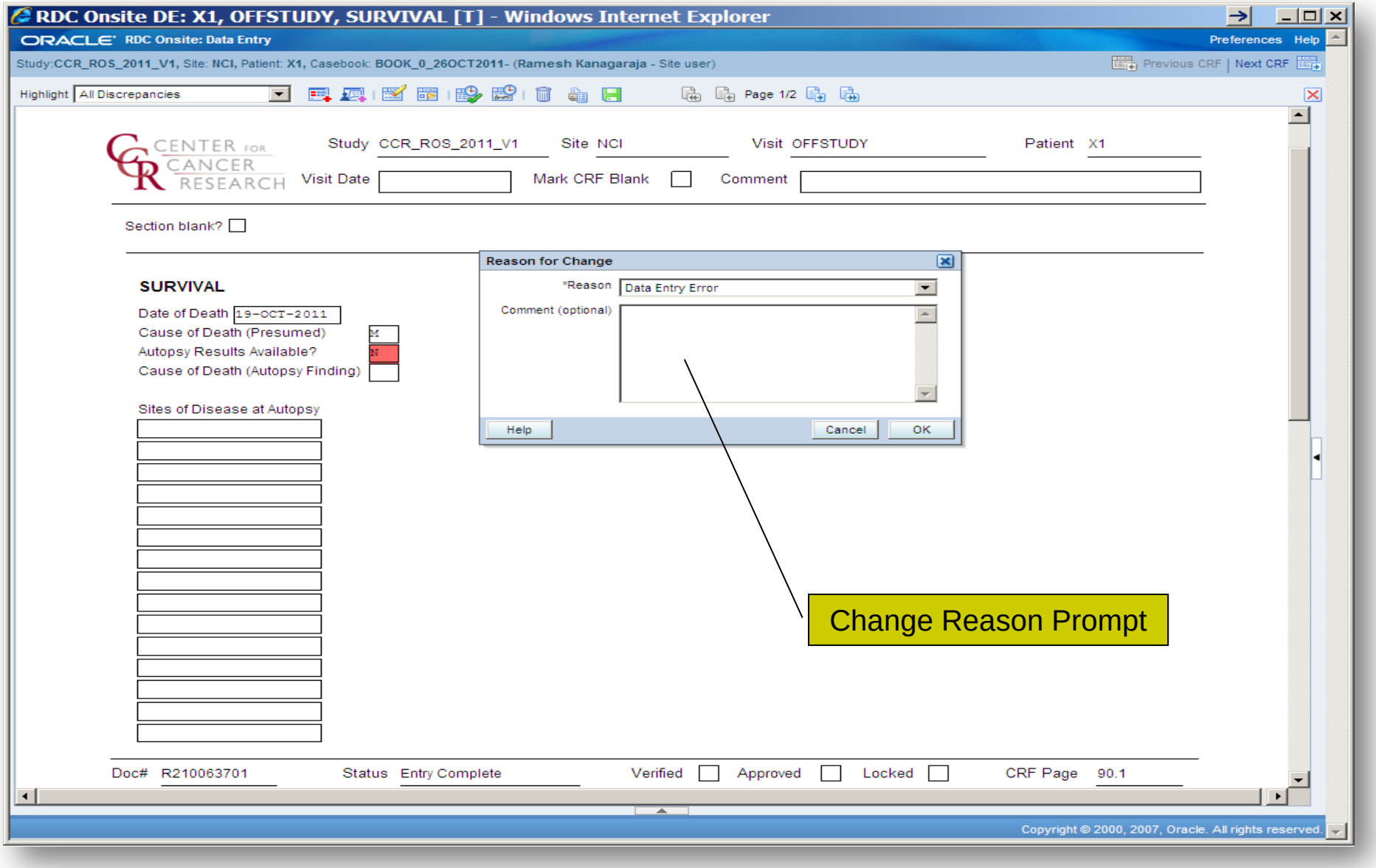

RDC Onsite DE: 1010001, URINALYSIS, URINALYSIS - Windows Internet Explorer
ORACLE RDC Onsite: Data Entry
Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)
Highlight None
Page 1/2
page 1
Save Icon
CENTER FOR CANCER RESEARCH
Study CCR_ROS_2011_V1
Patient 1010001
Visit URINALYSIS
Site NCI
Comment
Lab Date 11-NOV-2011
Mark CRF Blank
Lab
Time 11:11:00
Section blank?
Save Prompt
URINALYSIS
Course #
Lab Test
GLUCOSE_UR
PROTEIN_QUAL_UR
UROBILINOGEN_UR
PH_UR
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

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.

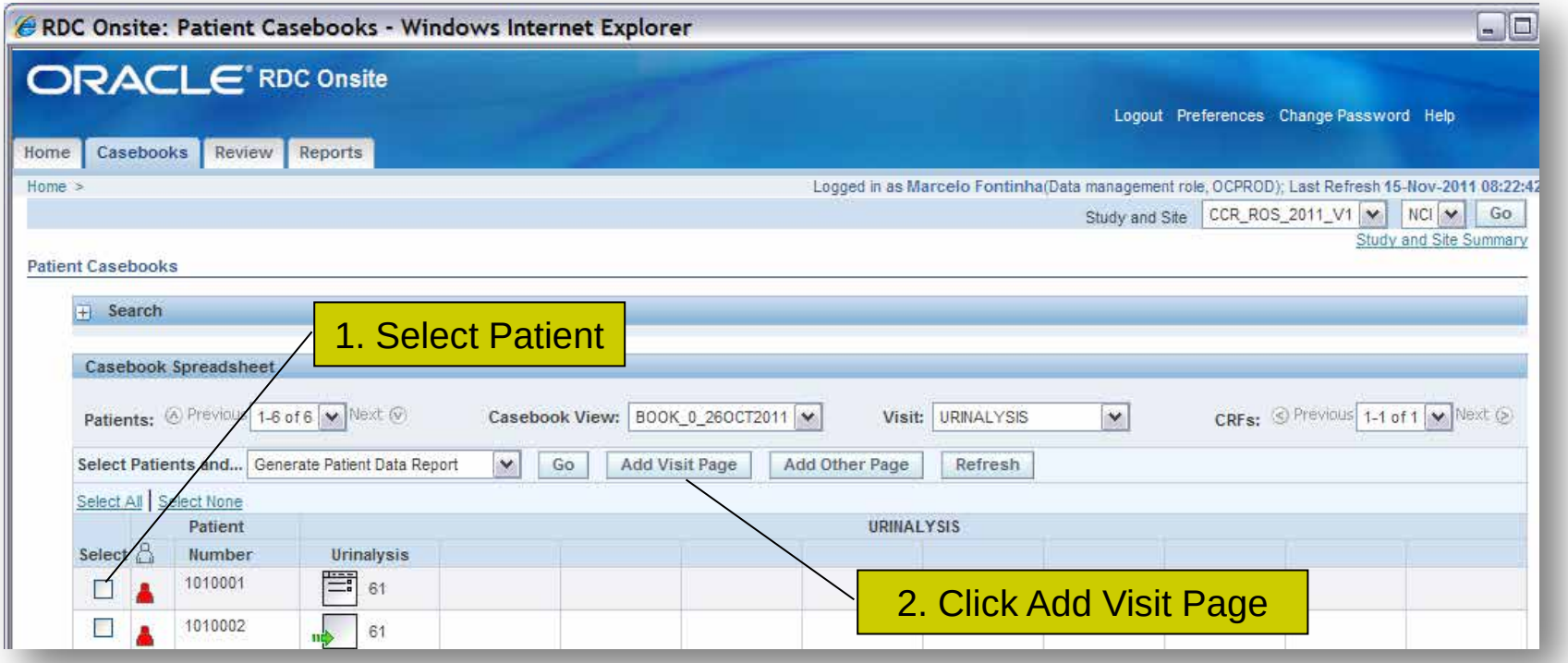
- **Quick Tip:**
  - Do not use personnel/patient names or identifiers in the comments.

Data Entry Change Reason



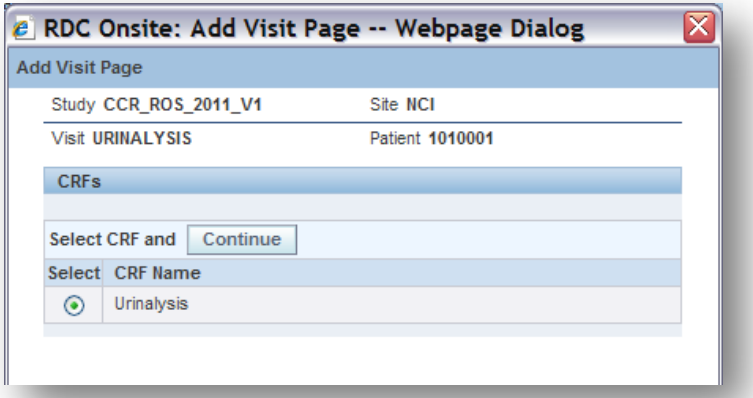
Entering/Viewing Laboratory Data

- 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**.

