Introduction to C^{3}D

Harris Corporation

Jan 2015

Introduction

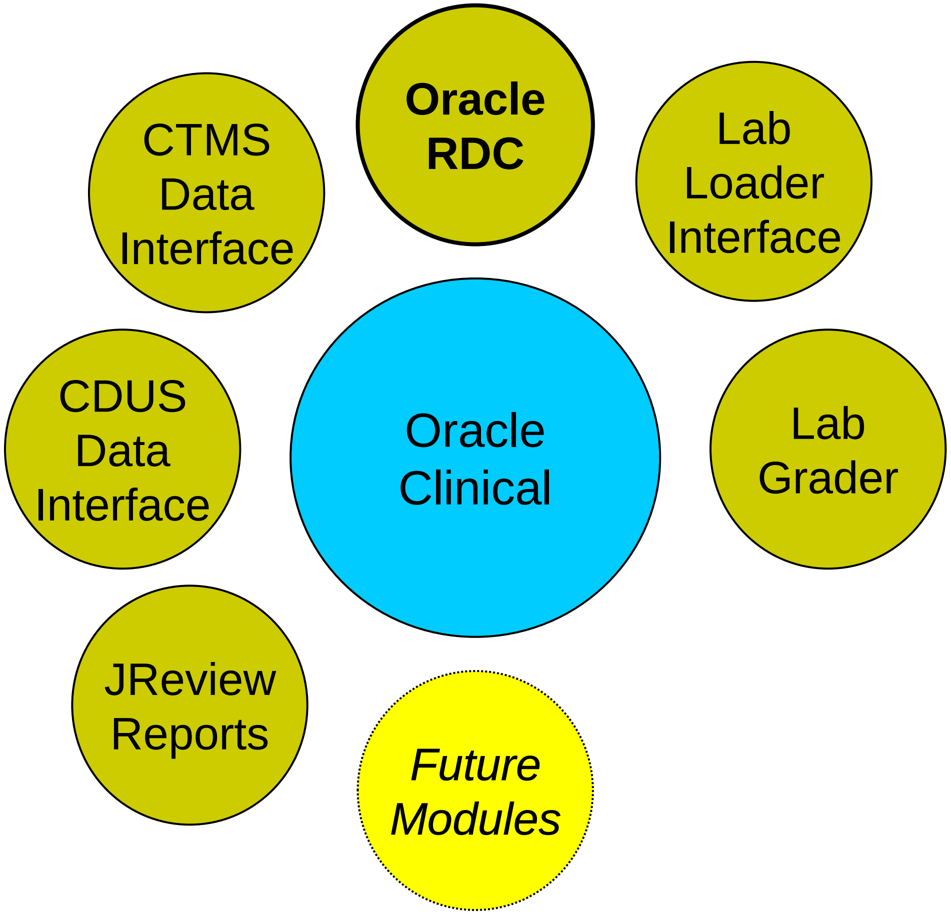
- C^3D - **C**ancer **C**entral **C**linical **D**atabase
- eCRFs Instructions Manual
- Support
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval
- Lab Loading

What is 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).
  - For studies prior with Clinical Center Number prior to 2012: The Java Runtime Environment (JRE) version 1.7.0_45 (or later) is required.
- 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

Oracle Clinical

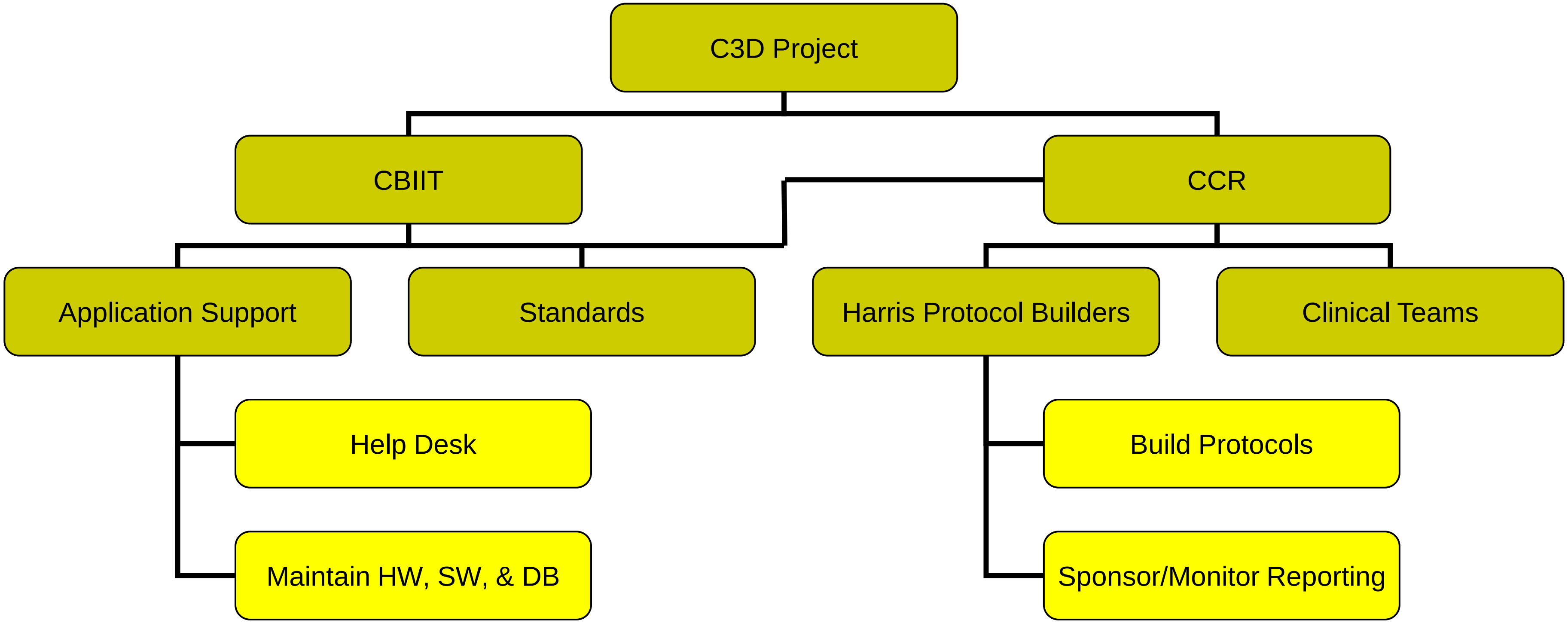
CDUS Data Interface

Lab Grader

JReview Reports

Future Modules

C^{3}D Organization



C3D Project

CBIIT

CCR

Application Support

Standards

Harris Protocol Builders

Clinical Teams

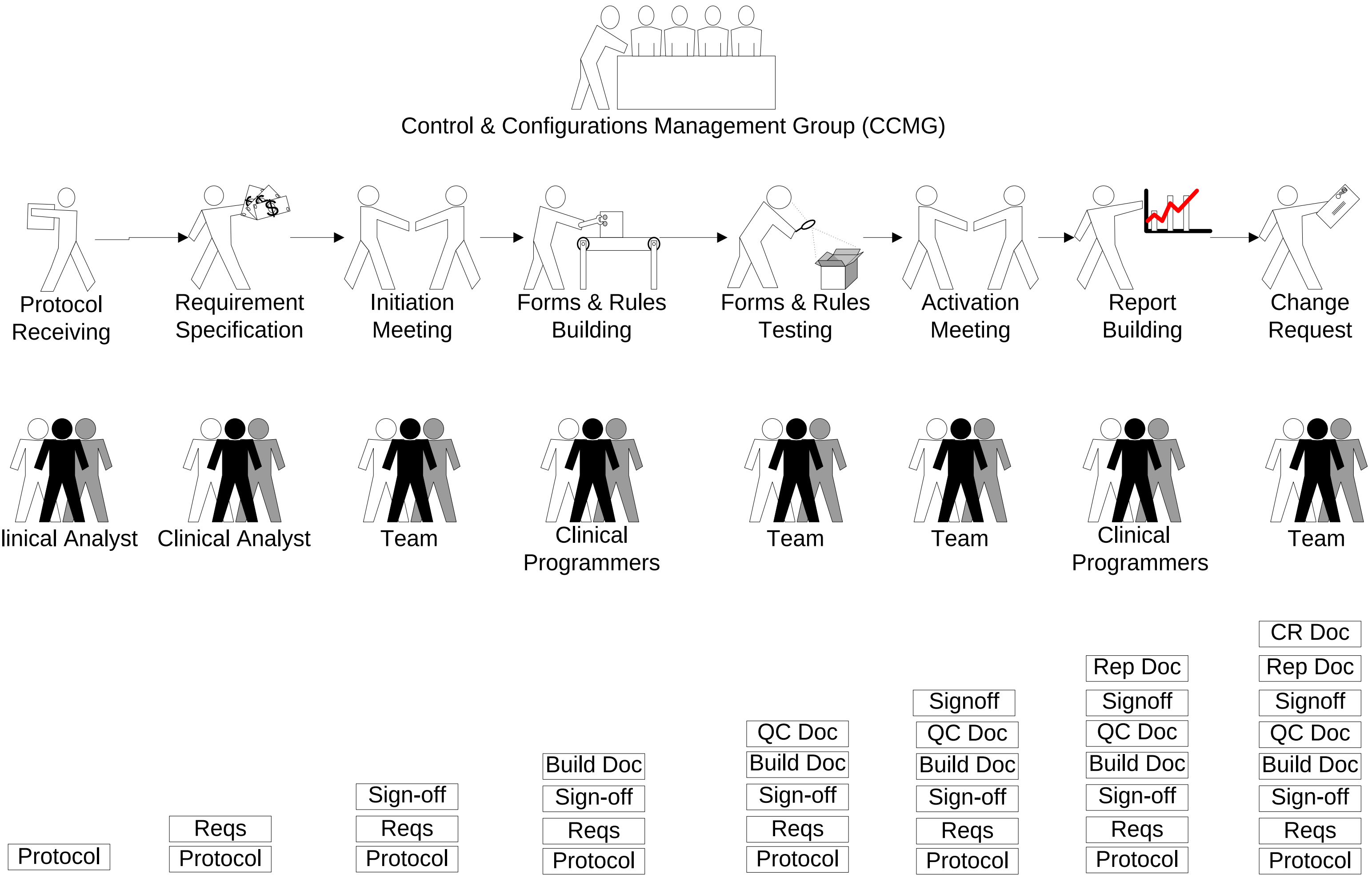
Help Desk

Maintain HW, SW, & DB

Build Protocols

Sponsor/Monitor Reporting

Designing Protocols in C^{3}D



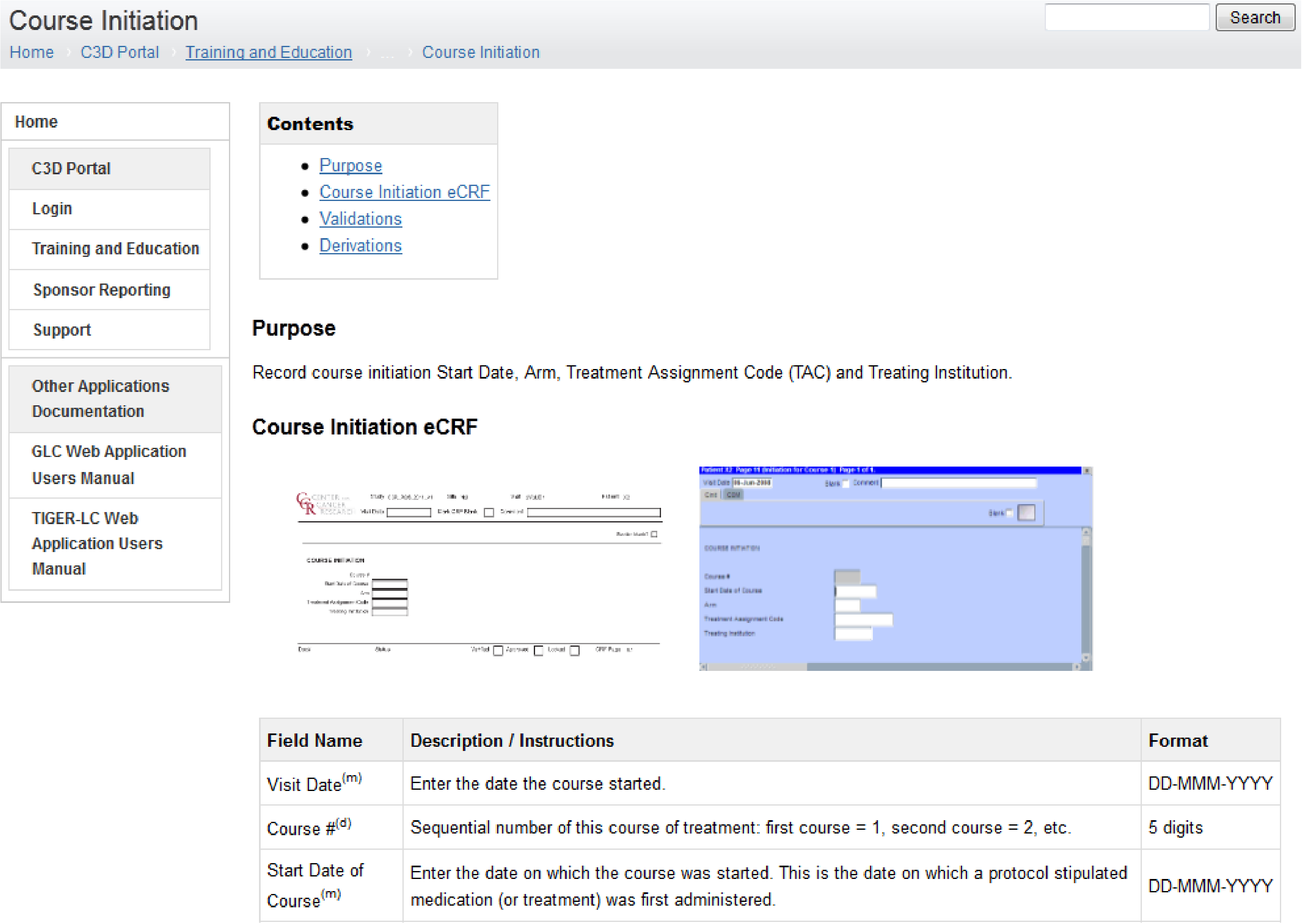
Control & Configurations Management Group (CCMG)

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

Course Initiation

Contents

- Purpose
- Course Initiation eCRF
- Validations
- Derivations

Purpose

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

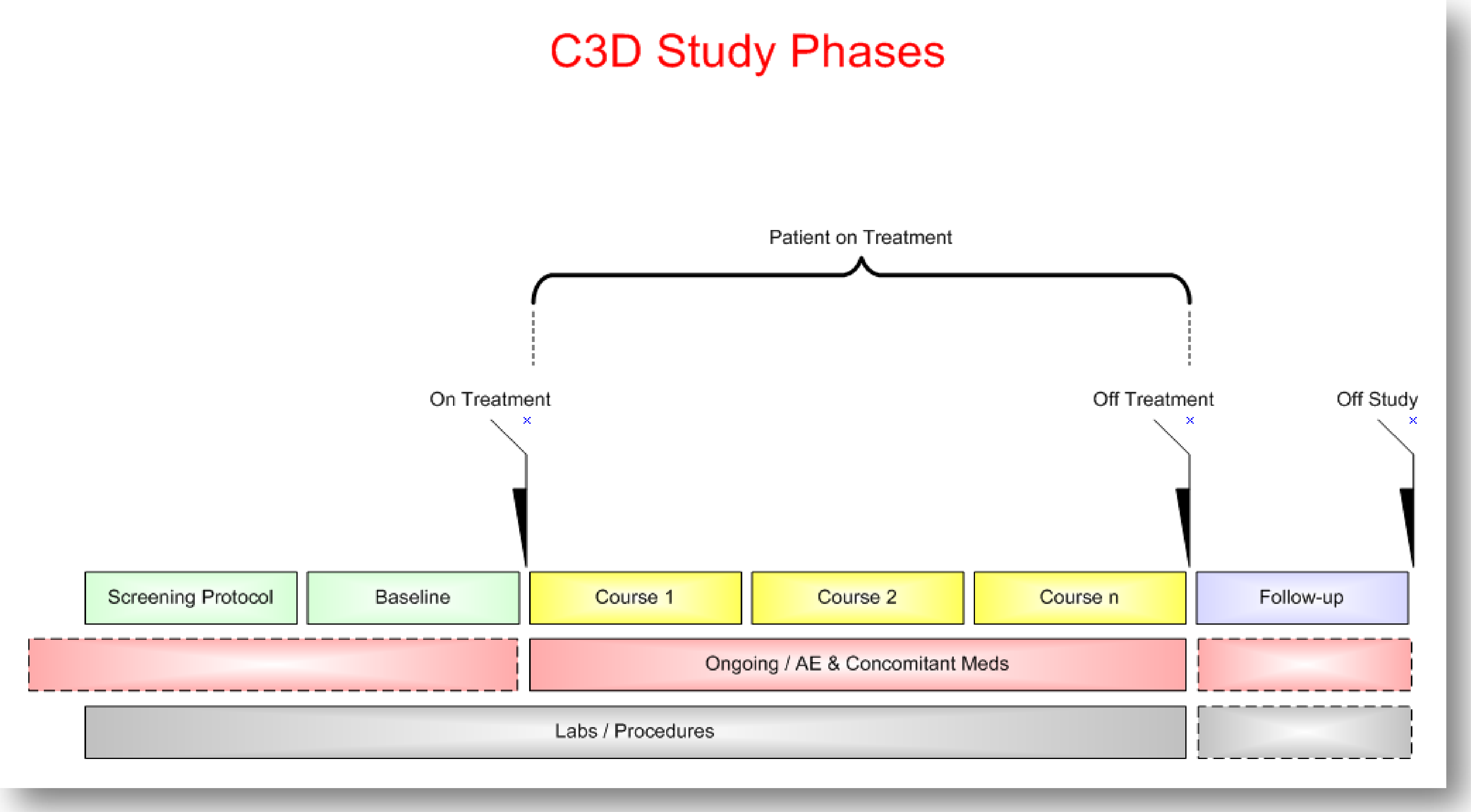
Course Initiation eCRF

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	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

C^{3}D Support

- CBIIT provides the first line of support for C^{3}D 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: $ % & ‘ ‘’ /.
- Production Database is called **ocprod**
- About C^{3}D Password:
  - Do not share the password with others!
  - Password needs to be changed the first time you login.
  - Passwords expire every 3 months and need 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

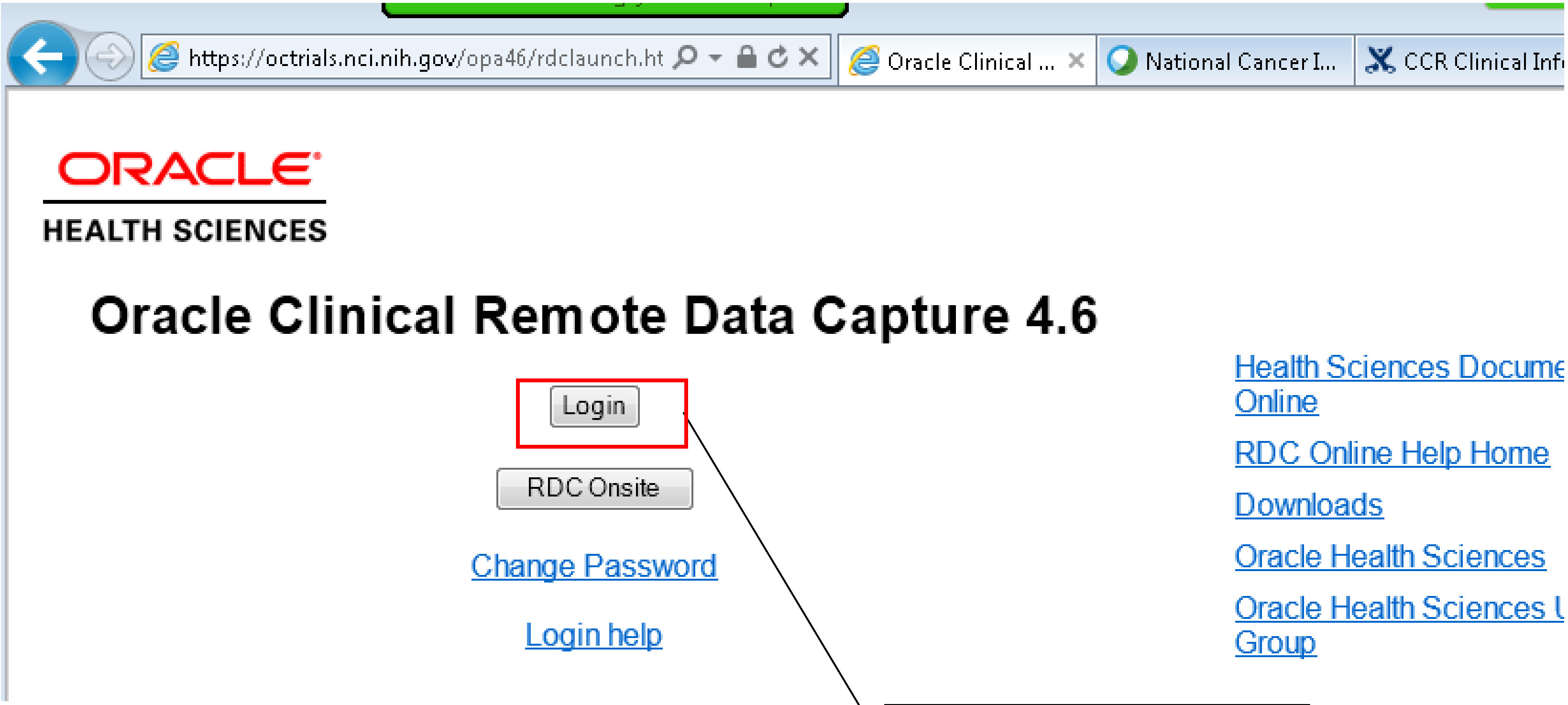
- C^{3}D Production Login Page:

  https://octrials.nci.nih.gov/opa46/rdclaunch.htm

- C^{3}D provides a separate Data Entry environment to test protocol design
  - Test Login page: https://octrials.nci.nih.gov/opa46/rdclauncht.htm

C^{3}D Login Web Page

For studies with NCI Clinical Center Number prior to 2012 (ex: 11_C_0001, 10_C_0002), click on the Login button.



https://octrials.nci.nih.gov/opa46/rdclaunch.ht

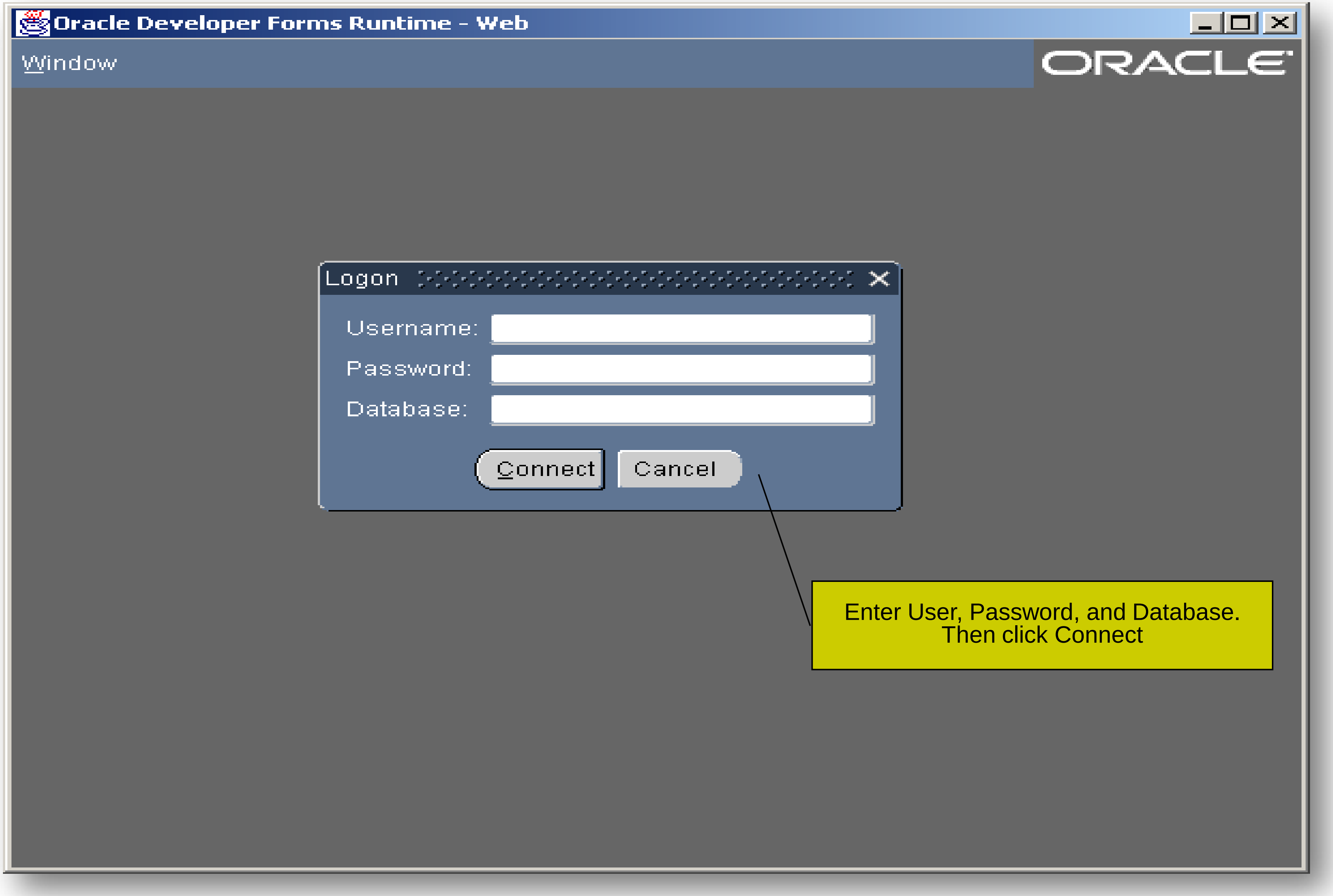
ORACLE
HEALTH SCIENCES

Oracle Clinical Remote Data Capture 4.6

Oracle Clinical ...
National Cancer I...
CCR Clinical Inf
Login
RDC Onsite
Change Password
Login help
Health Sciences Docume
Online
RDC Online Help Home
Downloads
Oracle Health Sciences
Oracle Health Sciences U
Group

