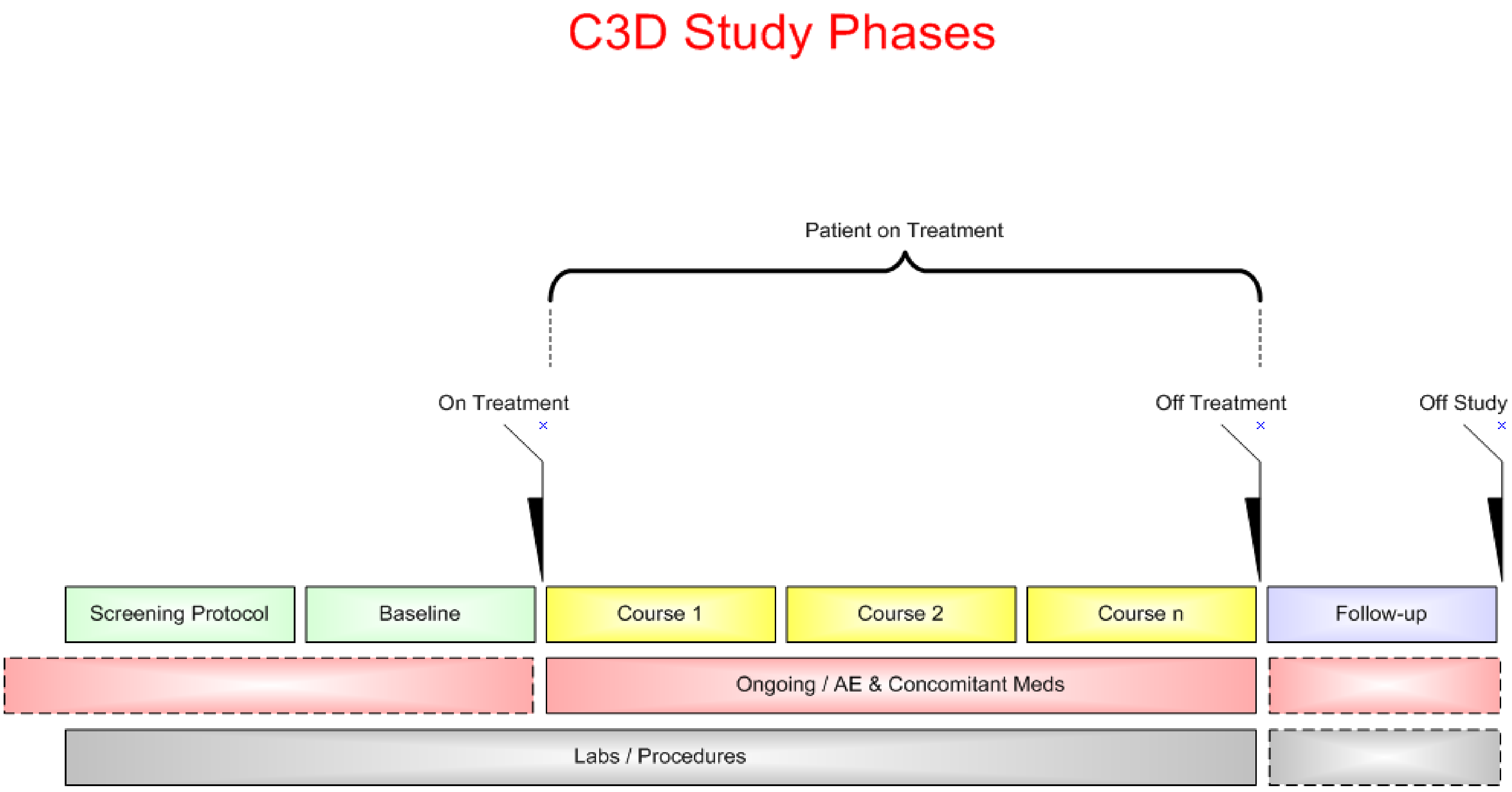
# Introduction to C$^3$D

Harris Corporation

Rev 8/10

# 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

# C$^3$D Protocol Phases

- C$^3$D Protocol is typically organized in the following Phases
  - Screening/Baseline
  - Courses/Cycles
  - Ongoing
  - Labs
  - Off Treatment/Off Study
- Each Phase contains one or more visit within

# Standard Forms

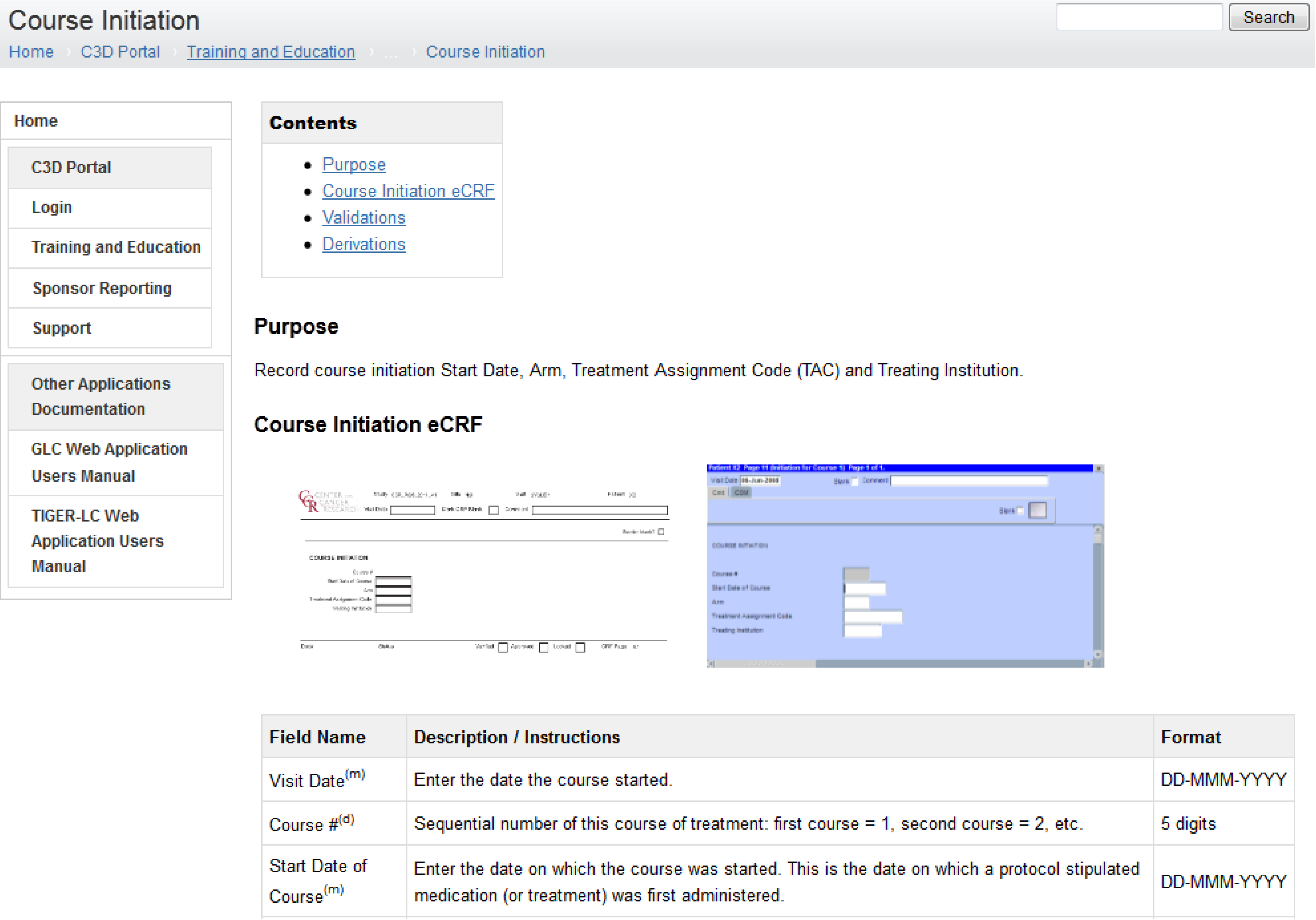
- Library of Standard Forms & Rules is available as a starting point to build protocol specific forms & rules
- Each Form contains mandatory and derived fields
- Detailed Instructions are available for each Standard Form

  https://ccrod.cancer.gov/confluence/x/9QiJAw

# Standard Forms

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

# eCRF Instructions



## Course Initiation

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

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

**Contents**

- Purpose
- Course Initiation eCRF
- Validations
- Derivations

### Purpose

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

### Course Initiation eCRF

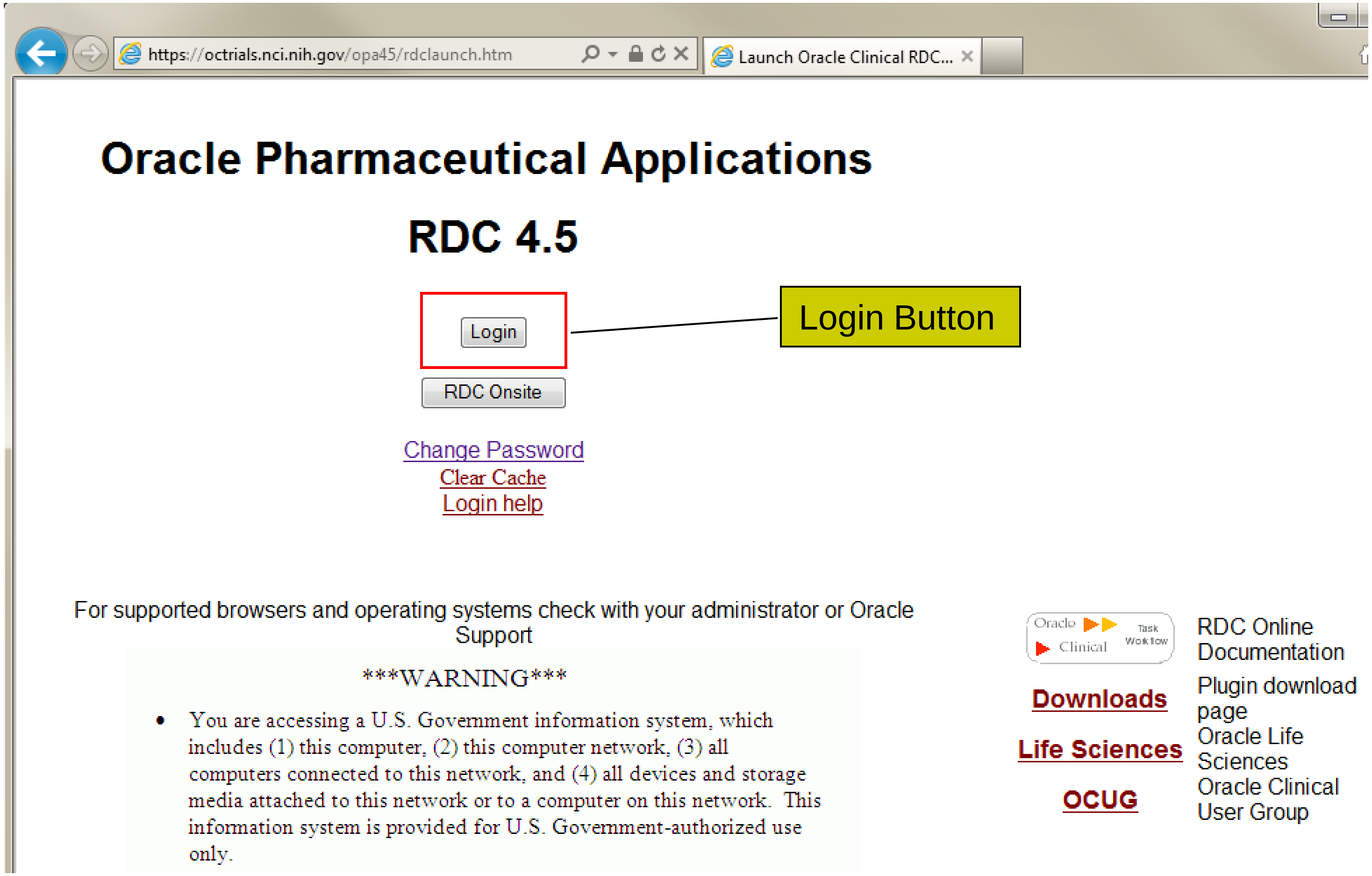
| Field Name | Description / Instructions | Format |
|---|---|---|
| Visit Date(m) | Enter the date the course started. | DD-MMM-YYYY |
| Course #(d) | Sequential number of this course of treatment: first course = 1, second course = 2, etc. | 5 digits |
| Start Date of Course(m) | Enter the date on which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

# eCRF Instructions

- Detailed Instructions are provided for Standard Forms including
  - Screen Shot
  - General Description
  - Field Specific Description (Mandatory, Derived, etc.)
  - Validation/Derivation Rules

- **Quick Tip:**
  - Protocol Specific Forms and Rules may have minor deviations to accommodate for protocol requirements.

# C$^3$D Web Site


https://octrials.nci.nih.gov/opa45/rdclaunch.htm
Launch Oracle Clinical RDC...
Login
RDC Onsite
Login Button

## Oracle Pharmaceutical Applications

## RDC 4.5

Change Password
Clear Cache
Login help

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

***WARNING***

- You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

| | |
|---|---|
| Oracle Clinical Task Workflow | RDC Online Documentation |
| **Downloads** | Plugin download page |
| **Life Sciences** | Oracle Life Sciences |
| **OCUG** | Oracle Clinical User Group |

# C$^3$D Web Sites

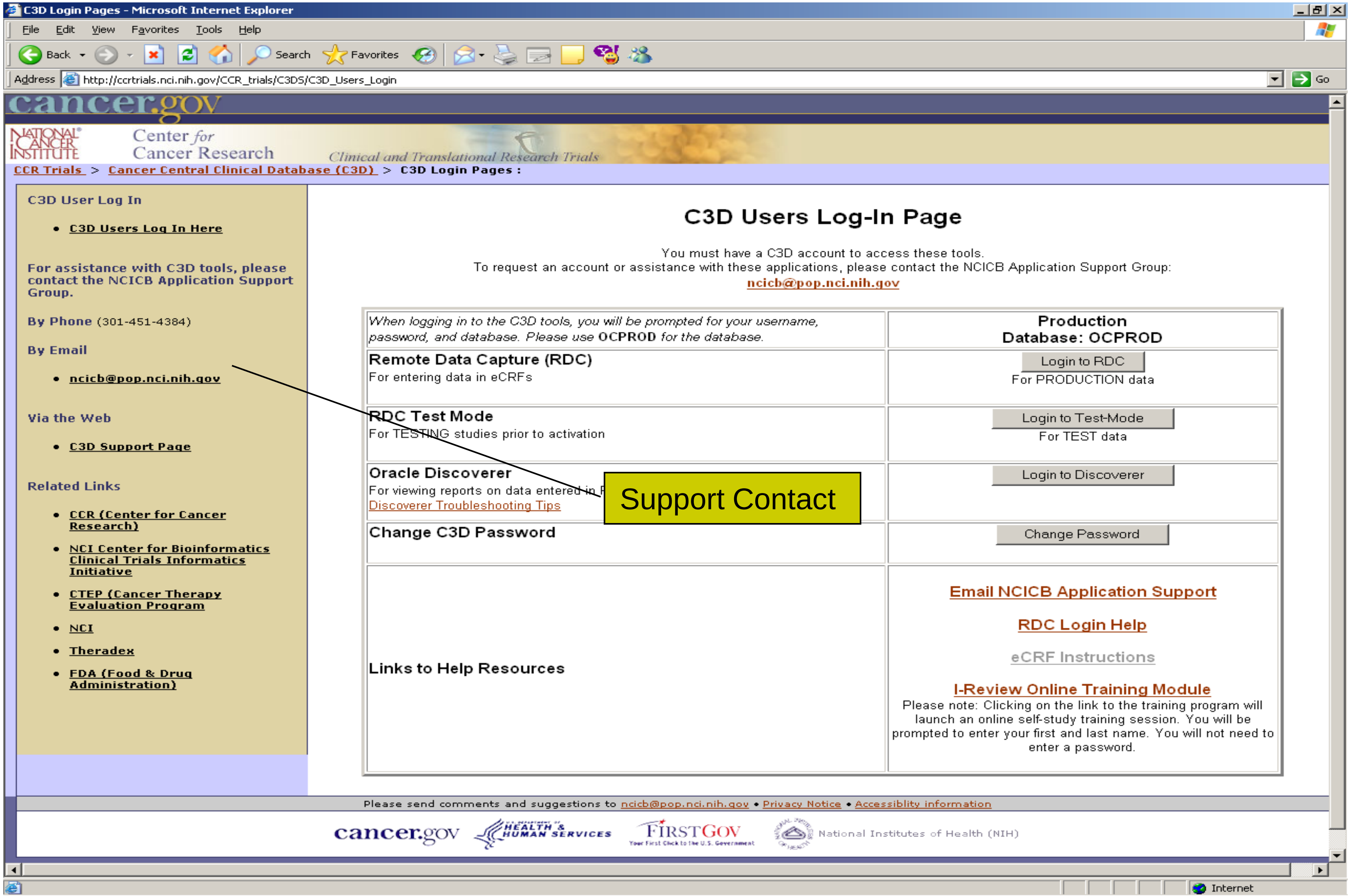
- Internal (Within NIH LAN)

  http://ccrtrials.nci.nih.gov/CCR_trials/C3DS/C3D_Users_Login
- External (Outside NIH Firewall)

  https://octrials.nci.nih.gov/opa45/rdclaunch.htm

- **Quick Tip:**
  - C$^3$D provides a separate Data Entry environment to test protocol design

# C3D Support



C3D Login Pages - Microsoft Internet Explorer

Address http://ccrtrials.nci.nih.gov/CCR_trials/C3DS/C3D_Users_Login

cancer.gov

NATIONAL CANCER INSTITUTE Center *for* Cancer Research *Clinical and Translational Research Trials*

CCR Trials > Cancer Central Clinical Database (C3D) > **C3D Login Pages :**

**C3D User Log In**

- **C3D Users Log In Here**

**For assistance with C3D tools, please contact the NCICB Application Support Group.**

**By Phone** (301-451-4384)

**By Email**

- **ncicb@pop.nci.nih.gov**

**Via the Web**

- **C3D Support Page**

**Related Links**

- **CCR (Center for Cancer Research)**
- **NCI Center for Bioinformatics Clinical Trials Informatics Initiative**
- **CTEP (Cancer Therapy Evaluation Program**
- **NCI**
- **Theradex**
- **FDA (Food & Drug Administration)**

## C3D Users Log-In Page

You must have a C3D account to access these tools.
To request an account or assistance with these applications, please contact the NCICB Application Support Group:
**ncicb@pop.nci.nih.gov**

| *When logging in to the C3D tools, you will be prompted for your username, password, and database. Please use* OCPROD *for the database.* | **Production<br>Database: OCPROD** |
|---|---|
| **Remote Data Capture (RDC)**<br>For entering data in eCRFs | Login to RDC<br>For PRODUCTION data |
| **RDC Test Mode**<br>For TESTING studies prior to activation | Login to Test-Mode<br>For TEST data |
| **Oracle Discoverer**<br>For viewing reports on data entered in<br>Discoverer Troubleshooting Tips | Login to Discoverer |
| **Change C3D Password** | Change Password |
| **Links to Help Resources** | **Email NCICB Application Support**<br>**RDC Login Help**<br>**eCRF Instructions**<br>**I-Review Online Training Module**<br>Please note: Clicking on the link to the training program will launch an online self-study training session. You will be prompted to enter your first and last name. You will not need to enter a password. |

Please send comments and suggestions to ncicb@pop.nci.nih.gov • Privacy Notice • Accessiblity information