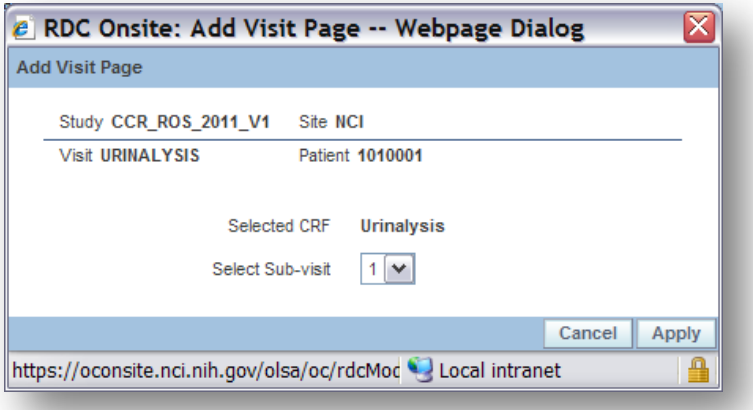


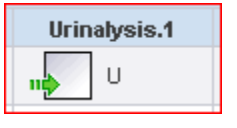
Entering/Viewing Laboratory Data

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



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



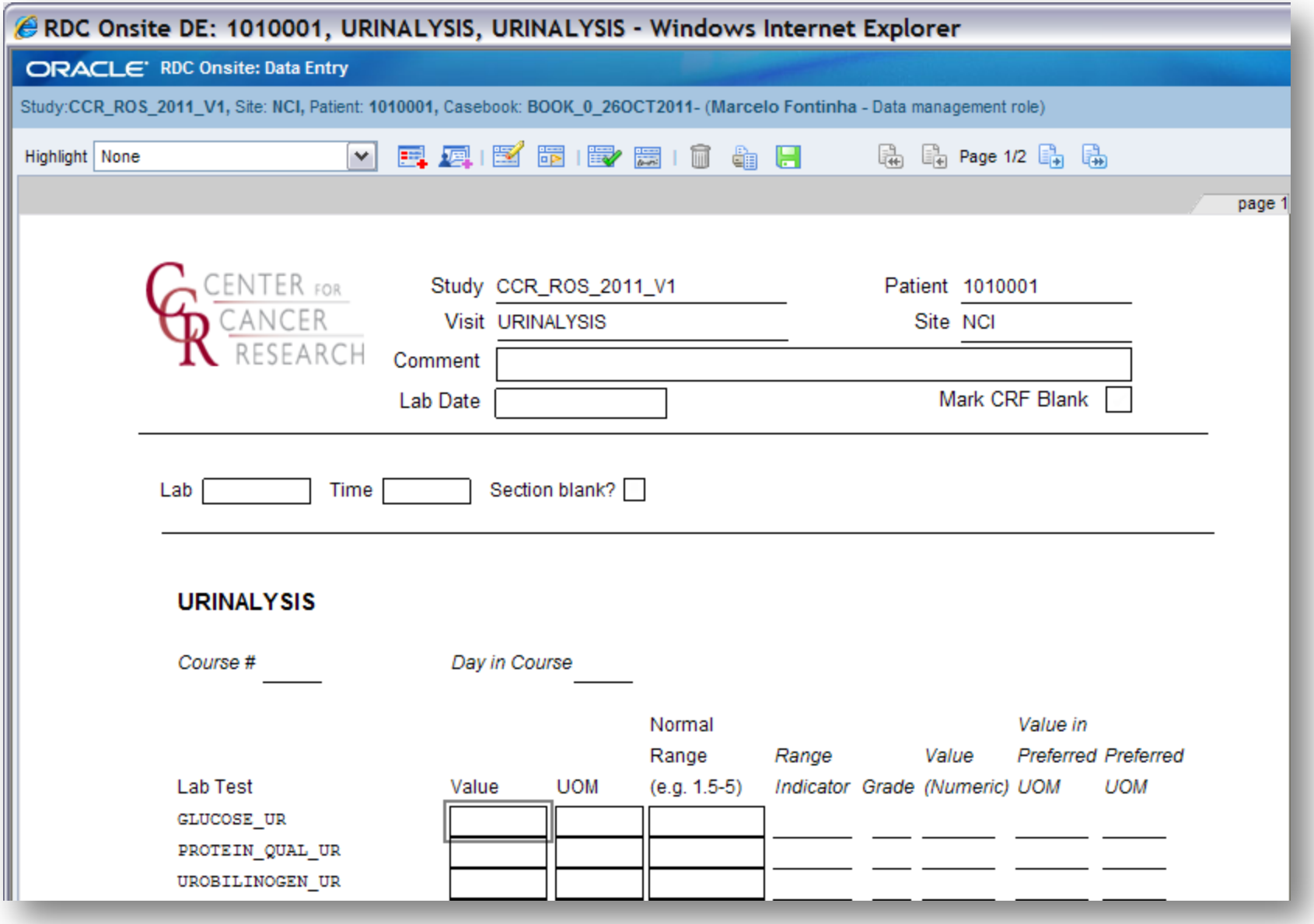
- Click on the new Unplanned Lab eCRF icon 

to begin data entry.

Entering/Viewing Laboratory Data

- Enter the Lab Date (Sample Collection Date).
- Enter the Lab Time (Sample Collection Time) using military time.
- Optionally, choose a Lab Source from the Lab dropdown list.
  - **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^3D will automatically populate the UOM and Normal Range.
- C^3D 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



What is a Discrepancy?

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

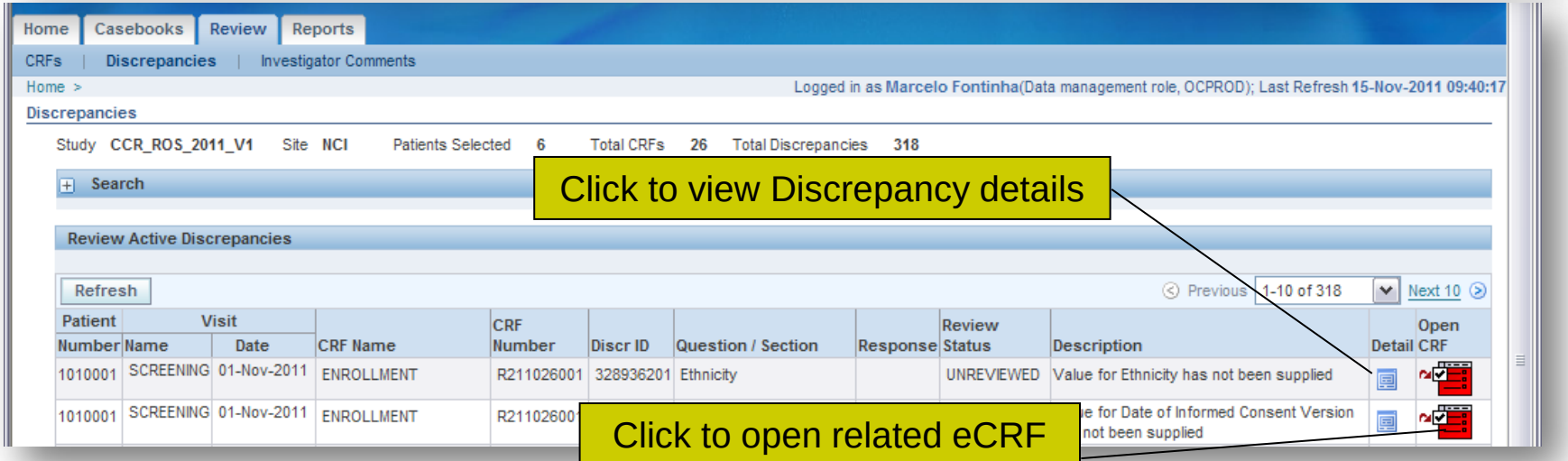
Types	Example:	Resolutions
Data Type	Text entered in numeric or date field.	Review Source Document and enter appropriate data.
Length Problems	Too many characters entered.	Use NIH accepted Abbreviations.
Value not on the Pick List	Generic Agent not present in Concomitant Agent Pick List and user typed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