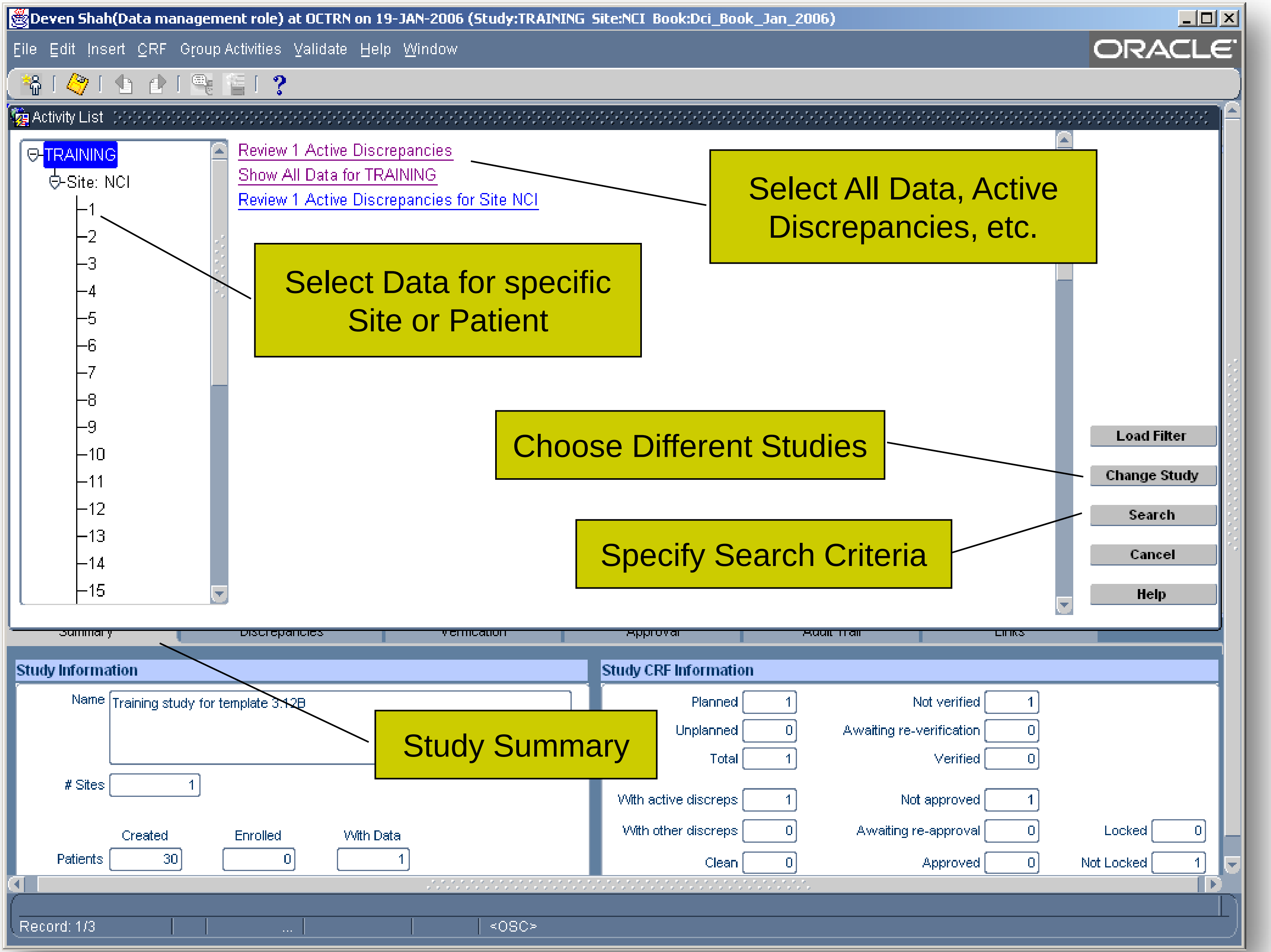
Click on Login Button

Login


Oracle Developer Forms Runtime - Web
Window
ORACLE
Logon
Username:
Password:
Database:
Connect
Cancel

Enter User, Password, and Database.
Then click Connect

C^{3}D Activity List



Deven Shah(Data management role) at OCTRN on 19-JAN-2006 (Study:TRAINING Site:NCI Book:Dci_Book_Jan_2006)

File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Activity List
TRAINING
Site: NCI
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
Review 1 Active Discrepancies
Show All Data for TRAINING
Review 1 Active Discrepancies for Site NCI
Load Filter
Change Study
Search
Cancel
Help
Summary
Discrepancies
Verification
Approval
Audit Trail
Links
Study Information
Study CRF Information

Select All Data, Active Discrepancies, etc.

Select Data for specific Site or Patient

Choose Different Studies

Specify Search Criteria

Study Summary

Study Information

Name: Training study for template 3.12B

Sites: 1

	Created	Enrolled	With Data
Patients	30	0	1

Study CRF Information

Planned	1	Not verified	1		
Unplanned	0	Awaiting re-verification	0		
Total	1	Verified	0		
With active discreps	1	Not approved	1		
With other discreps	0	Awaiting re-approval	0	Locked	0
Clean	0	Approved	0	Not Locked	1

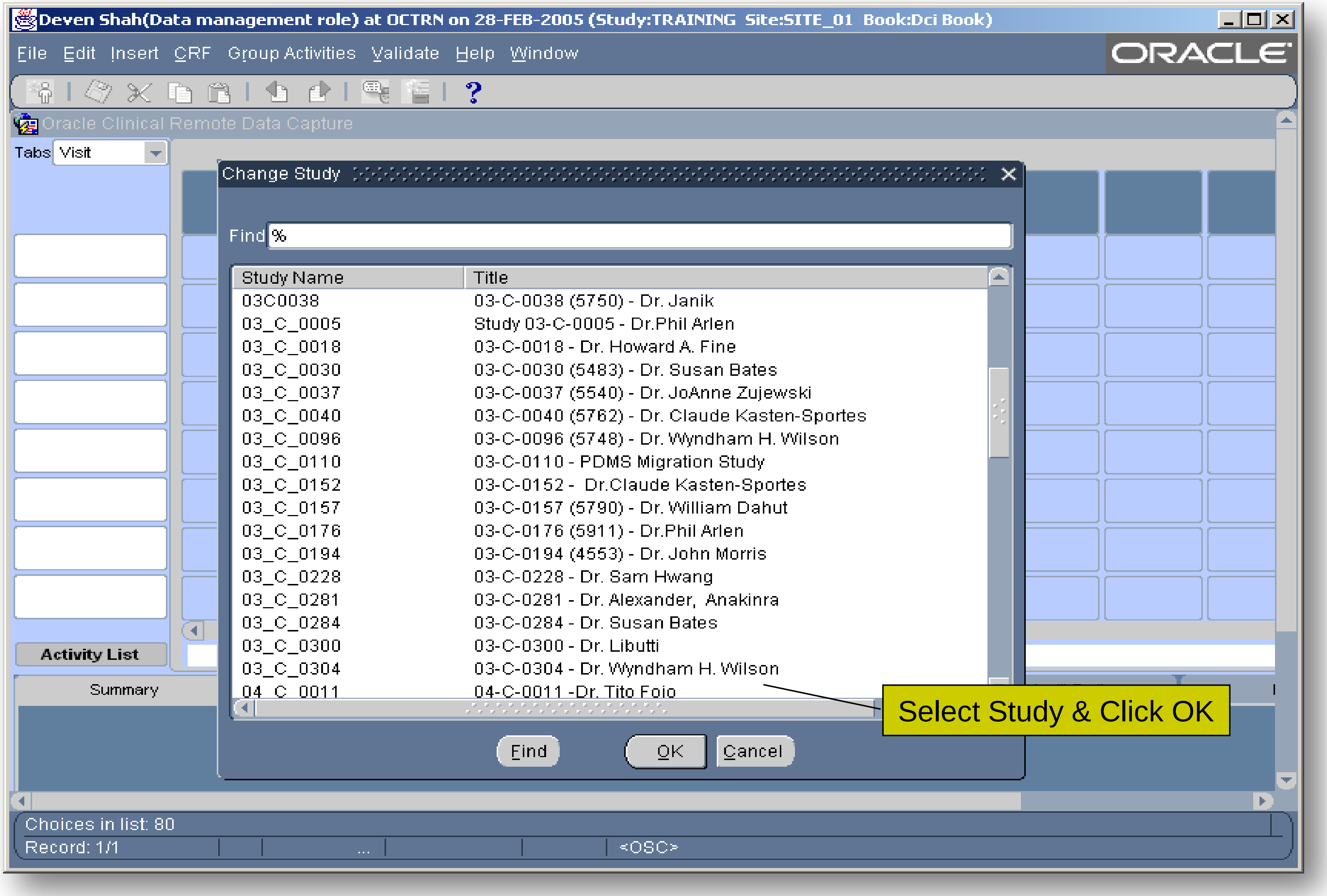
Record: 1/3 ... <OSC>

Selecting Activity

- Quick Links to View
  - All Study Data
  - Discrepant Data
  - Site Specific or Patient Specific Data
- Change Study button to choose a Different Study
  - Default Study is preserved from prior login
  - Access to study sites and C^3D features are controlled by user role
- Search button used to locate eCRFs based on one or more criterion

- **Quick Tip:**
  - This screen provides a quick review of open discrepancies in your study
  - **It is strongly recommended to work with one patient at a time when performing data entry to avoid entering data in the wrong patient position.**

Selecting Study


File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Oracle Clinical Remote Data Capture
Change Study
Activity List
Summary
Find
OK
Cancel

Deven Shah(Data management role) at OCTRN on 28-FEB-2005 (Study:TRAINING Site:SITE_01 Book:Dci Book)

Tabs Visit

Find %

Study Name	Title
03C0038	03-C-0038 (5750) - Dr. Janik
03_C_0005	Study 03-C-0005 - Dr.Phil Arlen
03_C_0018	03-C-0018 - Dr. Howard A. Fine
03_C_0030	03-C-0030 (5483) - Dr. Susan Bates
03_C_0037	03-C-0037 (5540) - Dr. JoAnne Zujewski
03_C_0040	03-C-0040 (5762) - Dr. Claude Kasten-Sportes
03_C_0096	03-C-0096 (5748) - Dr. Wyndham H. Wilson
03_C_0110	03-C-0110 - PDMS Migration Study
03_C_0152	03-C-0152 - Dr.Claude Kasten-Sportes
03_C_0157	03-C-0157 (5790) - Dr. William Dahut
03_C_0176	03-C-0176 (5911) - Dr.Phil Arlen
03_C_0194	03-C-0194 (4553) - Dr. John Morris
03_C_0228	03-C-0228 - Dr. Sam Hwang
03_C_0281	03-C-0281 - Dr. Alexander, Anakinra
03_C_0284	03-C-0284 - Dr. Susan Bates
03_C_0300	03-C-0300 - Dr. Libutti
03_C_0304	03-C-0304 - Dr. Wyndham H. Wilson
04_C_0011	04-C-0011 -Dr. Tito Fojo

Choices in list: 80

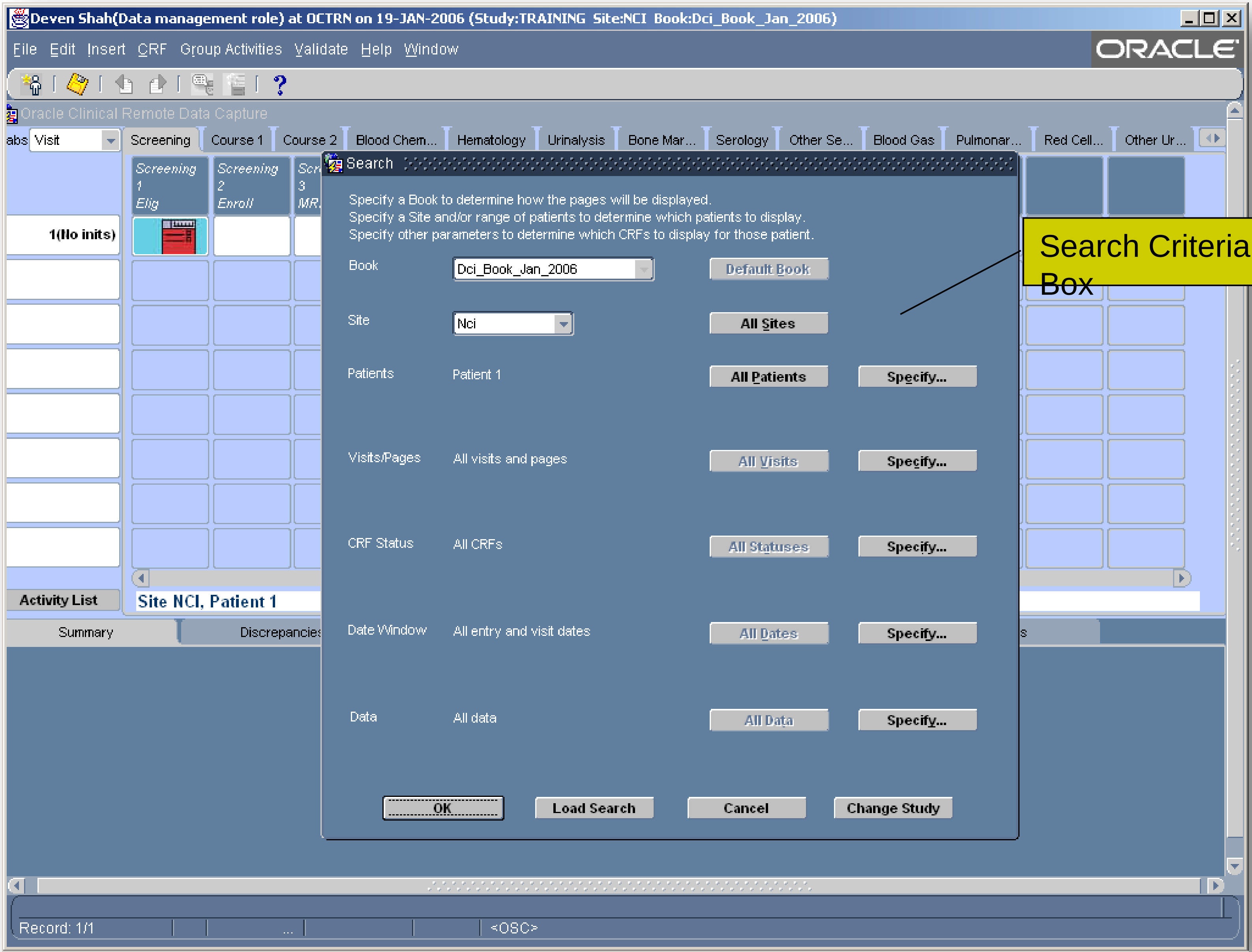
Record: 1/1 ... <OSC>

Select Study & Click OK

Study Access

- Study/Site access and C^{3}D features determined by user role
- User Roles:
  - Data Managers (Performs Data Entry)
  - Research Nurse (Performs Data Entry and Verifies eCRFs)
  - Monitor (Read-only access and Approves eCRFs)
  - Principal Investigator (Read-only access)
  - Reviewer (Read-only access)

Search Criteria


File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
abs Visit
Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology Other Se... Blood Gas Pulmonar... Red Cell... Other Ur...
Screening 1 Elig
Screening 2 Enroll
Scr 3 MR.
1(No inits)
Activity List
Summary
Discrepancies
Search
Default Book
All Sites
All Patients
Specify...
All Visits
All Statuses
All Dates
All Data
OK
Load Search
Cancel
Change Study
Record: 1/1
<OSC>

Deven Shah(Data management role) at OCTRN on 19-JAN-2006 (Study:TRAINING Site:NCI Book:Dci_Book_Jan_2006)

Site NCI, Patient 1

Specify a Book to determine how the pages will be displayed.
Specify a Site and/or range of patients to determine which patients to display.
Specify other parameters to determine which CRFs to display for those patient.

Book: Dci_Book_Jan_2006

Site: Nci

Patients: Patient 1

Visits/Pages: All visits and pages

CRF Status: All CRFs

Date Window: All entry and visit dates

Data: All data

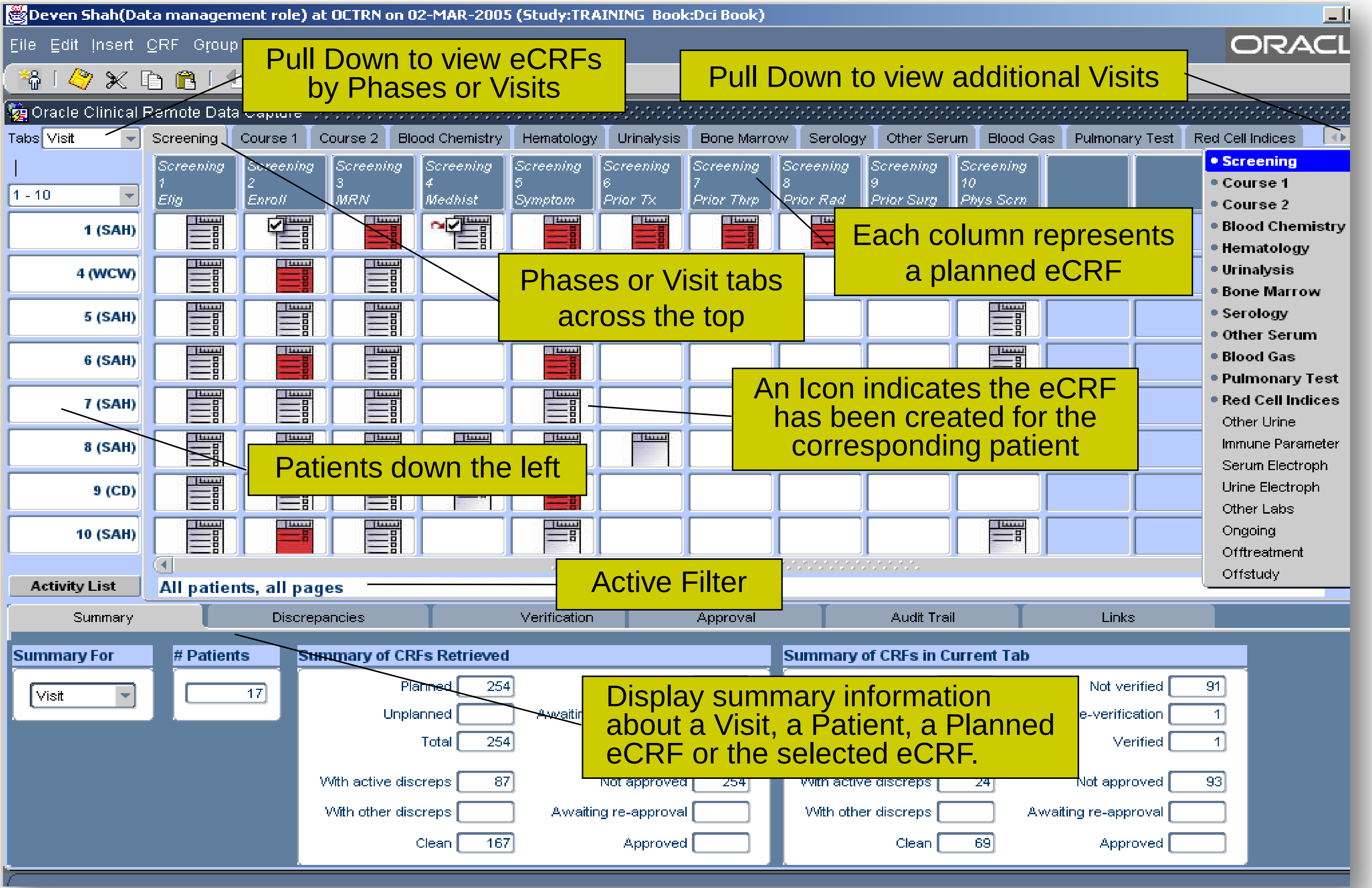
Search Criteria Dialog Box

Search Criteria

- Search options:
  - Book - collection of CRFs for a particular version of the protocol (initial version or amendments)
  - Site
  - Patients
    - Range of Patients
  - Visits/Pages
    - Phases, Visits, etc.
  - CRF Status
    - Complete, Discrepant, Verified, Approved, etc.
  - CRF Entry Date Window
    - Entry or Modification Date Ranges
  - Data
    - Data entered in an eCRF

- **Quick Tip:**
  - Protocol Amendments may require different DCI Book. Latest DCI book is the default one. Use Search option to select a previous book.
  - Search Criteria Could be saved for future use.

RDC Spreadsheet


Deven Shah(Data management role) at OCTRN on 02-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group
ORACL
Oracle Clinical Remote Data Capture
Tabs
Screening
Course 1
Course 2
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
Pulmonary Test
Red Cell Indices
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
Screening
Course 1
Course 2
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
Pulmonary Test
Red Cell Indices
Other Urine
Immune Parameter
Serum Electroph
Urine Electroph
Other Labs
Ongoing
Offtreatment
Offstudy
1 (SAH)
4 (WCW)
5 (SAH)
6 (SAH)
7 (SAH)
8 (SAH)
9 (CD)
10 (SAH)
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

Tabs: Visit

1 - 10

All patients, all pages

Pull Down to view eCRFs by Phases or Visits

Pull Down to view additional Visits

Each column represents a planned eCRF

Phases or Visit tabs across the top

An Icon indicates the eCRF has been created for the corresponding patient

Patients down the left

Active Filter

Display summary information about a Visit, a Patient, a Planned eCRF or the selected eCRF.