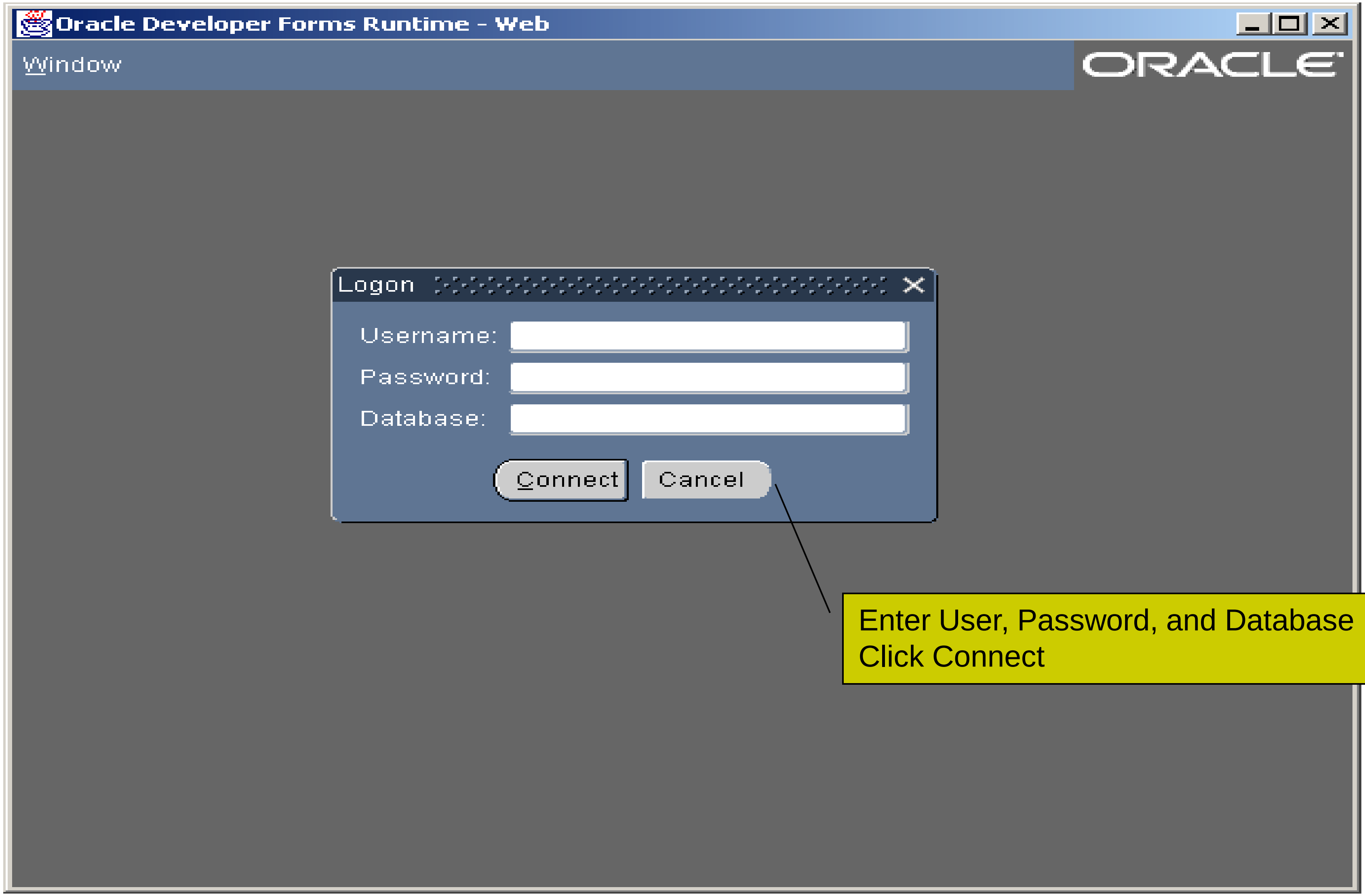
Support Contact

File Edit View Favorites Tools Help
Back
Search
Favorites
Go
cancer.gov
HEALTH & HUMAN SERVICES
FIRSTGOV Your First Click to the U.S. Government
National Institutes of Health (NIH)
Internet

# C$^3$D Support

- Contact
  - Email: ncicbiit@mail.nih.gov
  - Phone: 240-276-5541
- CBIIT provides the first line of support for C$^3$D related issues
- Protocol specific issues are escalated to the Protocol Builder by CBIIT
- Changes to Standards are escalated to Controls & Configuration Management Group (CCMG)

# Login

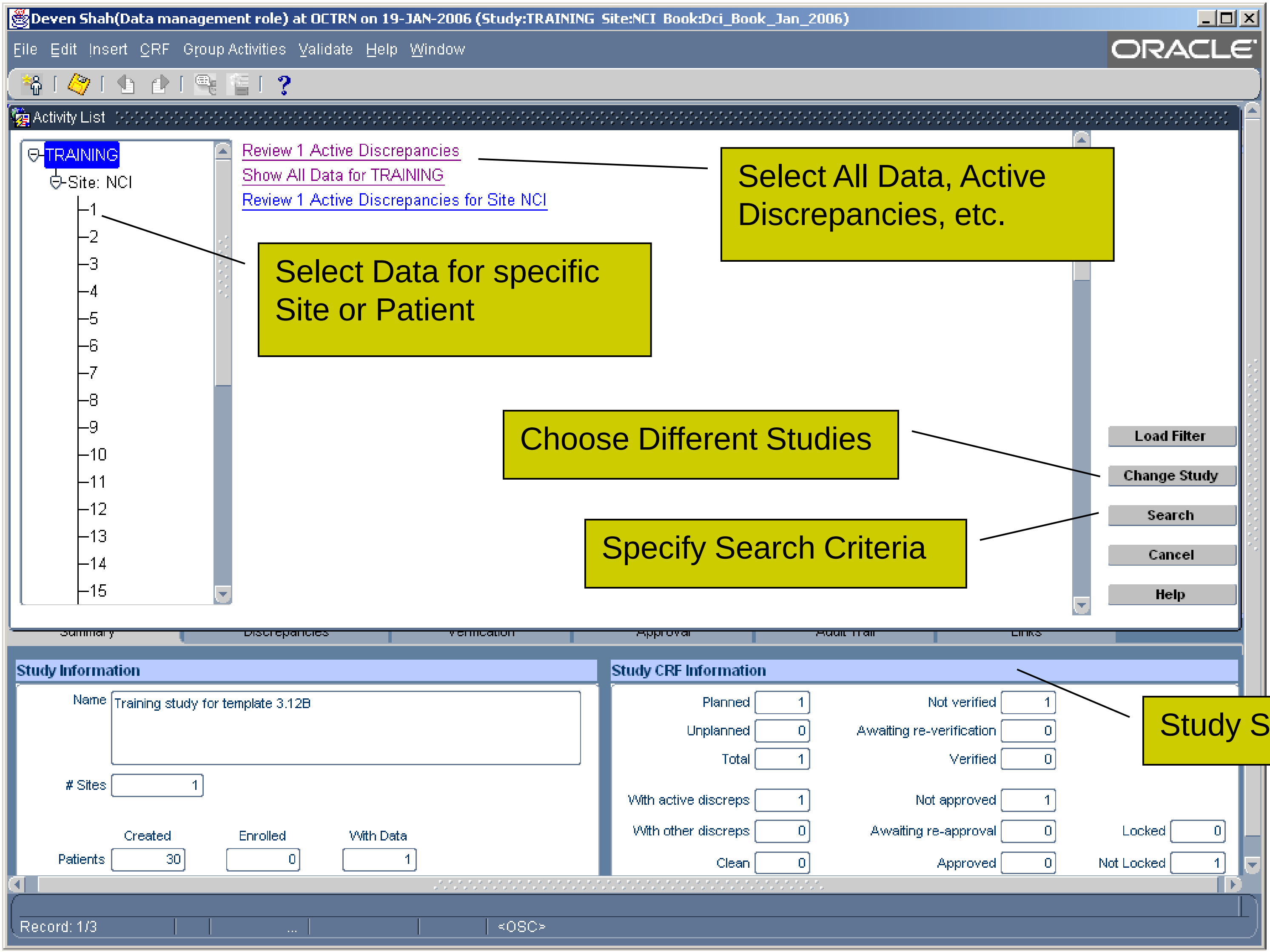

Oracle Developer Forms Runtime - Web
Window
ORACLE
Logon
Username:
Password:
Database:
Connect
Cancel

Enter User, Password, and Database
Click Connect

# Username & Password

- Username is of the format **ops$**smiths
- Password has to be 8 characters starting with a letter and containing **at least one number and one special characters** (e.g. ! # )
- Production Database is called **ocprod**
- About C3D Password
  - Do not share the password with others!
  - Password needs to be changed the first time you login
  - Passwords expire every 6 months and need to be changed
  - Account gets locked upon three unsuccessful attempts

# Selecting Activity



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
Load Filter
Change Study
Search
Cancel
Help

Review 1 Active Discrepancies
Show All Data for TRAINING
Review 1 Active Discrepancies for Site NCI

**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>

Select All Data, Active Discrepancies, etc.

Select Data for specific Site or Patient

Choose Different Studies

Specify Search Criteria

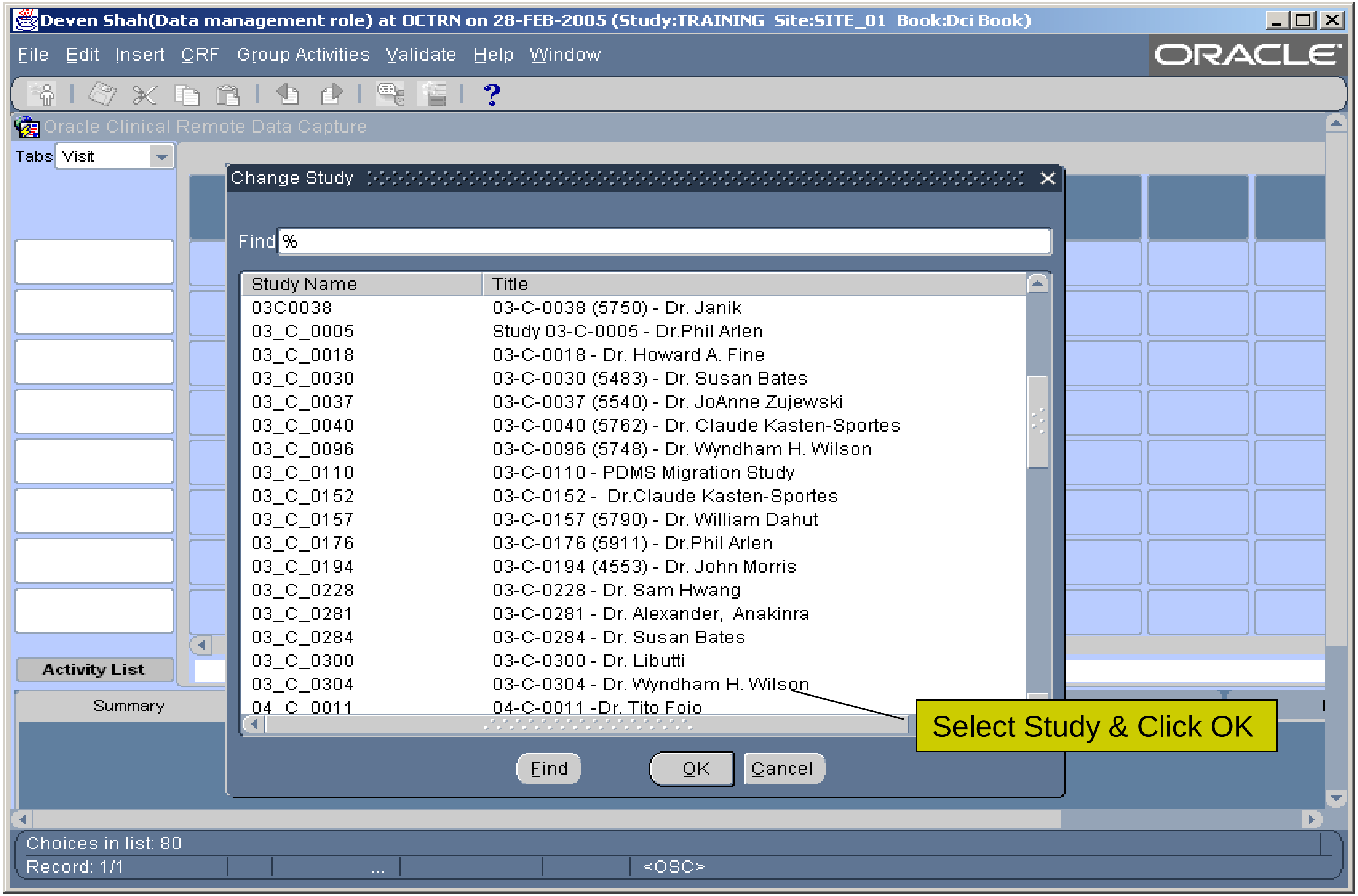
Study Summary

# Selecting Activity

- Quick Link to View
  - All Study Data
  - Discrepant Data
  - Site Specific or Patient Specific Data
- Choose a Different Study
  - Access to studies is controlled by user role
  - Default Study is preserved from prior login
- Specify Search Criteria

- **Quick Tip:**
  - This screen provides a quick review of open discrepancies in your study

# Selecting Study


Deven Shah(Data management role) at OCTRN on 28-FEB-2005 (Study:TRAINING Site:SITE_01 Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Activity List
Summary
Change Study
Find
OK
Cancel

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

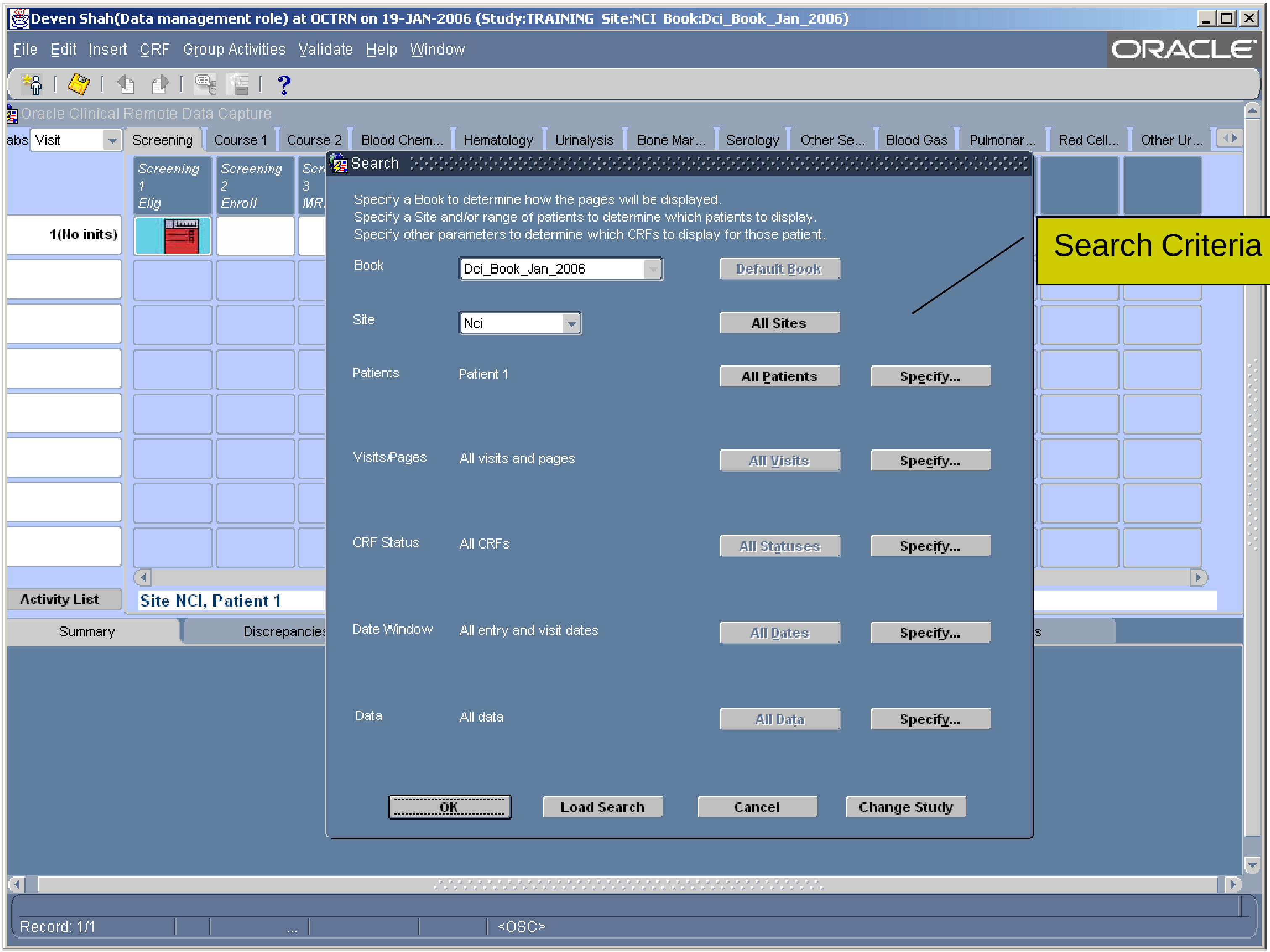
Record: 1/1 ... <OSC>

Select Study & Click OK

# Study Access

- Study Access is provided by User
- Types of Access
  - Data Managers
  - Research Nurse
  - Monitor
  - Principal Investigator
  - Reviewer

# Search Criteria



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

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

Site NCI, Patient 1

Record: 1/1

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
Specify...
All Statuses
Specify...
All Dates
Specify...
All Data
Specify...
OK
Load Search
Cancel
Change Study
<OSC>

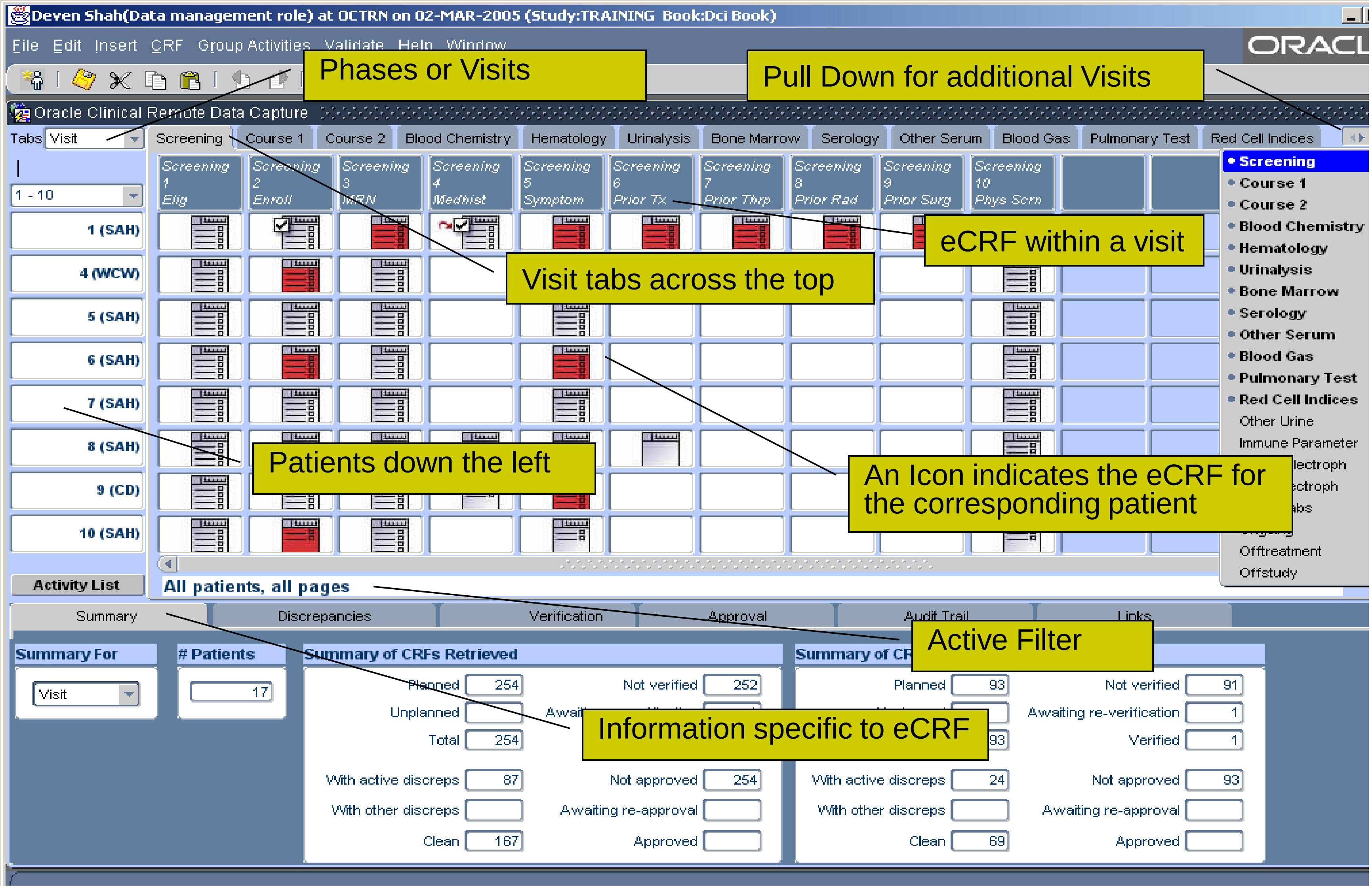
Search Criteria Dialog Box

# Search Criteria

- Search options:
  - Book - collection of CRFs in the protocol/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