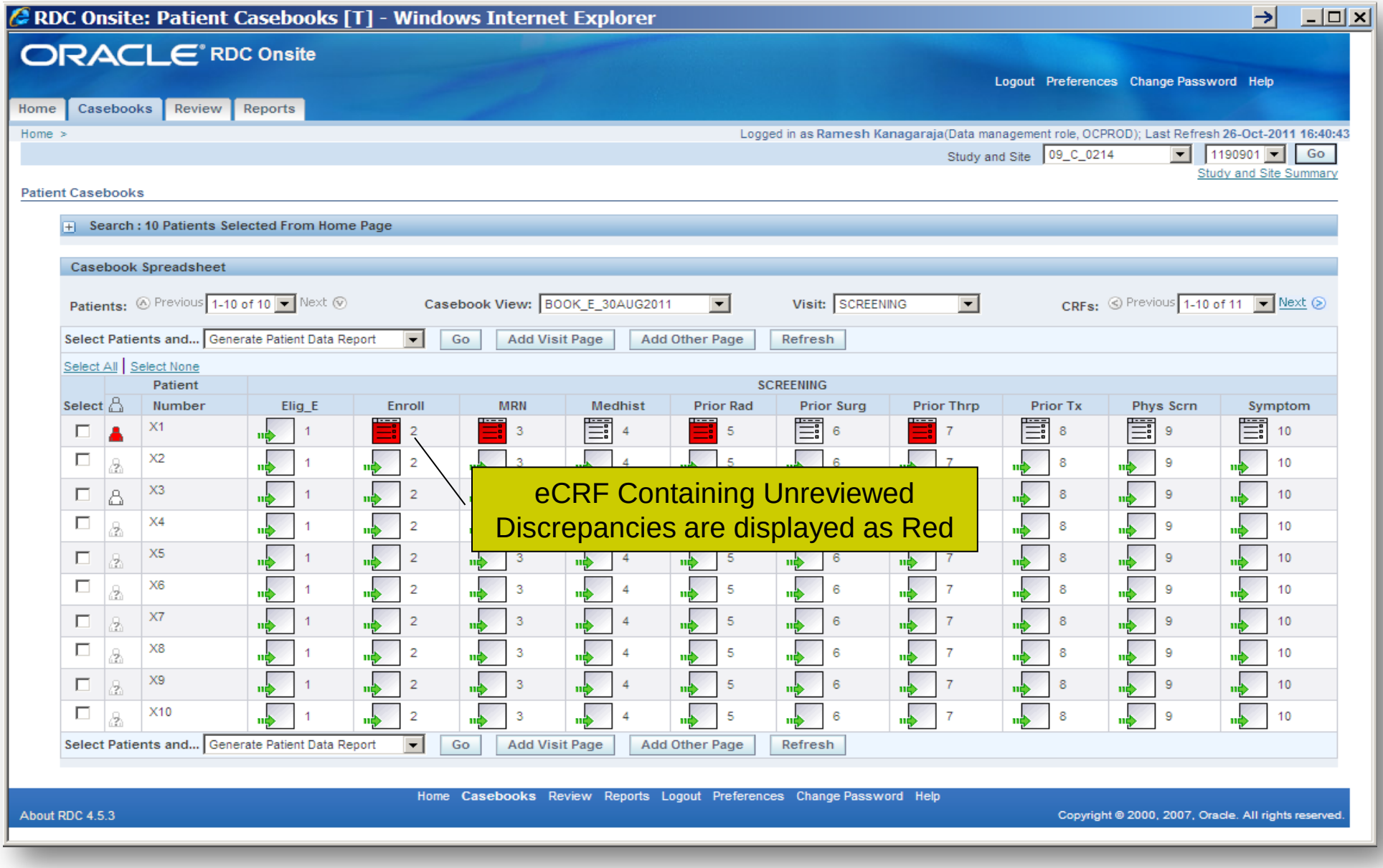
- Total number of Discrepancies in a study are shown in the Home Page Activities section
- Clicking on the **Review ### Active Discrepancies** will present a lists of all discrepancies under the Review Page.
- eCRF containing discrepancies are shown in Red icon

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

Outstanding Discrepancies in a Study



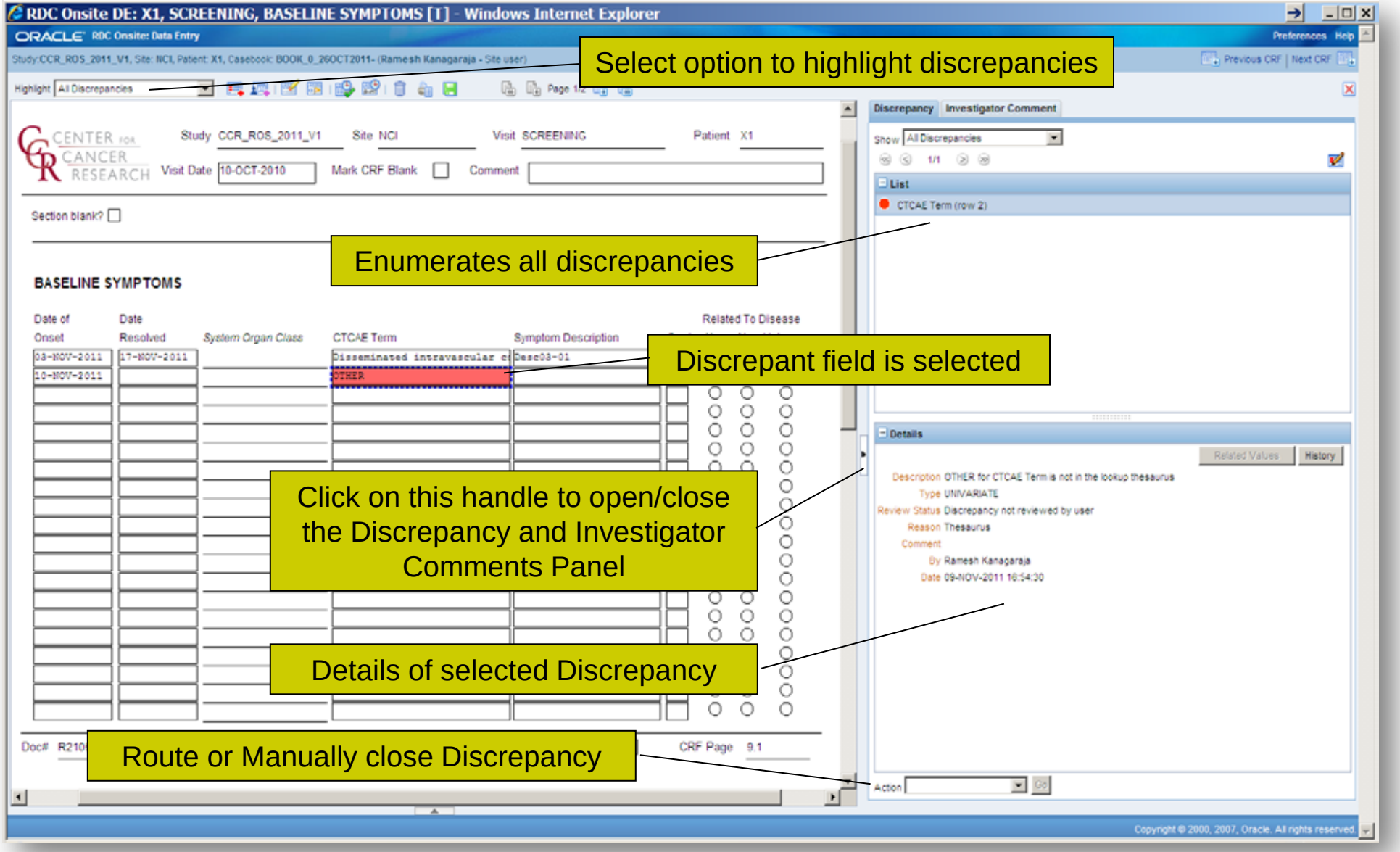
eCRFs Containing Discrepancies



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

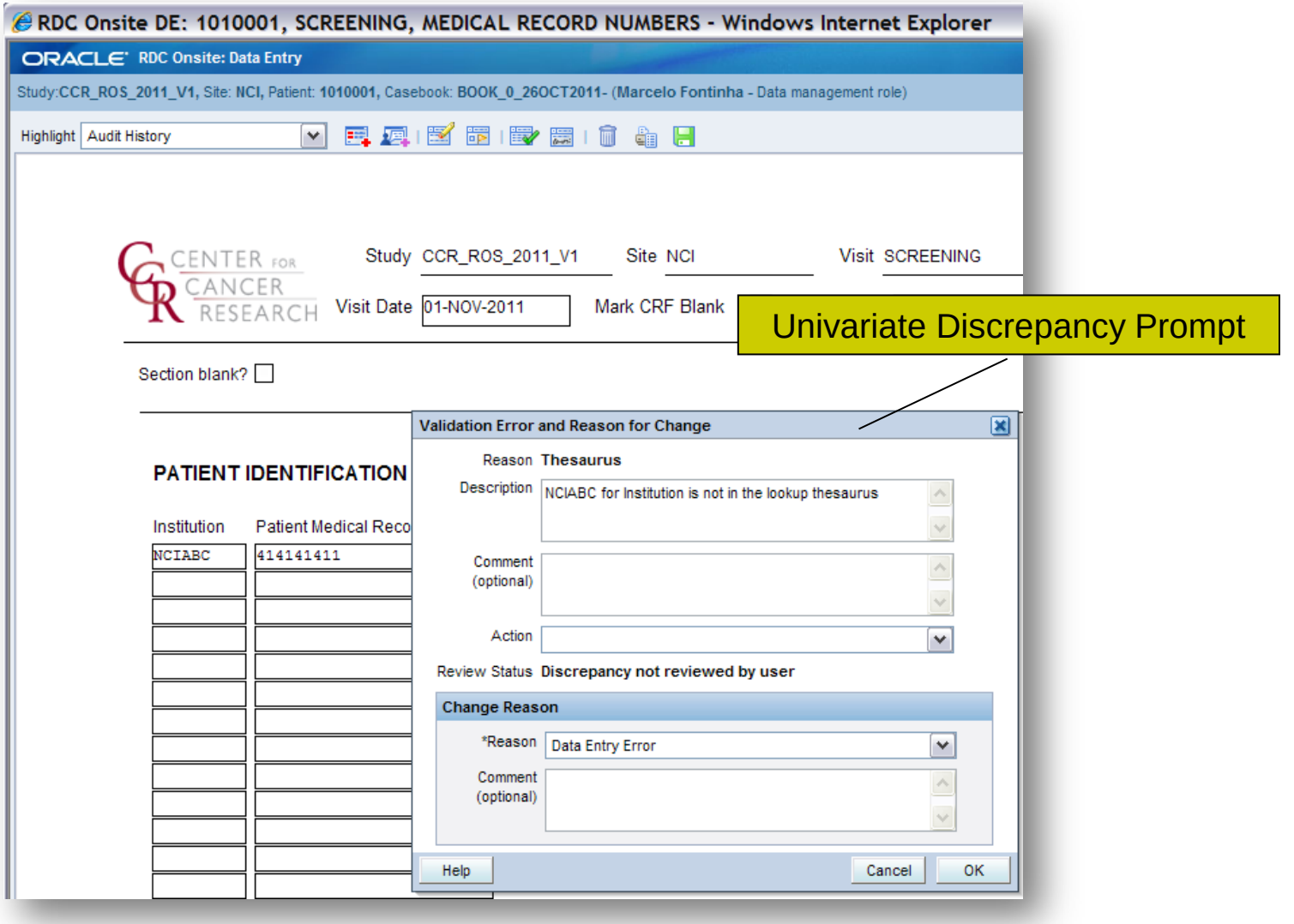


How are Univariate Disc. Created?