Summary For

Visit

# Patients

17

Summary of CRFs Retrieved

Planned 254
Unplanned
Total 254
With active discreps 87
With other discreps
Clean 167
Awaitin
Not approved 254
Awaiting re-approval
Approved

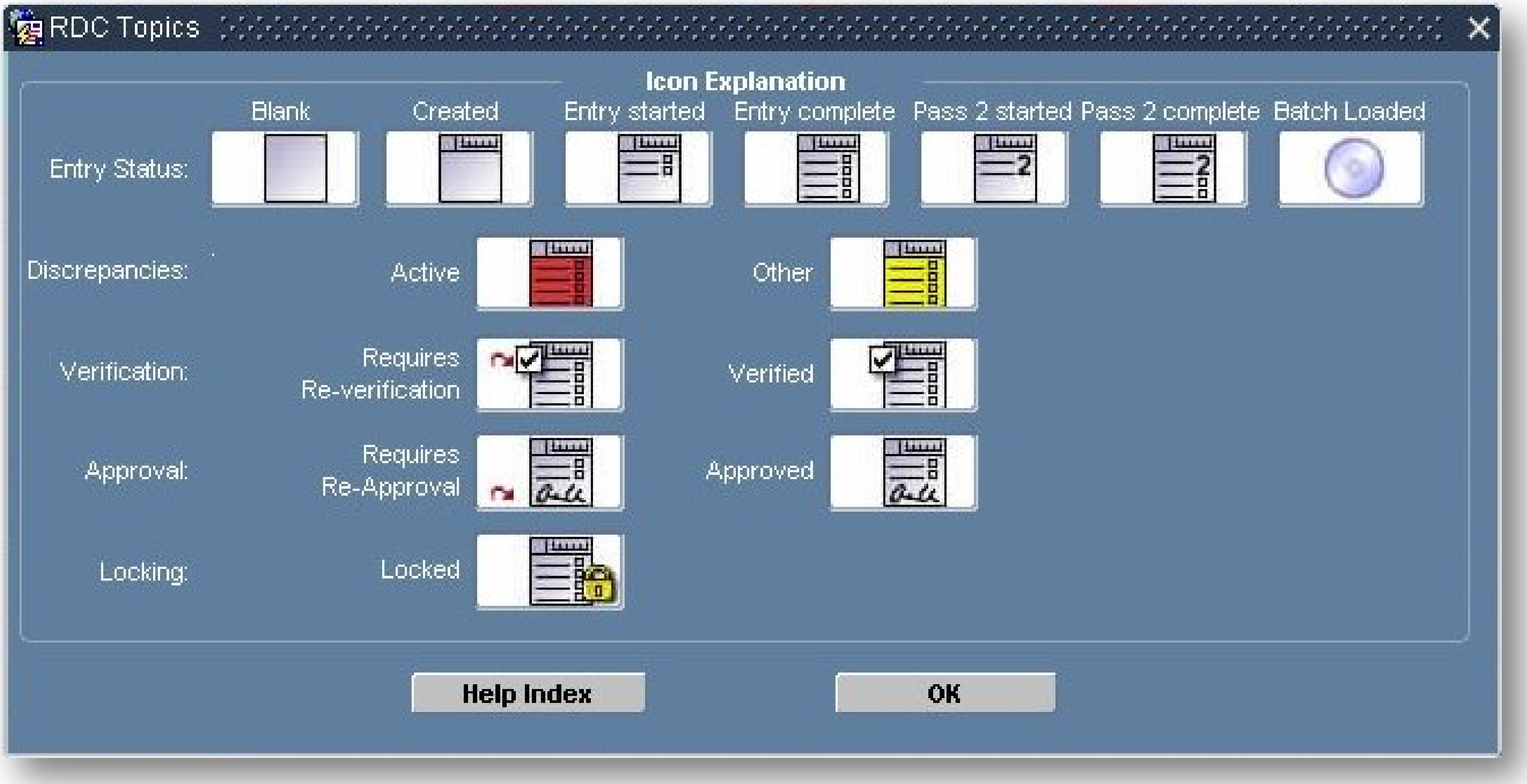
Summary of CRFs in Current Tab

Not verified 91
e-verification 1
Verified 1
With active discreps 24
With other discreps
Clean 69
Not approved 93
Awaiting re-approval
Approved

Navigating RDC Spreadsheet

- Spreadsheet Layout
  - Patients along Rows
  - Phases or Visits Tabs along Columns; pull down for additional visits
  - eCRF within Tabs
  - Cells represents an eCRF for the corresponding Patient-Visit
- Tabs can be organized by Study, Phase, & Visit
  - When working with Lab eCRFs, choose to work with Visits instead of Phases or Study.
- Information Tabs for Summary, Discrepancies, Verification, Audit-trail, etc. at the bottom
- Navigation Functions via
  - Menu
  - Toolbar
  - Hot Keys

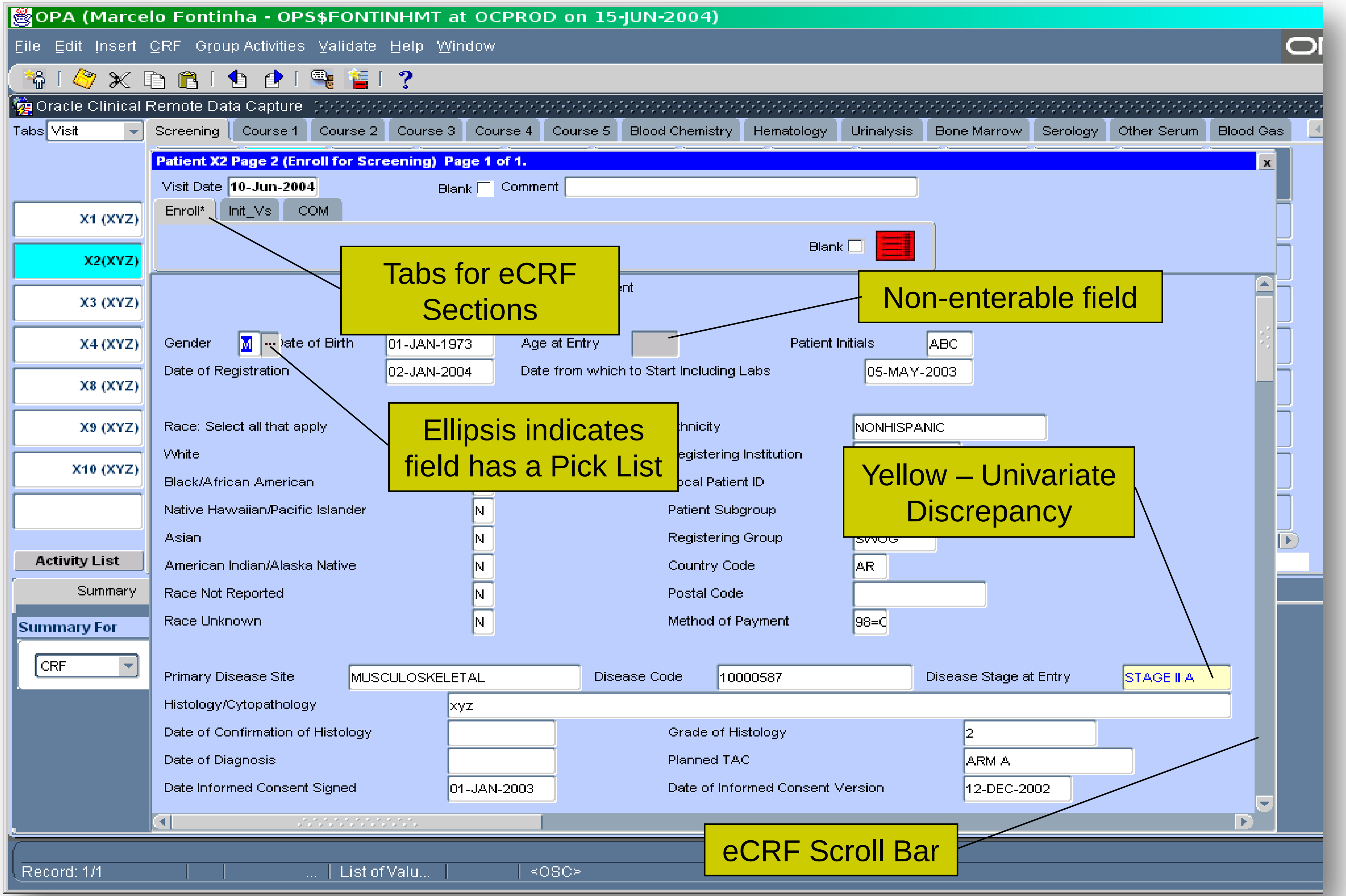
eCRF Icons


RDC Topics
Icon Explanation
Entry Status:
Blank
Created
Entry started
Entry complete
Pass 2 started
Pass 2 complete
Batch Loaded
Discrepancies:
Active
Other
Verification:
Requires Re-verification
Verified
Approval:
Requires Re-Approval
Approved
Locking:
Locked
Help Index
OK

Important eCRF Icons

- Square icon represents manual entry
- Round icon represents automated entry (lab load)
- An eCRF just created, but without data has no lines within the icon
- Partially entered eCRF has lines across half of the icon
- Completed eCRF have lines across the whole icon
- Blank Square icon indicates eCRF has been marked blank
- Red icon indicates one or more open discrepancies

Electronic CRF (eCRF)


File Edit Insert CRF Group Activities Validate Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Course 3
Course 4
Course 5
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
X1 (XYZ)
X2(XYZ)
X3 (XYZ)
X4 (XYZ)
X8 (XYZ)
X9 (XYZ)
X10 (XYZ)
Activity List
Summary
Summary For
CRF
Enroll*
Init_Vs
COM

OPA (Marcelo Fontinha - OPS$FONTINHMT at OCPROD on 15-JUN-2004)

Patient X2 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date 10-Jun-2004 Blank ☐ Comment

Blank ☐

Gender M ... Date of Birth 01-JAN-1973 Age at Entry Patient Initials ABC

Date of Registration 02-JAN-2004 Date from which to Start Including Labs 05-MAY-2003

Race: Select all that apply

White

Black/African American

Native Hawaiian/Pacific Islander N

Asian N

American Indian/Alaska Native N

Race Not Reported N

Race Unknown N

thnicity NONHISPANIC

egistering Institution

ocal Patient ID

Patient Subgroup

Registering Group SWOG

Country Code AR

Postal Code

Method of Payment 98=C

Primary Disease Site MUSCULOSKELETAL Disease Code 10000587 Disease Stage at Entry STAGE II A

Histology/Cytopathology xyz

Date of Confirmation of Histology Grade of Histology 2

Date of Diagnosis Planned TAC ARM A

Date Informed Consent Signed 01-JAN-2003 Date of Informed Consent Version 12-DEC-2002

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

Tabs for eCRF Sections

Non-enterable field

Ellipsis indicates field has a Pick List

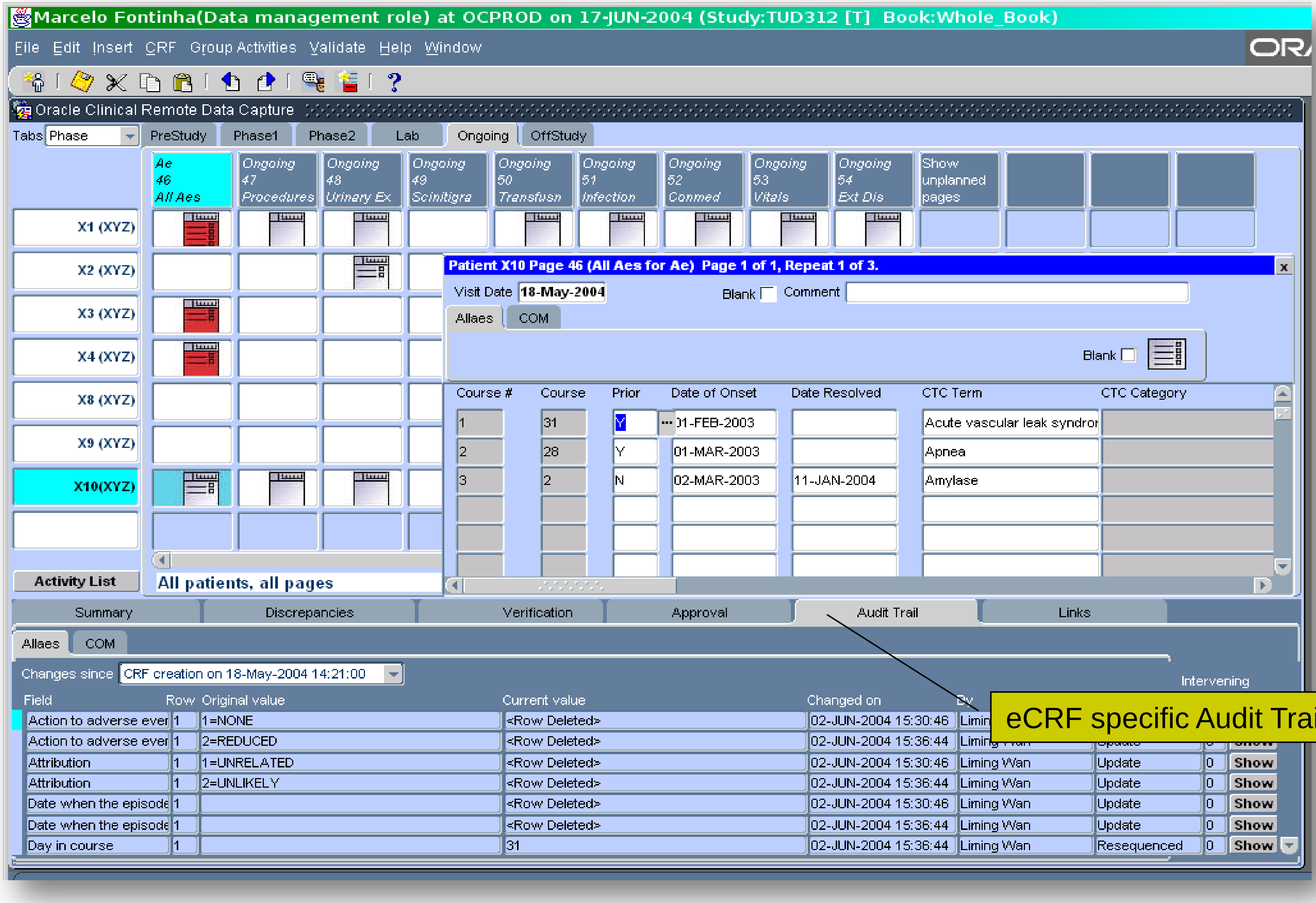
Yellow – Univariate Discrepancy

eCRF Scroll Bar

eCRF Navigation

- Clicking on eCRF icon open the eCRF
- eCRF may contain tabs for the different sections of the eCRF
- Grey Fields indicates non-enterable fields (Derived, Defaulted, etc.)
- eCRF Scroll Bars indicate additional information
- Ellipsis indicates the field has a Pick List. Click on the ellipsis or press F9 to display the Pick List.

Audit Trail



File Edit Insert CRF Group Activities Validate Help Window
Oracle Clinical Remote Data Capture
Tabs Phase
PreStudy
Phase1
Phase2
Lab
Ongoing
OffStudy
Ae 46 All Aes
Ongoing 47 Procedures
Ongoing 48 Urinary Ex
Ongoing 49 Scintigra
Ongoing 50 Transfusn
Ongoing 51 Infection
Ongoing 52 Conmed
Ongoing 53 Vitals
Ongoing 54 Ext Dis
Show unplanned pages
X1 (XYZ)
X2 (XYZ)
X3 (XYZ)
X4 (XYZ)
X8 (XYZ)
X9 (XYZ)
X10(XYZ)
Activity List
All patients, all pages
Allaes
COM
Blank ☐
Comment
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

Marcelo Fontinha(Data management role) at OCPROD on 17-JUN-2004 (Study:TUD312 [T] Book:Whole_Book)

Patient X10 Page 46 (All Aes for Ae) Page 1 of 1, Repeat 1 of 3.

Visit Date 18-May-2004

Course #	Course	Prior	Date of Onset	Date Resolved	CTC Term	CTC Category
1	31	Y	01-FEB-2003		Acute vascular leak syndror	
2	28	Y	01-MAR-2003		Apnea	
3	2	N	02-MAR-2003	11-JAN-2004	Amylase	

Changes since CRF creation on 18-May-2004 14:21:00

Field	Row	Original value	Current value	Changed on	By		Intervening	
Action to adverse ever	1	1=NONE	<Row Deleted>	02-JUN-2004 15:30:46	Limin			
Action to adverse ever	1	2=REDUCED	<Row Deleted>	02-JUN-2004 15:36:44	Liming			
Attribution	1	1=UNRELATED	<Row Deleted>	02-JUN-2004 15:30:46	Liming Wan	Update	0	Show
Attribution	1	2=UNLIKELY	<Row Deleted>	02-JUN-2004 15:36:44	Liming Wan	Update	0	Show
Date when the episode	1		<Row Deleted>	02-JUN-2004 15:30:46	Liming Wan	Update	0	Show
Date when the episode	1		<Row Deleted>	02-JUN-2004 15:36:44	Liming Wan	Update	0	Show
Day in course	1		31	02-JUN-2004 15:36:44	Liming Wan	Resequenced	0	Show

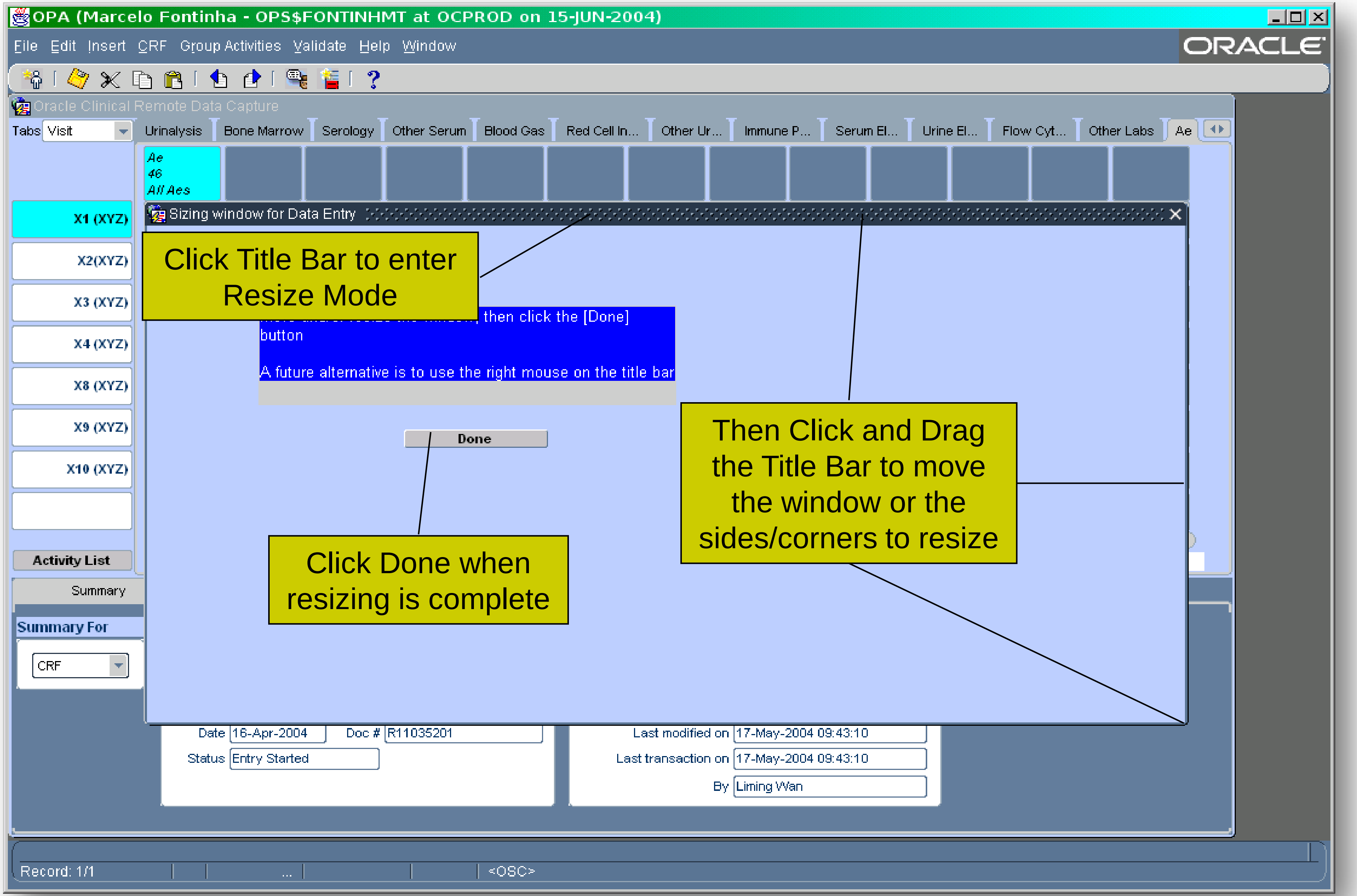
eCRF specific Audit Trail

Audit Trail

- Audit Trail Tab shows history of all changes made to a specific eCRFs
- Shows current and prior values for each changed eCRF field along with the date of change and the user who made the change

- **Quick Tips**:
  - Auditing Begins after Form is marked complete
  - Do not share user ids and passwords!

Resizing eCRF Window


OPA (Marcelo Fontinha - OPS$FONTINHMT at OCPROD on 15-JUN-2004)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
Red Cell In...
Other Ur...
Immune P...
Serum El...
Urine El...
Flow Cyt...
Other Labs
Ae
Ae
46
All Aes
X1 (XYZ)
X2(XYZ)
X3 (XYZ)
X4 (XYZ)
X8 (XYZ)
X9 (XYZ)
X10 (XYZ)
Activity List
Summary
Summary For
CRF
Sizing window for Data Entry
Done
Record: 1/1
...
<OSC>

..., then click the [Done] button

A future alternative is to use the right mouse on the title bar

Date 16-Apr-2004 Doc # R11035201

Status Entry Started

Last modified on 17-May-2004 09:43:10

Last transaction on 17-May-2004 09:43:10

By Liming Wan

Click Title Bar to enter Resize Mode

Then Click and Drag the Title Bar to move the window or the sides/corners to resize

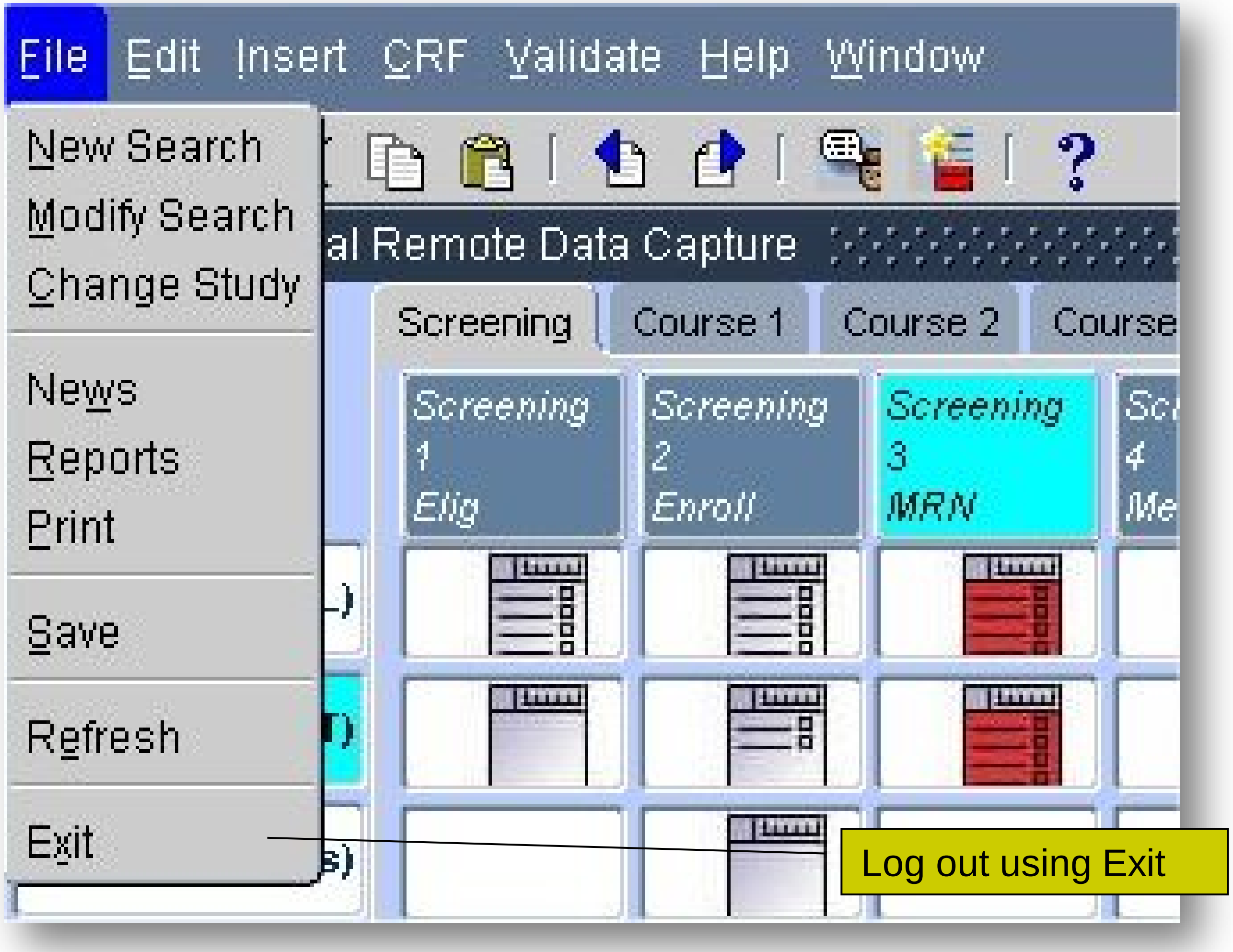
Click Done when resizing is complete

Resizing eCRF Window

- Click on the eCRF title bar to enter resize mode
- Click and drag title bar to move window
- Click and drag window edge to expand/ reduce window size
- Click OK when Done

- **Quick Tip:**
    - Right mouse click on the eCRF title bar to show a pop-up menu with options to move/resize the eCRF window.