- **Quick Tip:**
  - Protocol Amendments may require different DCI Book. Use Search option to pick the appropriate 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 Activities Validate Help Window
ORACL
Oracle Clinical Remote Data Capture
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
lectroph
ctroph
abs
Offtreatment
Offstudy
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

Tabs: Visit

1 - 10

1 (SAH)
4 (WCW)
5 (SAH)
6 (SAH)
7 (SAH)
8 (SAH)
9 (CD)
10 (SAH)

All patients, all pages

Summary For: Visit

# Patients: 17

**Summary of CRFs Retrieved**

| | | | |
|---|---|---|---|
| Planned | 254 | Not verified | 252 |
| Unplanned | | Awai | |
| Total | 254 | | |
| With active discreps | 87 | Not approved | 254 |
| With other discreps | | Awaiting re-approval | |
| Clean | 167 | Approved | |

**Summary of CR**

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

Phases or Visits

Pull Down for additional Visits

eCRF within a visit

Visit tabs across the top

Patients down the left

An Icon indicates the eCRF for the corresponding patient

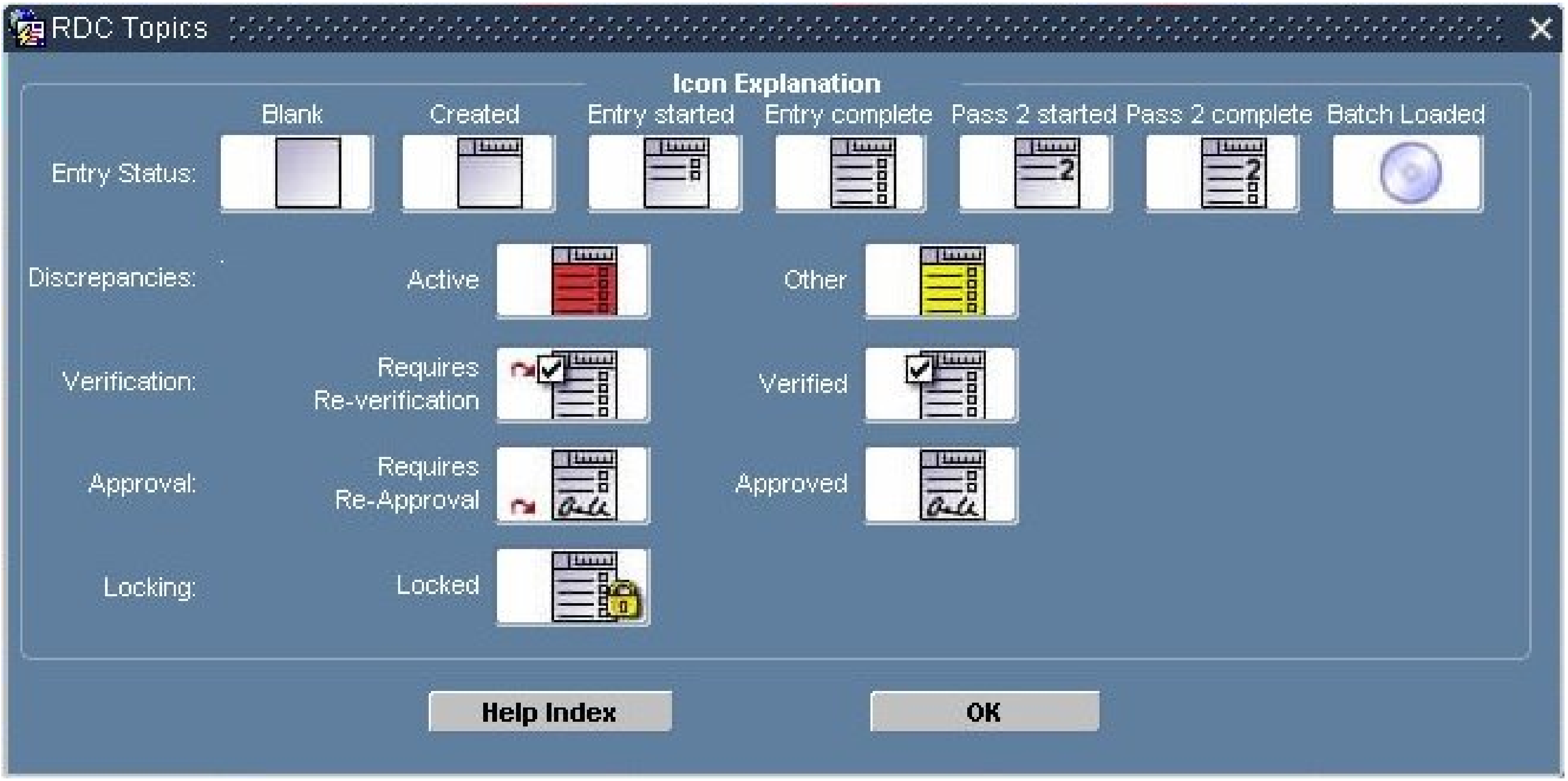
Active Filter

Information specific to eCRF

# Navigating RDC Spreadsheet

- Spreadsheet Layout
  - Patients along Rows
  - Visit 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
- Information Tabs for Summary, Discrepancies, Verification, Audit-trail, etc. at the bottom
- Navigation Functions via
  - Menu
  - Toolbar
  - Hot Keys

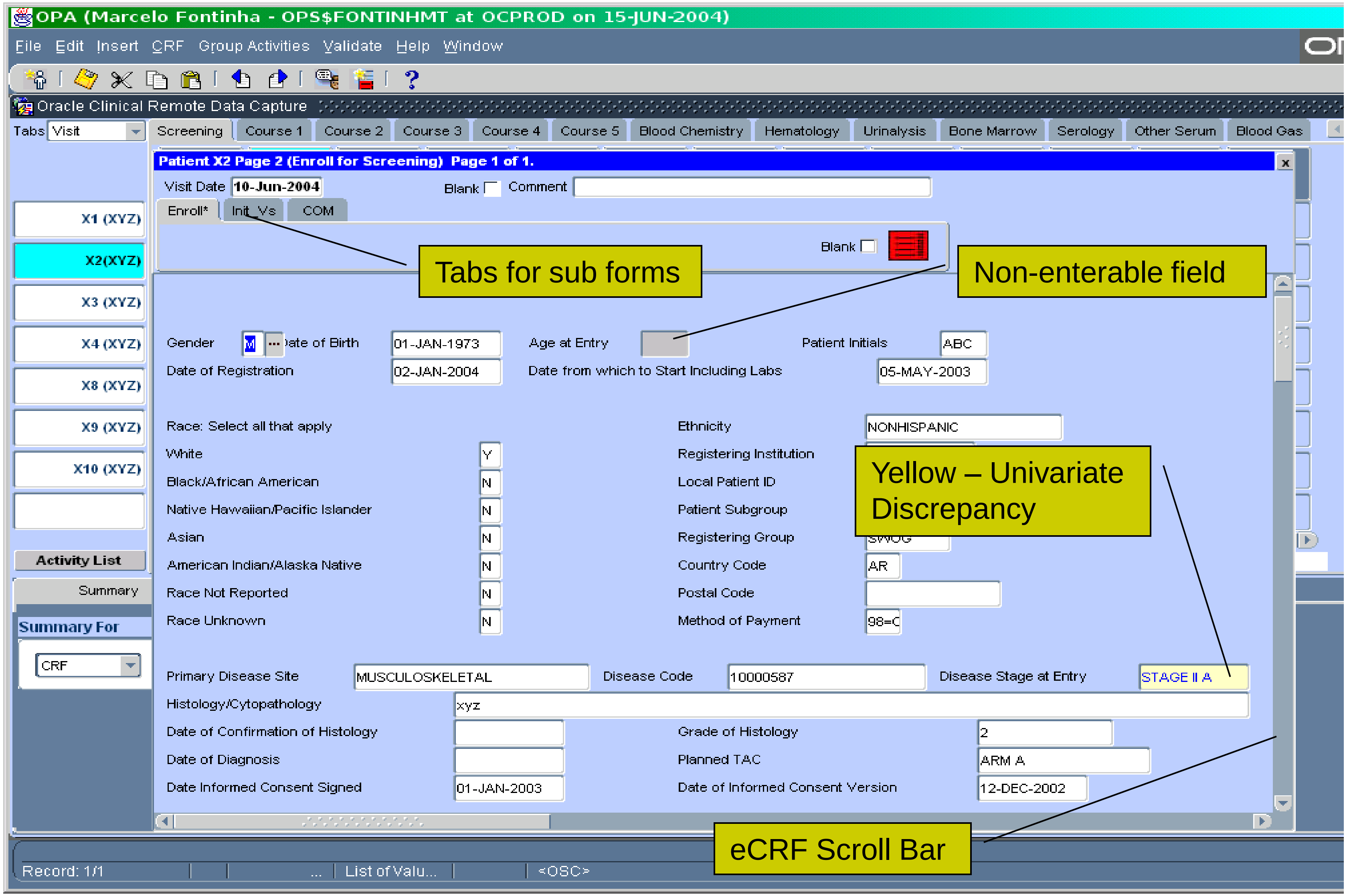
# eCRF Icons


RDC Topics
Icon Explanation
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

# 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)


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

**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 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 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

Tabs for sub forms

Non-enterable field

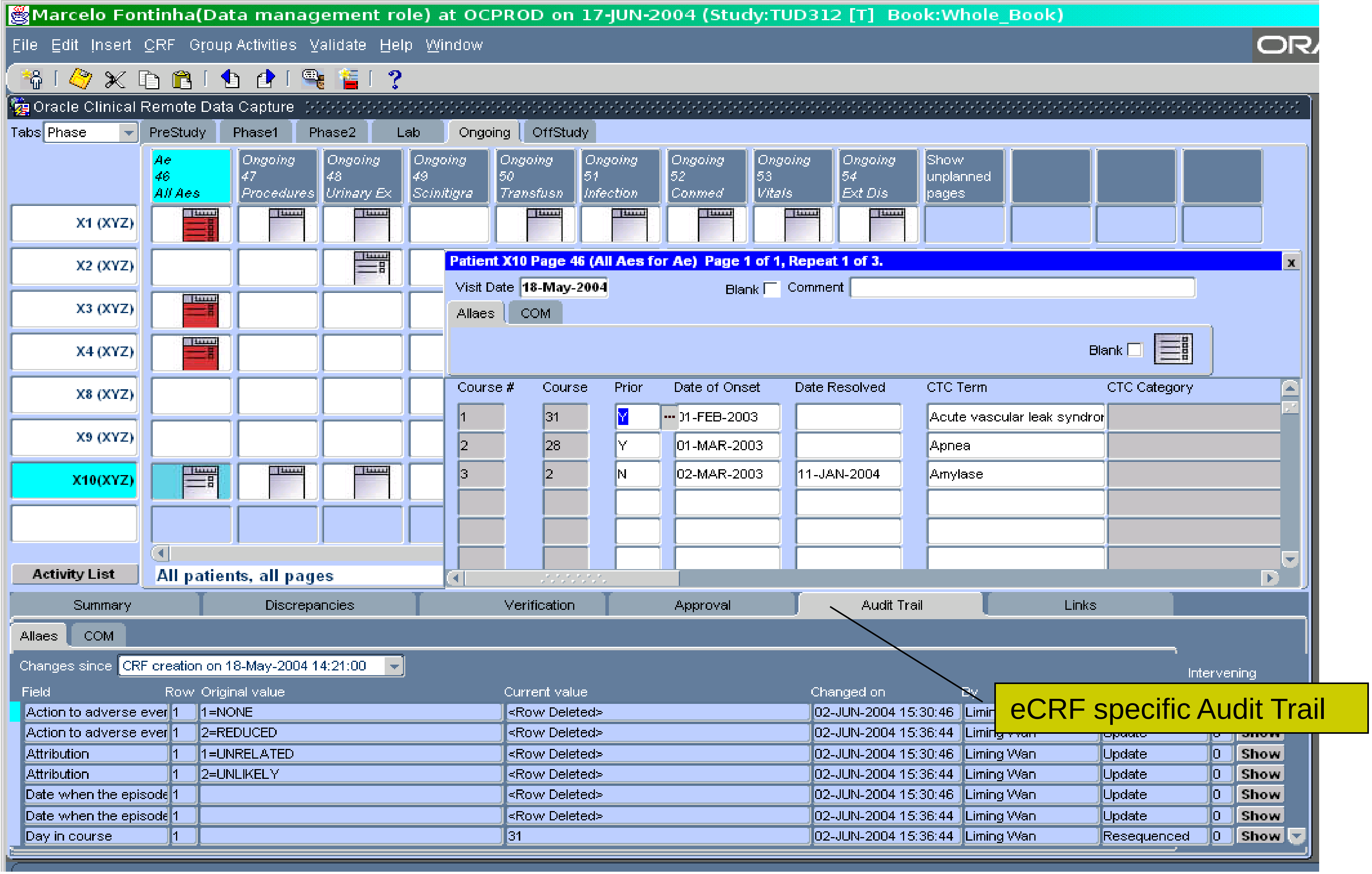
Yellow – Univariate Discrepancy

eCRF Scroll Bar

# eCRF Navigation

- Clicking on eCRF icon brings up the eCRF
- eCRF may contain sub-tabs
- Grey Fields indicates non-enterable fields (Derived, Defaulted, etc.)
- eCRF Scroll Bars indicate additional information

# Audit Trail


Marcelo Fontinha(Data management role) at OCPROD on 17-JUN-2004 (Study:TUD312 [T] Book:Whole_Book)
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
Summary Discrepancies Verification Approval Audit Trail Links
Allaes COM

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

Visit Date **18-May-2004** Blank ☐ Comment

Allaes COM

Blank ☐

| Course # | Course | Prior | Date of Onset | Date Resolved | CTC Term | CTC Category |
|---|---|---|---|---|---|---|
| 1 | 31 | Y | )1-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 | Limir | | | |
| Action to adverse ever | 1 | 2=REDUCED | <Row Deleted> | 02-JUN-2004 15:36:44 | Liming Wan | Update | 0 | Show |
| 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 |

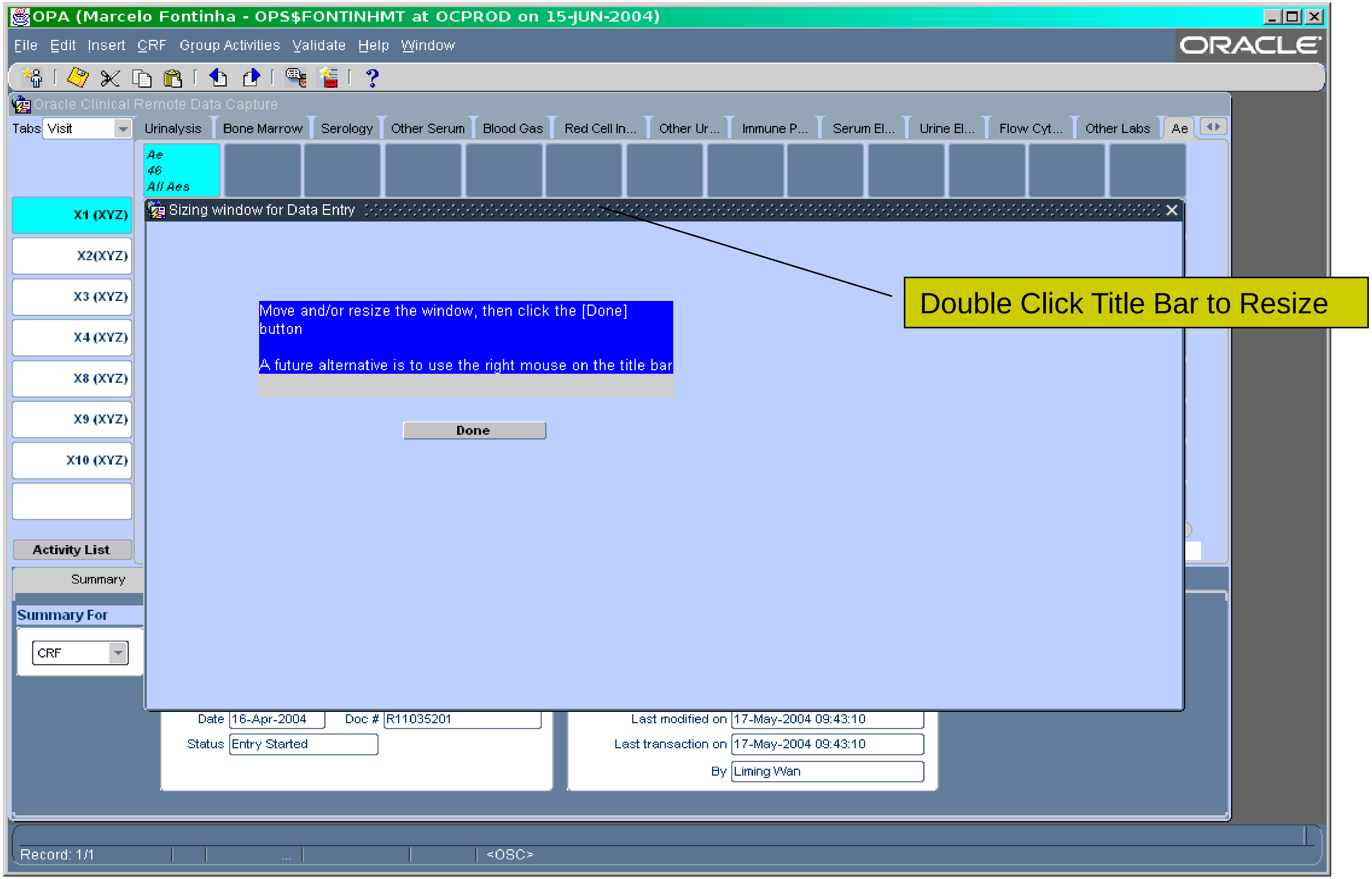
eCRF specific Audit Trail

# 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>

Move and/or resize the window, 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

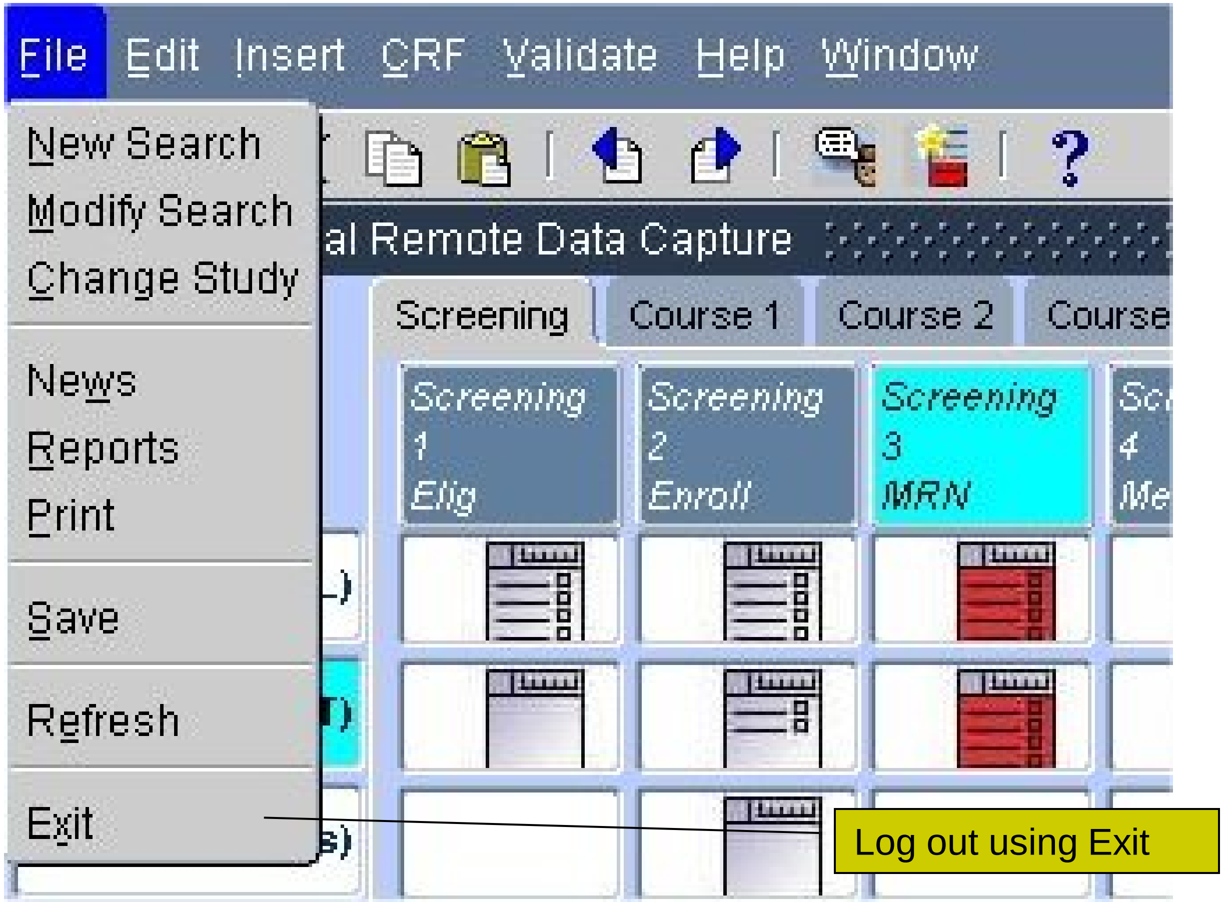
Double Click Title Bar to Resize

# Resizing eCRF Window

- Click on the eCRF title bar
- 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