- Univariate Discrepancies pop-up is 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
  - Partial Date entered when a complete date is required
- Data Entry operator can:
  - Cancel the pop-up and fix the value
  - Or accept the discrepancy

- **Quick Tip:**
  - Univariate Discrepancies are reassessed during Batch Validation for Design Changes.

How are Univariate Disc. Created?



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.

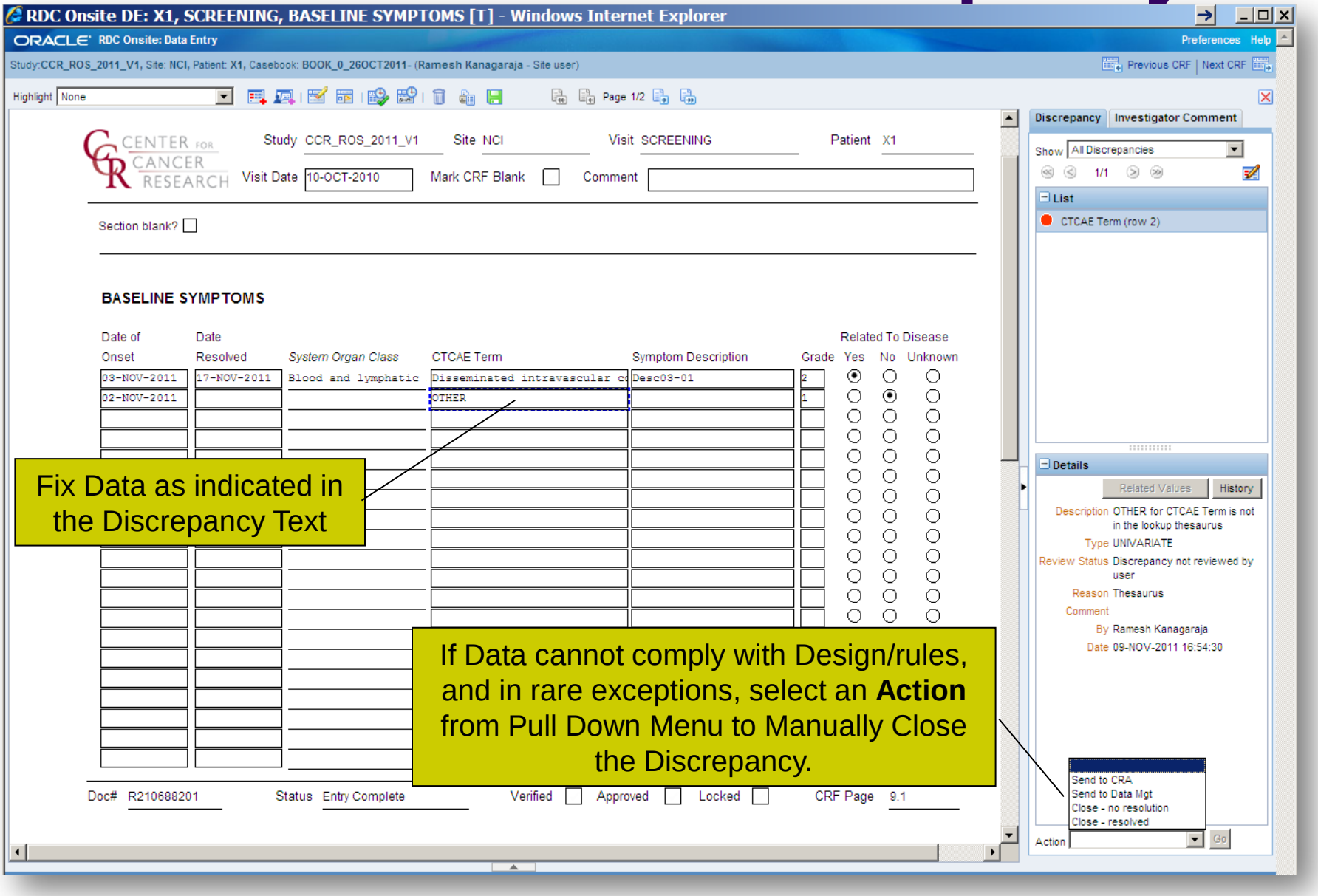
- **Quick Tip:**
  - Complex rules run overnight.

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.