Log Out

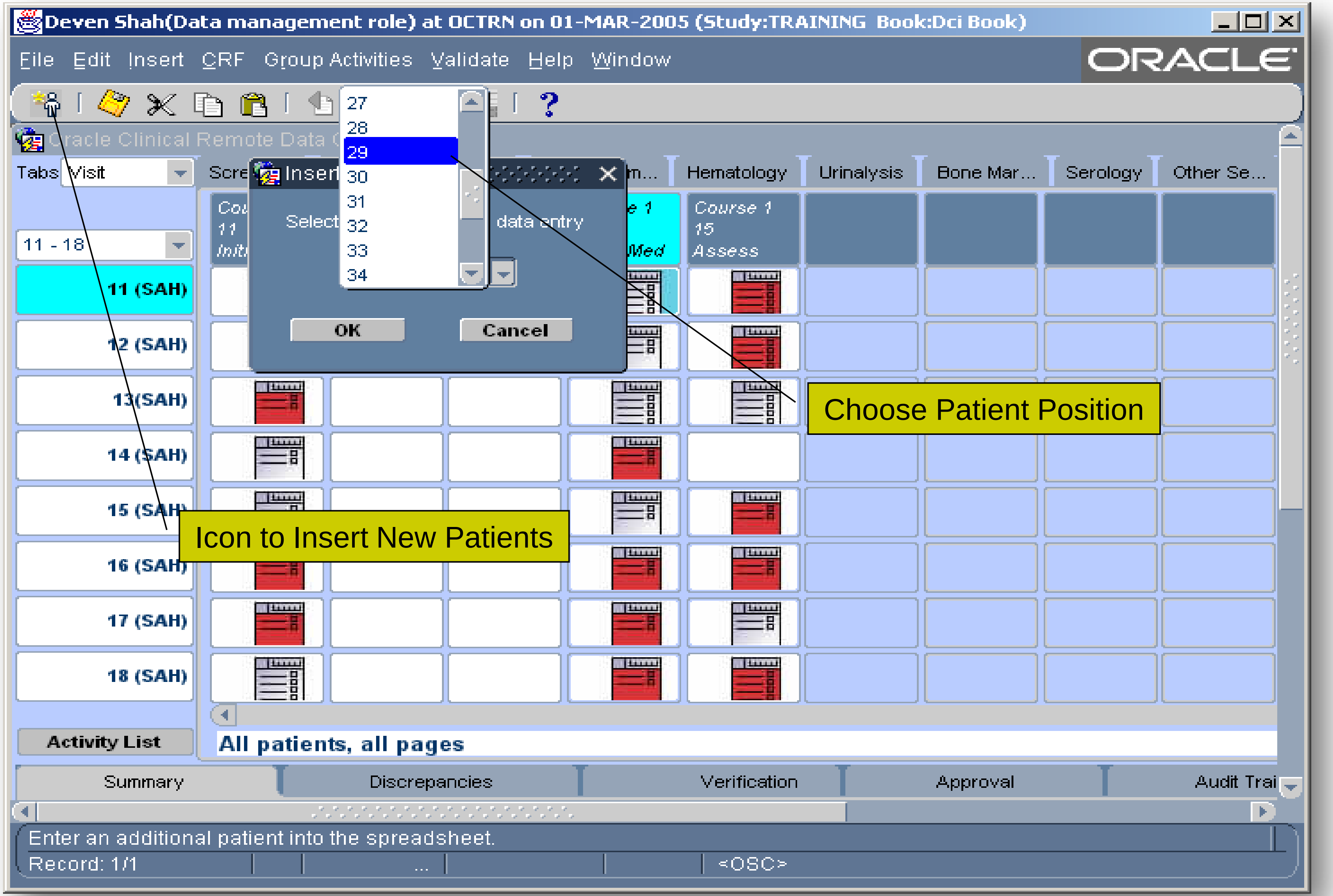

File
Edit
Insert
CRF
Validate
Help
Window
New Search
Modify Search
Change Study
News
Reports
Print
Save
Refresh
Exit
al Remote Data Capture
Screening
Course 1
Course 2
Course
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Sc 4 Me

Log out using Exit

Log Out

- Exit C^{3}D before closing the Browser
- Inactivity for more than 30 minutes logs your out automatically. **Any unsaved work is lost!**

Inserting New Patient


Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data C
Tabs Visit
11 - 18
11 (SAH)
12 (SAH)
13(SAH)
14 (SAH)
15 (SAH)
16 (SAH)
17 (SAH)
18 (SAH)
Activity List
Scre
Insert
Select
data entry
27
28
29
30
31
32
33
34
OK
Cancel
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Course 1
15
Assess
All patients, all pages
Summary
Discrepancies
Verification
Approval
Audit Trai

Enter an additional patient into the spreadsheet.

Record: 1/1

<OSC>

Choose Patient Position

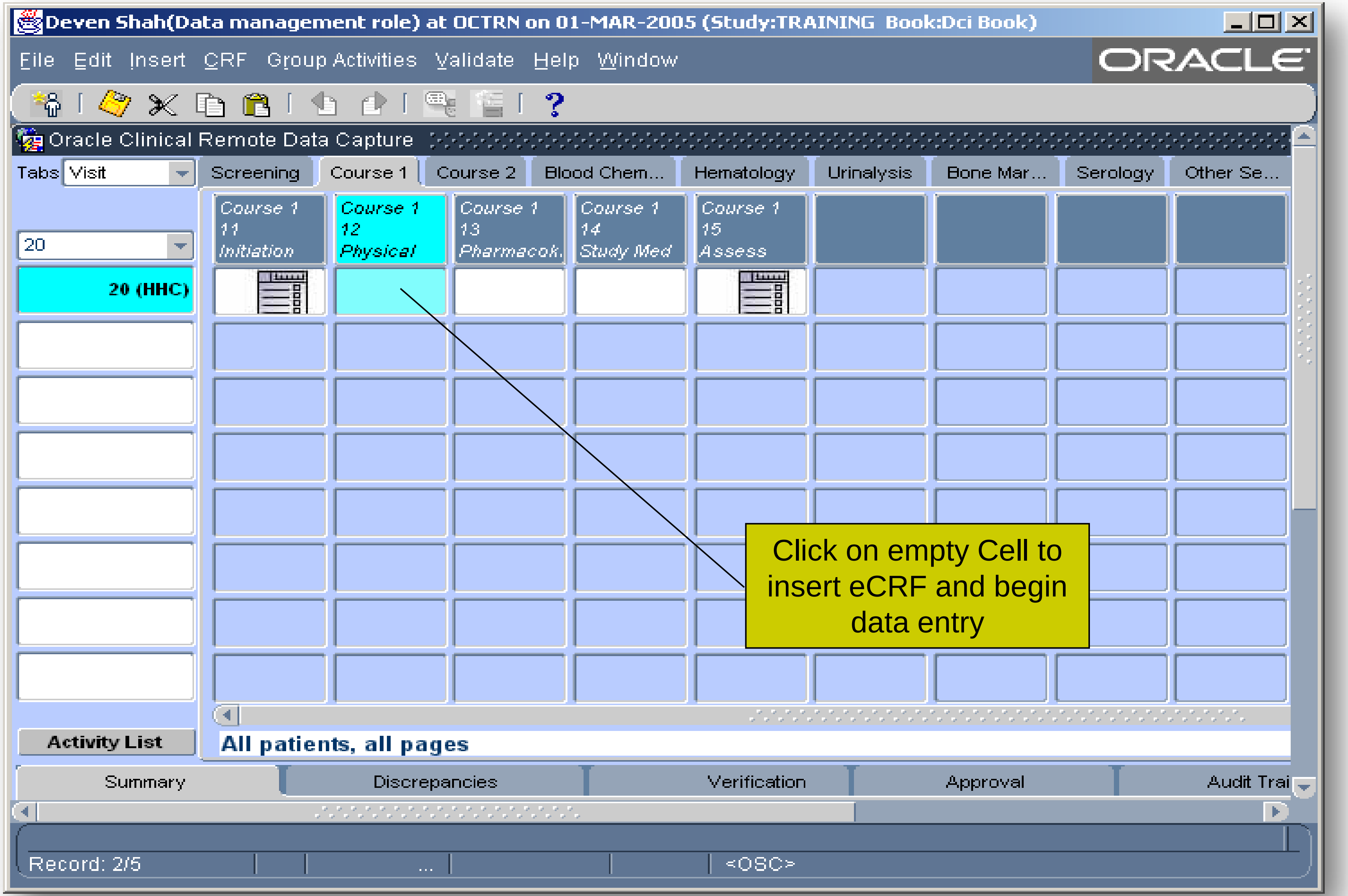
Icon to Insert New Patients

Inserting New Patient

- Click Patient Icon or Select Insert -> Patient from the menu bar
- Choose a Patient Position Number from the pick list
- New Patient Row is Created

- **Quick Tips:**
  - The total number of Patients available for entry are governed by protocol ceiling accrual. Request additional patient numbers if protocol is amended.
  - It is a good practice to use the patient numbers in sync with those assigned by Central Registration Office (CRO)

Starting New Planned eCRF

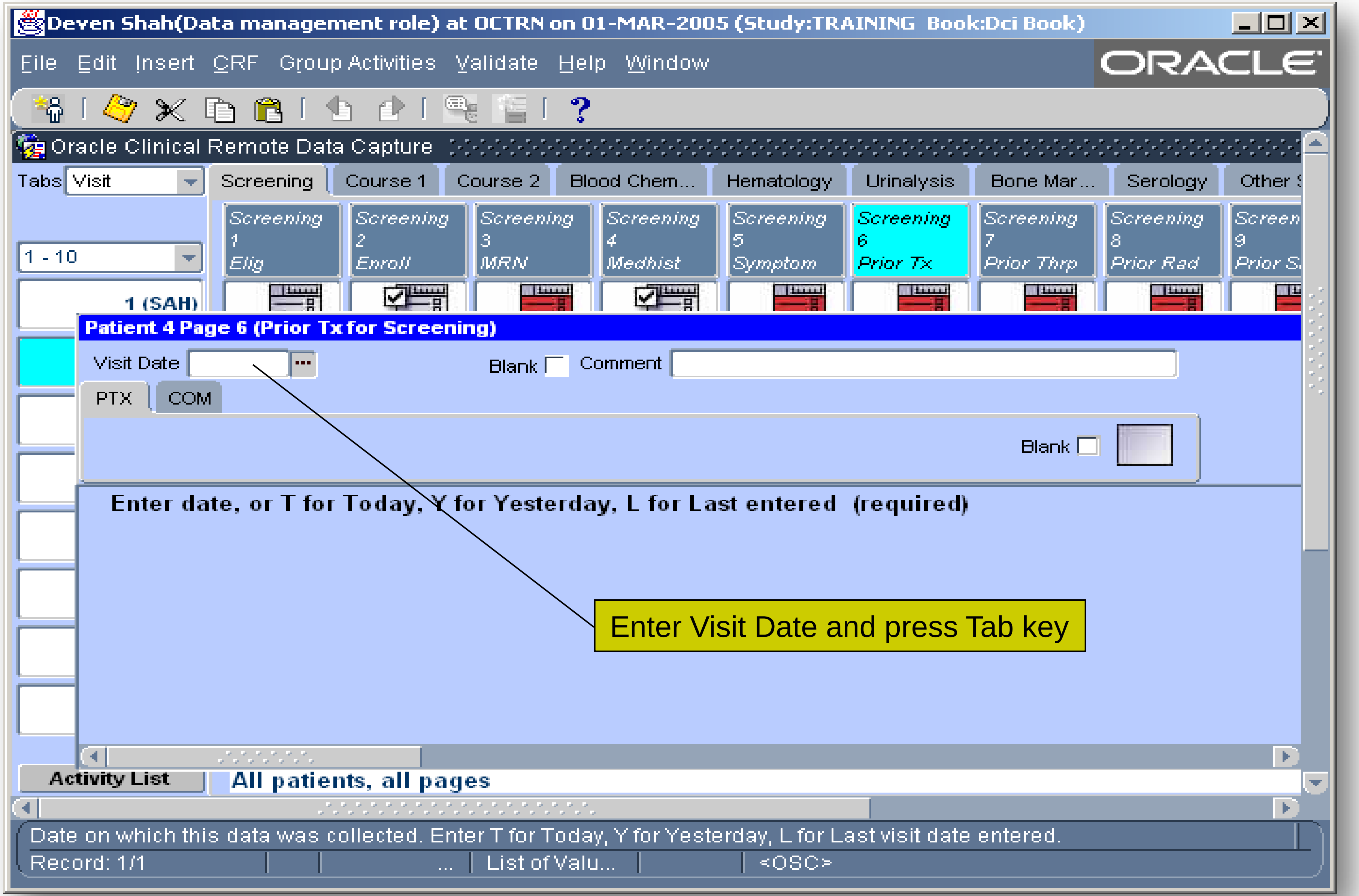

Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Course 1 11 Initiation
Course 1 12 Physical
Course 1 13 Pharmacok.
Course 1 14 Study Med
Course 1 15 Assess
20
20 (HHC)
Activity List
All patients, all pages
Summary
Discrepancies
Verification
Approval
Audit Trai
Record: 2/5
...
<OSC>

Click on empty Cell to insert eCRF and begin data entry

Starting New Planned eCRF

- Click on an empty cell to insert eCRF and begin data entry
- Resize if necessary

Entering Visit Date


Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology Other
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
1 - 10
1 (SAH)
PTX
COM
Activity List

Patient 4 Page 6 (Prior Tx for Screening)

Visit Date ☐ Blank ☐ Comment

Blank ☐

Enter date, or T for Today, Y for Yesterday, L for Last entered (required)

All patients, all pages

Date on which this data was collected. Enter T for Today, Y for Yesterday, L for Last visit date entered.

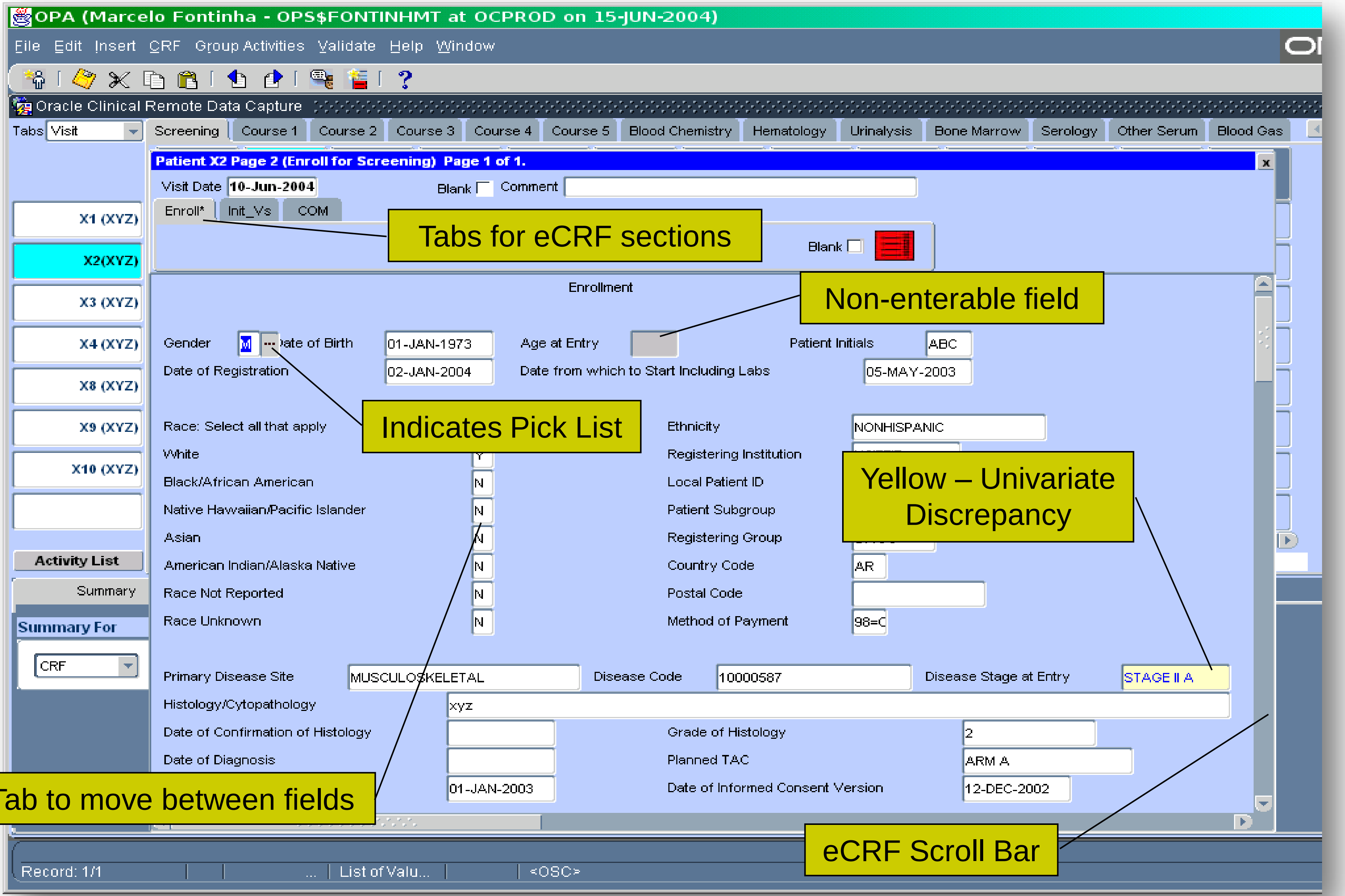
Record: 1/1 ... List of Valu... <OSC>

Enter Visit Date and press Tab key

Entering New eCRF

- Click on the empty Cell to insert appropriate eCRF
- Enter the Visit Date
  - **Visit Date is the Lab Sample Collection Date for Lab eCRFs!**
  - Visit Date is mandatory except for Ongoing Visit eCRFs.
  - Partial dates are not acceptable.
  - Consult eCRFs Instructions Manual for eCRF specific guidance:
    - Usually Evaluation Date, Administration Date, Initiation Date, Lab Date, Course Start Date, etc.

Entering Data in eCRF


OPA (Marcelo Fontinha - OPS$FONTINHMT at OCPROD on 15-JUN-2004)
File Edit Insert CRF Group Activities Validate Help Window
Oracle Clinical Remote Data Capture
Tabs
Visit
Screening
Course 1
Course 2
Course 3
Course 4
Course 5
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
X1 (XYZ)
X2(XYZ)
X3 (XYZ)
X4 (XYZ)
X8 (XYZ)
X9 (XYZ)
X10 (XYZ)
Activity List
Summary
Summary For
CRF
Enroll*
Init_Vs
COM
Blank ☐
Enrollment

Patient X2 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date 10-Jun-2004

Blank ☐ Comment

Gender M

Date of Birth 01-JAN-1973

Age at Entry

Patient Initials ABC

Date of Registration 02-JAN-2004

Date from which to Start Including Labs 05-MAY-2003

Race: Select all that apply

White Y

Black/African American N

Native Hawaiian/Pacific Islander N

Asian N

American Indian/Alaska Native N

Race Not Reported N

Race Unknown N

Ethnicity NONHISPANIC

Registering Institution

Local Patient ID

Patient Subgroup

Registering Group

Country Code AR

Postal Code

Method of Payment 98=C

Primary Disease Site MUSCULOSKELETAL

Disease Code 10000587

Disease Stage at Entry STAGE II A

Histology/Cytopathology xyz

Date of Confirmation of Histology

Grade of Histology 2

Date of Diagnosis

Planned TAC ARM A

01-JAN-2003

Date of Informed Consent Version 12-DEC-2002

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

Tabs for eCRF sections

Non-enterable field

Indicates Pick List

Yellow – Univariate Discrepancy

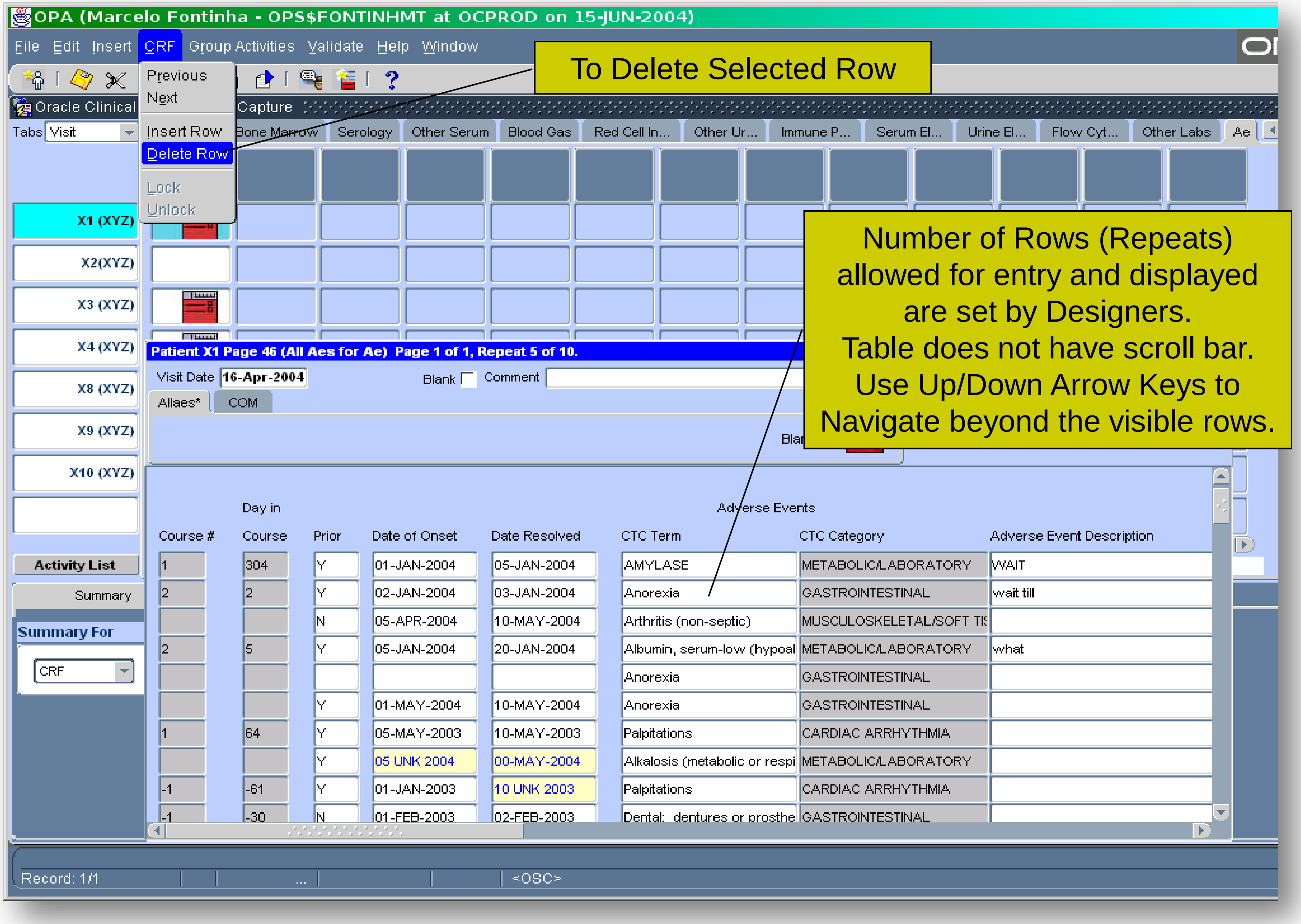
Use Tab to move between fields

eCRF Scroll Bar

Entering Data in eCRF

- Navigating between Fields
  - Use Tab Key to move to Next Field
  - Use Shift Tab to move to Previous Field
  - Use Mouse Click to navigate to a Specific Field
- Fields with Ellipsis indicate a Pick List (Use the Pick List!)
- 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)

Tabular eCRF



OPA (Marcelo Fontinha - OPS$FONTINHMT at OCPROD on 15-JUN-2004)
File Edit Insert CRF Group Activities Validate Help Window
Previous
Next
Insert Row
Delete Row
Lock
Unlock
Oracle Clinical
Capture
Tabs Visit
Bone Marrow
Serology
Other Serum
Blood Gas
Red Cell In...
Other Ur...
Immune P...
Serum El...
Urine El...
Flow Cyt...
Other Labs
Ae
X1 (XYZ)
X2(XYZ)
X3 (XYZ)
X4 (XYZ)
X8 (XYZ)
X9 (XYZ)
X10 (XYZ)
Activity List
Summary
Summary For
CRF
Allaes*
COM
Blank
Record: 1/1
<OSC>

To Delete Selected Row

Number of Rows (Repeats) allowed for entry and displayed are set by Designers.
Table does not have scroll bar.
Use Up/Down Arrow Keys to Navigate beyond the visible rows.

Patient X1 Page 46 (All Aes for Ae) Page 1 of 1, Repeat 5 of 10.