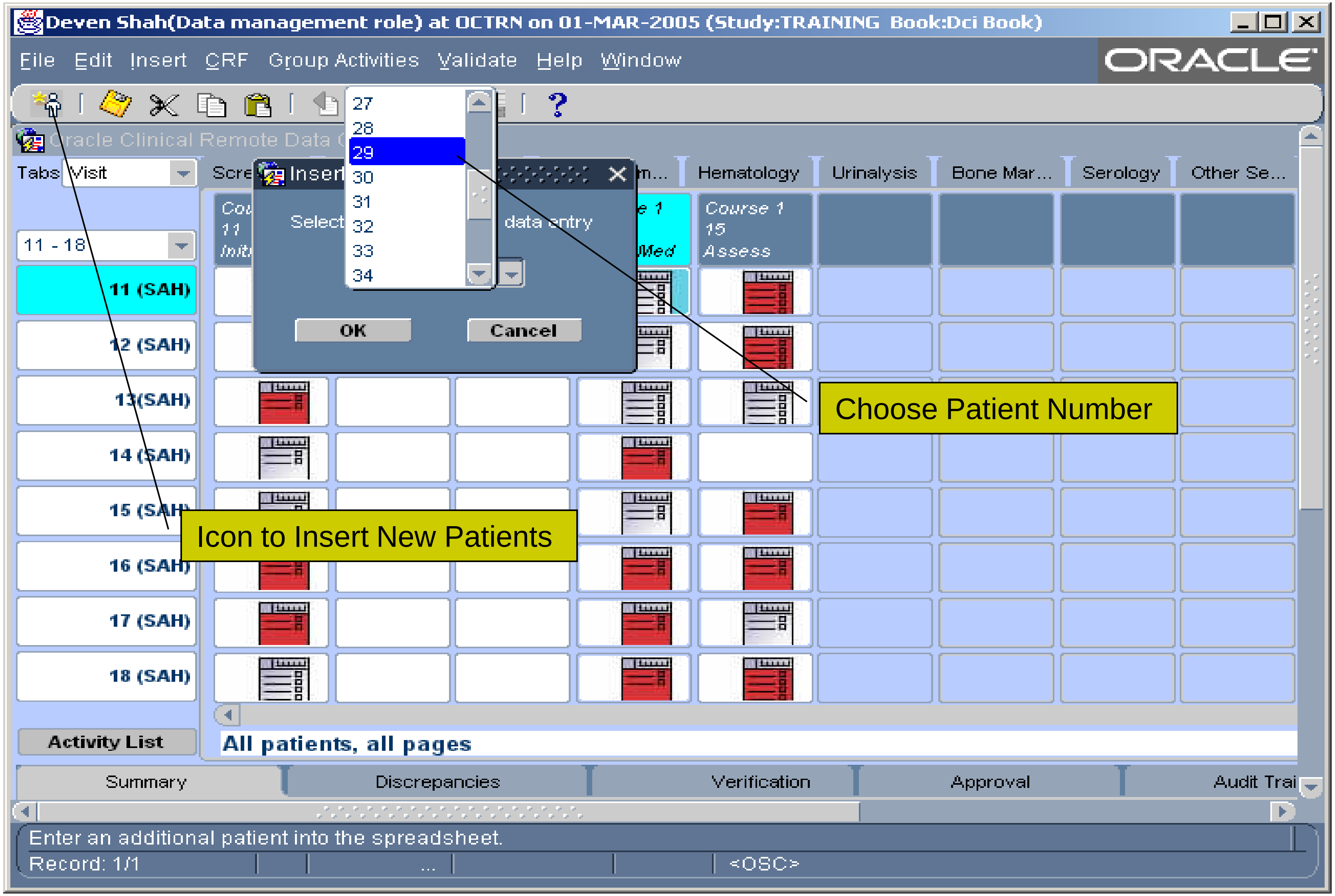

File
Edit
Insert
CRF
Validate
Help
Window
New Search
Modify Search
Change Study
News
Reports
Print
Save
Refresh
Exit
al Remote Data Capture
Screening
Course 1
Course 2
Course
Screening 1 Elig
Screening 2 Enroll
Screening 3 MRN
Sc 4 Me

Log out using Exit

# Log Out

- Exit C3D before closing the Browser
- Inactivity for more than 30 minutes logs your out automatically

# 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
Scre
m...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
11 - 18
11 (SAH)
12 (SAH)
13(SAH)
14 (SAH)
15 (SAH)
16 (SAH)
17 (SAH)
18 (SAH)
Cou 11 Init
e 1 Med
Course 1 15 Assess
Insert
Select
data entry
27
28
29
30
31
32
33
34
OK
Cancel
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trai

All patients, all pages

Enter an additional patient into the spreadsheet.

Record: 1/1 ... <OSC>

Choose Patient Number

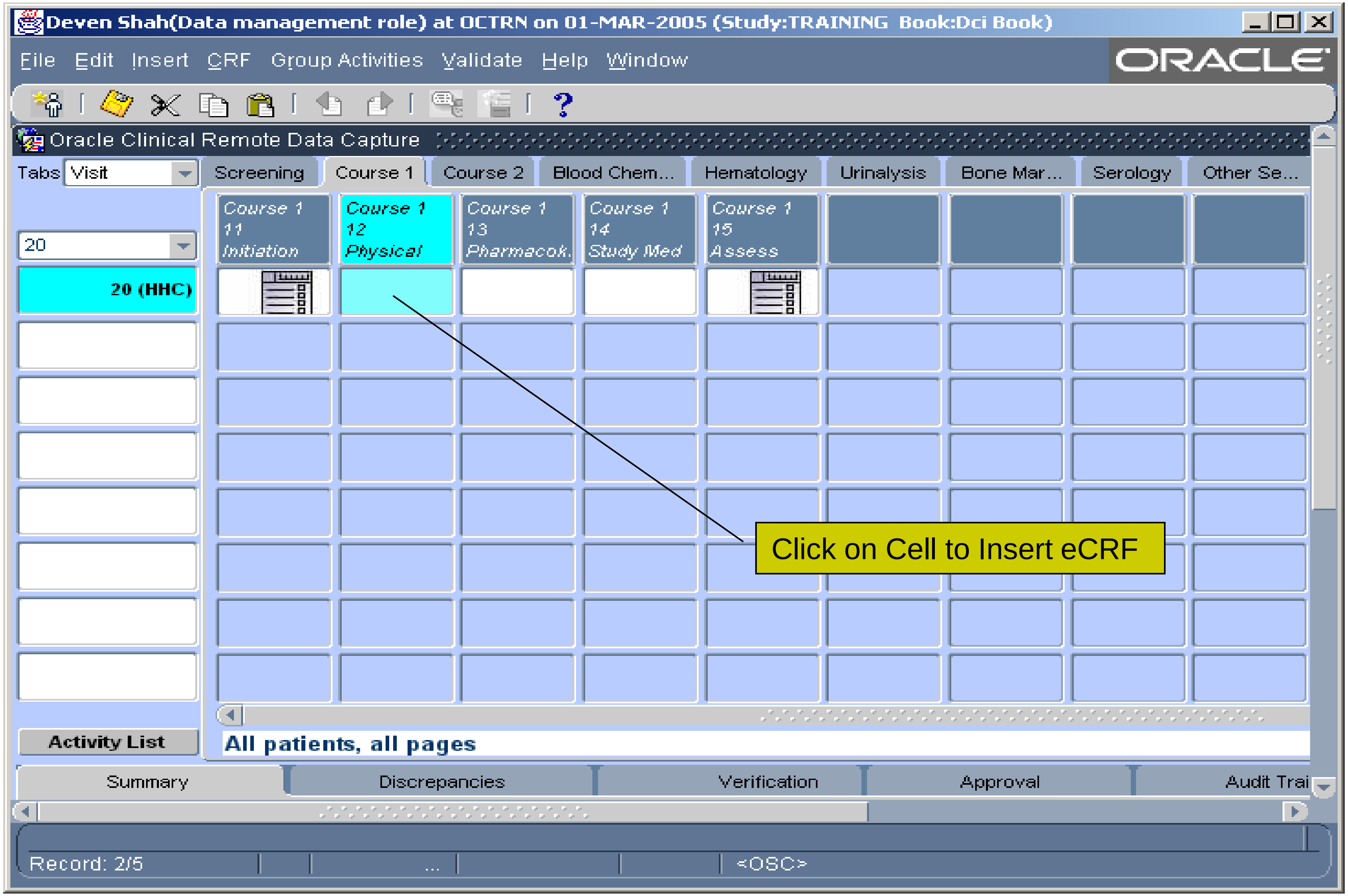
Icon to Insert New Patients

# Inserting New Patient

- Click Patient Icon or Select Insert -> Patient from the menu bar
- Choose a Patient 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



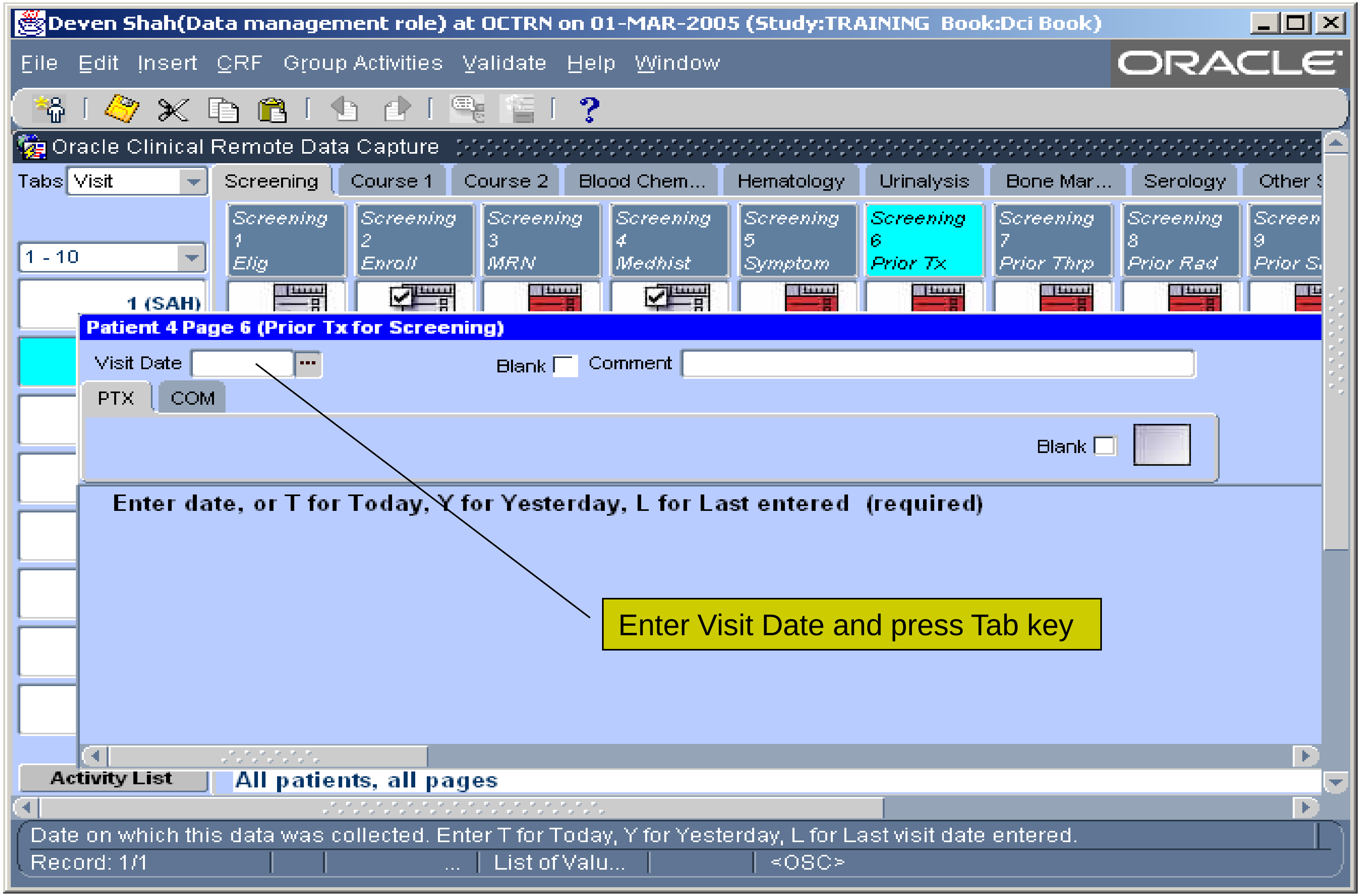
Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)
File Edit Insert CRF Group Activities Validate Help Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs Visit
Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology Other Se...
Course 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 Cell to Insert eCRF

# Starting New Planned eCRF

- Click on cell to insert eCRF
- Resize if necessary

# Entering eCRF Header



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
1 - 10
1 (SAH)
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 S
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>

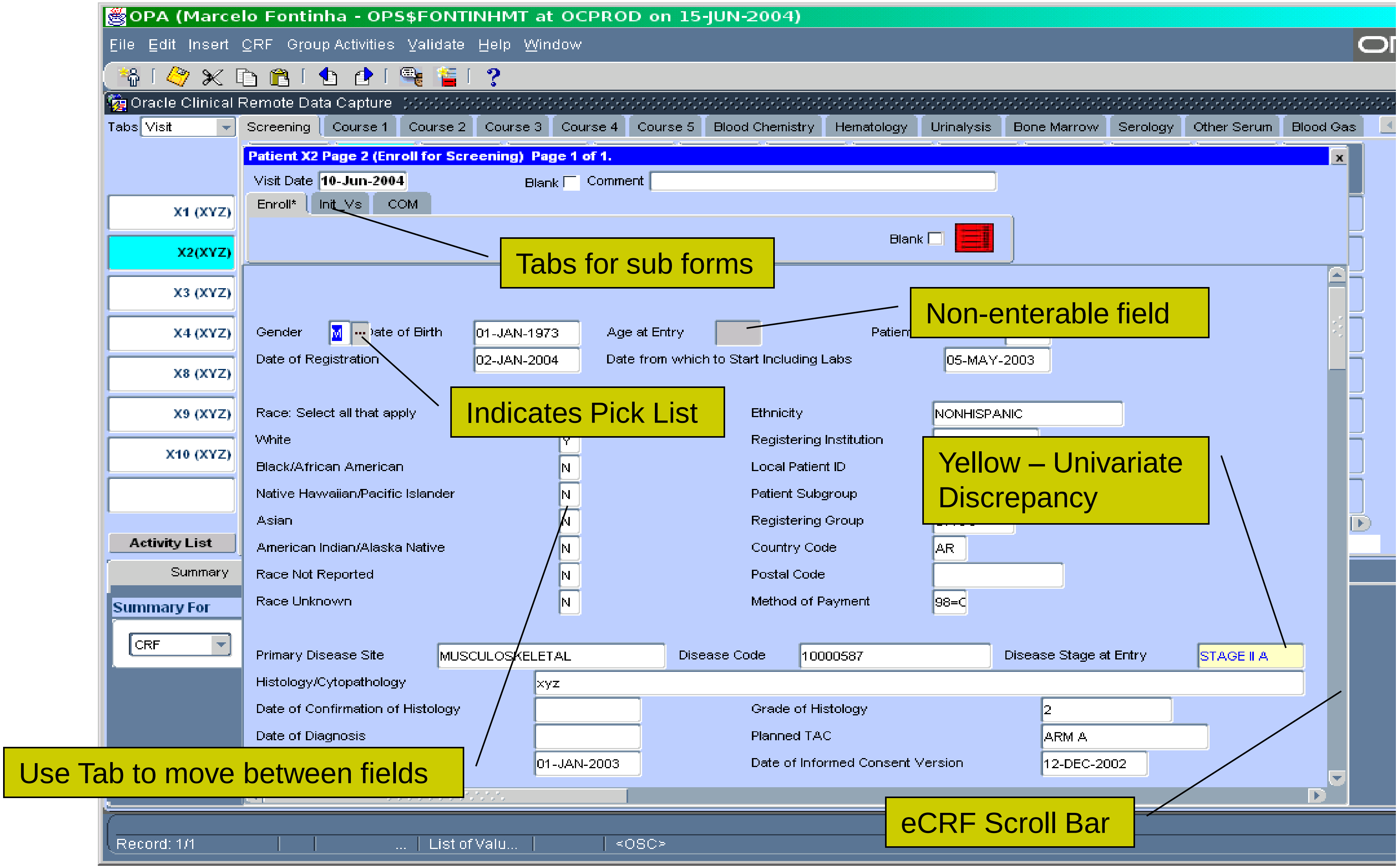
Enter Visit Date and press Tab key

# Entering New eCRF

- Click on the empty Cell to insert appropriate eCRF
- Visit Date is mandatory for most forms
  - Interpret as Evaluation Date, Administration Date, Initiation Date, Lab Date, etc.
  - Use t for today, y for yesterday, or enter date in the MMDDYYYY format.
  - Partial dates are not acceptable when a visit date is mandatory

- **Quick Tip:**
  - Visit Date can be left Blank for Ongoing forms such as AE, Conmeds, etc.