- **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

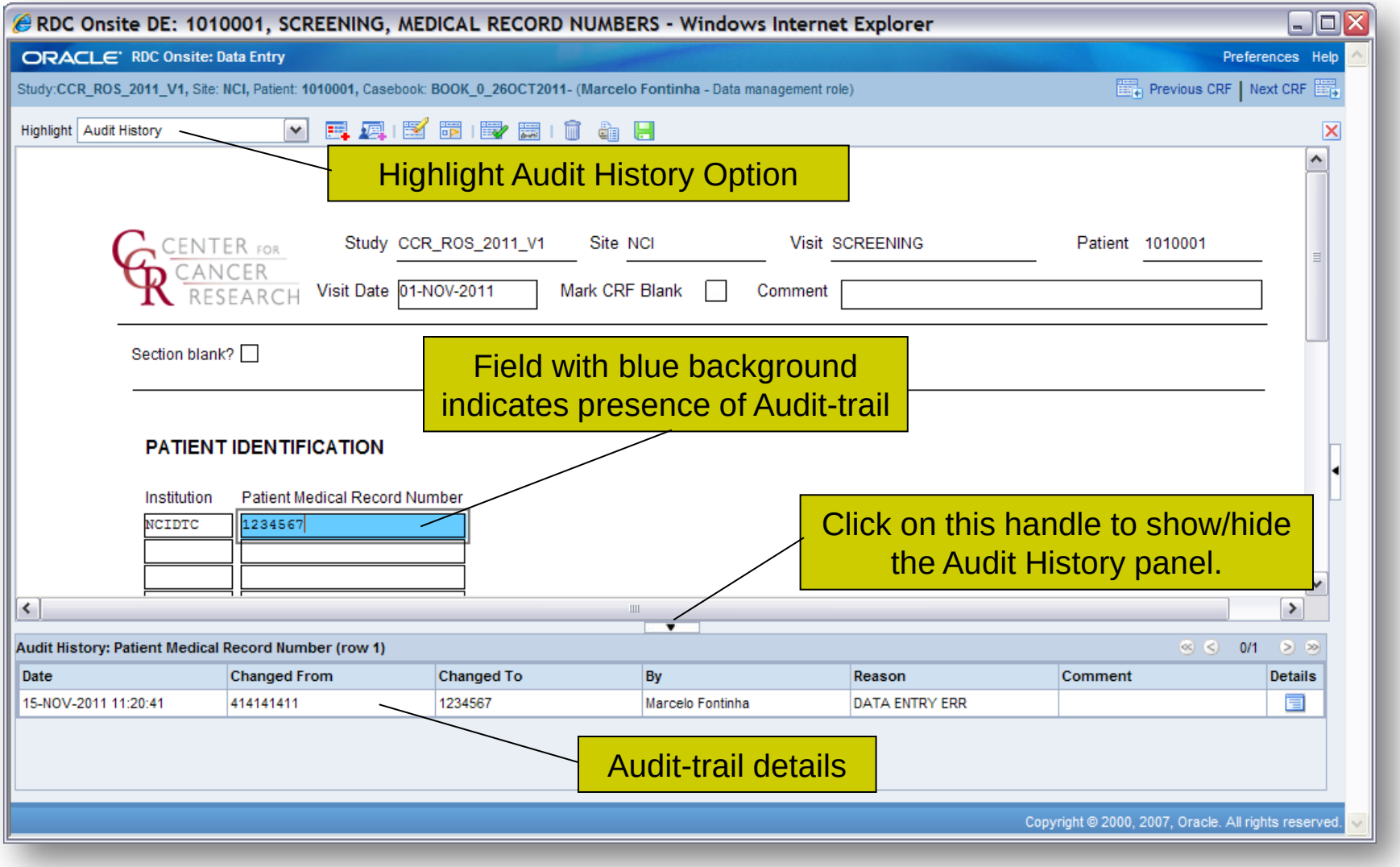


Audit Trail

- 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


RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - Windows Internet Explorer
ORACLE RDC Onsite: Data Entry
Preferences Help
Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)
Previous CRF | Next CRF
Highlight Audit History
Highlight Audit History Option
CENTER FOR CANCER RESEARCH
Study CCR_ROS_2011_V1
Site NCI
Visit SCREENING
Patient 1010001
Visit Date 01-NOV-2011
Mark CRF Blank
Comment
Section blank?
Field with blue background indicates presence of Audit-trail
PATIENT IDENTIFICATION
Institution
Patient Medical Record Number
NCIDTC
1234567
Click on this handle to show/hide the Audit History panel.
Audit History: Patient Medical Record Number (row 1)
0/1
Date
Changed From
Changed To
By
Reason
Comment
Details
15-NOV-2011 11:20:41
414141411
1234567
Marcelo Fontinha
DATA ENTRY ERR
Audit-trail details
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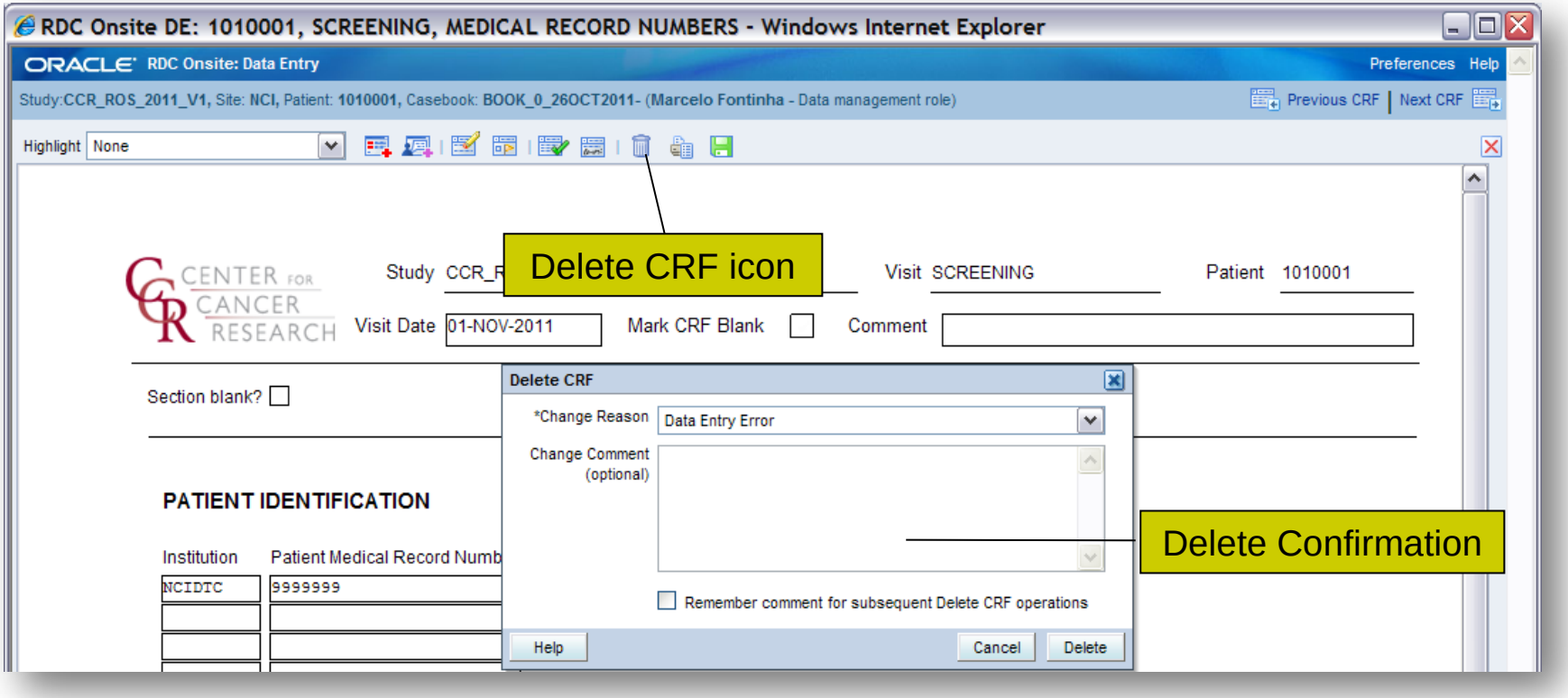
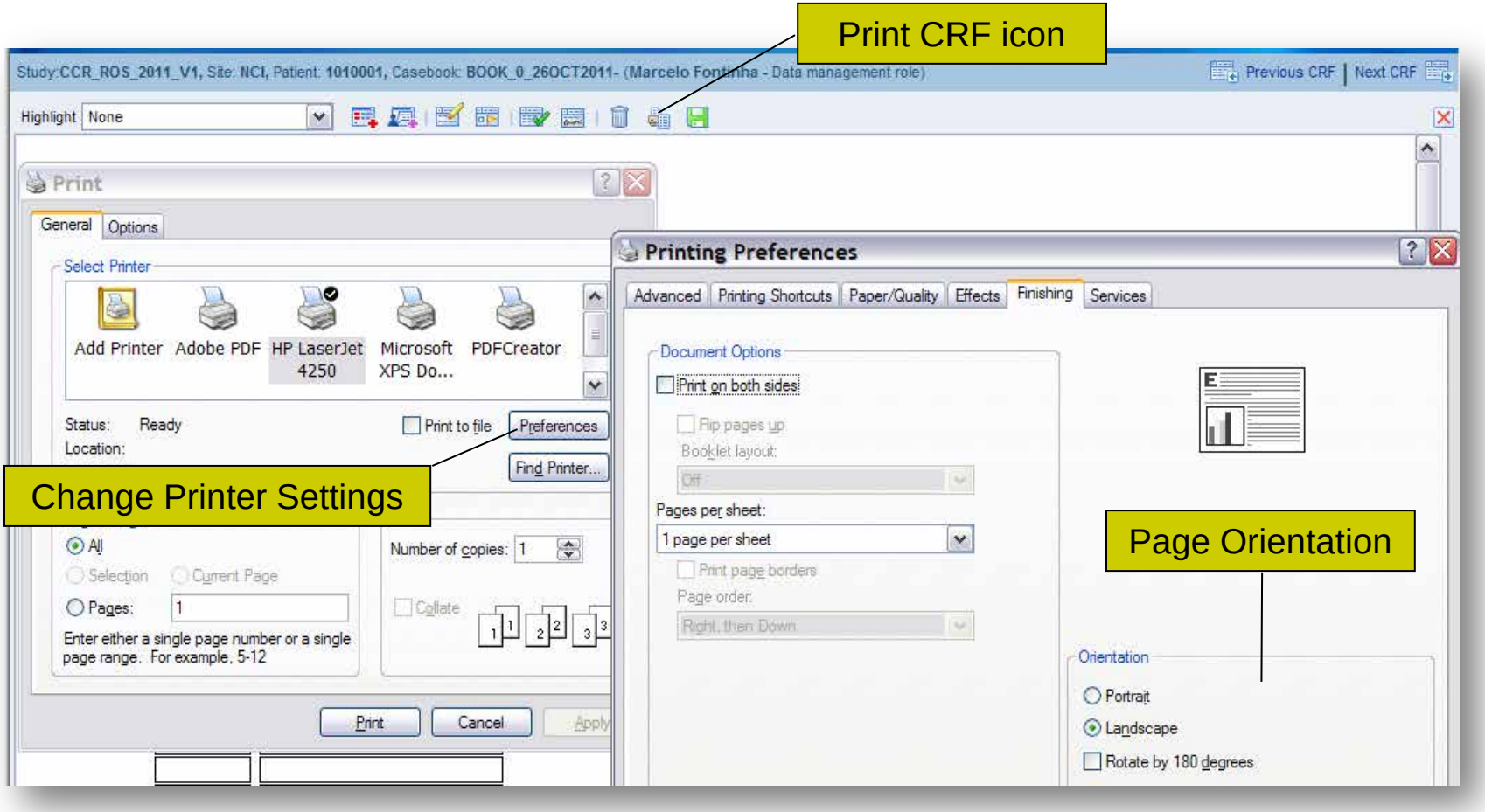
Delete eCRF

- 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.