Visit Date 16-Apr-2004 Blank ☐ Comment

Adverse Events

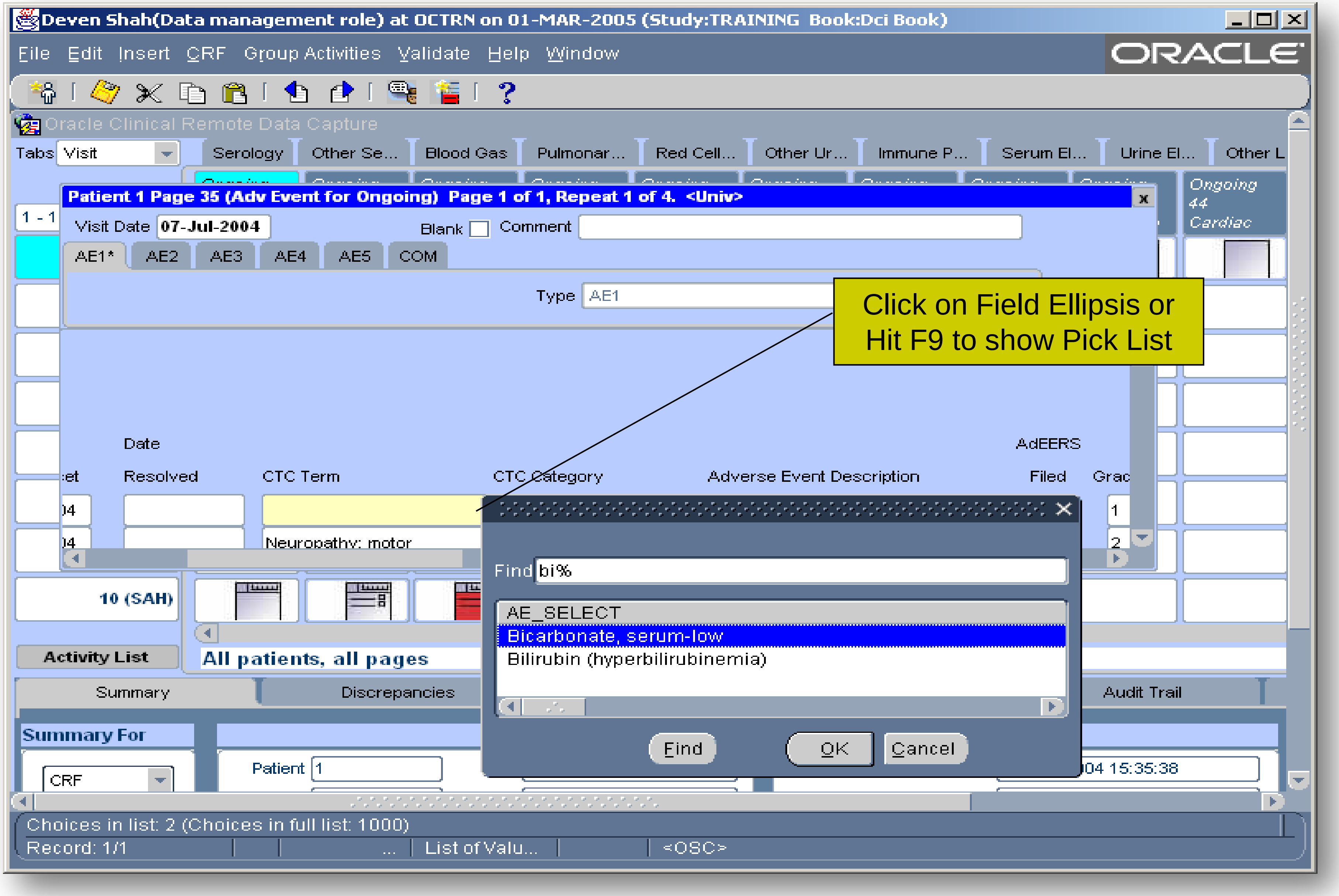
Course #	Day in Course	Prior	Date of Onset	Date Resolved	CTC Term	CTC Category	Adverse Event Description
1	304	Y	01-JAN-2004	05-JAN-2004	AMYLASE	METABOLIC/LABORATORY	WAIT
2	2	Y	02-JAN-2004	03-JAN-2004	Anorexia	GASTROINTESTINAL	wait till
		N	05-APR-2004	10-MAY-2004	Arthritis (non-septic)	MUSCULOSKELETAL/SOFT TI	
2	5	Y	05-JAN-2004	20-JAN-2004	Albumin, serum-low (hypoal	METABOLIC/LABORATORY	what
					Anorexia	GASTROINTESTINAL	
		Y	01-MAY-2004	10-MAY-2004	Anorexia	GASTROINTESTINAL	
1	64	Y	05-MAY-2003	10-MAY-2003	Palpitations	CARDIAC ARRHYTHMIA	
		Y	05 UNK 2004	00-MAY-2004	Alkalosis (metabolic or respi	METABOLIC/LABORATORY	
-1	-61	Y	01-JAN-2003	10 UNK 2003	Palpitations	CARDIAC ARRHYTHMIA	
-1	-30	N	01-FEB-2003	02-FEB-2003	Dental: dentures or prosthe	GASTROINTESTINAL	

Tabular eCRF

- Fields shown in a grid layout
- Scroll up and down the rows of the table using arrow keys (No Scroll Bars!!)

- **Quick Tips:**
  - Use the menu option CRF -> Insert Row to insert a row between two rows (below the currently selected row).
  - **A row cannot be left blank and must be deleted before proceeding to another row**.
    - Select the menu option CRF -> Delete Row.

Using Pick List



Click on Field Ellipsis or Hit F9 to show Pick List

Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)

Patient 1 Page 35 (Adv Event for Ongoing) Page 1 of 1, Repeat 1 of 4. <Univ>

Visit Date 07-Jul-2004

Type AE1

Find bi%

AE_SELECT

Bicarbonate, serum-low

Bilirubin (hyperbilirubinemia)

Choices in list: 2 (Choices in full list: 1000)

Record: 1/1

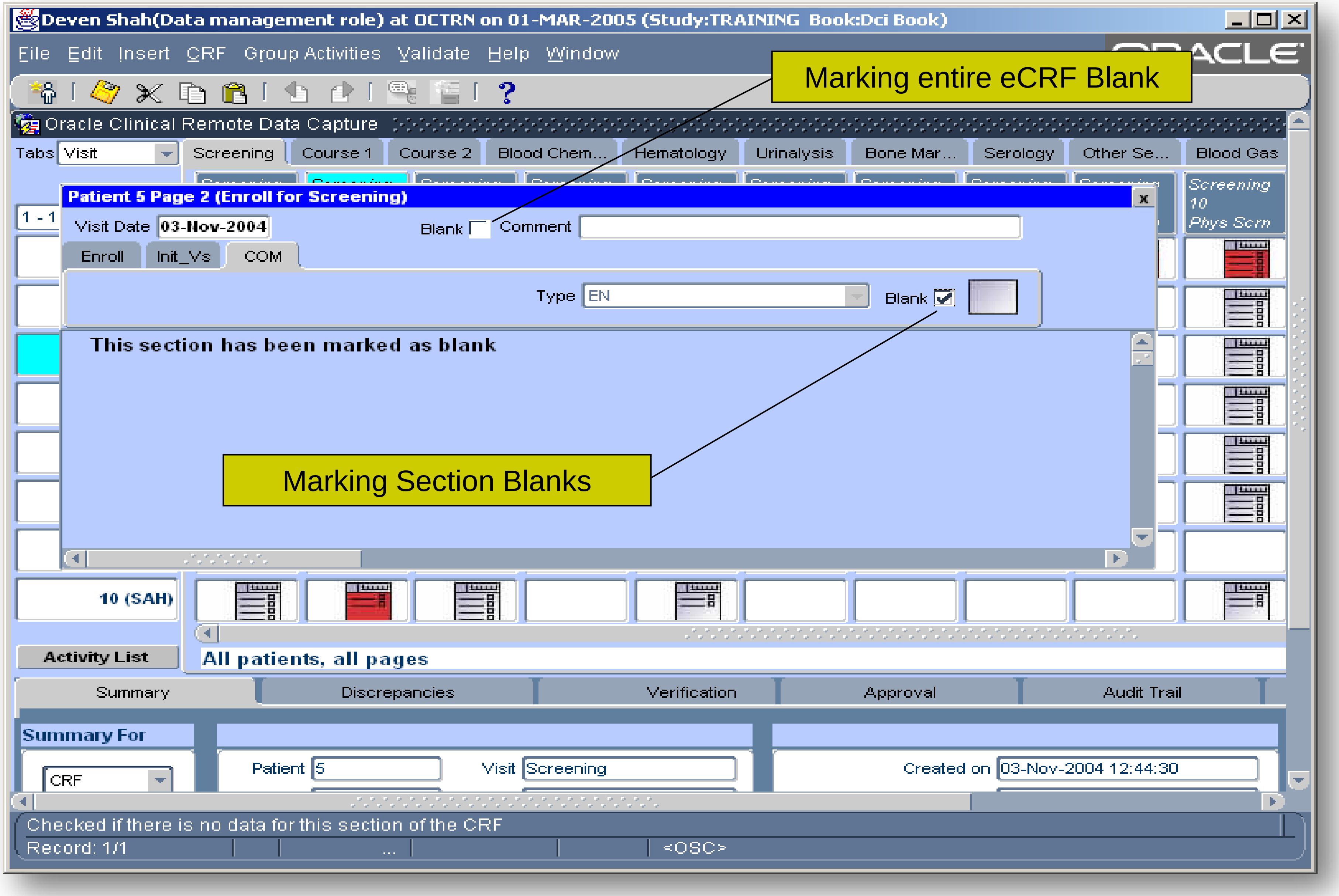
File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs
Visit
Serology
Other Se...
Blood Gas
Pulmonar...
Red Cell...
Other Ur...
Immune P...
Serum El...
Urine El...
Other L
Ongoing
44
Cardiac
1 - 1
Blank ☐
Comment
AE1*
AE2
AE3
AE4
AE5
COM
Date
Resolved
CTC Term
CTC Category
Adverse Event Description
AdEERS
Filed
Grad
Neuropathy: motor
10 (SAH)
Activity List
All patients, all pages
Summary
Discrepancies
Audit Trail
Summary For
CRF
Patient 1
04 15:35:38
Find
OK
Cancel
List of Valu...
<OSC>

Using Pick List

- Fields with Ellipsis contain a Pick List
- Pick List can be accessed by clicking the Ellipsis or pressing the F9 Key
- Searching the Pick List:
    - Start typing in some letter and the list is filtered as you type or;
    - Click on the Find box, enter a some letters surrounded by the wildcard % character (ex: %ypo%) and click on the Find button. Select one of the values.
    - **If the Pick List has more than 1,000 items, items beyond 1,000 cannot be searched after the Pick List is shown.** Close the Pick List and use the wildcard find shown above then press the F9 key or click on the ellipsis. This way the entire list will be searched and matched items shown. The following Pick Lists have more than 1,000 items:
        - CTCAE Term (version 3.0) pick list on the Adverse Events and Baseline Symptoms;
        - Agents in the Concomitant Measures and Medications;
        - Enrollment eCRF Disease Term (only when using comprehensive CTEP list of Diseases);
        - Enrollment eCRF Registering Institute;
        - Course Initiation eCRF Treating Institute.

- **Quick Tips:**
    - If a value is not in the pick list enter it, consult your DM Supervisor. Entering a value that is not on the pick list will create a discrepancy.

Marking eCRF Blank



Marking entire eCRF Blank

Marking Section Blanks

Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)

Oracle Clinical Remote Data Capture

Patient 5 Page 2 (Enroll for Screening)

Visit Date 03-Nov-2004

Blank ☐ Comment

Type EN

Blank ☑

This section has been marked as blank

10 (SAH)

All patients, all pages

Summary For CRF

Patient 5

Visit Screening

Created on 03-Nov-2004 12:44:30

Checked if there is no data for this section of the CRF

Record: 1/1

<OSC>

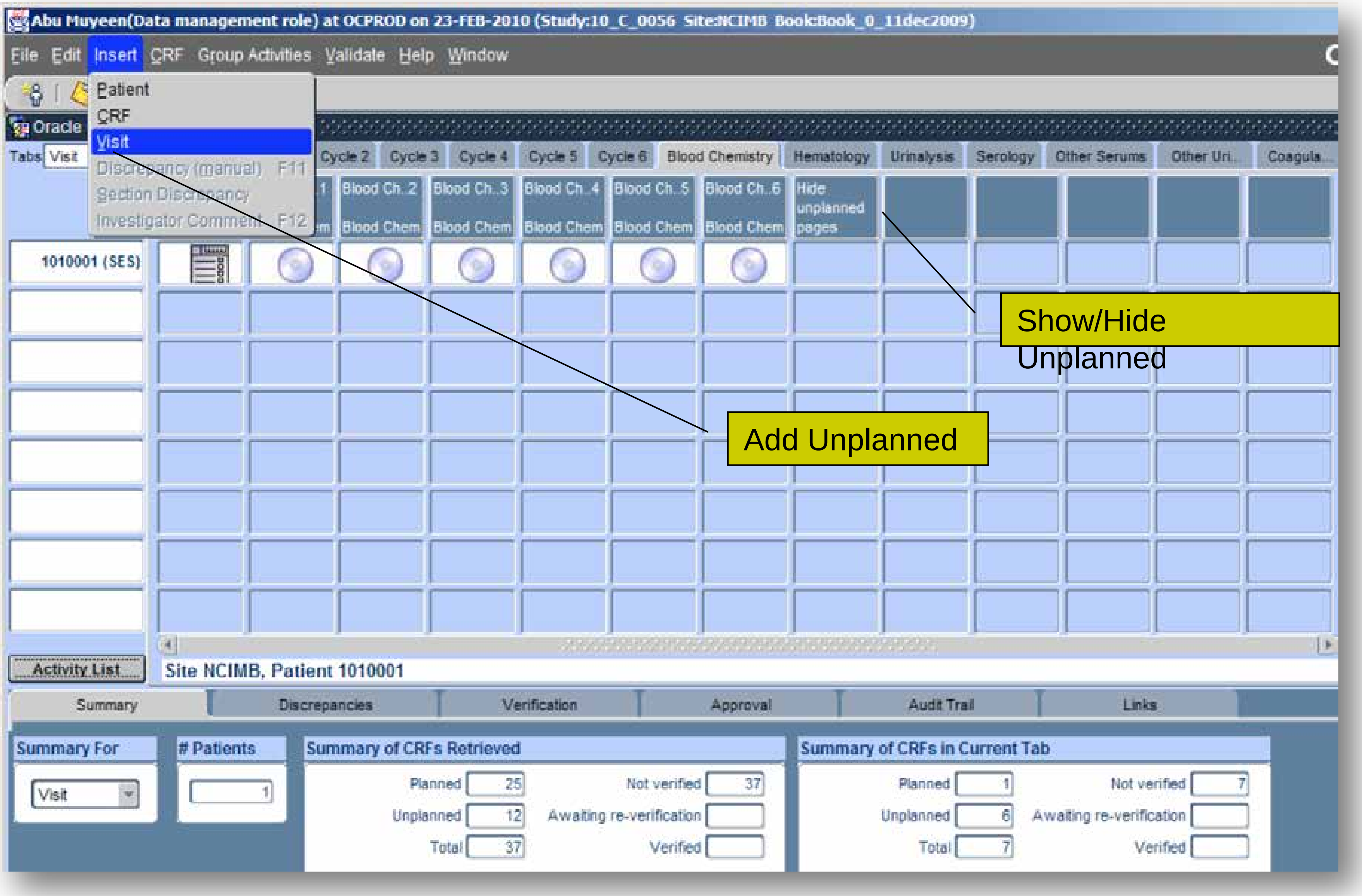
File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Tabs
Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Blood Gas
Screening 10 Phys Scrn
1 - 1
Enroll
Init_Vs
COM
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trail

Marking eCRF Blank

- Entire eCRF can be marked Blank
- Individual Sections of an eCRF can be marked Blank
- Checking Blank Flag will erase any entered information from the eCRF/Section
- Blank Flag can be unchecked to enter information

- **Quick Tip:**
  - It is a good practice to mark Sections that will not have data entered as Blank.
  - Once all sections of a CRF are ‘addressed’ (by entering data or marking it as blank) the overall status of the eCRF becomes Entry Complete.

Entering/Viewing Laboratory Data



Abu Muyeen(Data management role) at OCPROD on 23-FEB-2010 (Study:10_C_0056 Site:NCIMB Book:Book_0_11dec2009)

File Edit Insert CRF Group Activities Validate Help Window
Patient
CRF
Visit
Discrepancy (manual) F11
Section Discrepancy
Investigator Comment F12
Oracle
Tabs Visit
Cycle 2
Cycle 3
Cycle 4
Cycle 5
Cycle 6
Blood Chemistry
Hematology
Urinalysis
Serology
Other Serums
Other Uri..
Coagula..
Blood Ch..2
Blood Ch..3
Blood Ch..4
Blood Ch..5
Blood Ch..6
Blood Chem
Hide unplanned pages
1010001 (SES)
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

Site NCIMB, Patient 1010001

Summary For: Visit

Patients: 1

Summary of CRFs Retrieved

Planned 25
Unplanned 12
Total 37
Not verified 37
Awaiting re-verification
Verified

Summary of CRFs in Current Tab

Planned 1
Unplanned 6
Total 7
Not verified 7
Awaiting re-verification
Verified

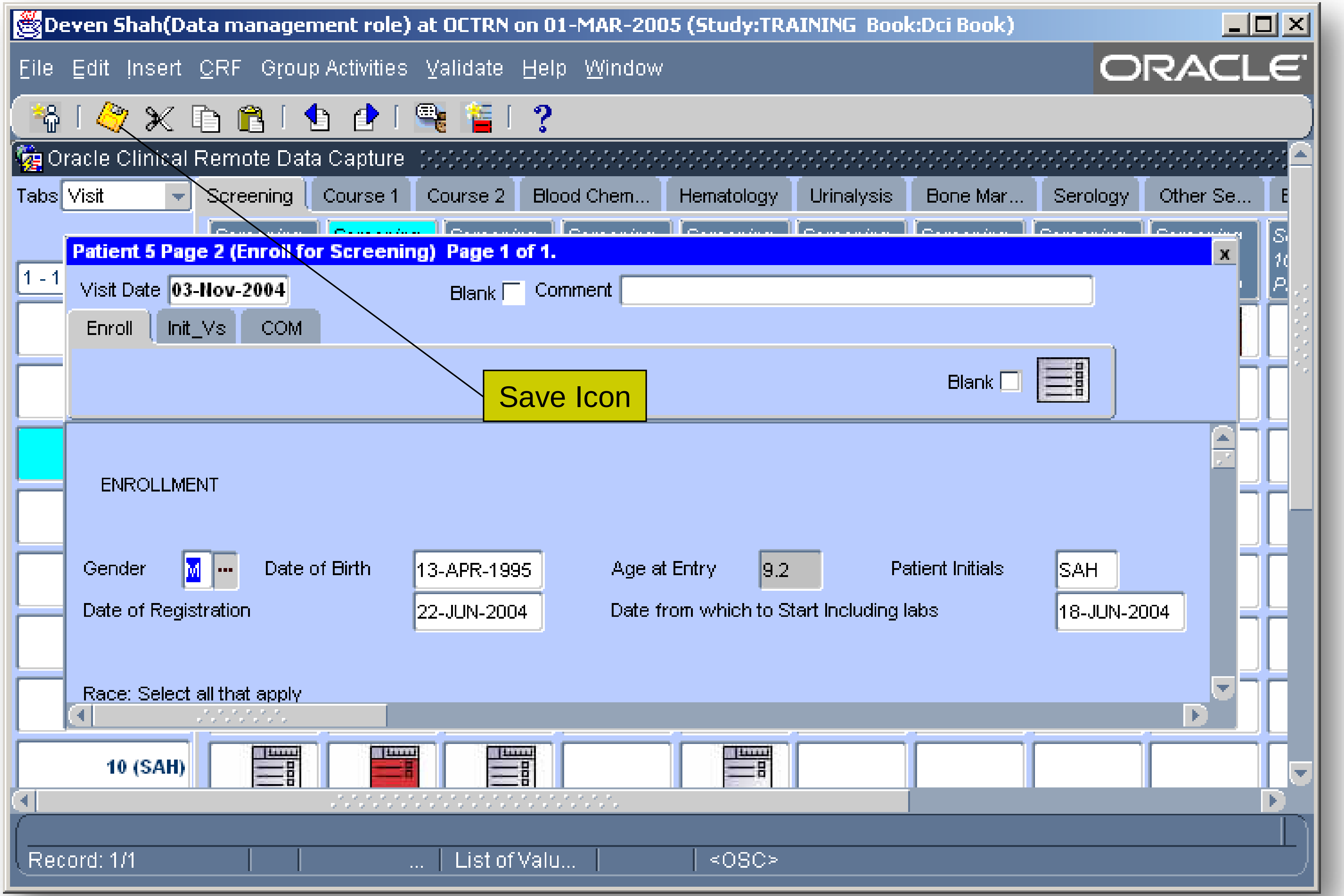
Show/Hide Unplanned

Add Unplanned

Entering/Viewing Laboratory Data

- Laboratory Data eCRFs are designed with dedicated Tabs (Hematology, Blood Chemistry, Urinalysis, etc.)
- Additional Lab eCRFs can be viewed by clicking Show Unplanned Events
- Additional Lab eCRFs can be added by:
  - Select the appropriate Lab Visit;
  - Open the patient’s last Lab eCRF on the selected visit;
  - Then select the menu option Insert -> Visit
    - **Do not select Insert -> CRF**

Saving eCRF


File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Enroll
Init_Vs
COM
10 (SAH)

Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)

Patient 5 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date 03-Nov-2004

Blank ☐ Comment

Blank ☐

ENROLLMENT

Gender M

Date of Birth 13-APR-1995

Age at Entry 9.2

Patient Initials SAH

Date of Registration 22-JUN-2004

Date from which to Start Including labs 18-JUN-2004

Race: Select all that apply

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

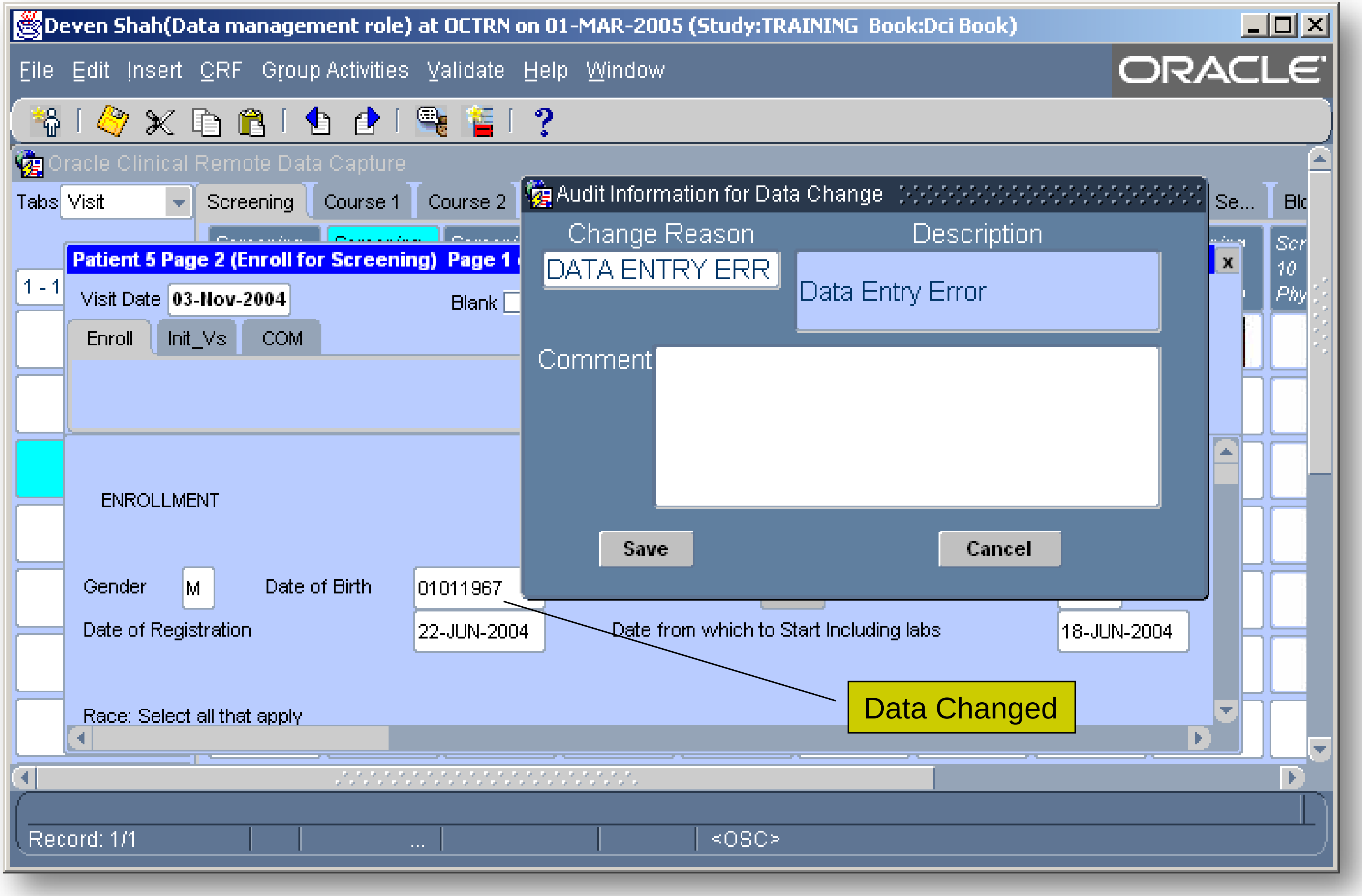
Save Icon

Saving eCRF

- eCRF can be saved using
  - Toolbar Save Icon (yellow floppy disk)
  - F10 Key
  - File -> Save menu option

- **Quick Tip:**
  - Save Often!! Especially while entering Ongoing Information such as AEs and ConMeds.
  - C^{3}D session terminates without warning if there is no activity for 30 minutes.

Data Entry Change Reason


Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)
File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs
Screening
Course 1
Course 2
Se...
Blc
Scr
10
Phy
1 - 1
Patient 5 Page 2 (Enroll for Screening) Page 1
Blank
Enroll
Init_Vs
COM
ENROLLMENT
Race: Select all that apply
Audit Information for Data Change
Comment
Save
Cancel
Record: 1/1
...
<OSC>

Tabs: Visit

Visit Date: 03-Nov-2004

Gender: M

Date of Birth: 01011967

Date of Registration: 22-JUN-2004

Date from which to Start Including labs: 18-JUN-2004

Change Reason	Description
DATA ENTRY ERR	Data Entry Error

Data Changed

Data Entry Change Reason

- Change Reason needs to be specified while changing data on completed eCRF
- Change Reason becomes part of the Audit Trail along with date of change and user name
- Comments can be provided in the change reason to further explain

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

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.