# Entering Data in eCRF


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

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

Oracle Clinical Remote Data Capture

**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
Patien
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 sub forms

Non-enterable field

Indicates Pick List

Yellow – Univariate Discrepancy

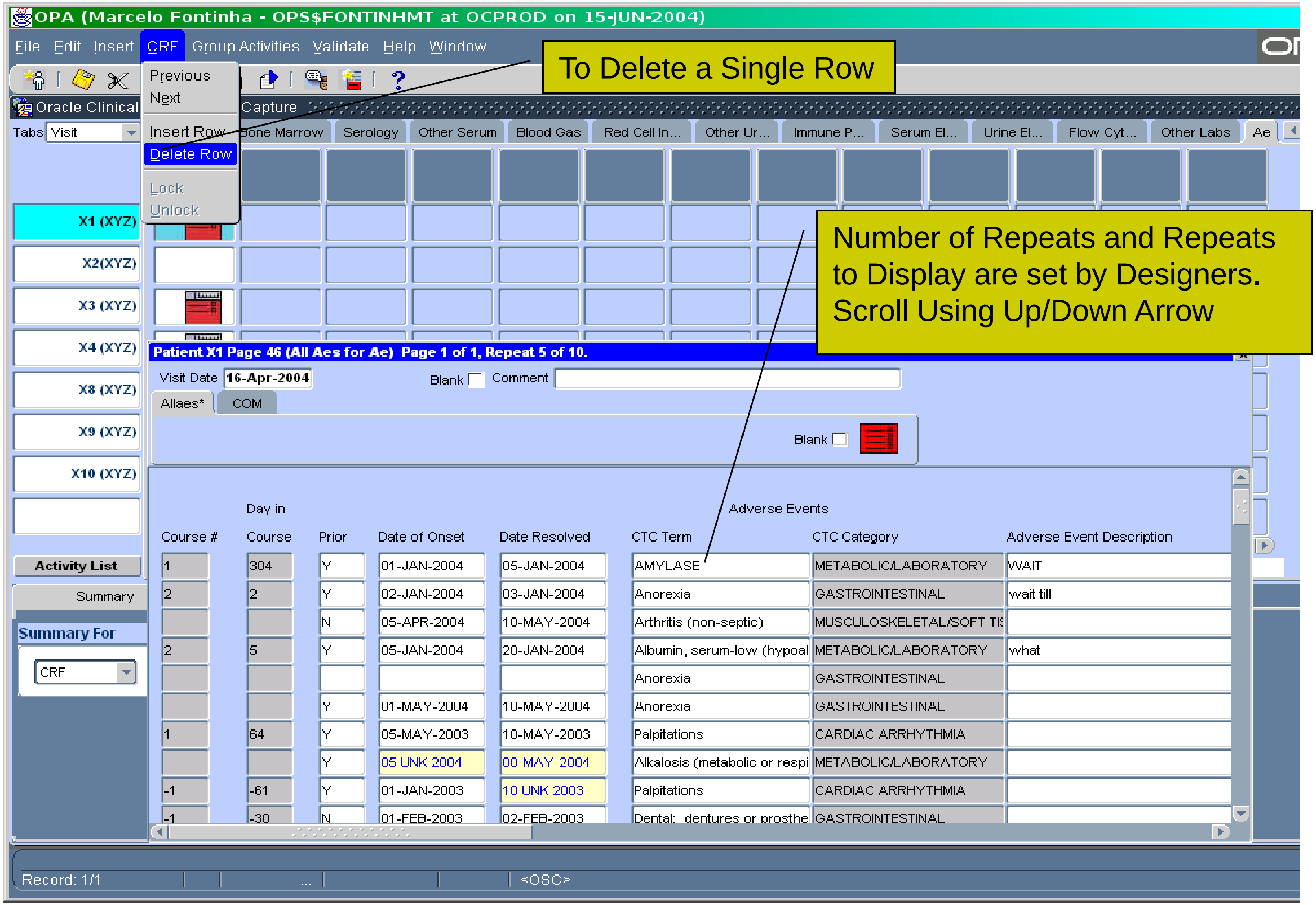
Use Tab to move between fields

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
  - MMDDYYYY for Current Information
  - MMYYYY for Prior Information is acceptable when complete date cannot be obtained

# 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

To Delete a Single Row

Number of Repeats and Repeats to Display are set by Designers. Scroll Using Up/Down Arrow

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

Visit Date 16-Apr-2004 Blank ☐ Comment

Blank ☐

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 TIS |  |
| 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 |  |

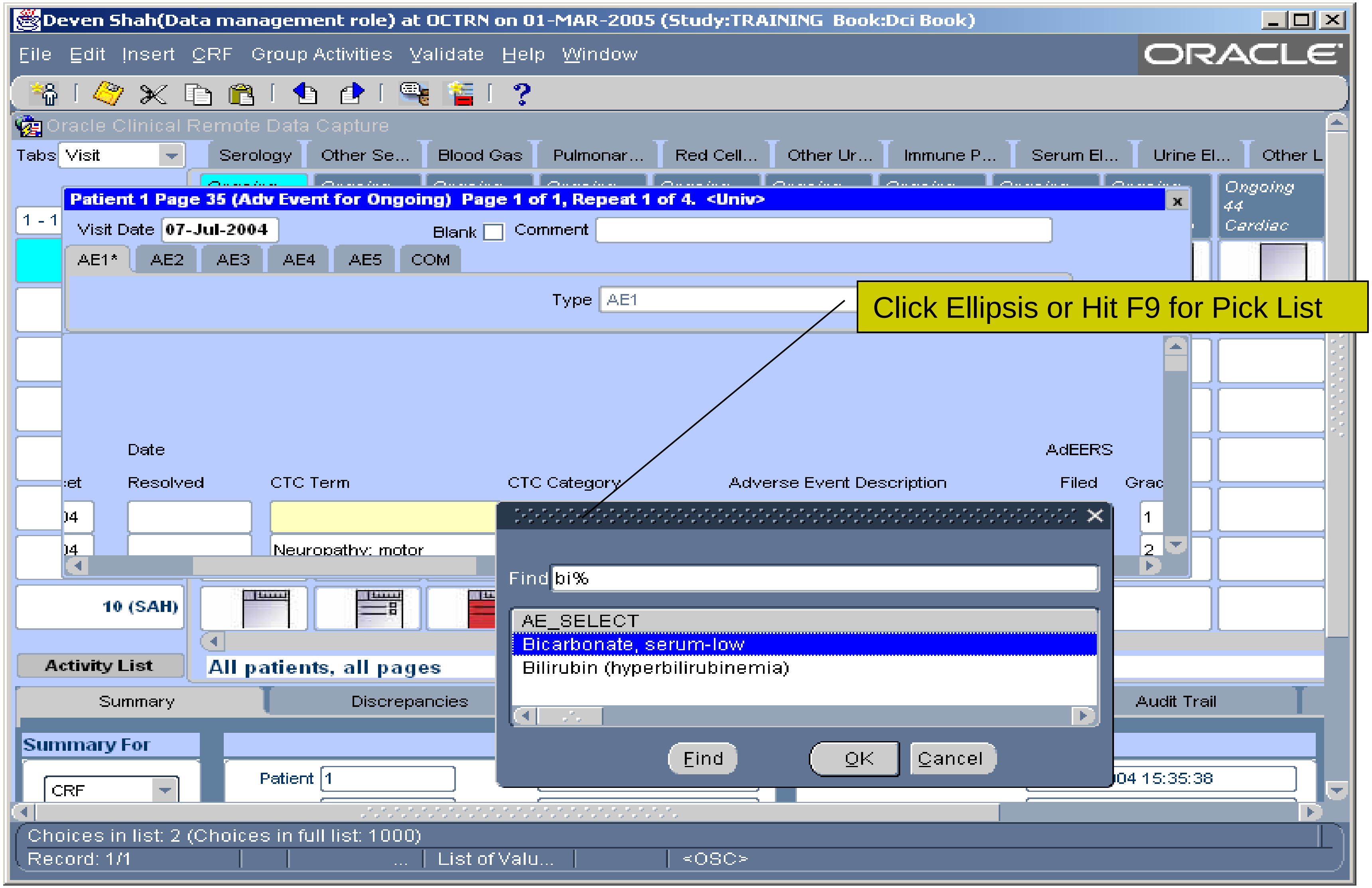
Record: 1/1 <OSC>

# 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



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

Blank ☐ Comment

Type AE1

Find bi%

AE_SELECT
Bicarbonate, serum-low
Bilirubin (hyperbilirubinemia)

Choices in list: 2 (Choices in full list: 1000)
Record: 1/1 ... List of Valu... <OSC>

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
AE1*
AE2
AE3
AE4
AE5
COM
Date Resolved
CTC Term
CTC Category
Adverse Event Description
AdEERS Filed
Grac
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

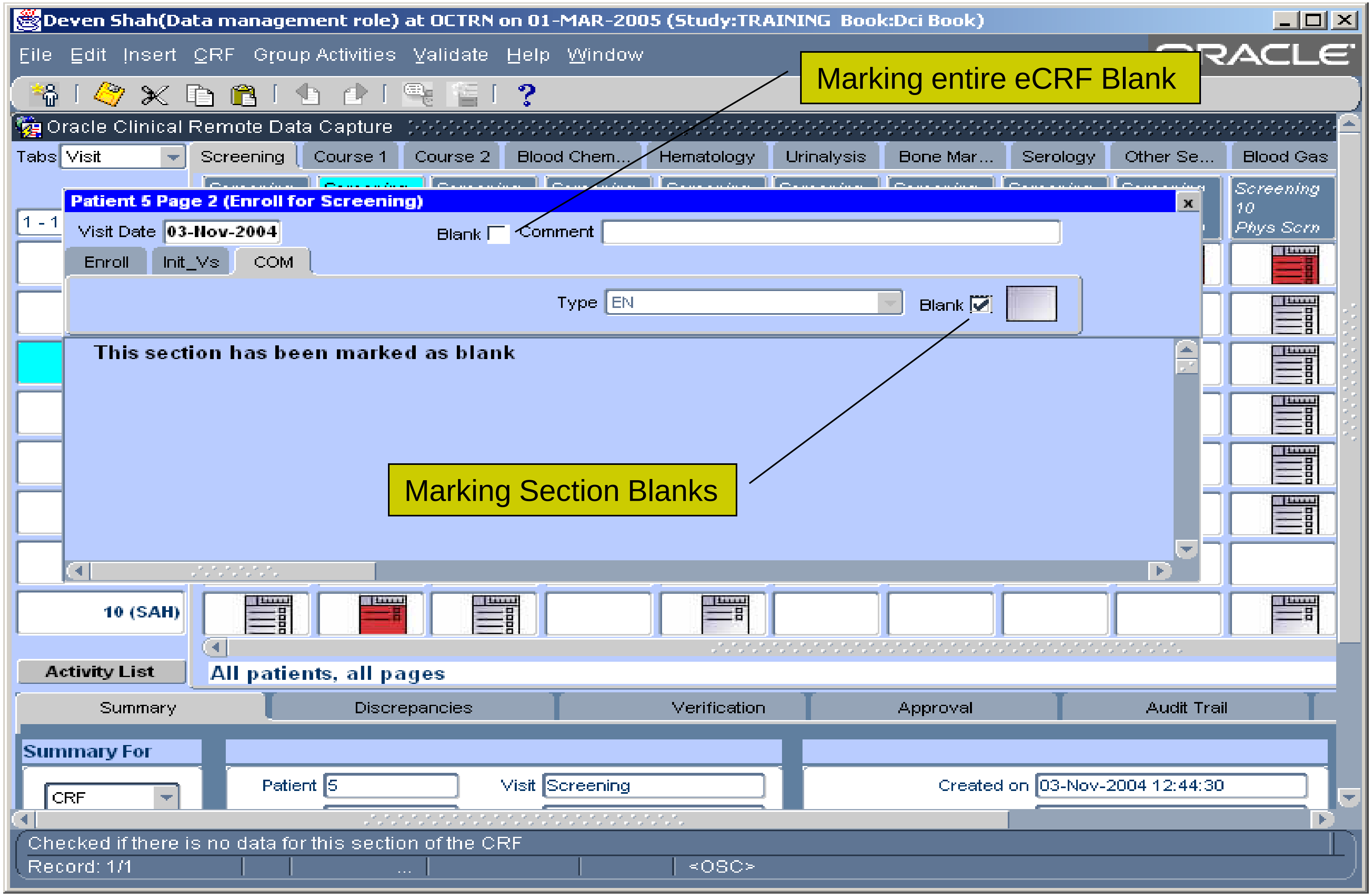
Click Ellipsis or Hit F9 for Pick List

# Using Pick List

- Fields with Ellipsis contain a Pick List
- Pick List can be accessed by clicking the Ellipsis or Entering the F9 Key
- Pick List is Sorted Alphabetically and gets shorter as characters are typed in.

- **Quick Tips:**
  - Pick Lists with more than 1000 entries needs to be queried differently. (Demo)
  - If a value is not in the pick list enter it, create a discrepancy, and consult your DM Supervisor.

# 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

Tabs: Visit

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

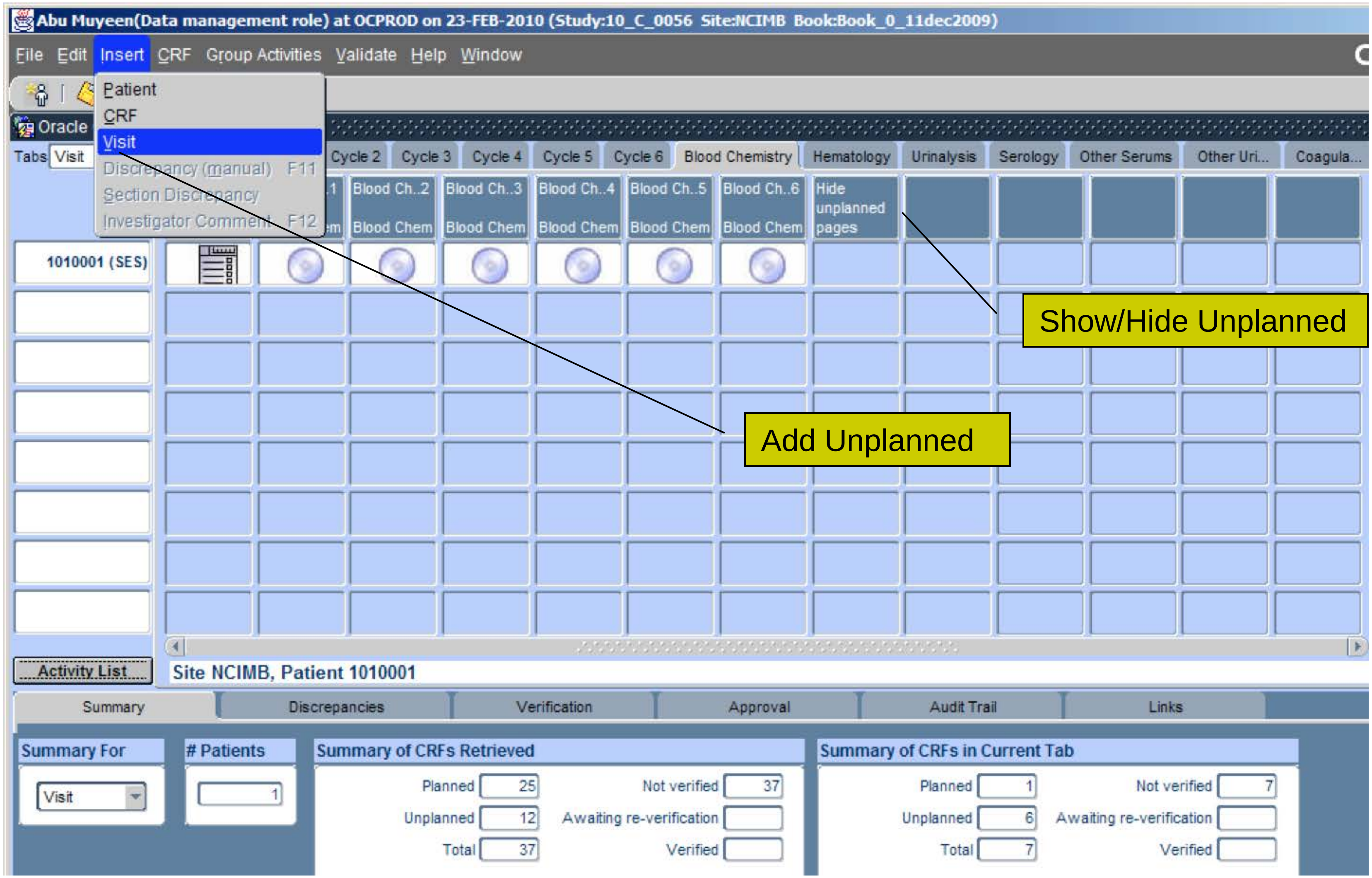
File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
Blood Gas
Screening 10 Phys Scrn
1 - 1
Enroll
Init_Vs
COM
Activity List
Summary
Discrepancies
Verification
Approval
Audit Trail
<OSC>

# Marking eCRF Blank

- Entire eCRF can be marked Blank
- Sections of 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 not entered as Blanks so that the overall status of the eCRF is marked Completed.

# 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 Chem
Blood Ch..3 Blood Chem
Blood Ch..4 Blood Chem
Blood Ch..5 Blood Chem
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

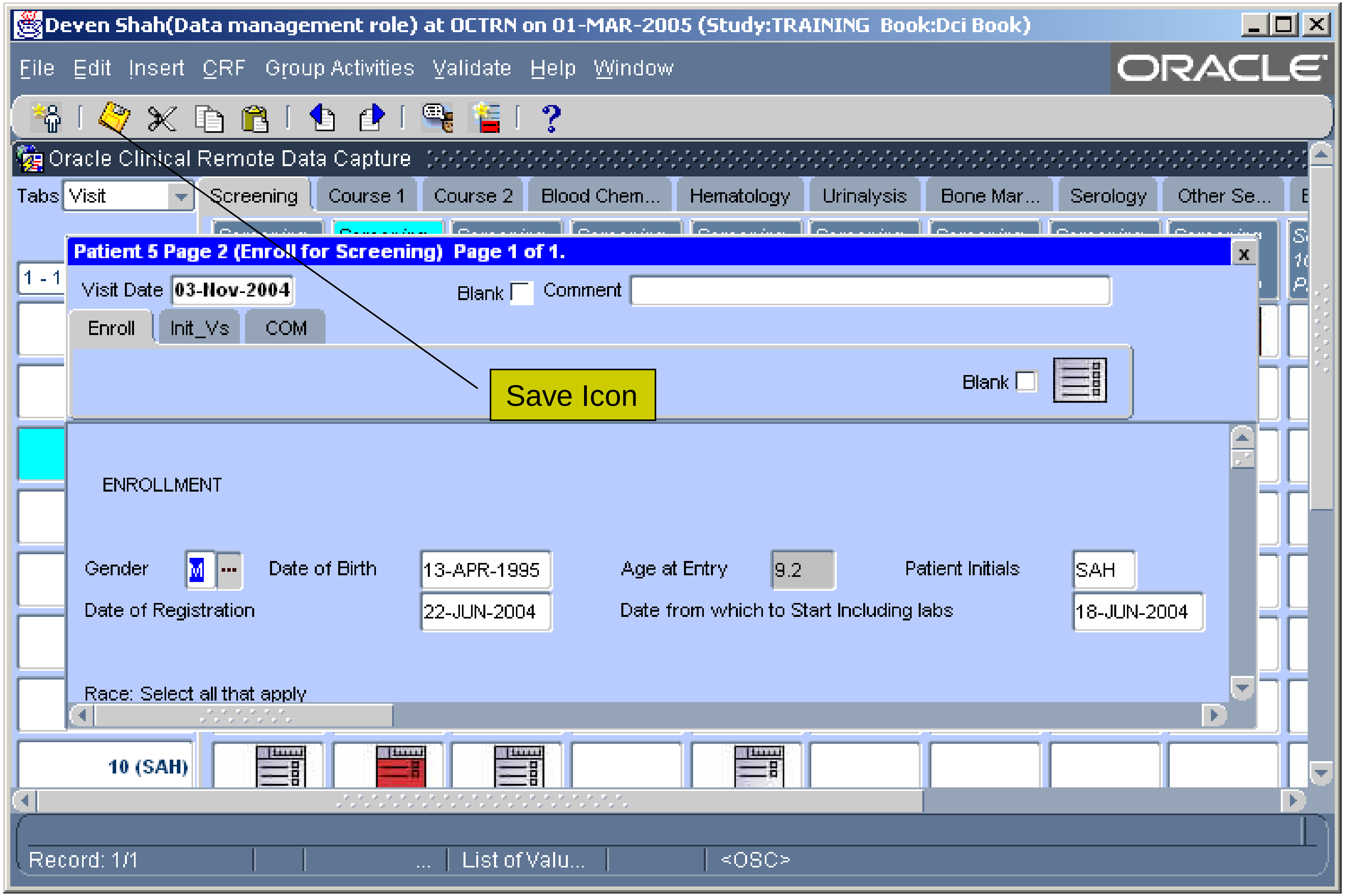
Show/Hide Unplanned

Add Unplanned

# Entering/Viewing Laboratory Data

- Laboratory Data eCRFs are designed with dedicated Tabs
- Additional Forms can be viewed by clicking Show Unplanned Events
- Additional Forms can be added by choosing menu option Insert -> Visit

# Saving eCRF



Save Icon

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) Page 1 of 1.

Visit Date 03-Nov-2004

Blank ☐ Comment

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

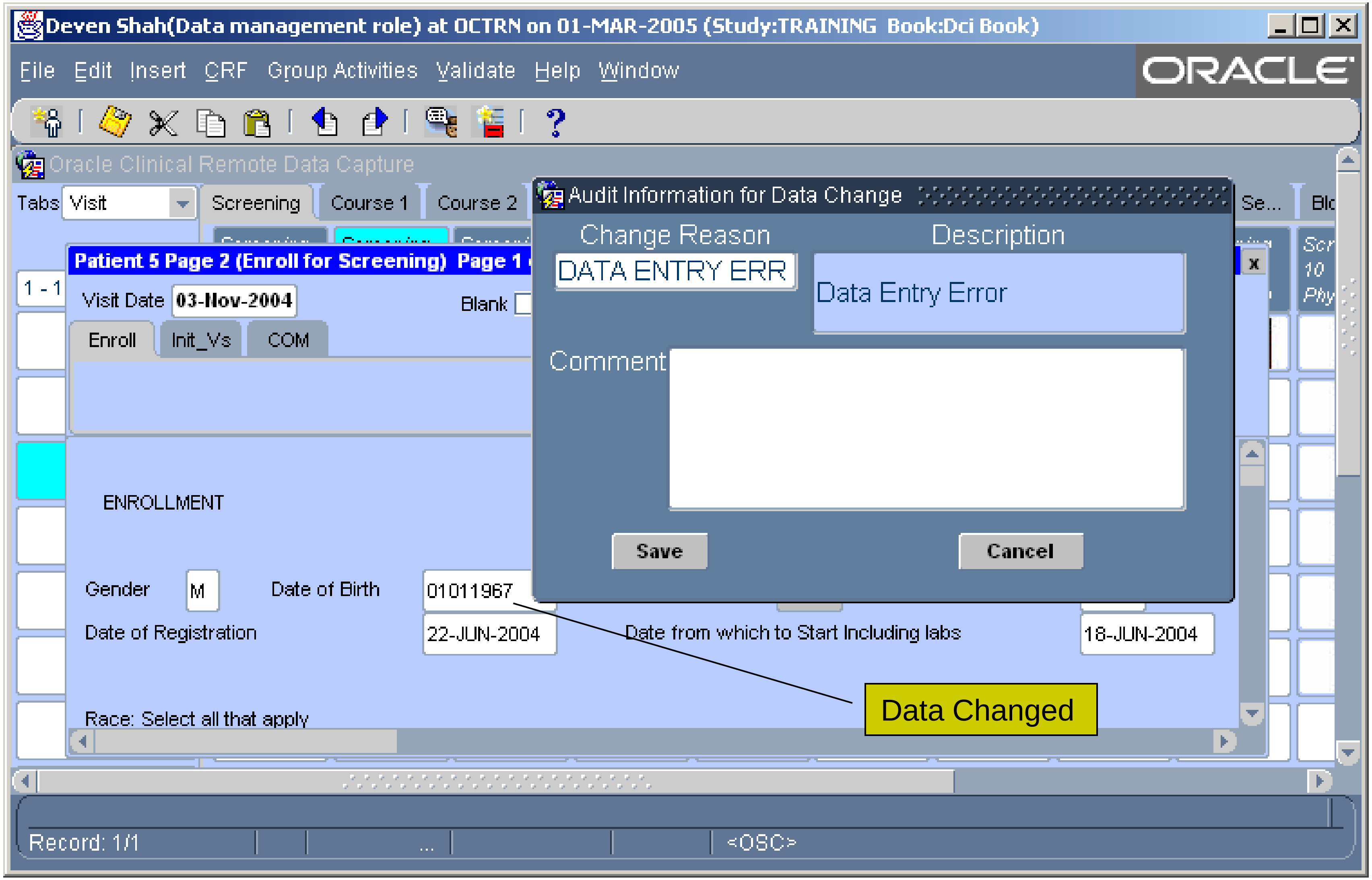
File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Tabs
Visit
Screening
Course 1
Course 2
Blood Chem...
Hematology
Urinalysis
Bone Mar...
Serology
Other Se...
1 - 1
Enroll
Init_Vs
COM
Blank ☐
10 (SAH)
List of Valu...
<OSC>

# Saving eCRF

- eCRF can be saved using
  - Save Icon
  - F10 Key
  - File -> Save menu option

- **Quick Tip:**
  - Save Often!! Especially while entering Ongoing Information such as AEs and ConMeds.