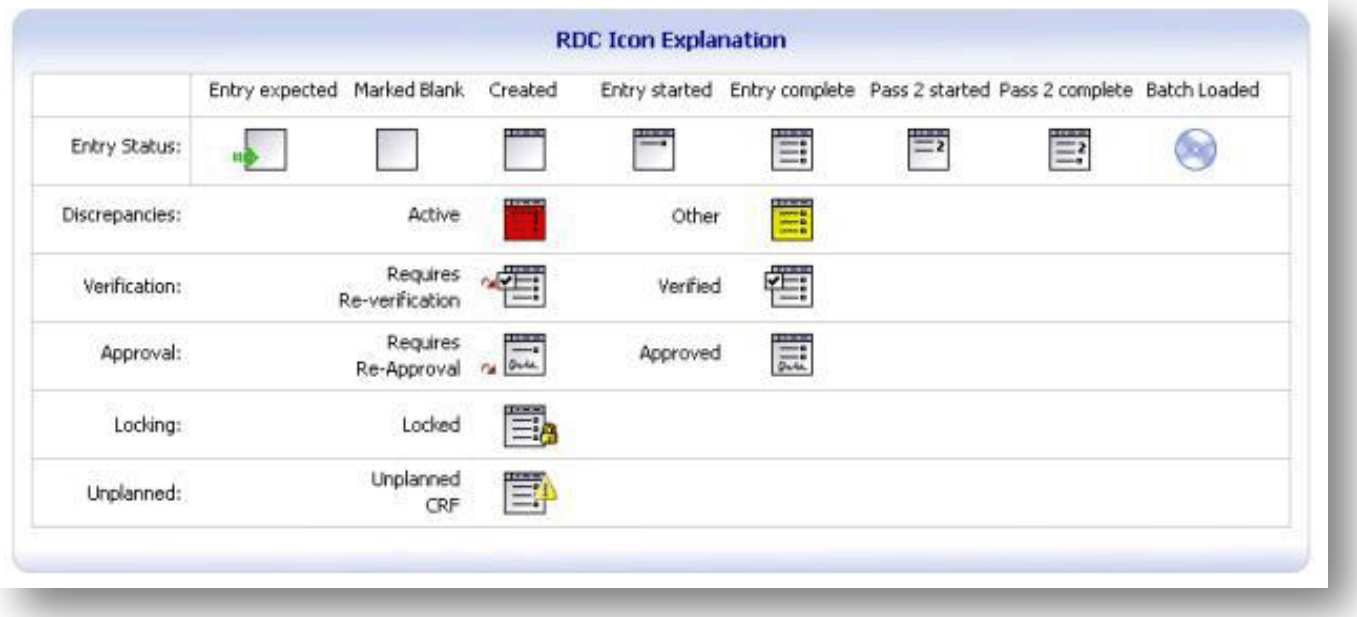
Print eCRF

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



Verification & Approval

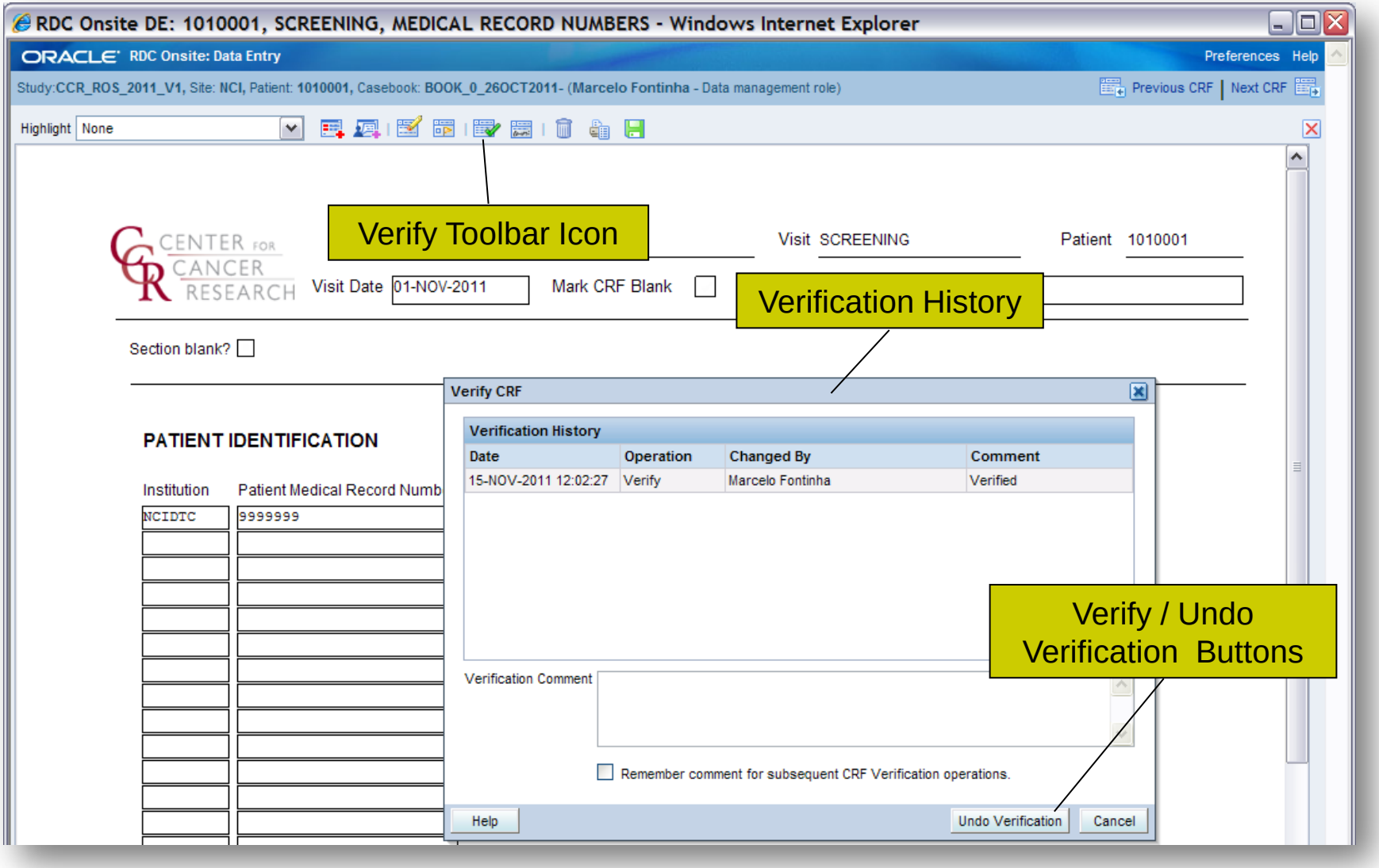
- C3D Verification & Approval functionality offer capabilities to track QA and Monitoring of eCRFs.
- Verification is associated with the Research Nurse User Role.
- Approval is associated with the Monitor User Role.