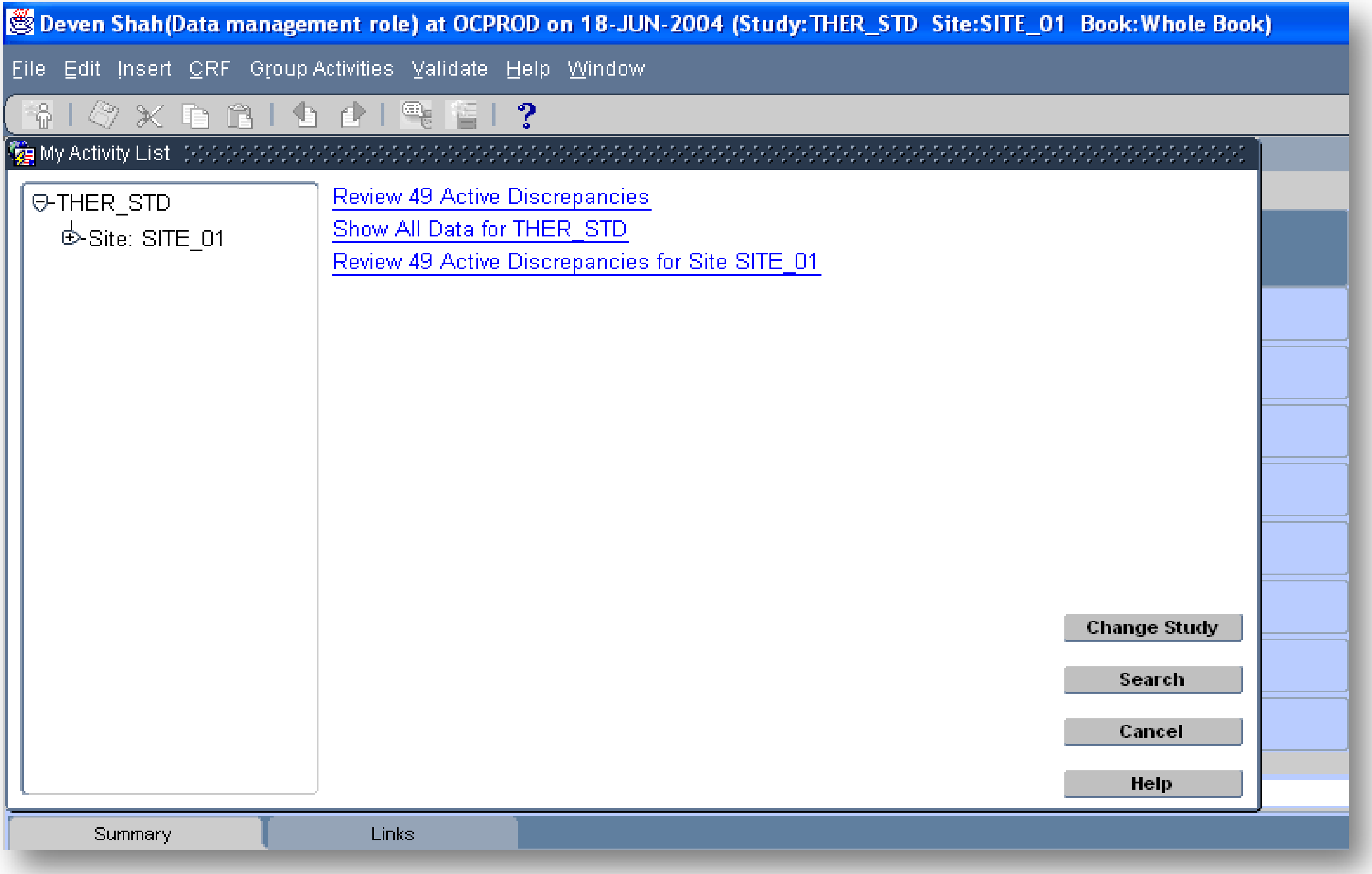
C^{3}D Discrepancy Types

- 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



Deven Shah(Data management role) at OCPROD on 18-JUN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

File Edit Insert CRF Group Activities Validate Help Window
My Activity List
THER_STD
Site: SITE_01

Review 49 Active Discrepancies

Show All Data for THER_STD

Review 49 Active Discrepancies for Site SITE_01

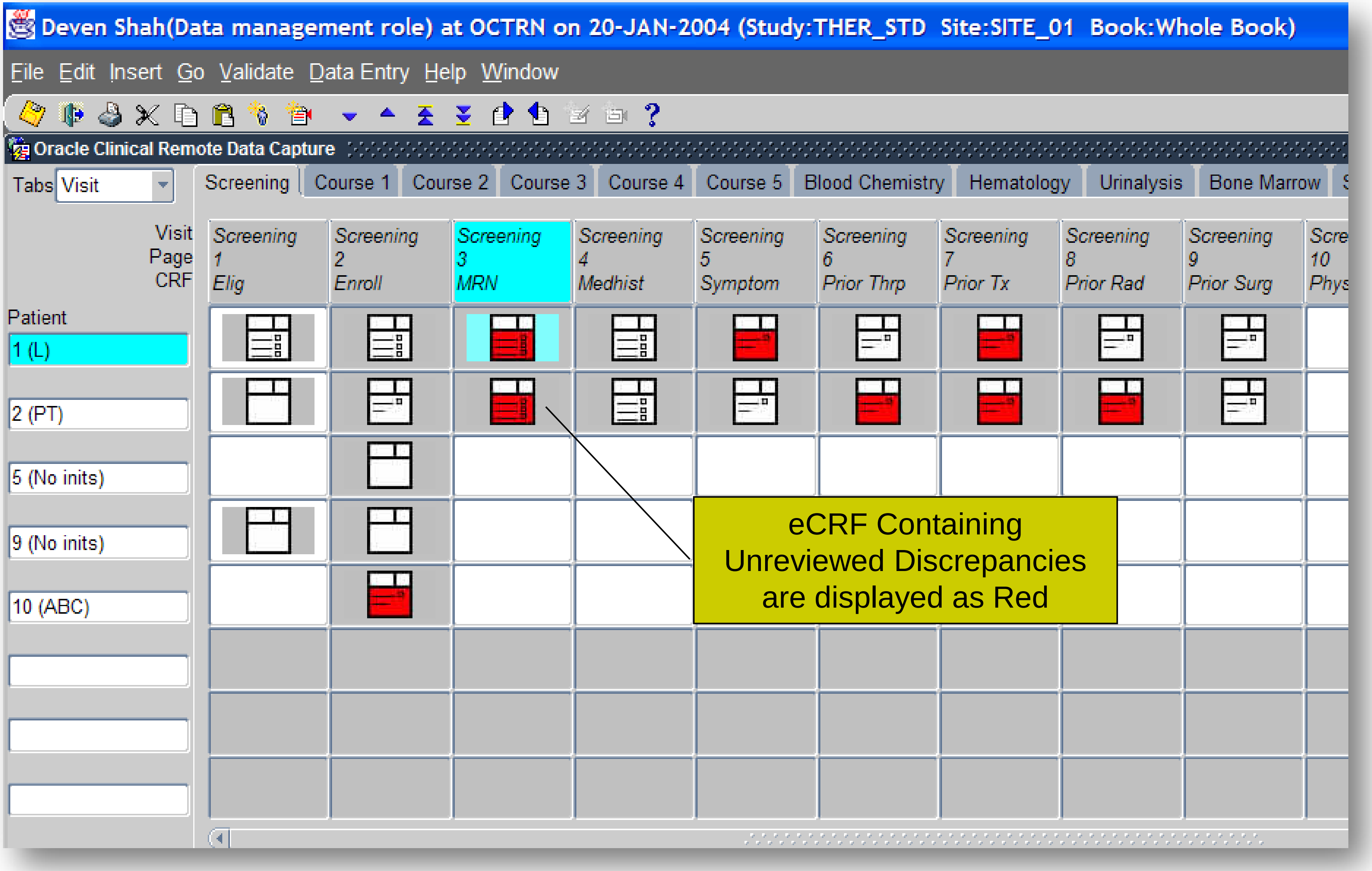
Change Study
Search
Cancel
Help
Summary
Links

Outstanding Discrepancies in a Study

- Total number of Discrepancies in a study are shown in the Activity List
- Clicking on the ‘Review xx Active Discrepancies’ link will present only the Discrepant eCRFs

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

eCRFs Containing Discrepancies



Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

File Edit Insert Go Validate Data Entry Help Window
?
Oracle Clinical Remote Data Capture
Screening
Course 1
Course 2
Course 3
Course 4
Course 5
Blood Chemistry
Hematology
Urinalysis
Bone Marrow

Tabs: Visit

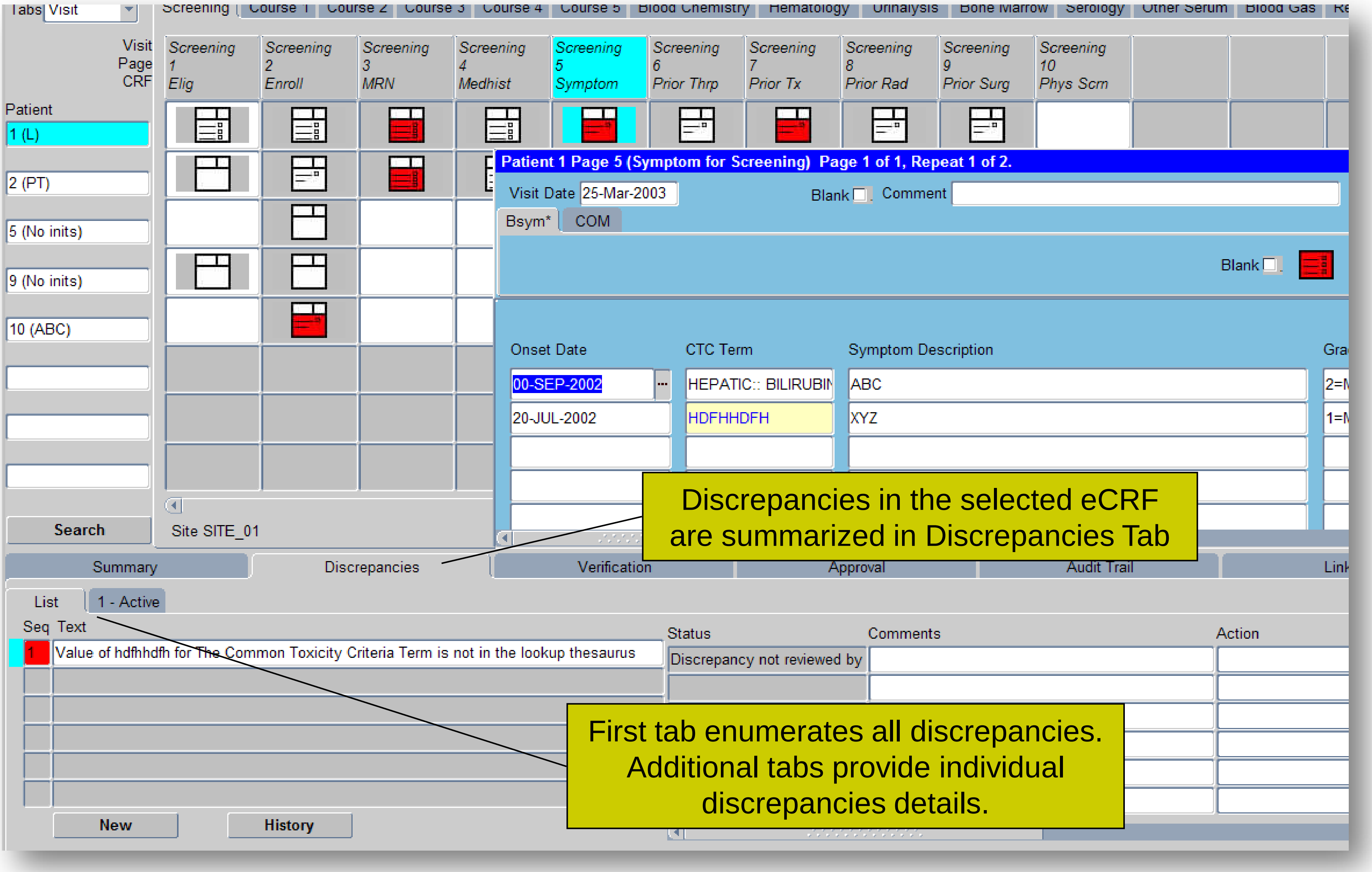
Visit Page CRF	Screening 1 Elig	Screening 2 Enroll	Screening 3 MRN	Screening 4 Medhist	Screening 5 Symptom	Screening 6 Prior Thrp	Screening 7 Prior Tx	Screening 8 Prior Rad	Screening 9 Prior Surg	Scre 10 Phys
Patient										
1 (L)	☐	☐	🟥	☐	🟥	☐	🟥	☐	☐	
2 (PT)	☐	☐	🟥	☐	☐	🟥	🟥	🟥	☐	
5 (No inits)		☐								
9 (No inits)	☐	☐								
10 (ABC)		🟥								

eCRF Containing Unreviewed Discrepancies are displayed as Red

eCRF Containing Discrepancies

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

Discrepancies Tab


Tabs
Visit
Screening
Course 1
Course 2
Course 3
Course 4
Course 5
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
Visit
Page
CRF
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Thrp
Screening 7 Prior Tx
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
Patient
1 (L)
2 (PT)
5 (No inits)
9 (No inits)
10 (ABC)
Search
Site SITE_01
Bsym*
COM
Summary
Discrepancies
Verification
Approval
Audit Trail
Link
List
1 - Active
New
History

Patient 1 Page 5 (Symptom for Screening) Page 1 of 1, Repeat 1 of 2.

Visit Date 25-Mar-2003 Blank ☐ Comment

Blank ☐

Onset Date	CTC Term	Symptom Description	Gra
00-SEP-2002	HEPATIC:: BILIRUBIN	ABC	2=M
20-JUL-2002	HDFHHDFH	XYZ	1=M

Seq	Text	Status	Comments	Action
1	Value of hdfhhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus	Discrepancy not reviewed by		

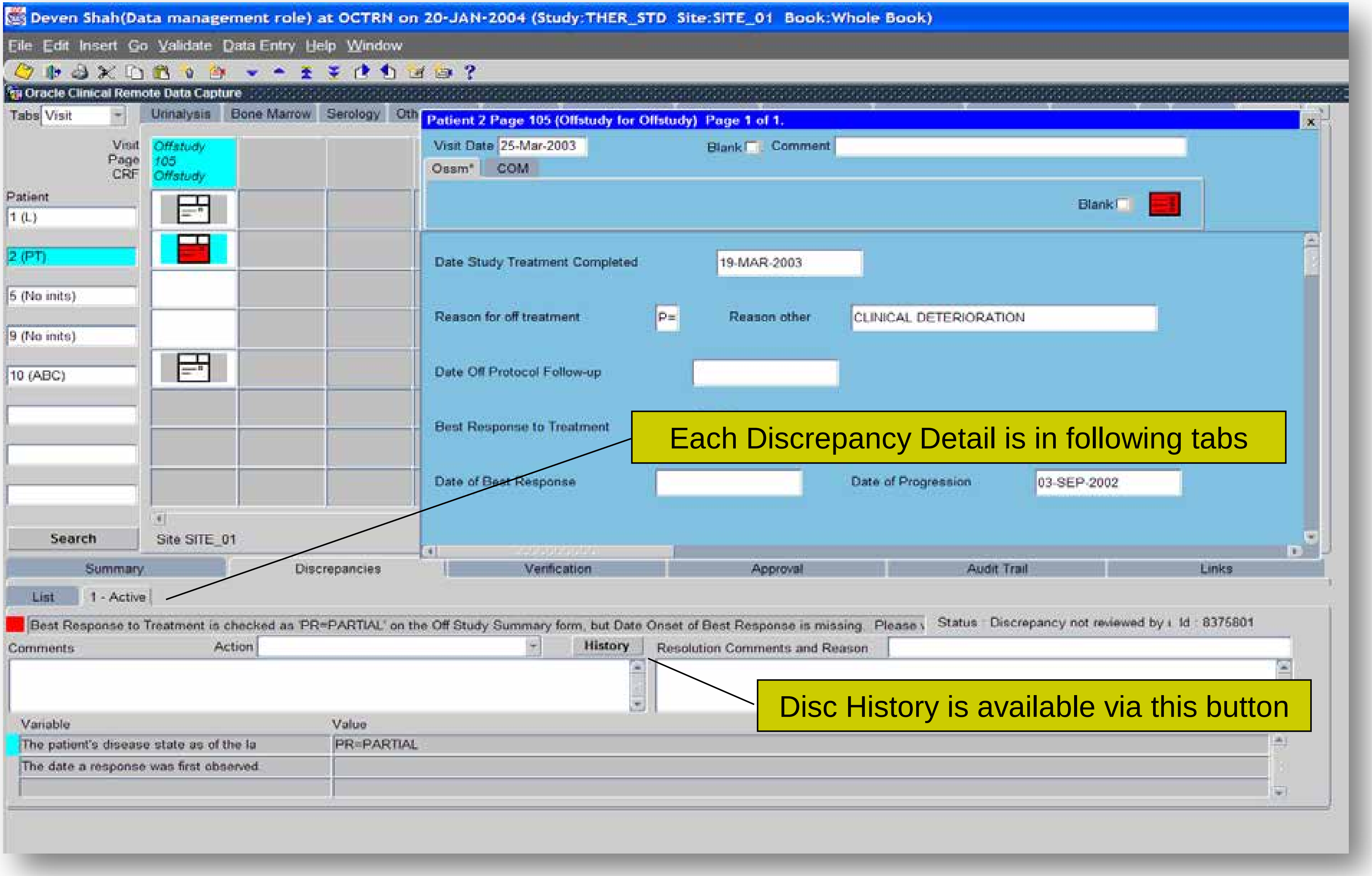
Discrepancies in the selected eCRF are summarized in Discrepancies Tab

First tab enumerates all discrepancies. Additional tabs provide individual discrepancies details.

Discrepancies Tab

- While viewing an eCRF, clicking on the Discrepancies Tab shows the discrepancies on that eCRF
- The first tab gives the summary of all discrepancies in that eCRF (open and closed)
- Additional tabs provide individual discrepancies details.

Discrepancy Details



Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

Patient 2 Page 105 (Offstudy for Offstudy) Page 1 of 1.

Visit Date 25-Mar-2003

Date Study Treatment Completed 19-MAR-2003

Reason for off treatment P=

Reason other CLINICAL DETERIORATION

Date of Progression 03-SEP-2002

Site SITE_01

Best Response to Treatment is checked as 'PR=PARTIAL' on the Off Study Summary form, but Date Onset of Best Response is missing. Please

Status Discrepancy not reviewed by

Id 8375801

Variable	Value
The patient's disease state as of the la	PR=PARTIAL
The date a response was first observed	

Each Discrepancy Detail is in following tabs

Disc History is available via this button

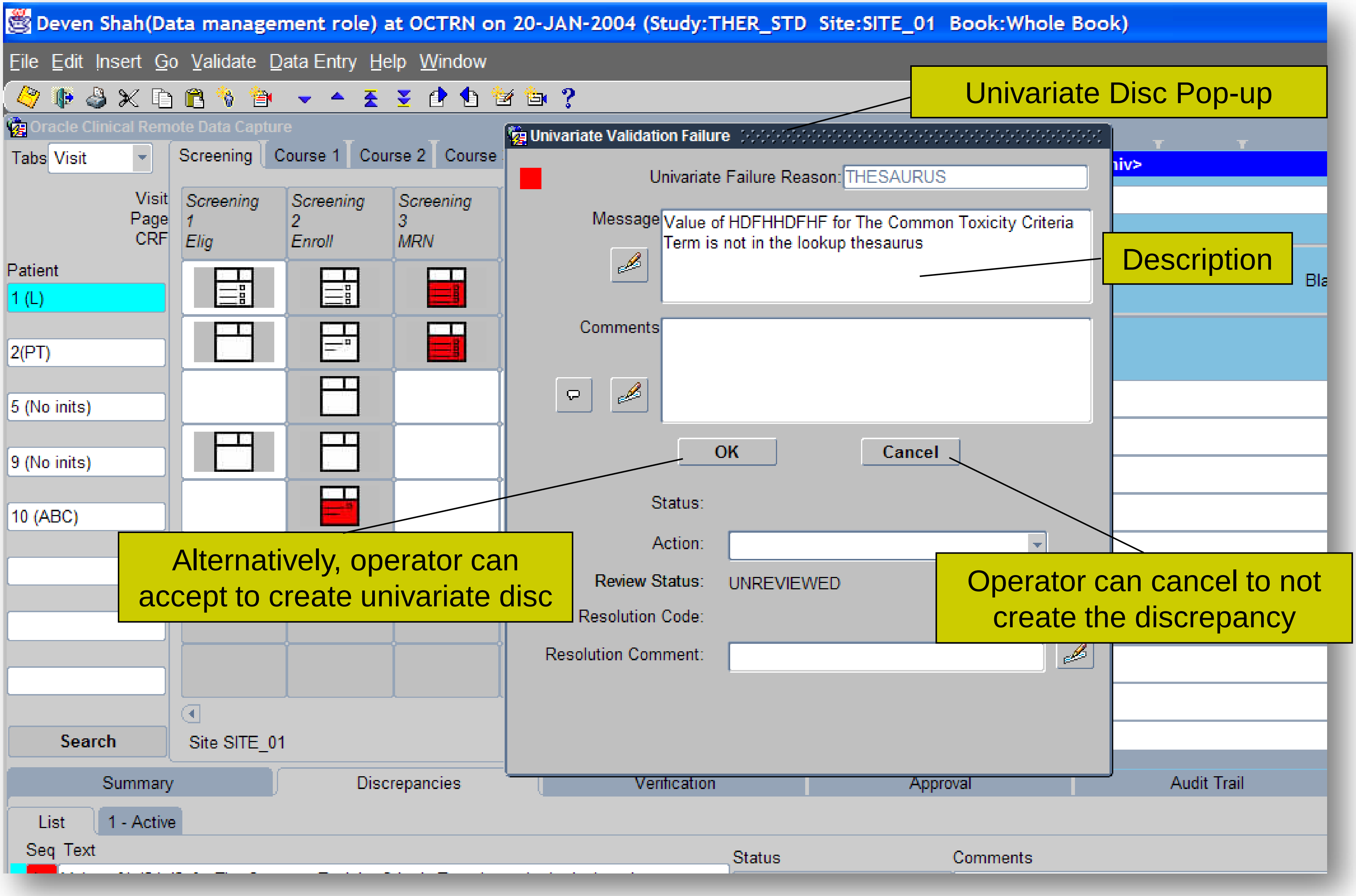
File Edit Insert Go Validate Data Entry Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Urinalysis
Bone Marrow
Serology
Visit
Page
CRF
Offstudy
105
Offstudy
Patient
1 (L)
2 (PT)
5 (No inits)
9 (No inits)
10 (ABC)
Search
Blank
Comment
Ossm*
COM
Date Off Protocol Follow-up
Best Response to Treatment
Date of Best Response
Summary
Discrepancies
Verification
Approval
Audit Trail
Links
List
1 - Active
Comments
Action
History
Resolution Comments and Reason

Discrepancy Details

- Subsequent tabs show details for each discrepancy
- Open Discrepancies are displayed first and are followed by Closed Discrepancies

- **Quick Tip:**
  - Double Clicking on the Discrepancy Text brings up a pop-up box with the entire message

How are Univariate Disc. Created?



Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

File Edit Insert Go Validate Data Entry Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Course
Visit
Page
CRF
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Patient
1 (L)
2(PT)
5 (No inits)
9 (No inits)
10 (ABC)
Search
Site SITE_01
Summary
Discrepancies
Verification
Approval
Audit Trail
List
1 - Active
Seq Text
Status
Comments
OK
Cancel

Univariate Validation Failure

Univariate Failure Reason: THESAURUS

Message: Value of HDFHHDFHF for The Common Toxicity Criteria Term is not in the lookup thesaurus

Comments:

Status:

Action:

Review Status: UNREVIEWED

Resolution Code:

Resolution Comment:

Univariate Disc Pop-up

Description

Alternatively, operator can accept to create univariate disc

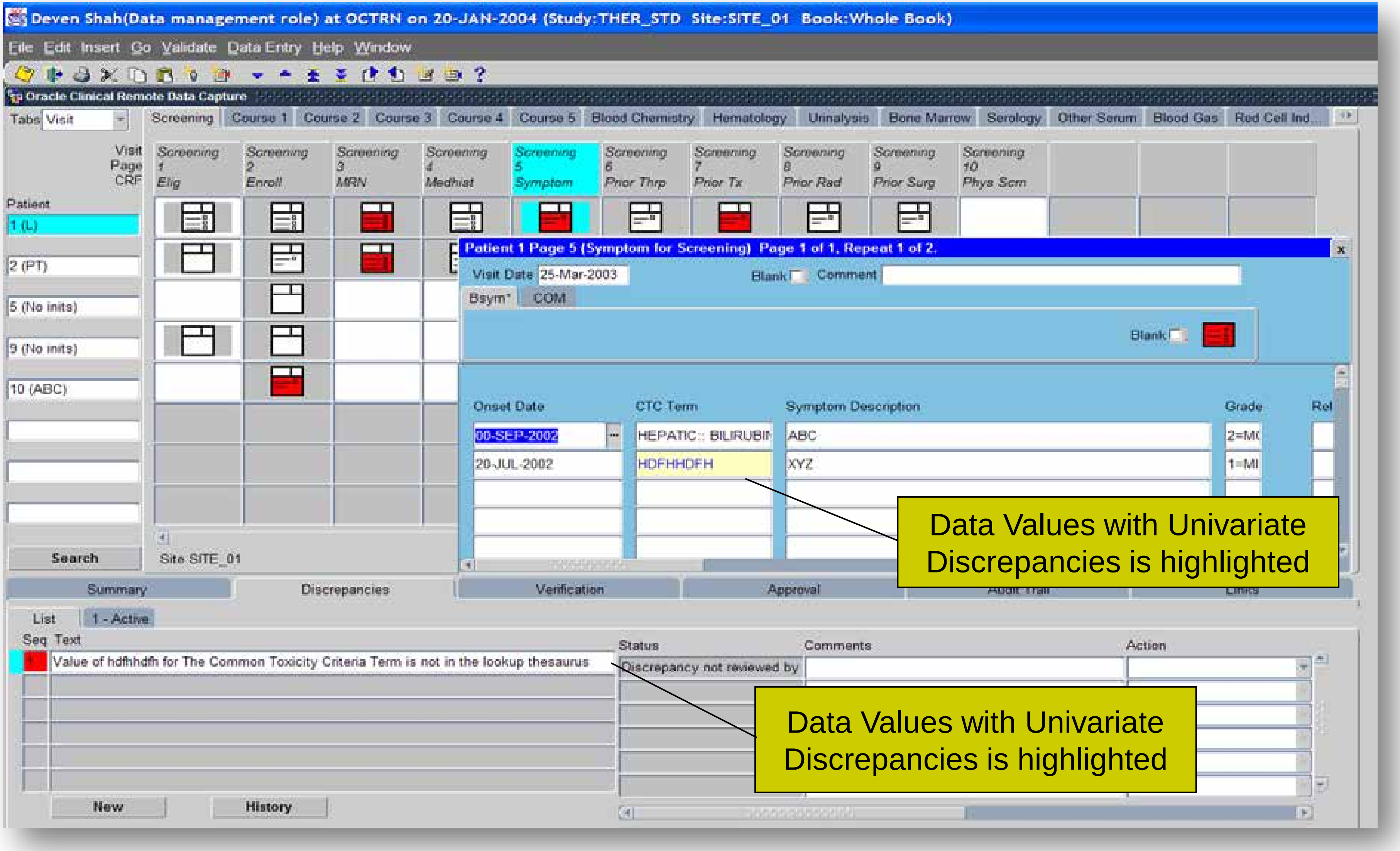
Operator can cancel to not create the discrepancy

How are Univariate Disc. Created?

- Univariate Discrepancies pop-up is presented during data entry when the entered value does not match the field definition.
  - 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 is a Univariate Disc. Displayed?



Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

File Edit Insert Go Validate Data Entry Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Screening Course 1 Course 2 Course 3 Course 4 Course 5 Blood Chemistry Hematology Urinalysis Bone Marrow Serology Other Serum Blood Gas Red Cell Ind...
Visit Page CRF
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Thrp
Screening 7 Prior Tx
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
Patient
1 (L)
2 (PT)
5 (No inits)
9 (No inits)
10 (ABC)
Search
Site SITE_01
Summary
Discrepancies
Verification
Approval
Audit Trail
Links
List
1 - Active
New
History

Patient 1 Page 5 (Symptom for Screening) Page 1 of 1, Repeat 1 of 2.

Visit Date 25-Mar-2003 Blank ☐ Comment

Bsym* COM

Blank ☐

Onset Date	CTC Term	Symptom Description	Grade	Rel
00-SEP-2002	HEPATIC:: BILIRUBIN	ABC	2=MO	
20-JUL-2002	HDFHHDFH	XYZ	1=MI	

Seq	Text	Status	Comments	Action
🟥	Value of hdfhhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus	Discrepancy not reviewed by		

Data Values with Univariate Discrepancies is highlighted

Data Values with Univariate Discrepancies is highlighted

How is a Univariate Disc. Displayed?

- Discrepant data is highlighted in Yellow
- Discrepancy text provides the details

- **Quick Tip:**
    - Double Click on the Discrepancy Message Text to view the entire message in a window.

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.

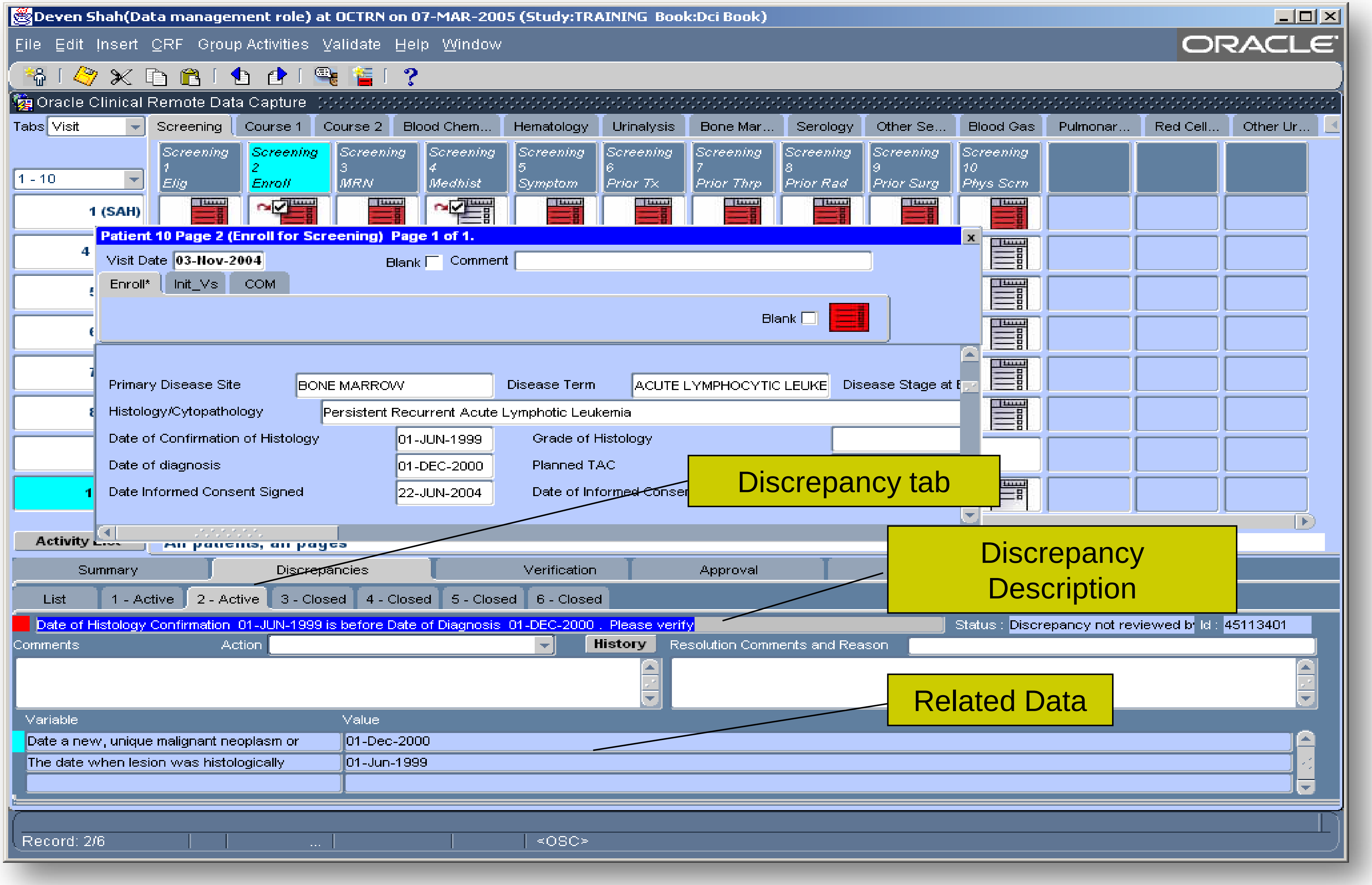
Evaluation of Multivariate Rules

- 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 is a Multivariate Disc. displayed?


Deven Shah(Data management role) at OCTRN on 07-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology Other Se... Blood Gas Pulmonar... Red Cell... Other Ur...
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
1 - 10
1 (SAH)
Enroll* Init_Vs COM
Activity List
All patients, all pages
Summary Discrepancies Verification Approval
List 1 - Active 2 - Active 3 - Closed 4 - Closed 5 - Closed 6 - Closed
History
Record: 2/6 <OSC>

Patient 10 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date: 03-Nov-2004 Blank ☐ Comment:

Blank ☐

Primary Disease Site	BONE MARROW	Disease Term	ACUTE LYMPHOCYTIC LEUKE
Histology/Cytopathology	Persistent Recurrent Acute Lymphotic Leukemia		
Date of Confirmation of Histology	01-JUN-1999	Grade of Histology	
Date of diagnosis	01-DEC-2000	Planned TAC	
Date Informed Consent Signed	22-JUN-2004	Date of Informed Consen	

Disease Stage at E

Date of Histology Confirmation 01-JUN-1999 is before Date of Diagnosis 01-DEC-2000 . Please verify

Status : Discrepancy not reviewed b Id : 45113401

Comments Action: Resolution Comments and Reason:

Variable	Value
Date a new, unique malignant neoplasm or	01-Dec-2000
The date when lesion was histologically	01-Jun-1999

Discrepancy tab

Discrepancy Description

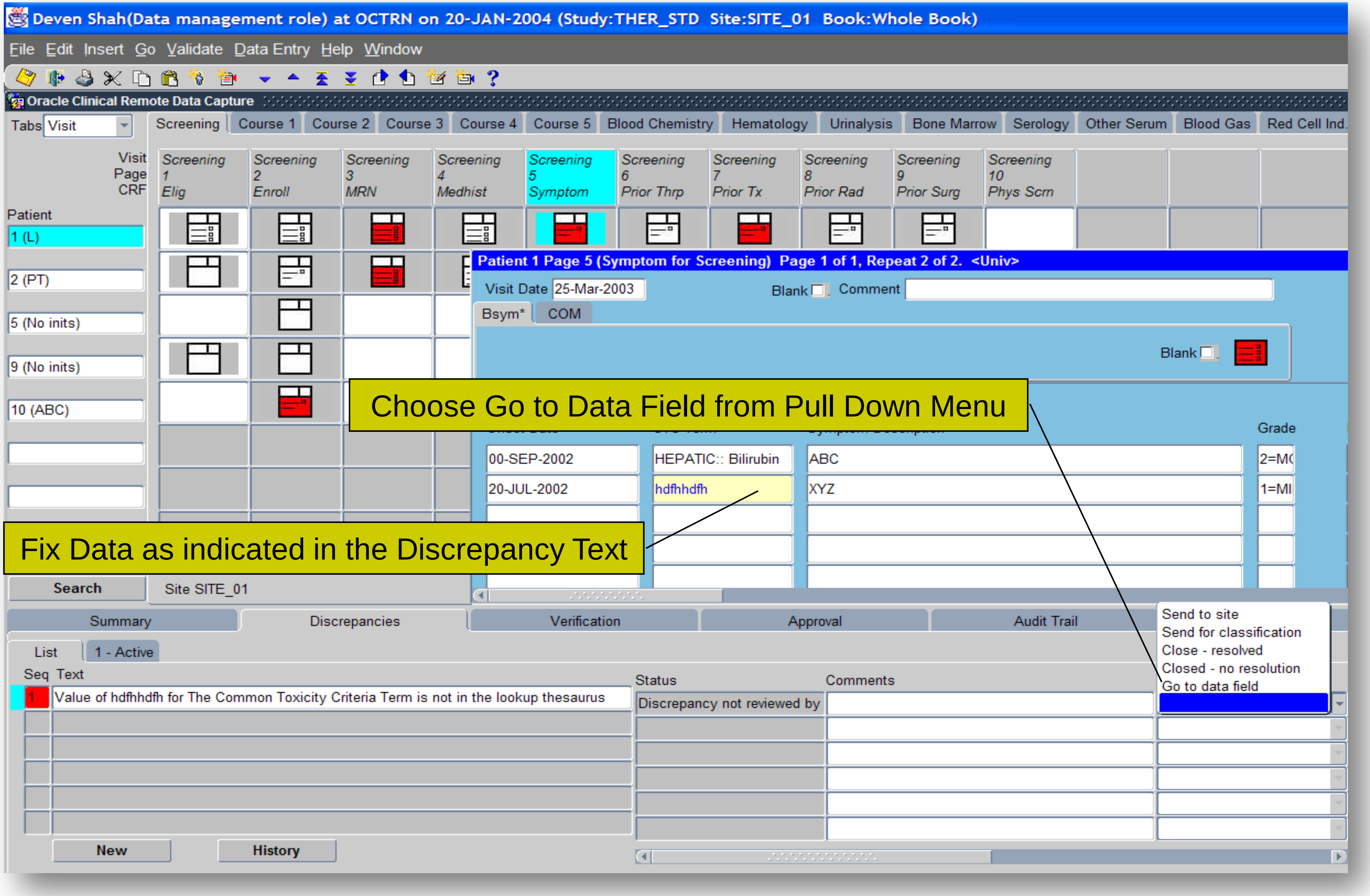
Related Data

How is a Multivariate Disc. displayed?

- Discrepancy is based on one or more fields and is NOT highlighted in Yellow
- Discrepancy tab provides the details
  - Discrepancy Text
  - Involved Clinical Data in the evaluation of the Discrepancy

- **Quick Tip:**
  - The Action pull-down “Go to Data Field” does not work as the discrepancy could be based on more than one field.

How to Address a Discrepancy



Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)

Patient 1 Page 5 (Symptom for Screening) Page 1 of 1, Repeat 2 of 2. <Univ>

Visit Date 25-Mar-2003

00-SEP-2002	HEPATIC:: Bilirubin	ABC	2=MC
20-JUL-2002	hdfhhdfh	XYZ	1=MI

Seq Text

1 Value of hdfhhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus

Status: Discrepancy not reviewed by

Choose Go to Data Field from Pull Down Menu

Fix Data as indicated in the Discrepancy Text

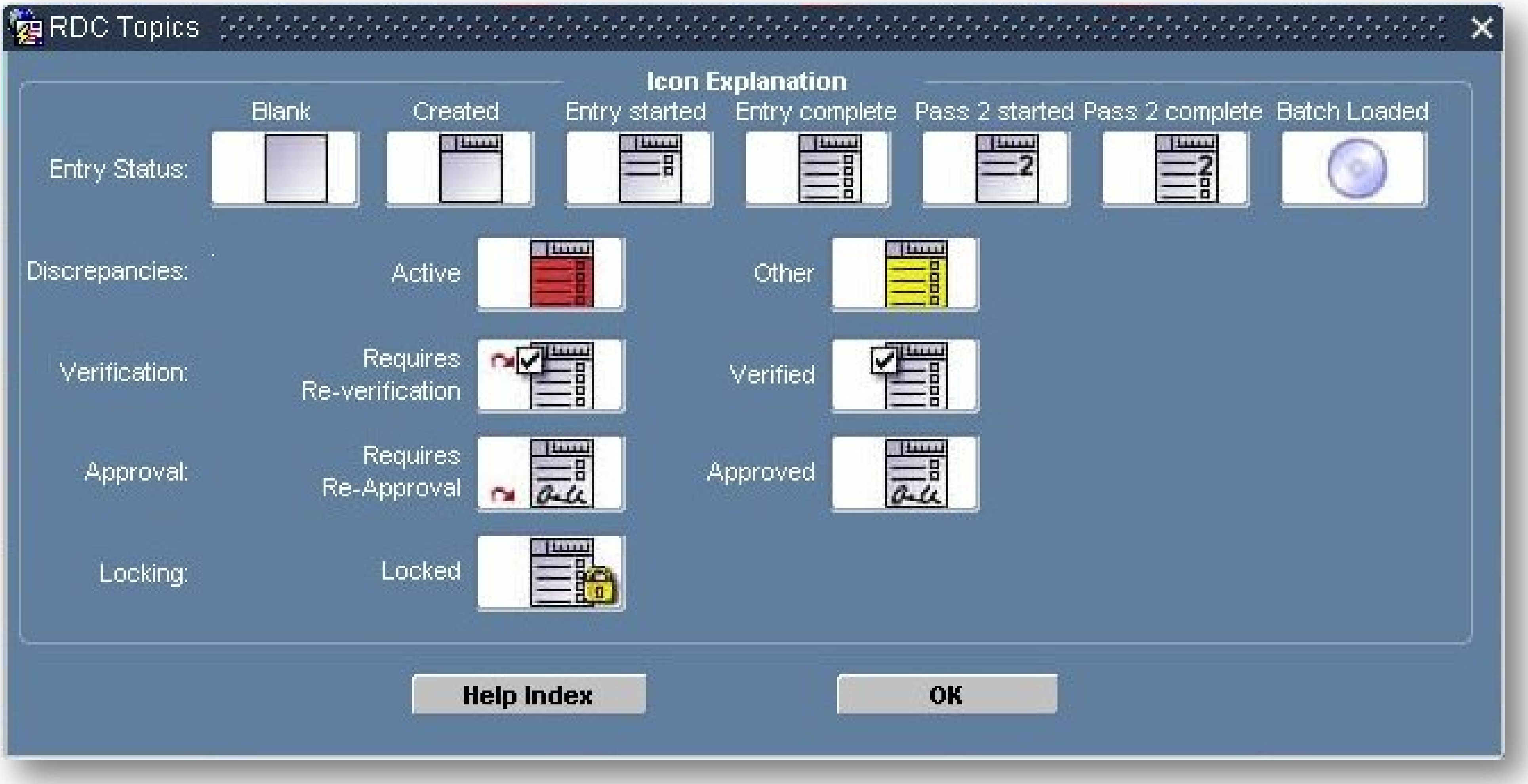
File Edit Insert Go Validate Data Entry Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Course 3
Course 4
Course 5
Blood Chemistry
Hematology
Urinalysis
Bone Marrow
Serology
Other Serum
Blood Gas
Red Cell Ind.
Visit
Page
CRF
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Thrp
Screening 7 Prior Tx
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
Patient
1 (L)
2 (PT)
5 (No inits)
9 (No inits)
10 (ABC)
Blank ☐
Comment
Bsym*
COM
Blank ☐
Grade
Search
Site SITE_01
Summary
Discrepancies
Verification
Approval
Audit Trail
List
1 - Active
Status
Comments
Send to site
Send for classification
Close - resolved
Closed - no resolution
Go to data field
New
History

How to Address a Discrepancy

- Review Discrepancy Details
- Whenever possible, use the Action pull down ‘Go to Data Field’ to jump to the Discrepant Field
- 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.

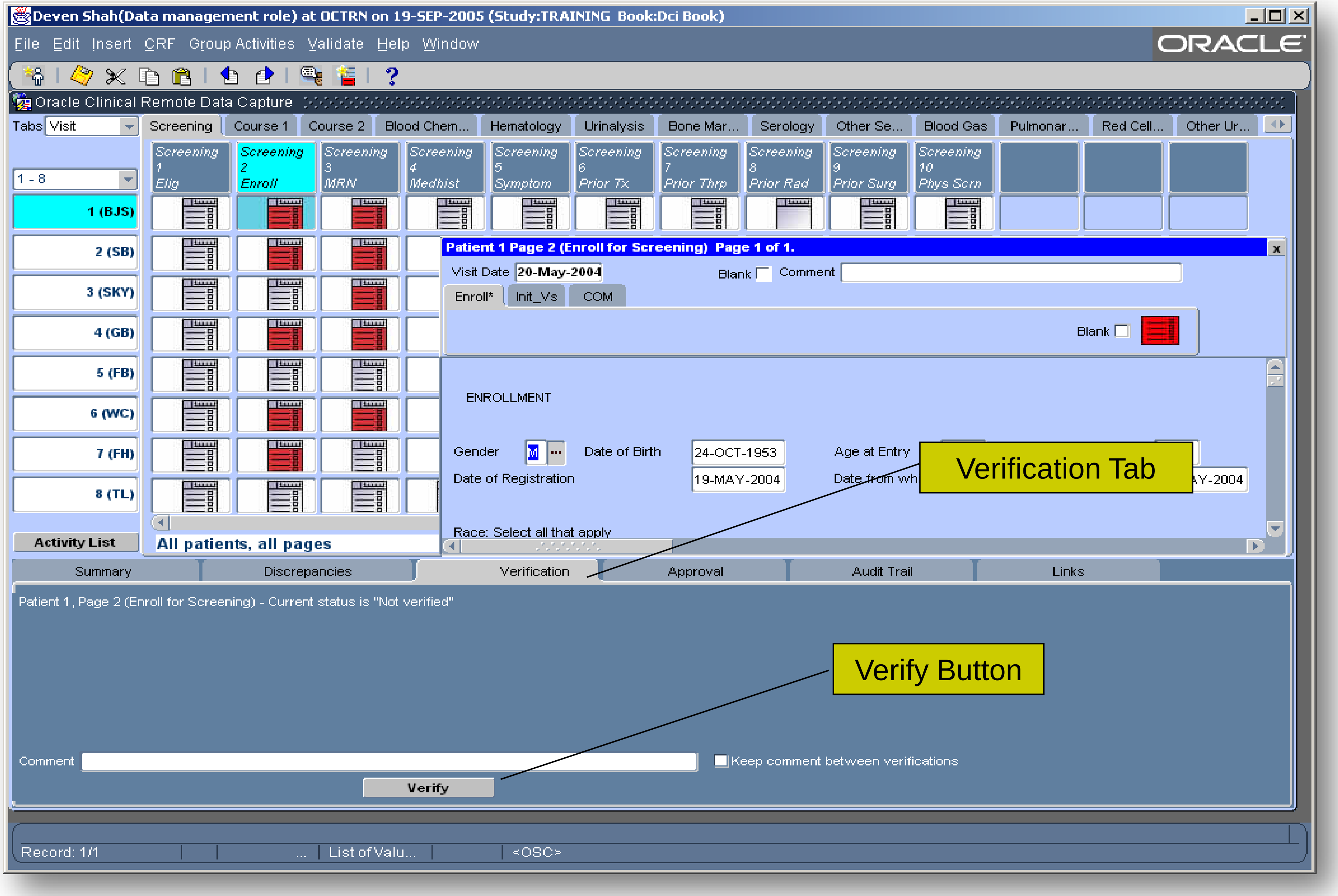
Verification & Approval


RDC Topics
Icon Explanation
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
Help Index
OK

Verification & Approval

- C^{3}D Verification & Approval functionality offer capability to track QA and Monitoring of eCRFs.
- Verification functionality is available for users with Research Nurse account role.
- Approval functionality is available for users with Monitor account role.