# Data Entry Change Reason


File
Edit
Insert
CRF
Group Activities
Validate
Help
Window
ORACLE
Oracle Clinical Remote Data Capture
Tabs
Screening
Course 1
Course 2
Se...
Blc
1 - 1
Enroll
Init_Vs
COM
Save
Cancel
Record: 1/1
...
<OSC>

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

Tabs: Visit

**Patient 5 Page 2 (Enroll for Screening) Page 1**

Visit Date: 03-Nov-2004

Blank ☐

Audit Information for Data Change

| Change Reason | Description |
|---|---|
| DATA ENTRY ERR | Data Entry Error |

Comment:

ENROLLMENT

Gender: M

Date of Birth: 01011967

Date of Registration: 22-JUN-2004

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

Race: Select all that apply

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 names in the comments.

# What is a Discrepancy?

- A discrepancy is the failure of entered data to pass a validation check as applied by C$^3$D
- C$^3$D validation checks are defined based on the definition of the fields, logical rules, protocol specifications, and sponsor requirements.

# Why Discrepancies?

- Discrepancies are tools to assist teams in programmatically identifying potential data inconsistencies
- Discrepancies facilitate real-time QA of clinical data

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

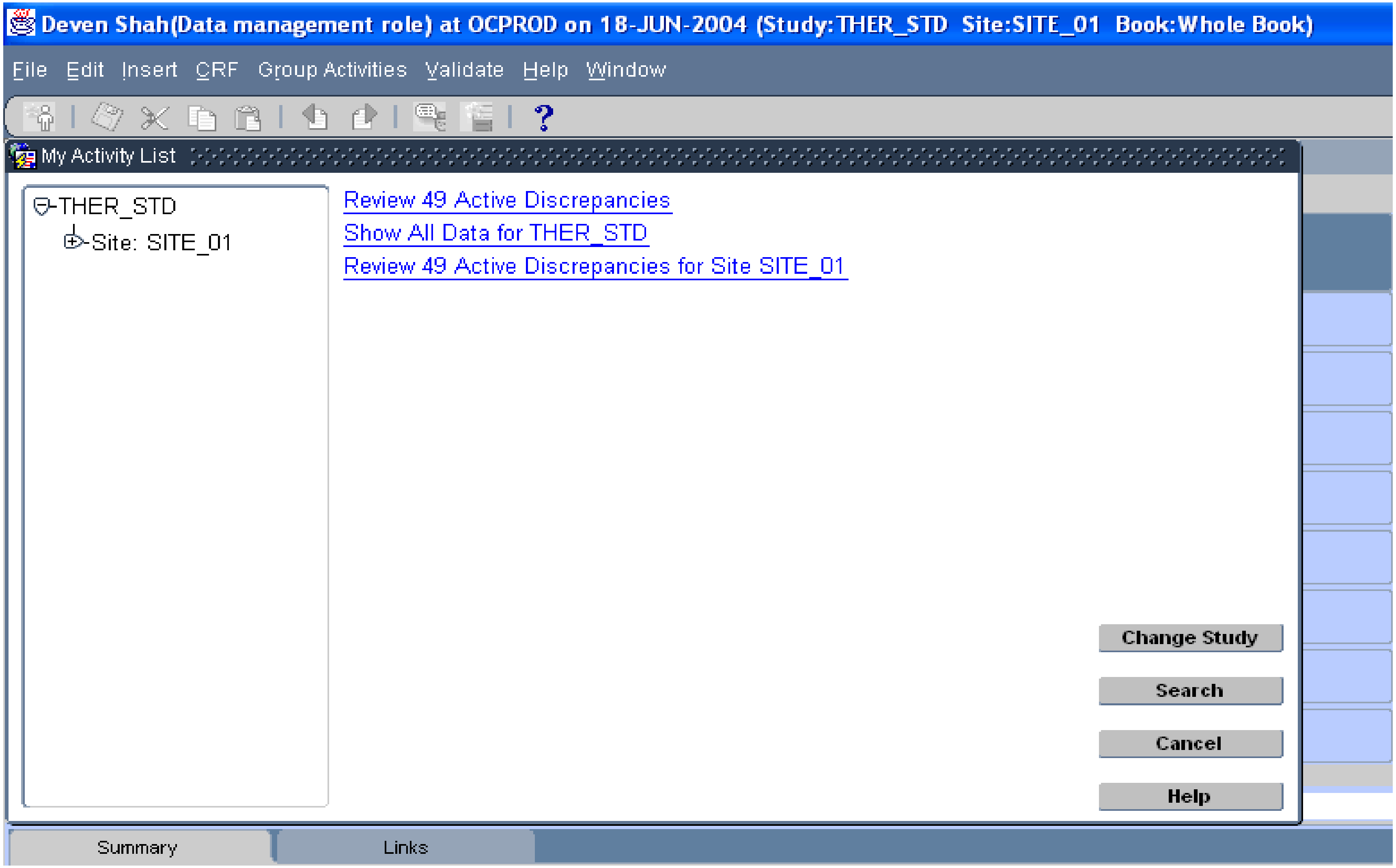
# C3D Discrepancy Types

- Univariate
  - Generated during data entry/load when data is in some way different from the Question definition (e.g. length, type, range, pick list, etc.)
- Multivariate
  - Based on a condition on one or more fields as defined in a validation rule
  - Generated on-line or when validation rules are run
- Manual
  - Generated by data entry operator seeking clarification on data values

# Some Typical Discrepancies

| Types | Resolution |
|---|---|
| Data Type | Review Source Document |
| Length Problems | Use NIH accepted Abbrev |
| Missing Pick list Values | Search for alternates, e.g. Generic; Consult TL/Liz. |
| Mandatory Value | Refer to Source Document; Design modification |
| Partial/Invalid Dates | 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

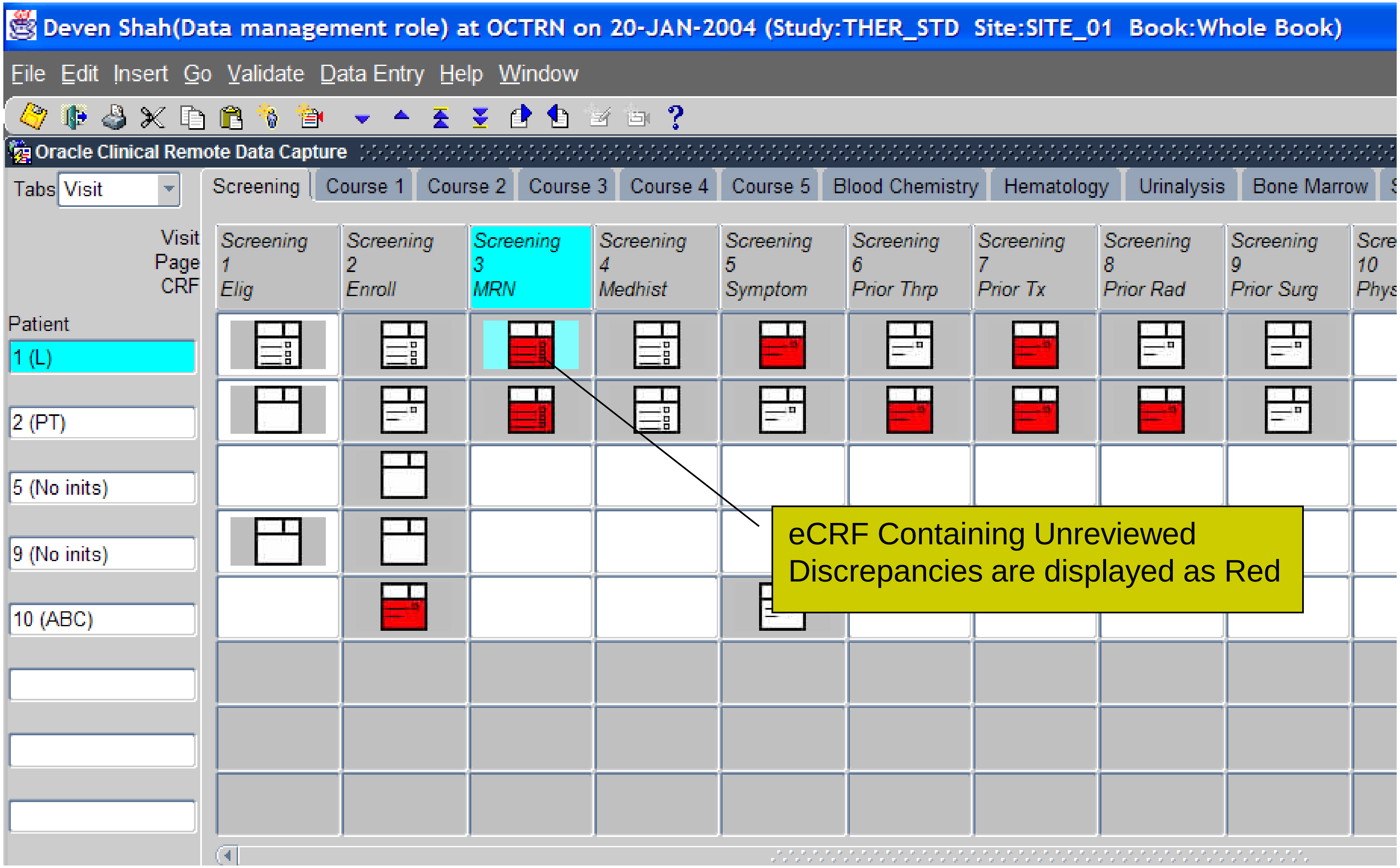
Change Study
Search
Cancel
Help
Summary
Links

# 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” will present only the Discrepant eCRFs

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

# eCRFs Containing Discrepancies


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

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

Tabs: Visit

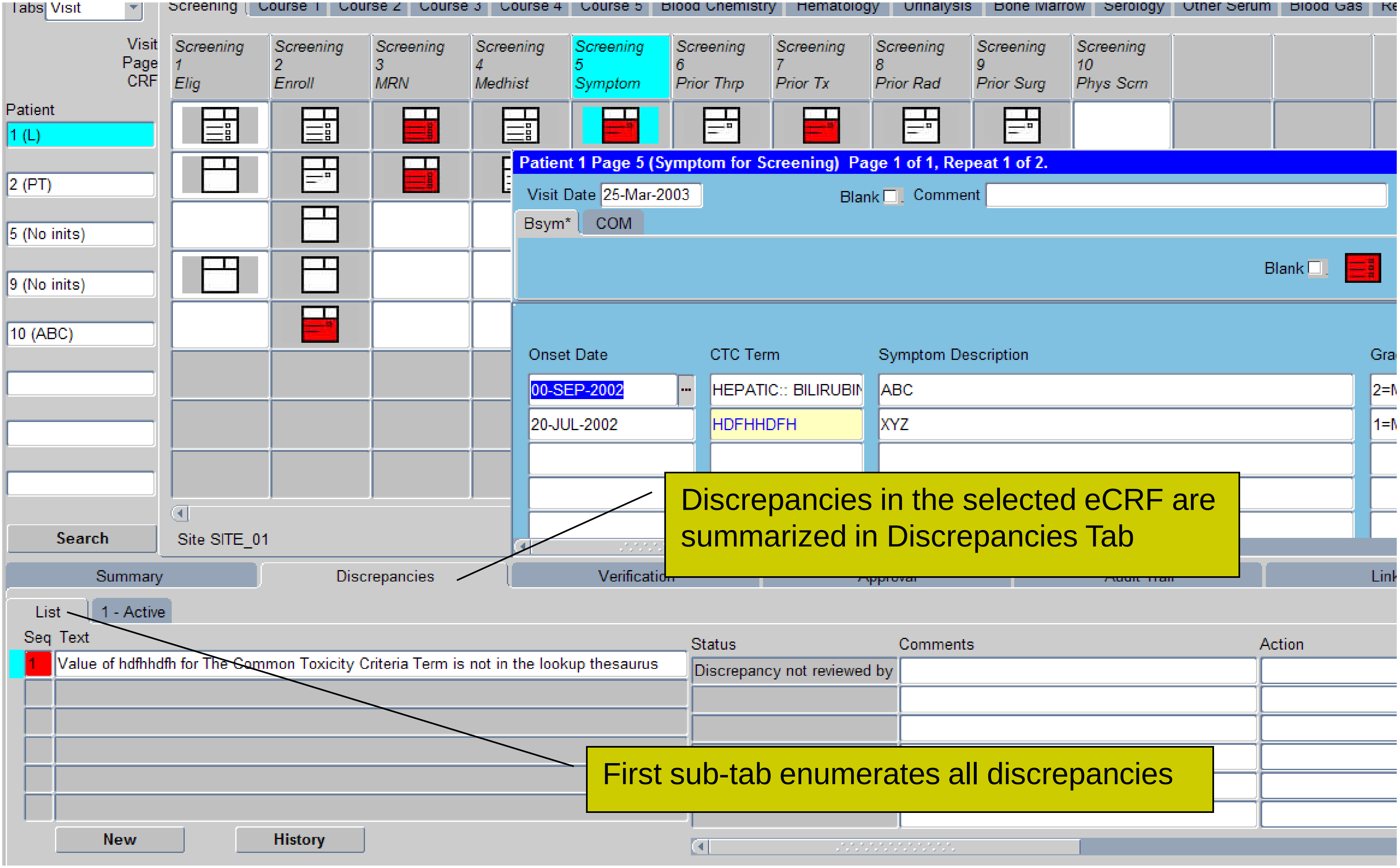
| Visit<br>Page<br>CRF | *Screening*<br>*1*<br>*Elig* | *Screening*<br>*2*<br>*Enroll* | *Screening*<br>*3*<br>*MRN* | *Screening*<br>*4*<br>*Medhist* | *Screening*<br>*5*<br>*Symptom* | *Screening*<br>*6*<br>*Prior Thrp* | *Screening*<br>*7*<br>*Prior Tx* | *Screening*<br>*8*<br>*Prior Rad* | *Screening*<br>*9*<br>*Prior Surg* | *Scre*<br>*10*<br>*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
Summary
Discrepancies
Verification
Approval
Audit Trail
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 | 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 | | |

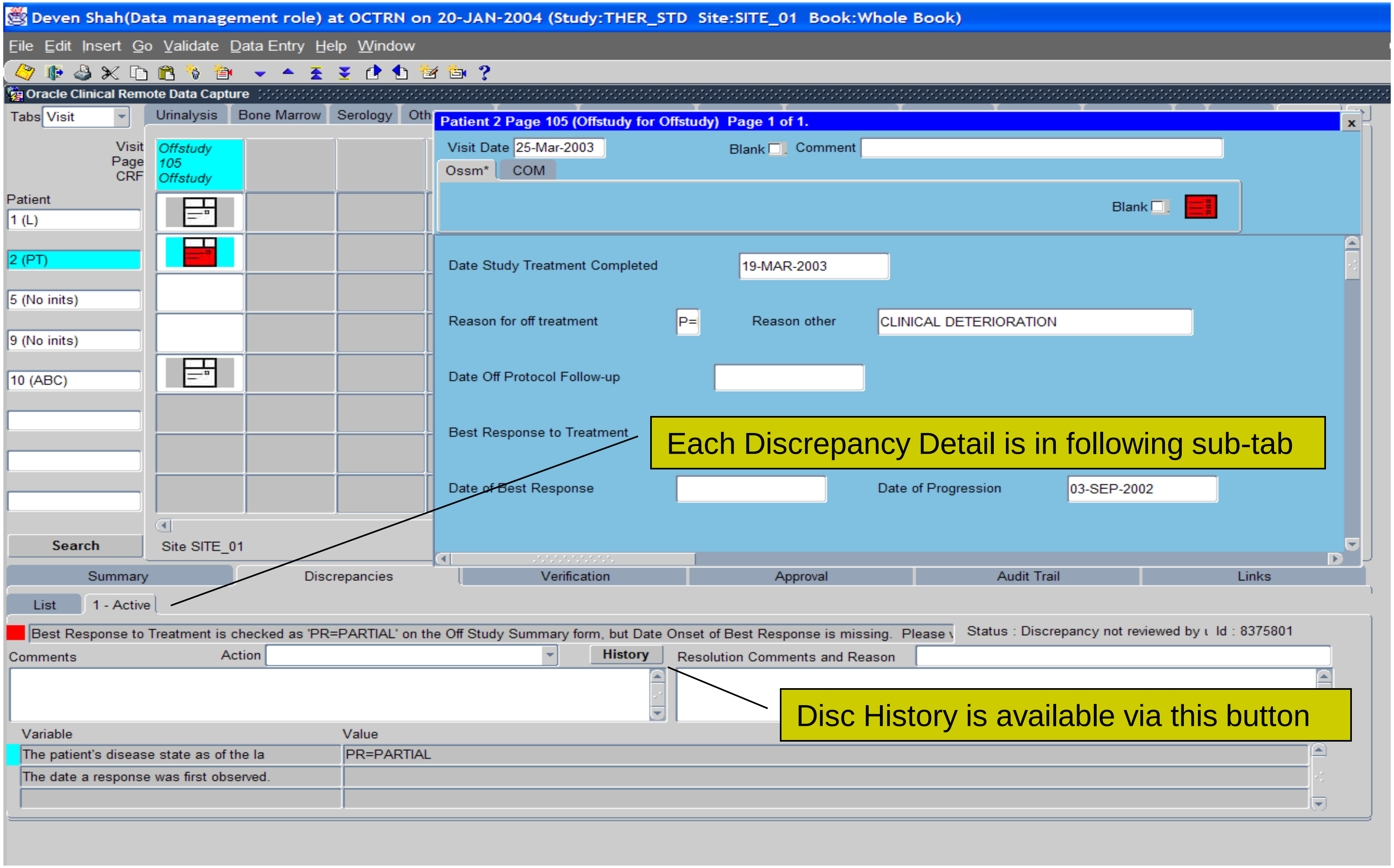
Discrepancies in the selected eCRF are summarized in Discrepancies Tab

First sub-tab enumerates all discrepancies

# Discrepancies Tab

- While viewing an eCRF, clicking on the Discrepancies Tab shows the discrepancies on that eCRF
- The first sub-tab gives the summary of all discrepancies in that eCRF (open and closed)

# Discrepancy Details



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
Urinalysis
Bone Marrow
Serology
Oth
Visit
Page
CRF
Offstudy
105
Offstudy
Patient
1 (L)
2 (PT)
5 (No inits)
9 (No inits)
10 (ABC)
Search
Site SITE_01