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

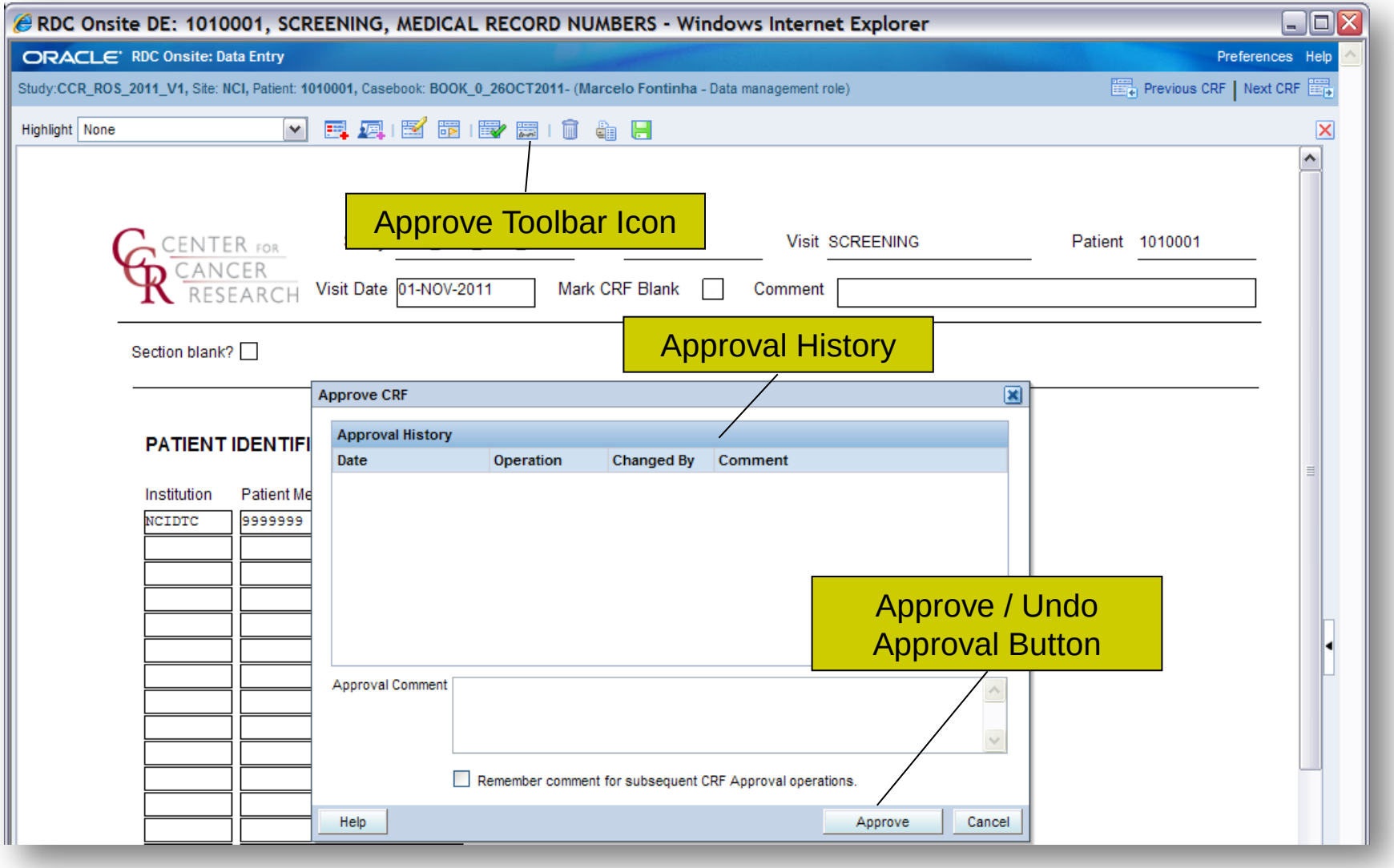
Verification



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

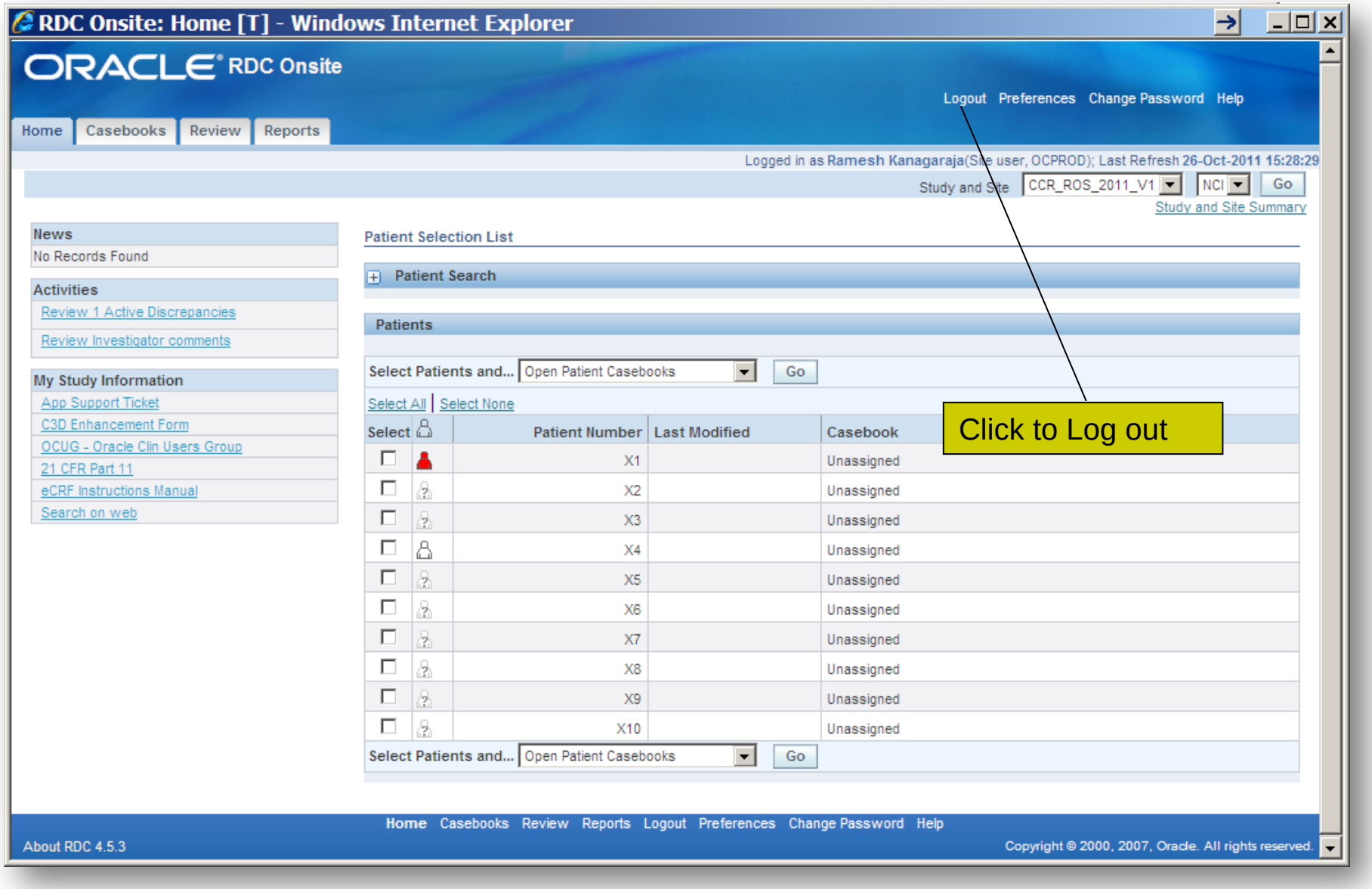
Approval


RDC Onsite DE: 1010001, SCREENING, MEDICAL RECORD NUMBERS - Windows Internet Explorer
ORACLE RDC Onsite: Data Entry
Preferences Help
Study:CCR_ROS_2011_V1, Site: NCI, Patient: 1010001, Casebook: BOOK_0_26OCT2011- (Marcelo Fontinha - Data management role)
Previous CRF | Next CRF
Highlight None
Approve Toolbar Icon
CENTER FOR CANCER RESEARCH
Visit SCREENING
Patient 1010001
Visit Date 01-NOV-2011
Mark CRF Blank
Comment
Section blank?
Approval History
Approve CRF
Approval History
Date
Operation
Changed By
Comment
PATIENT IDENTIFI
Institution
Patient Me
NCIDTC
9999999
Approve / Undo Approval Button
Approval Comment
Remember comment for subsequent CRF Approval operations.
Help
Approve
Cancel

Log Out

- Exit C^{3}D before closing the Browser
- C^{3}D session times out, without warning, after 30 minutes of Inactivity
- Unsaved data is lost if session times out or network connection is lost

Log Out


RDC Onsite: Home [T] - Windows Internet Explorer
ORACLE RDC Onsite
Logout Preferences Change Password Help
Home Casebooks Review Reports
Logged in as Ramesh Kanagaraja(Site user, OCPROD); Last Refresh 26-Oct-2011 15:28:29
Study and Site CCR_ROS_2011_V1 NCI Go
Study and Site Summary
News
No Records Found
Activities
Review 1 Active Discrepancies
Review Investigator comments
My Study Information
App Support Ticket
C3D Enhancement Form
OCUG - Oracle Clin Users Group
21 CFR Part 11
eCRF Instructions Manual
Search on web
Patient Selection List
Patient Search
Patients
Select Patients and... Open Patient Casebooks Go
Select All | Select None
Select
Patient Number
Last Modified
Casebook
X1 Unassigned
X2 Unassigned
X3 Unassigned
X4 Unassigned
X5 Unassigned
X6 Unassigned
X7 Unassigned
X8 Unassigned
X9 Unassigned
X10 Unassigned
Select Patients and... Open Patient Casebooks Go
Click to Log out
Home Casebooks Review Reports Logout Preferences Change Password Help
About RDC 4.5.3
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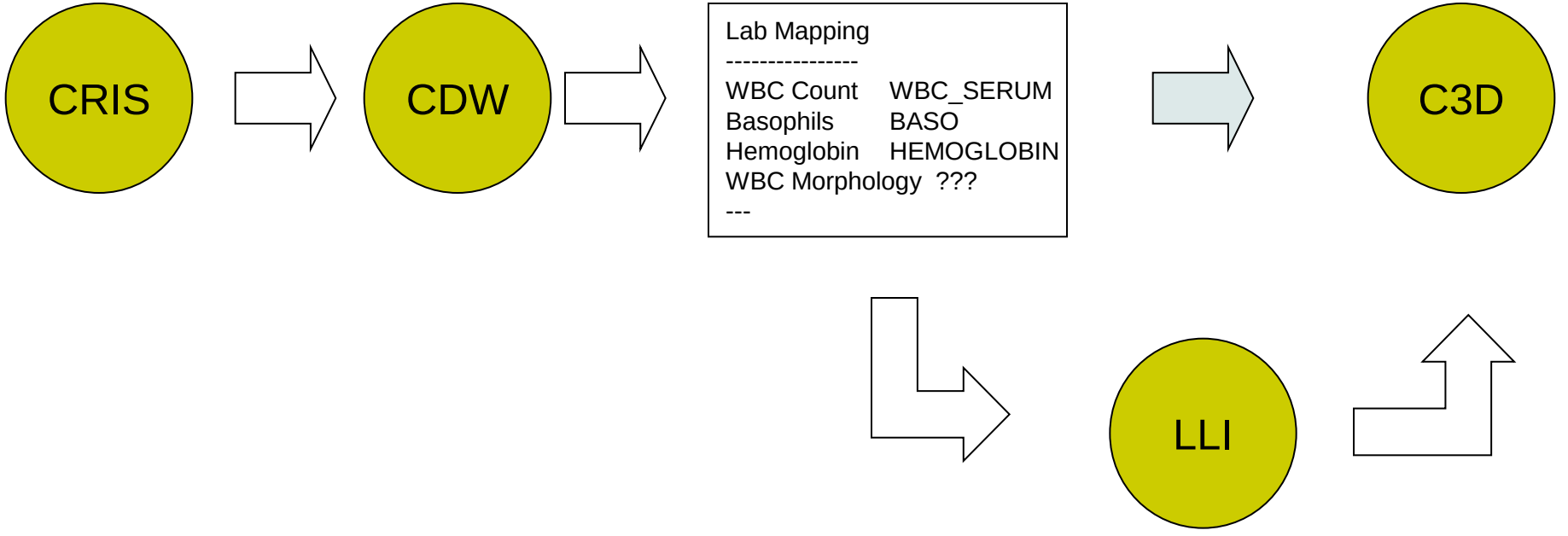
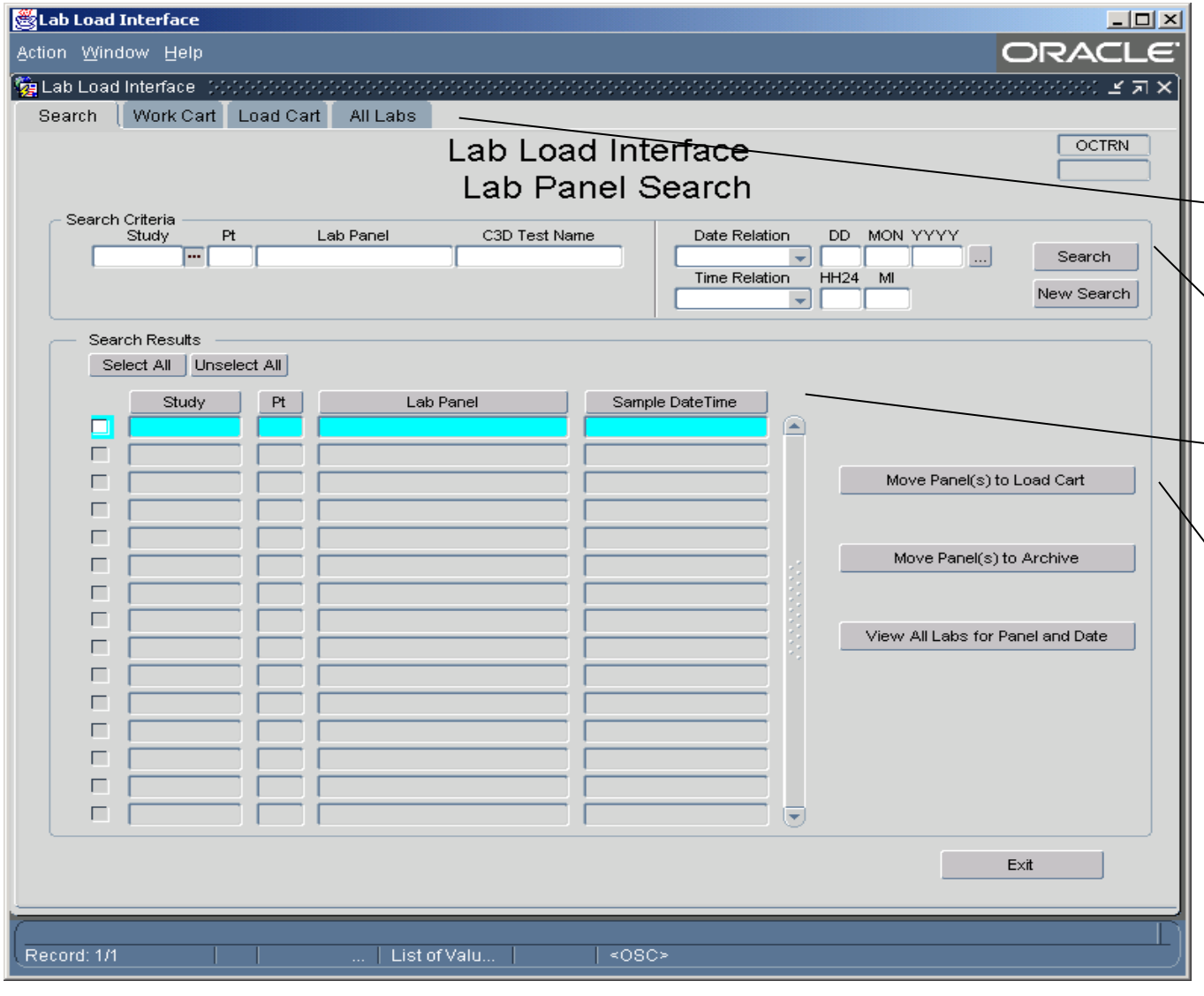
CRIS to C³D Lab Data Flow