Verification



Deven Shah(Data management role) at OCTRN on 19-SEP-2005 (Study:TRAINING Book:Dci Book)

Patient 1 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date 20-May-2004

ENROLLMENT

Gender M

Date of Birth 24-OCT-1953

Date of Registration 19-MAY-2004

Race: Select all that apply

Patient 1, Page 2 (Enroll for Screening) - Current status is "Not verified"

Comment

☐ Keep comment between verifications

Verification Tab

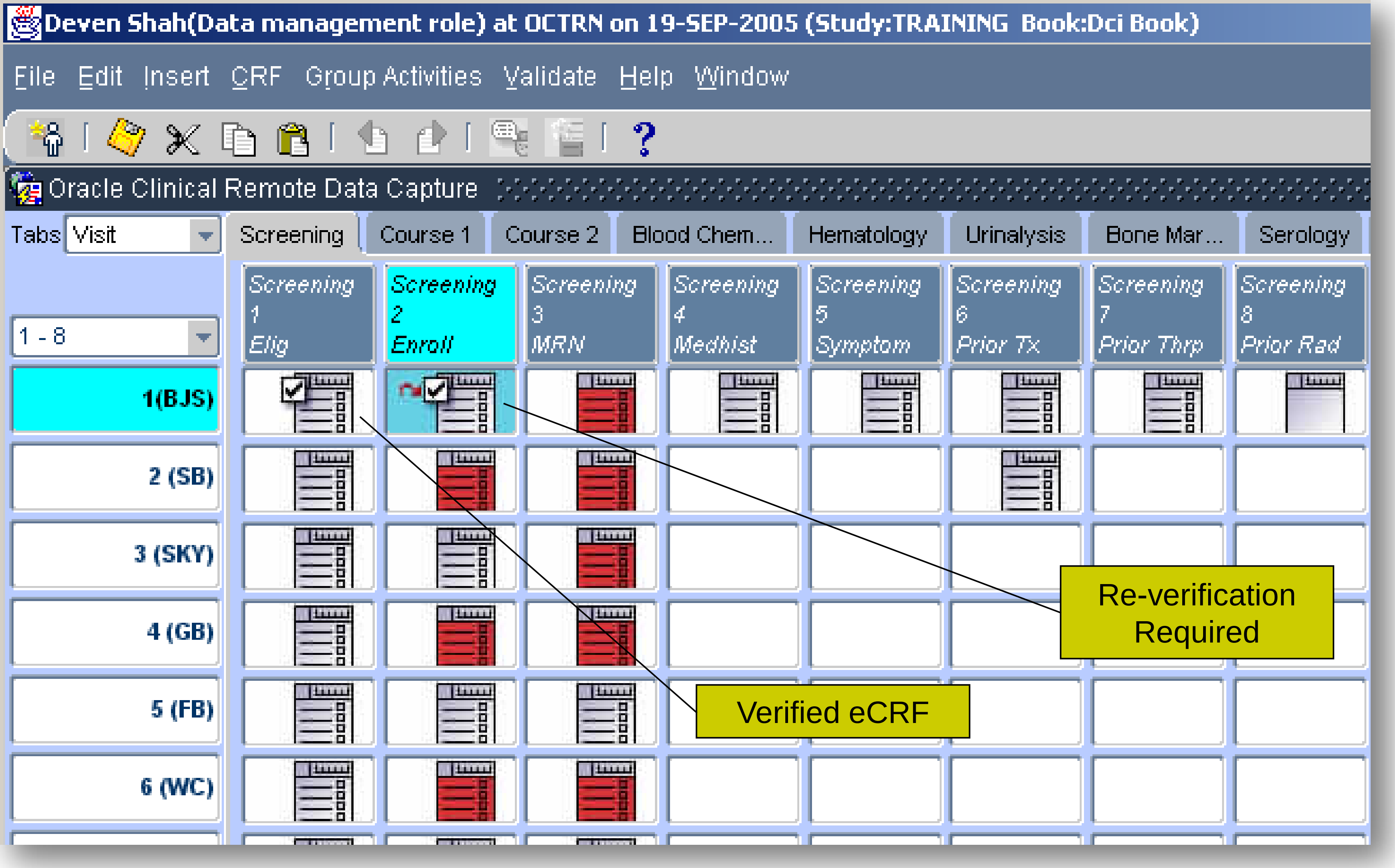
Verify Button

File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs
Visit
1 - 8
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Blood Gas
Pulmonar...
Red Cell...
Other Ur...
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
1 (BJS)
2 (SB)
3 (SKY)
4 (GB)
5 (FB)
6 (WC)
7 (FH)
8 (TL)
Activity List
All patients, all pages
Blank ☐
Comment
Enroll*
Init_Vs
COM
Blank ☐
Age at Entry
Date from whi
Y-2004
Summary
Discrepancies
Verification
Approval
Audit Trail
Links
Verify
Record: 1/1
...
List of Valu...
<OSC>

Verification

- Each eCRF can be verified by clicking on the 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



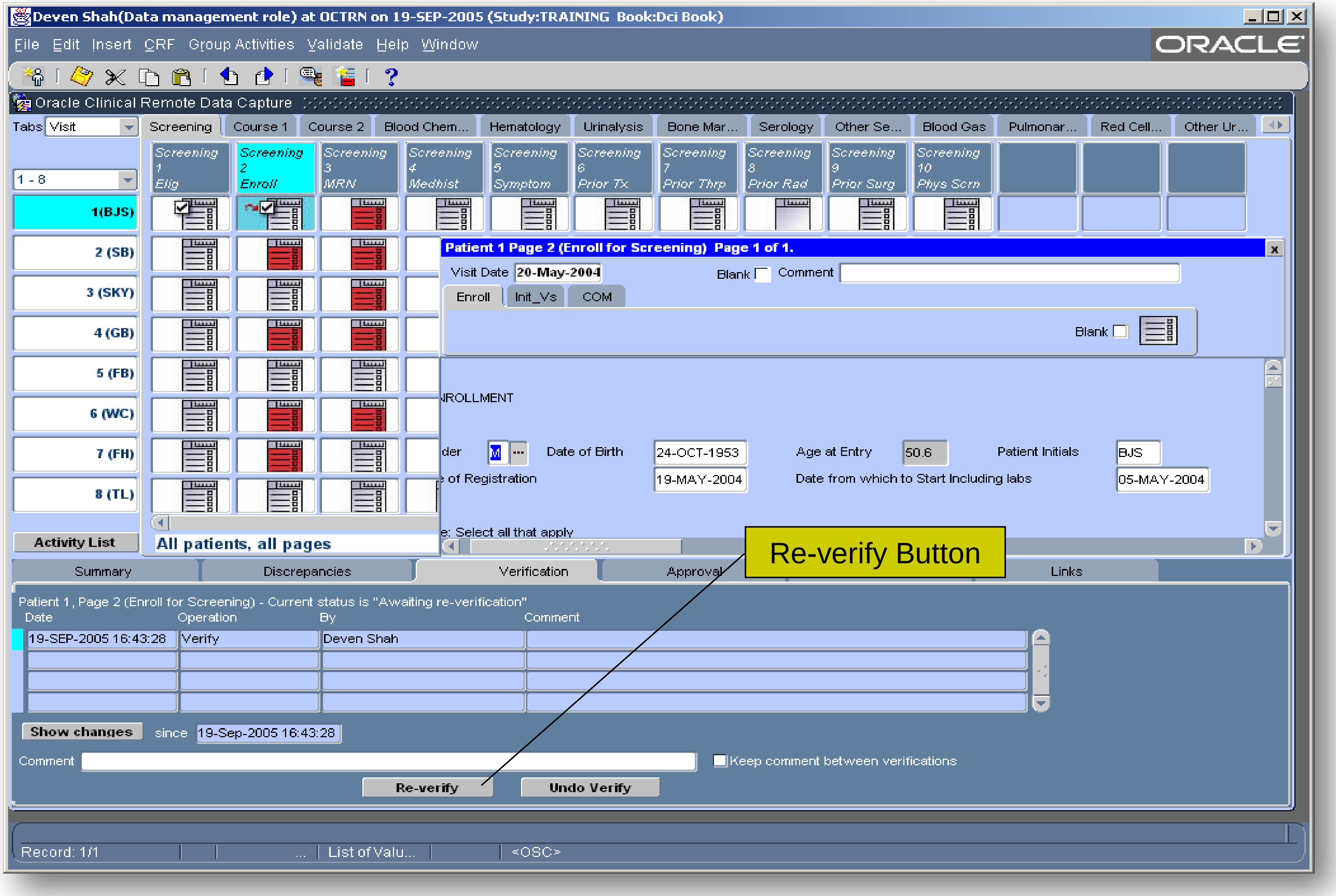
Deven Shah(Data management role) at OCTRN on 19-SEP-2005 (Study:TRAINING Book:Dci Book)

File Edit Insert CRF Group Activities Validate Help Window
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
1 - 8
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
1(BJS)
2 (SB)
3 (SKY)
4 (GB)
5 (FB)
6 (WC)

Re-verification Required

Verified eCRF

Verification



Deven Shah(Data management role) at OCTRN on 19-SEP-2005 (Study:TRAINING Book:Dci Book)

Patient 1 Page 2 (Enroll for Screening) Page 1 of 1.

Visit Date 20-May-2004

Date of Birth 24-OCT-1953

Age at Entry 50.6

Patient Initials BJS

19-MAY-2004

Date from which to Start Including labs 05-MAY-2004

Patient 1, Page 2 (Enroll for Screening) - Current status is "Awaiting re-verification"

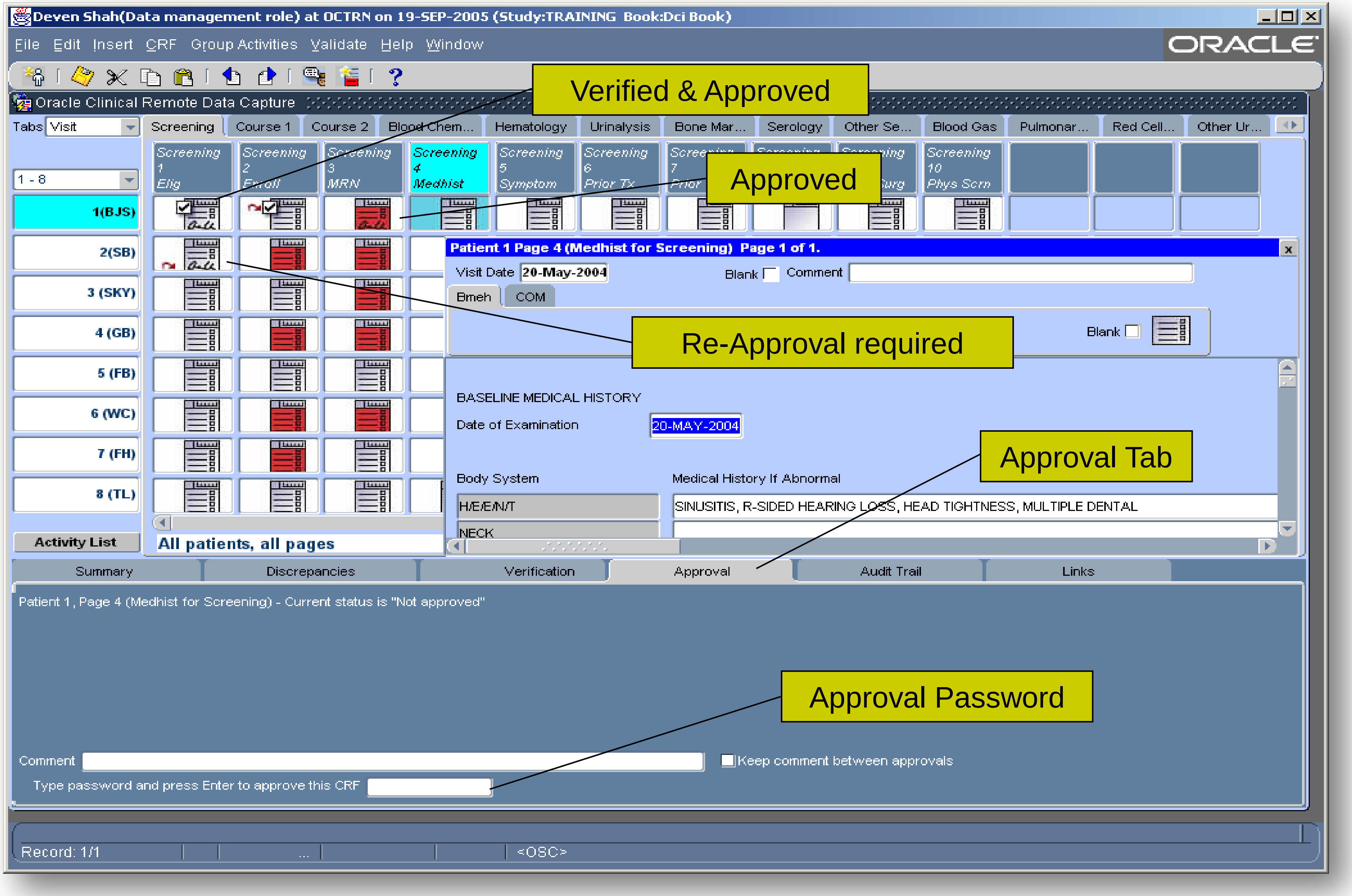
Date	Operation	By	Comment
19-SEP-2005 16:43:28	Verify	Deven Shah	

Show changes since 19-Sep-2005 16:43:28

File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Blood Gas
Pulmonar...
Red Cell...
Other Ur...
1 - 8
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior Thrp
Screening 8 Prior Rad
Screening 9 Prior Surg
Screening 10 Phys Scrn
1(BJS)
2 (SB)
3 (SKY)
4 (GB)
5 (FB)
6 (WC)
7 (FH)
8 (TL)
Activity List
All patients, all pages
Blank
Comment
Enroll
Init_Vs
COM
Blank
NROLLMENT
der
M
of Registration
e: Select all that apply
Summary
Discrepancies
Verification
Approval
Links
Comment
Keep comment between verifications
Re-verify
Undo Verify
Record: 1/1
List of Valu...
<OSC>

Re-verify Button

Approval



Verified & Approved

Approved

Re-Approval required

Approval Tab

Approval Password

Deven Shah(Data management role) at OCTRN on 19-SEP-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Blood Gas
Pulmonar...
Red Cell...
Other Ur...
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Screening 4 Medhist
Screening 5 Symptom
Screening 6 Prior Tx
Screening 7 Prior
Surg
Screening 10 Phys Scrn
1 - 8
1(BJS)
2(SB)
3 (SKY)
4 (GB)
5 (FB)
6 (WC)
7 (FH)
8 (TL)
Activity List
All patients, all pages
Bmeh
COM
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

Patient 1 Page 4 (Medhist for Screening) Page 1 of 1.

Visit Date 20-May-2004 Blank ☐ Comment

Blank ☐

BASELINE MEDICAL HISTORY

Date of Examination 20-MAY-2004

Body System	Medical History If Abnormal
H/E/E/N/T	SINUSITIS, R-SIDED HEARING LOSS, HEAD TIGHTNESS, MULTIPLE DENTAL
NECK	

Patient 1, Page 4 (Medhist for Screening) - Current status is "Not approved"

Comment ☐ Keep comment between approvals

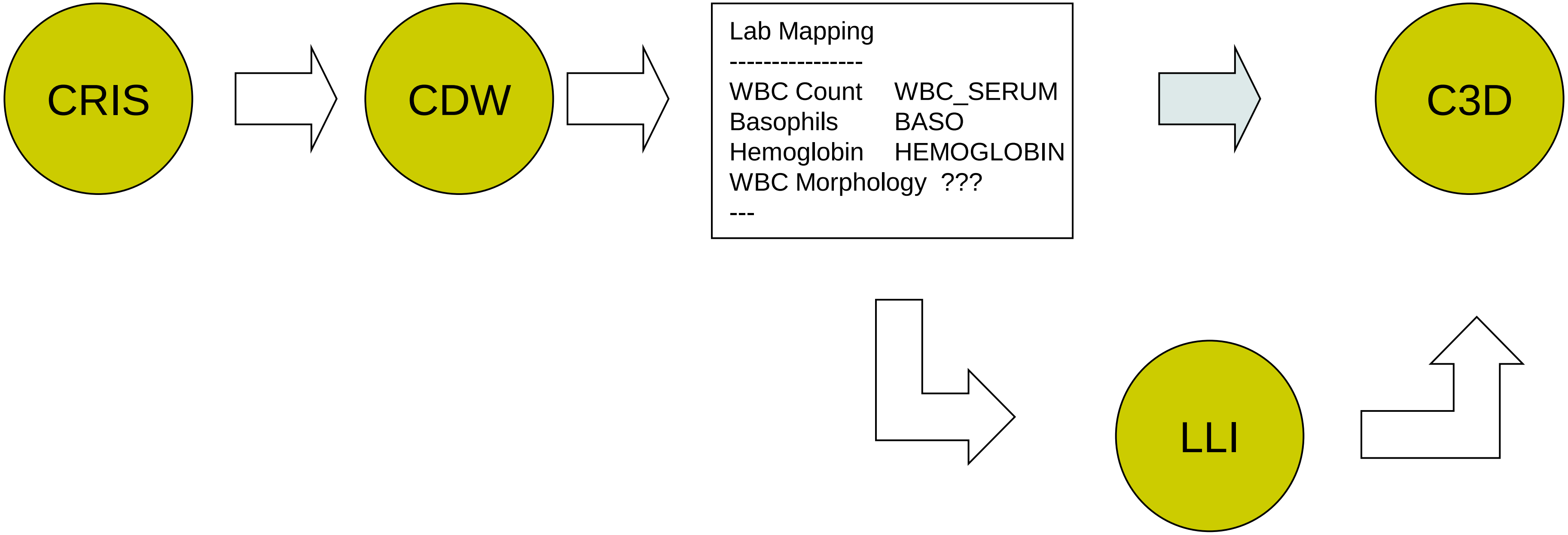
Type password and press Enter to approve this CRF

Record: 1/1 <OSC>

Approval

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

CRIS to C^{3}D Lab Data Flow



CRIS
CDW
C3D
LLI

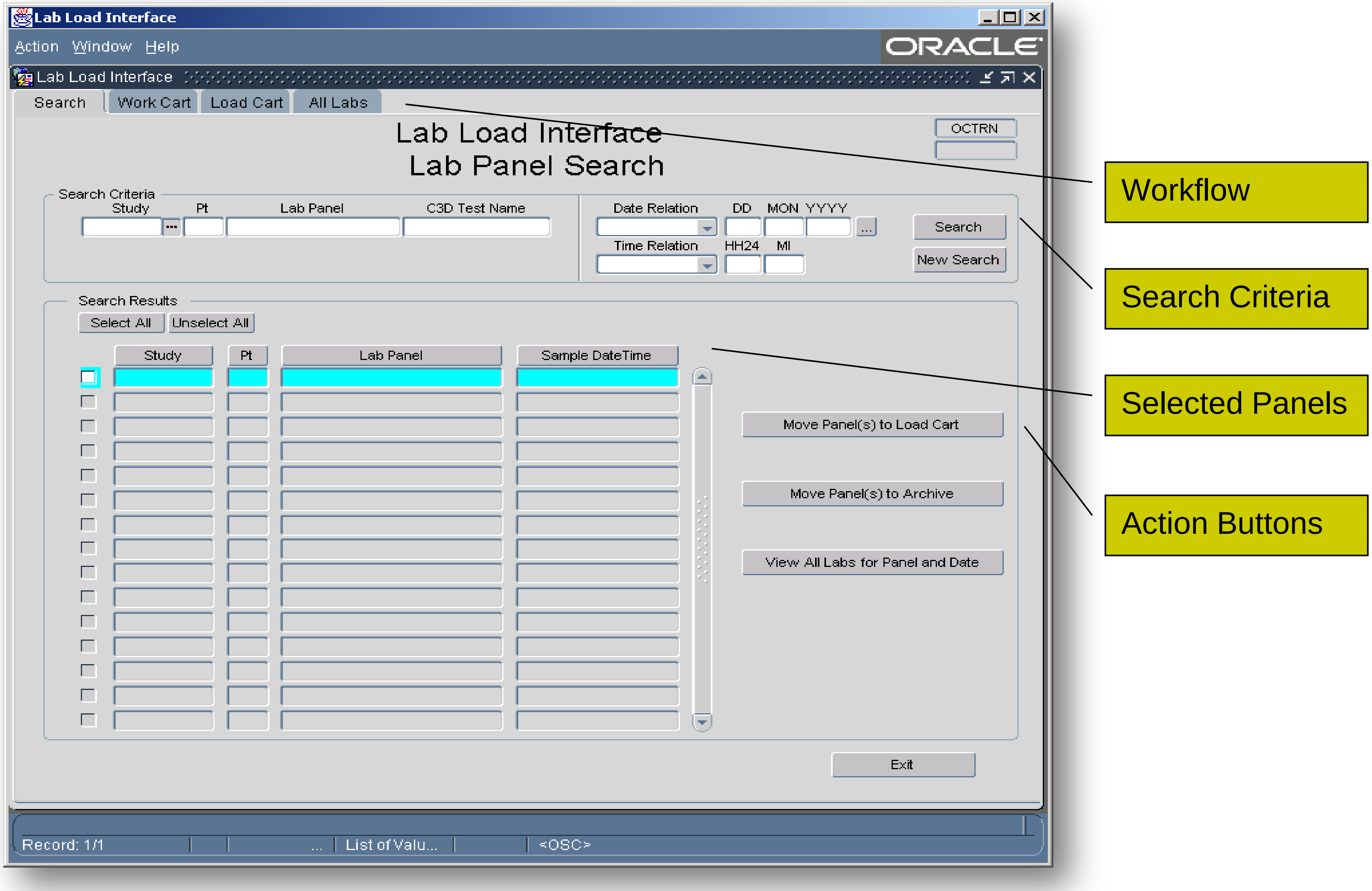
Lab Mapping

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
- URL: https://octrials.nci.nih.gov/opa46/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>

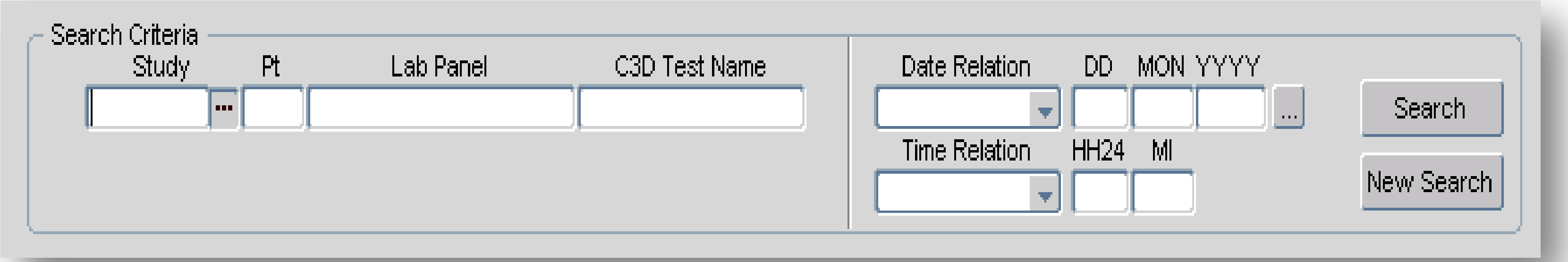
Workflow

Search Criteria

Selected Panels

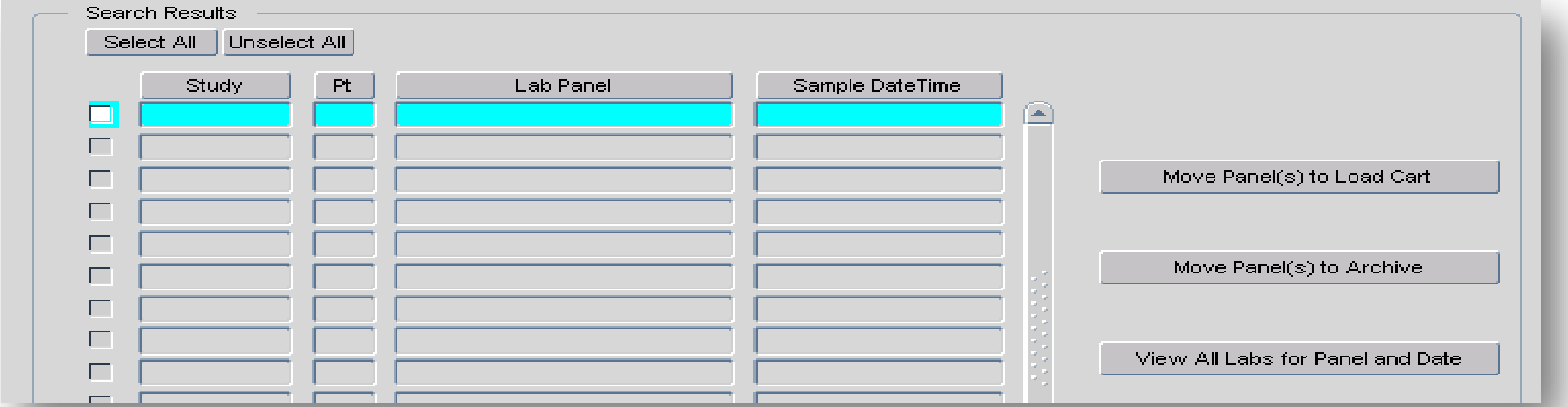
Action Buttons

LLI Search Criteria


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

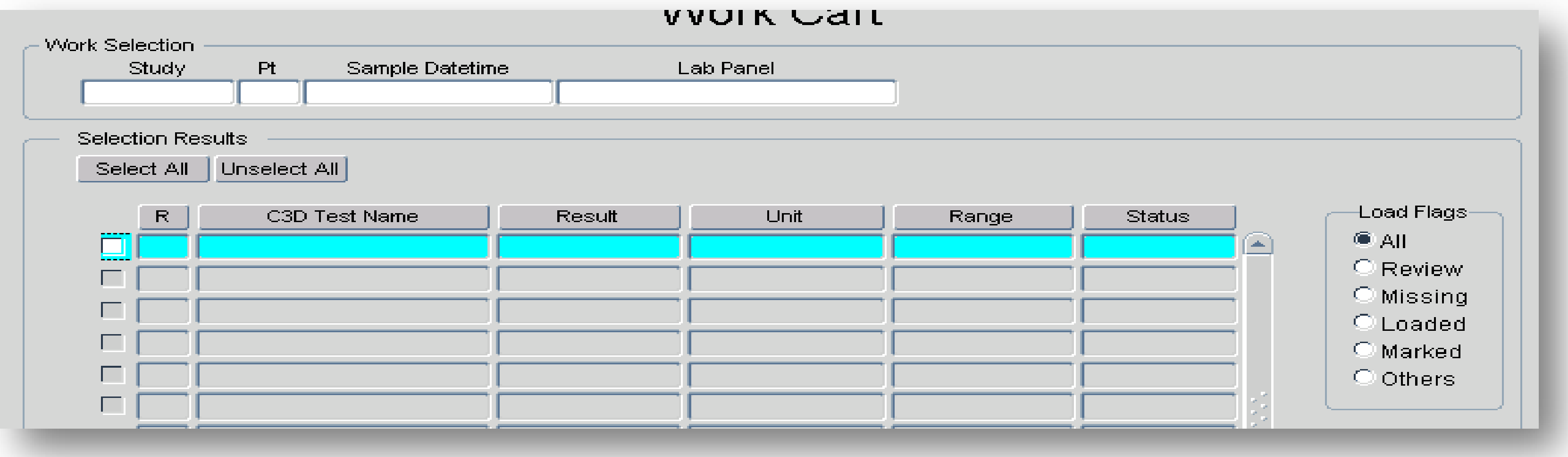
- **Searching**
  - – Can search by Study, Patient Number, Lab Panel, OC Lab Question, Date and/or Time
    - Each search field contains Pick List.
    - Date and Time allows the ‘%’ wild card
    - Date and Time provide the additional option of:
      - “On or Before”, “On or After” and “LIKE” comparisons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

Questions?