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

Visit Date 25-Mar-2003 Blank ☐ Comment

Ossm*
COM
Blank ☐

| | |
|---|---|
| Date Study Treatment Completed | 19-MAR-2003 |
| Reason for off treatment | P= |
| Reason other | CLINICAL DETERIORATION |
| Date Off Protocol Follow-up | |
| Best Response to Treatment | |
| Date of Best Response | |
| Date of Progression | 03-SEP-2002 |

Summary
Discrepancies
Verification
Approval
Audit Trail
Links
List
1 - Active

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

Status : Discrepancy not reviewed by u Id : 8375801

Comments Action

Resolution Comments and Reason

| 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 sub-tab

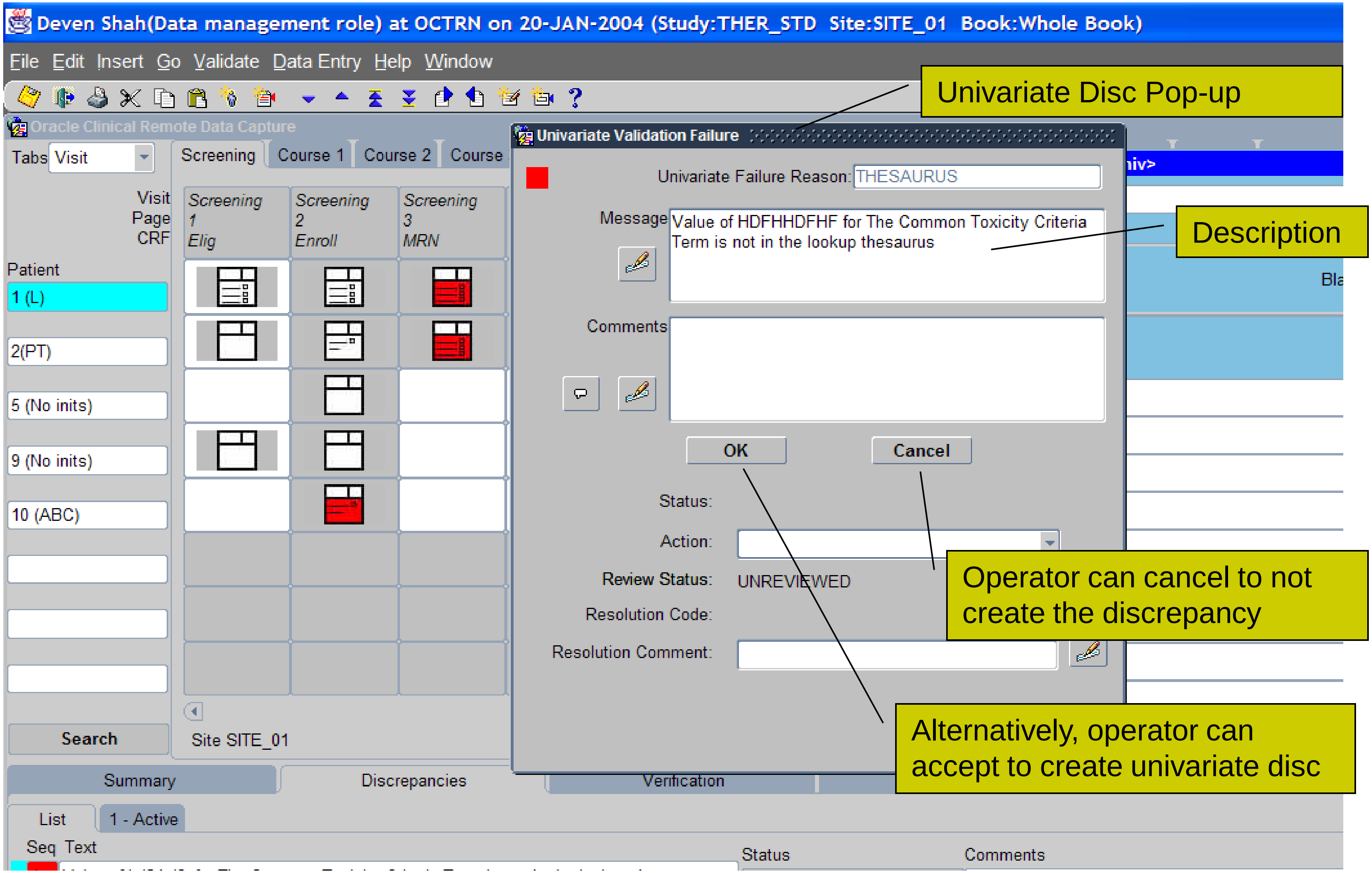
Disc History is available via this button

# Discrepancy Details

- Subsequent sub-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
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

Operator can cancel to not create the discrepancy

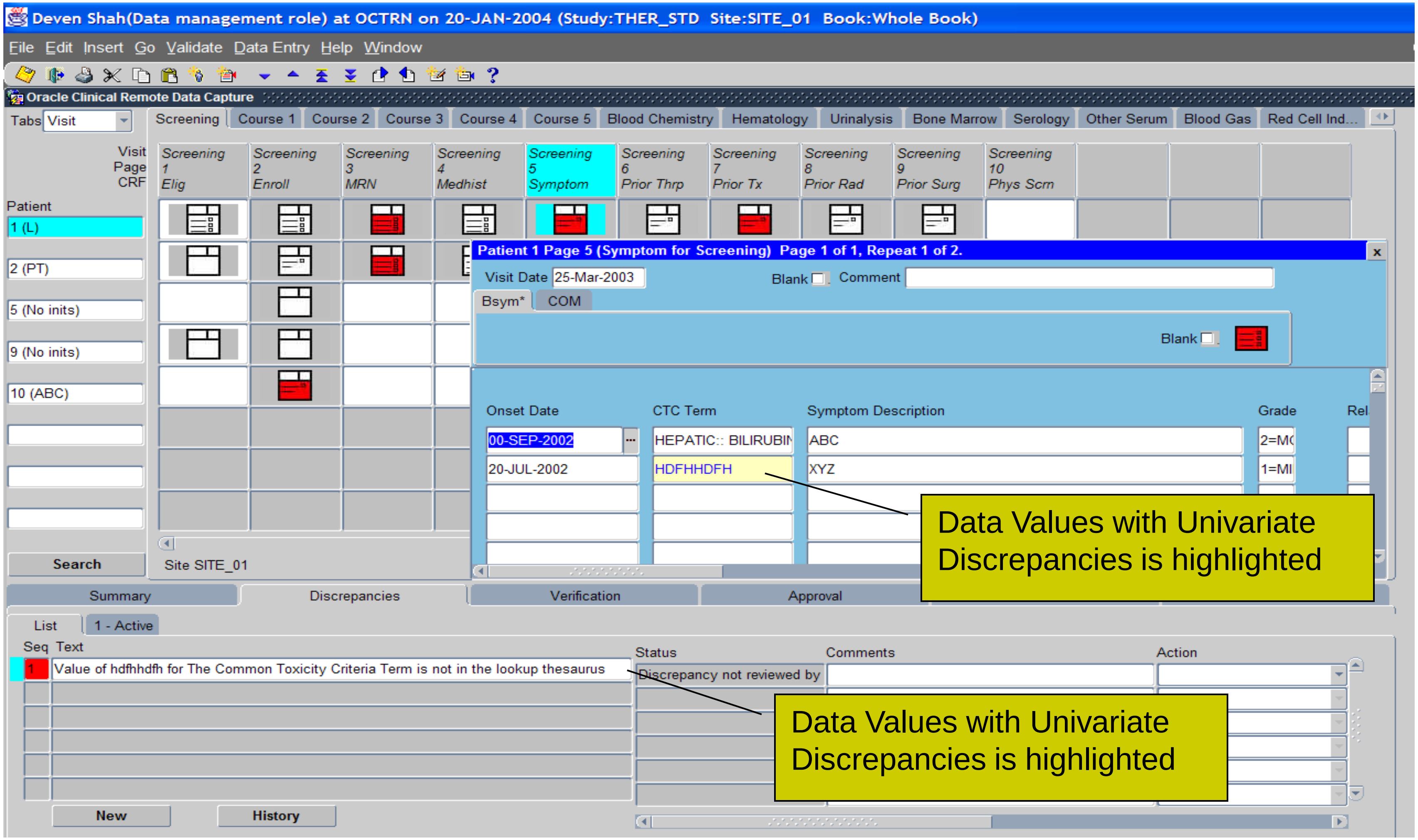
Alternatively, operator can accept to create univariate disc

# How are Univariate Disc. Created?

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


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
Blank
Comment
Bsym*
COM
Summary
Discrepancies
Verification
Approval
List
1 - Active
New
History

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 1 of 2.

Visit Date 25-Mar-2003

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

| 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 | | |

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?

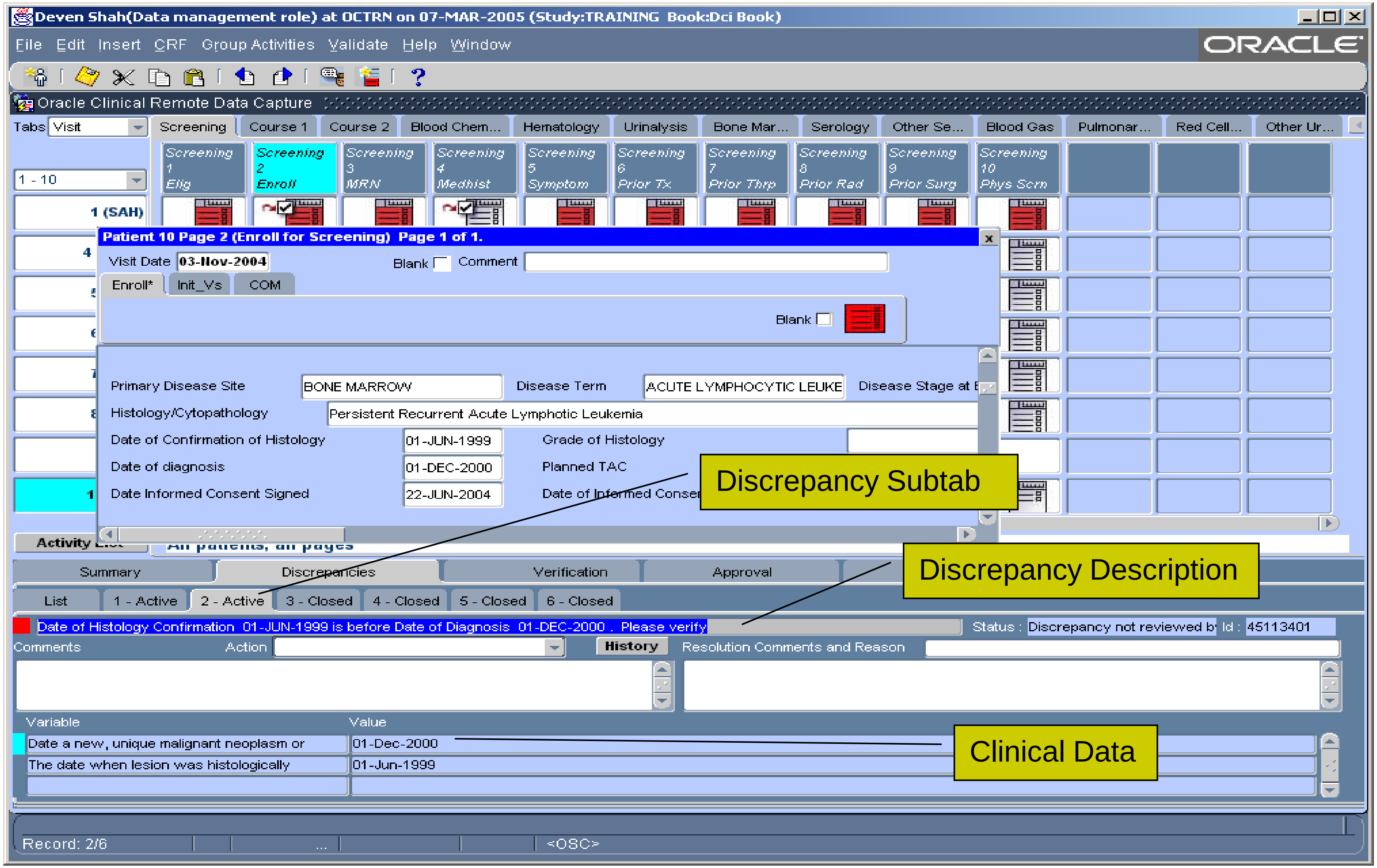
- Multivariate Discrepancies are created based on validation rules programmed in a study
  - Example 1: Create Discrepancy if the entered BSA is not within 10% of the calculated BSA
  - Example 2: Create Discrepancy if Date of Histological Confirmation is before Date of Diagnosis

- **Quick Tip:**
  - Rules available as a standard on each eCRF are summarized in the eCRF instruction manual.
  - Though several standard rules are implemented for each eCRF as specified on the eCRF instructions manual, clinical teams can request them to be turned off if they do not apply to a protocol.

# Evaluation of Multivariate Rules

- Validation Rules are evaluated
  - on-line upon completion of a form, or
  - during an overnight batch validation session
- **Quick Tip:**
  - Complex rules run overnight

# How is a Multivariate Disc. displayed?


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>

Deven Shah(Data management role) at OCTRN on 07-MAR-2005 (Study:TRAINING Book:Dci Book)

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

Disease Stage at

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 Conser

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 Subtab

Discrepancy Description

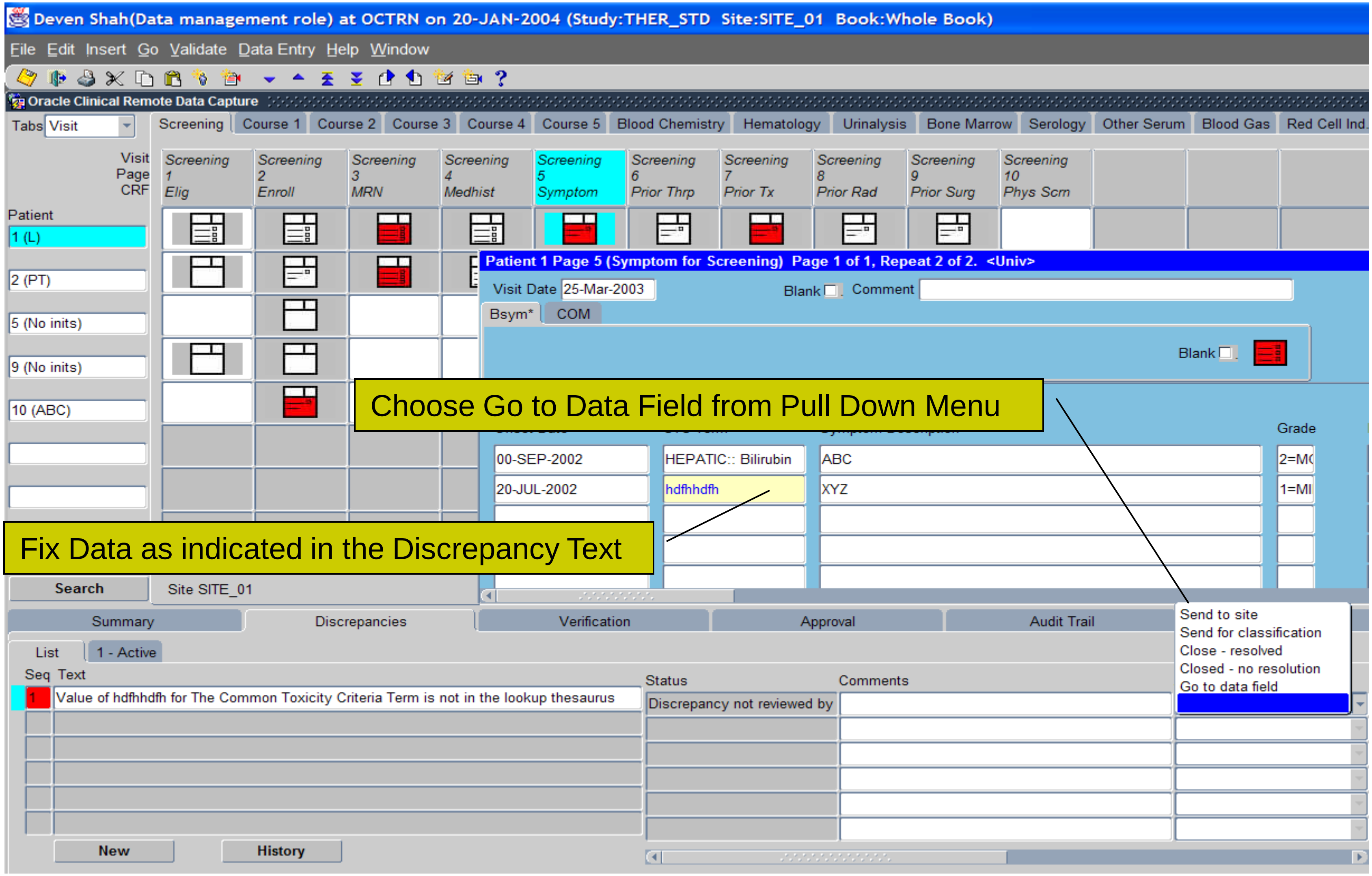
Clinical Data

# How is a Mulitvariate Disc. displayed?

- Discrepancy is based on one or more fields and is NOT highlighted in Yellow
- Discrepancy sub-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


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
Bsym*
COM
Blank ☐
Grade
Summary
Discrepancies
Verification
Approval
Audit Trail
List
1 - Active
New
History
Send to site
Send for classification
Close - resolved
Closed - no resolution
Go to data field

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

Site SITE_01

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

Visit Date 25-Mar-2003 Blank ☐ Comment

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

Choose Go to Data Field from Pull Down Menu

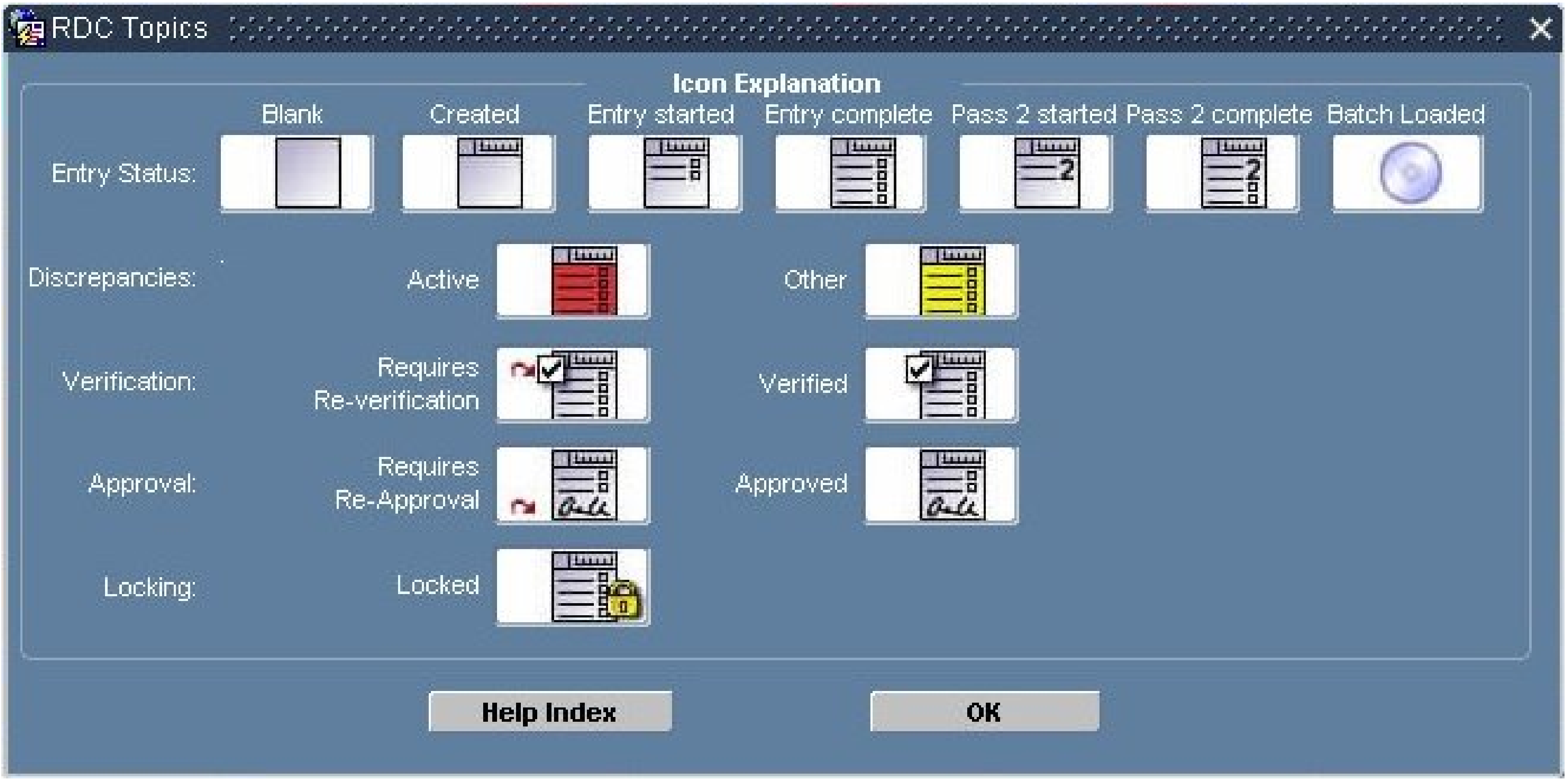
Fix Data as indicated in the Discrepancy Text

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

# How to Address a Discrepancy

- Review Discrepancy Text
- Whenever possible, use the Action pull down ‘Go to Data Field’ to jump to the Discrepant Field
- Resolve the discrepancy by:
  - Modifying incorrect data and specifying change reason
  - Requesting Design or Rule Change
- **Quick Tip:**
  - System obsoletes the discrepancy automatically when data is corrected.