What is LLI?

- LLI is a utility to review and identify specific Lab Test Results to be downloaded from the CRIS/CDW into C^3D
- URL: https://octrials.nci.nih.gov/opa46/labloadinter.htm
- Username & Password are same as C^3D

LLI Search Screen



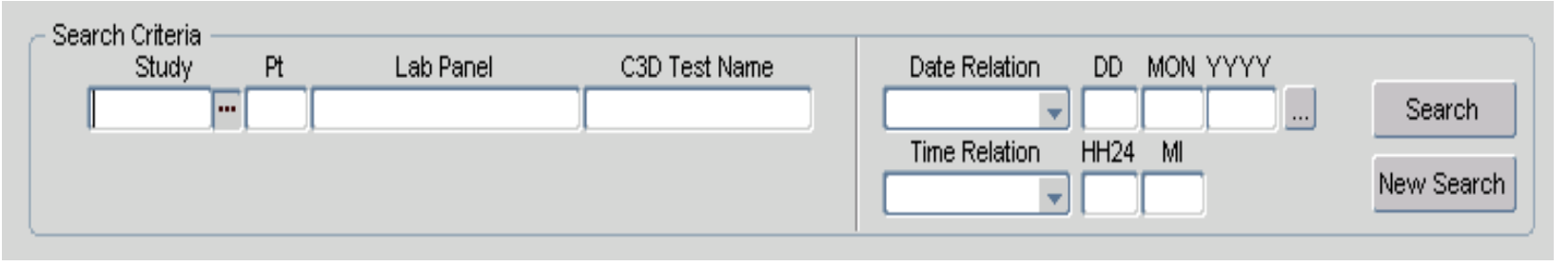
Workflow

Search Criteria

Selected Panels

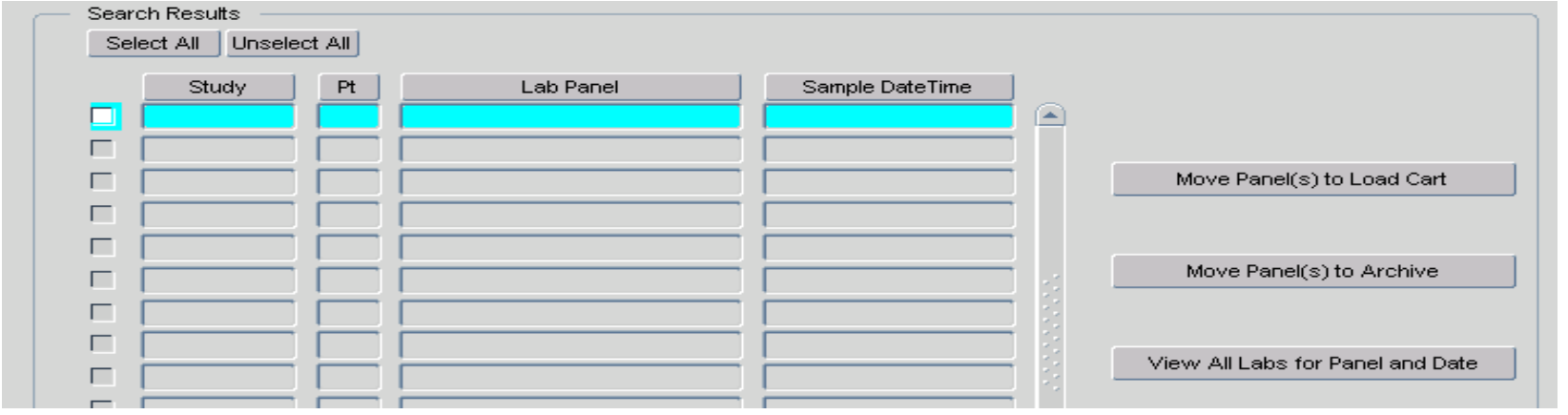
Action Buttons

LLI Search Criteria



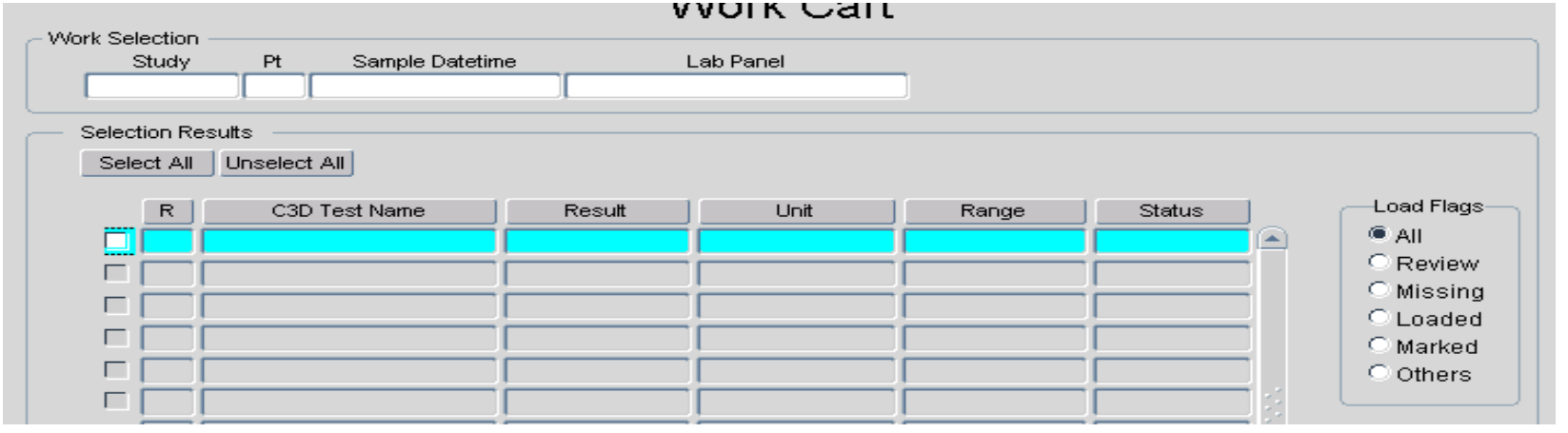
- **Searching**
  - Can search by Study, Patient Number, Lab Panel, OC Lab Question, Date and/or Time
    - Each search field contains Pick List.
    - Date and Time allows the '%' wild card
    - Date and Time provide the additional option of:
      - "On or Before", "On or After" and "LIKE" comparisons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

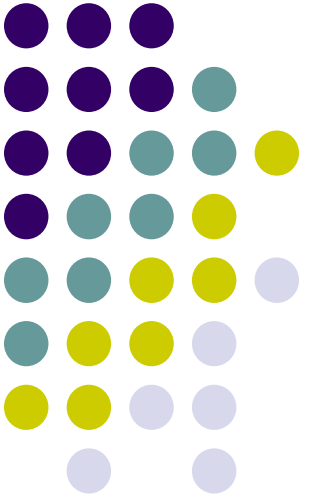
LLI Search Screen Results



- **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



- **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?