# Verification & Appoval



**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

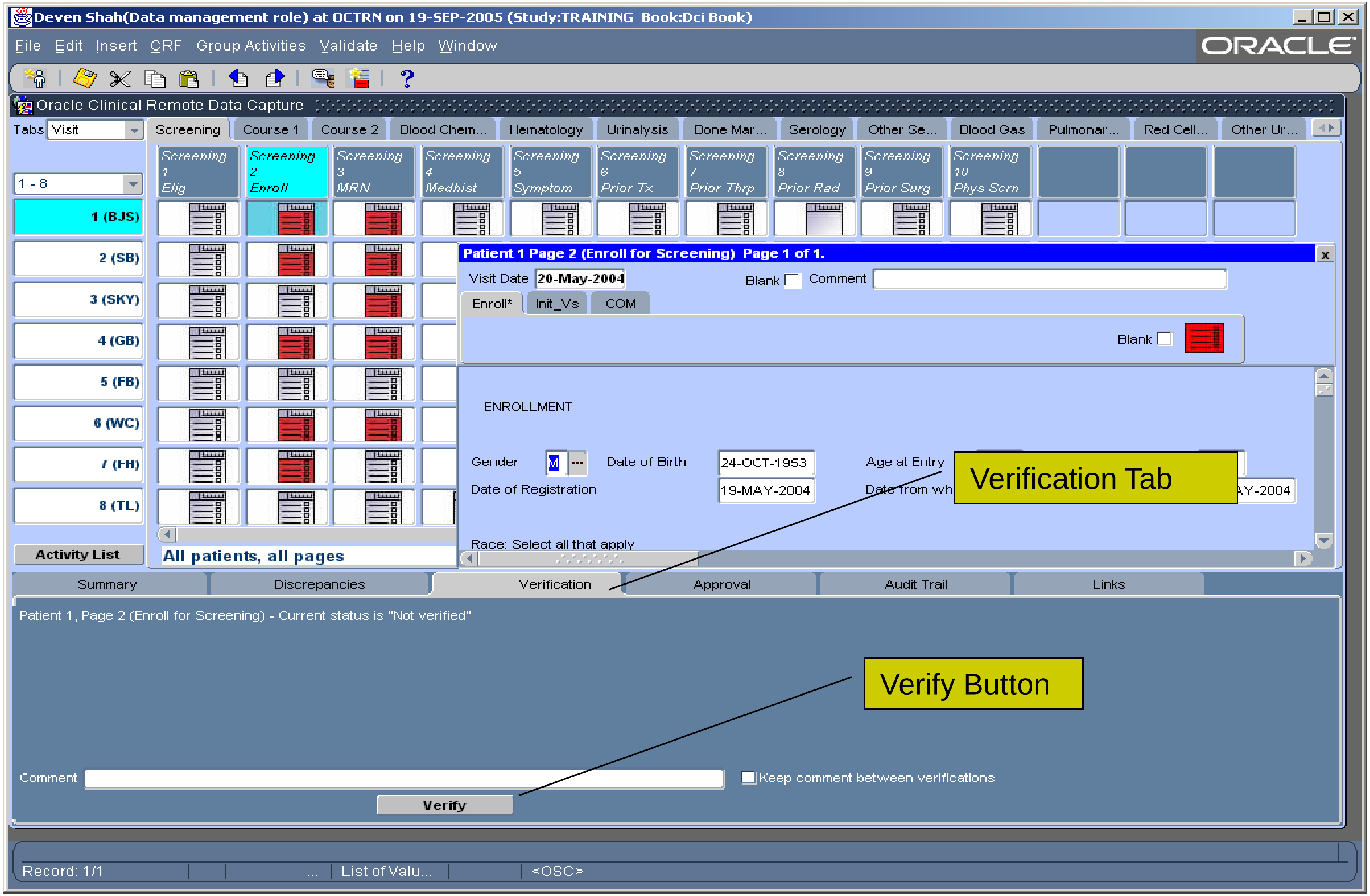
Approval: Requires Re-Approval, Approved

Locking: Locked

# Verification & Approval

- C3D Verification & Approval functionality offer capability to track QA and Monitoring of 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 Blank ☐ Comment

ENROLLMENT

Gender M Date of Birth 24-OCT-1953 Age at Entry

Date of Registration 19-MAY-2004 Date from wh… …AY-2004

Race: Select all that apply

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

Comment

☐ Keep comment between verifications

Record: 1/1 … List of Valu… <OSC>

Verification Tab

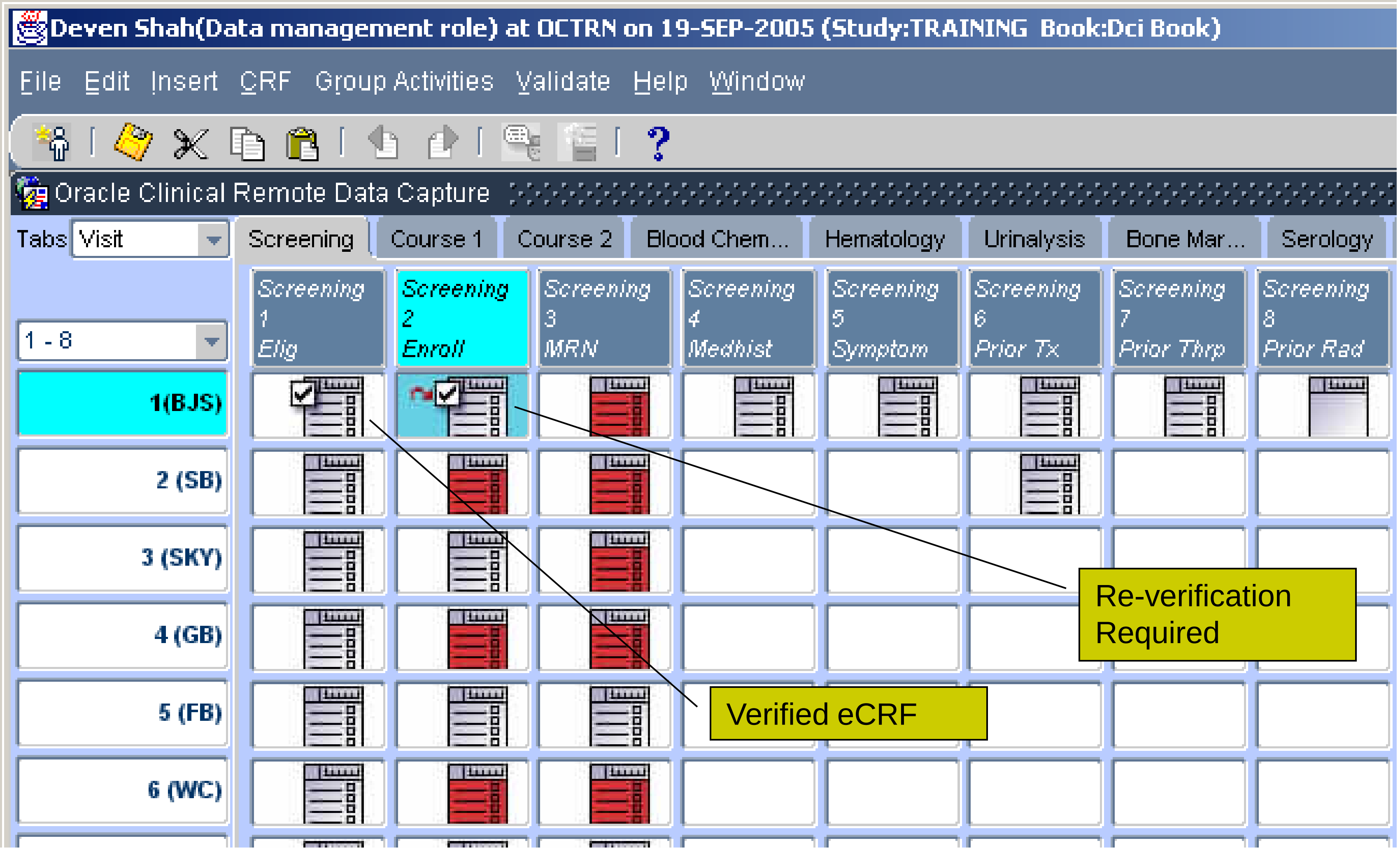
Verify Button

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
Enroll*
Init_Vs
COM
Blank ☐
Summary
Discrepancies
Verification
Approval
Audit Trail
Links
Verify

# 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 Tab

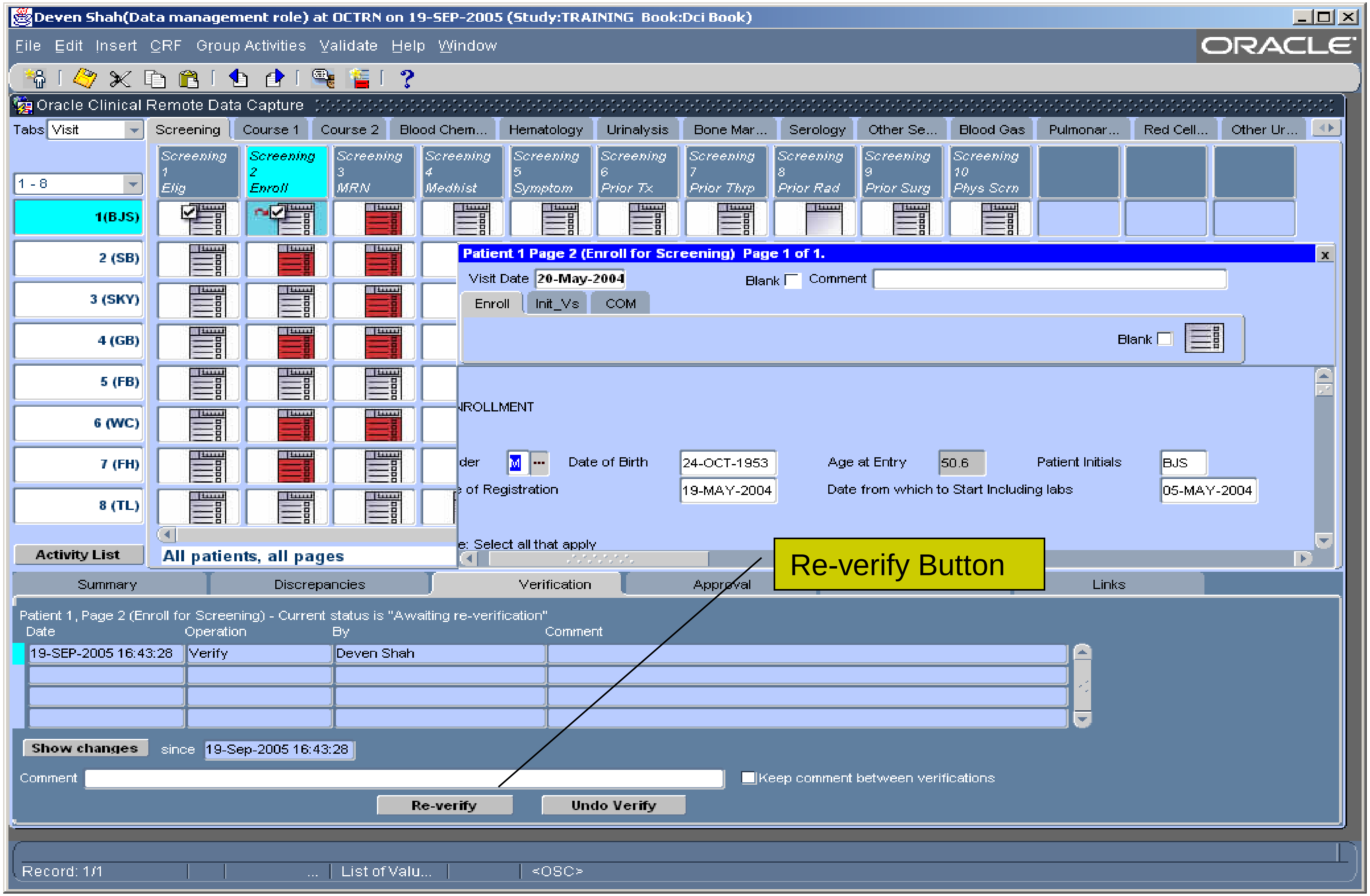
# Verification



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



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 - 8
1(BJS)
2 (SB)
3 (SKY)
4 (GB)
5 (FB)
6 (WC)
7 (FH)
8 (TL)
Activity List
All patients, all pages
Enroll
Init_Vs
COM
Summary
Discrepancies
Verification
Approval
Links
Show changes
Re-verify
Undo Verify
Record: 1/1
List of Valu...
<OSC>

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

Blank ☐ Comment

Blank ☐

NROLLMENT

nder M Date of Birth 24-OCT-1953 Age at Entry 50.6 Patient Initials BJS

e of Registration 19-MAY-2004 Date from which to Start Including labs 05-MAY-2004

e: Select all that apply

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 | |

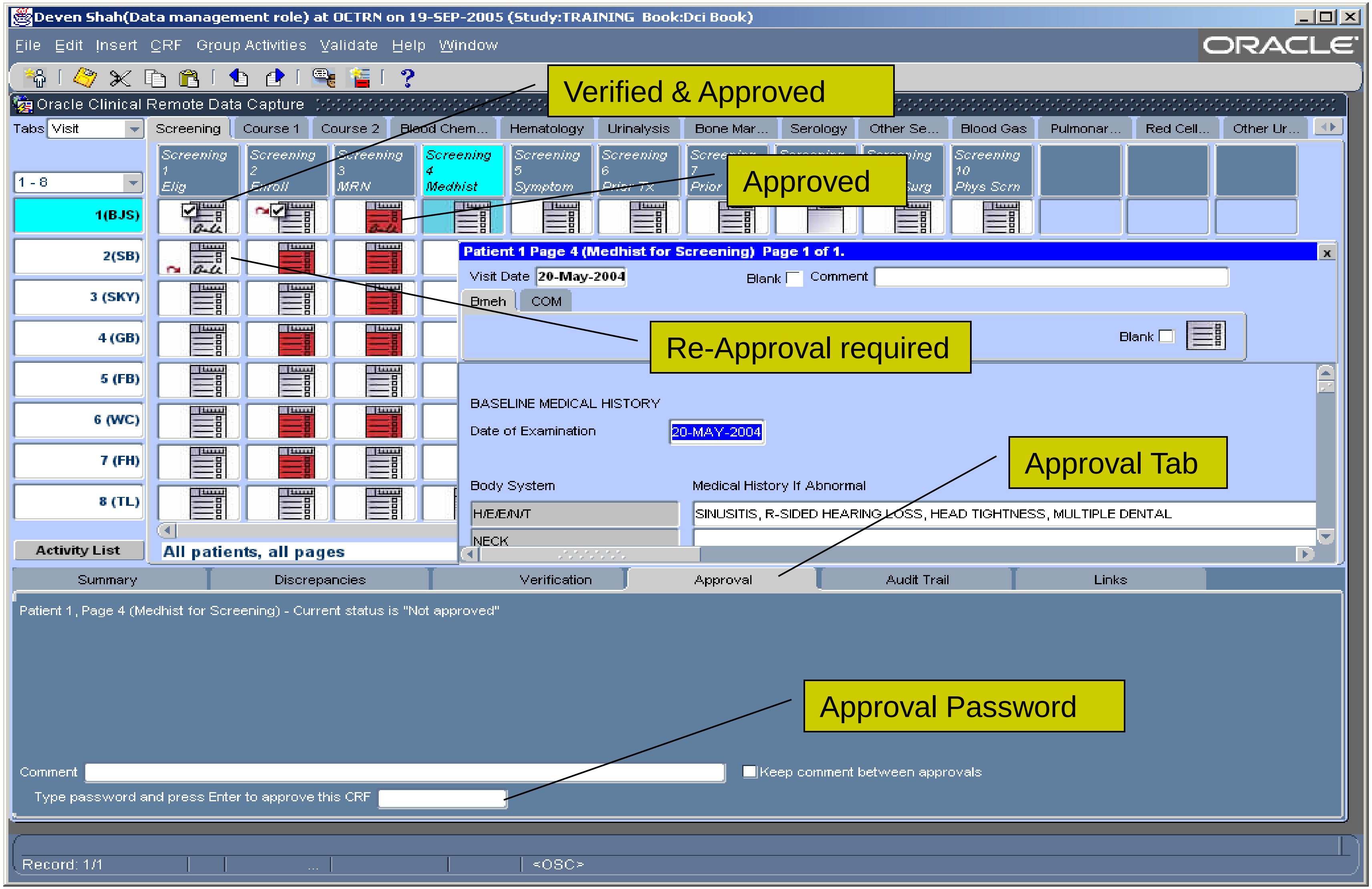
since 19-Sep-2005 16:43:28

Comment

☐ Keep comment between verifications

Re-verify Button

# Approval


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
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
Bmeh
COM
Summary
Discrepancies
Verification
Approval
Audit Trail
Links

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

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>

Verified & Approved

Approved

Re-Approval required

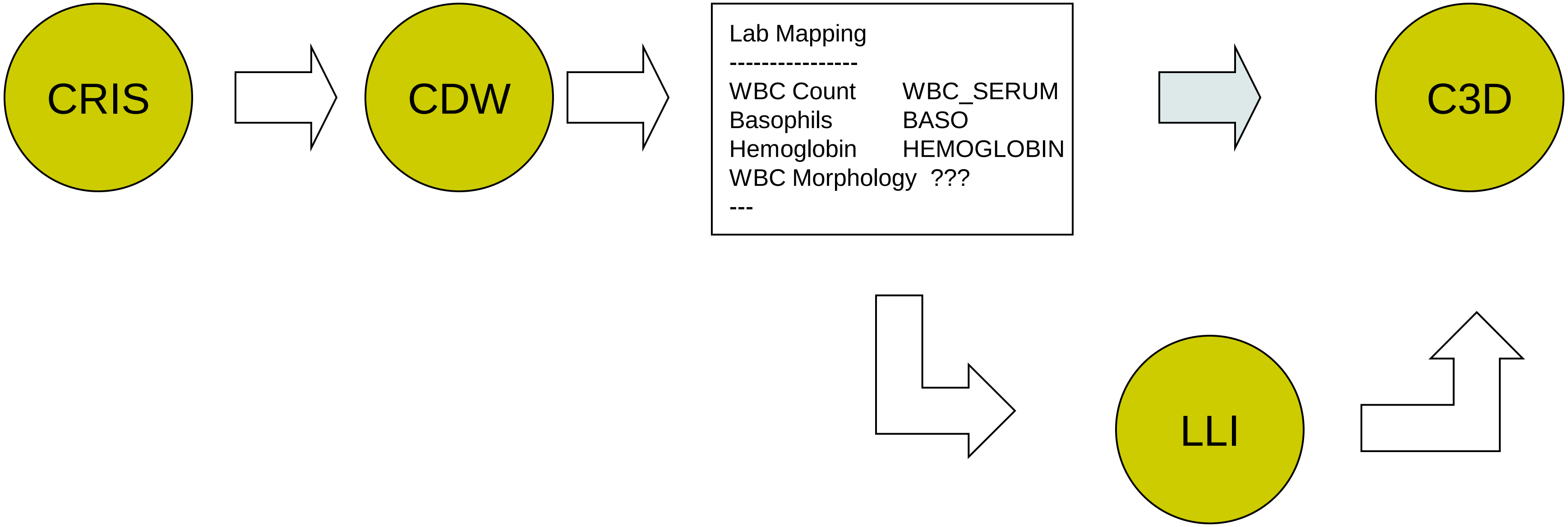
Approval Tab

Approval Password

# Approval

- Each eCRF can be approved by providing the C3D Password on the Approval Tab
- 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 Tab

# CRIS to C3D Lab Data Flow



CRIS

CDW

Lab Mapping

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

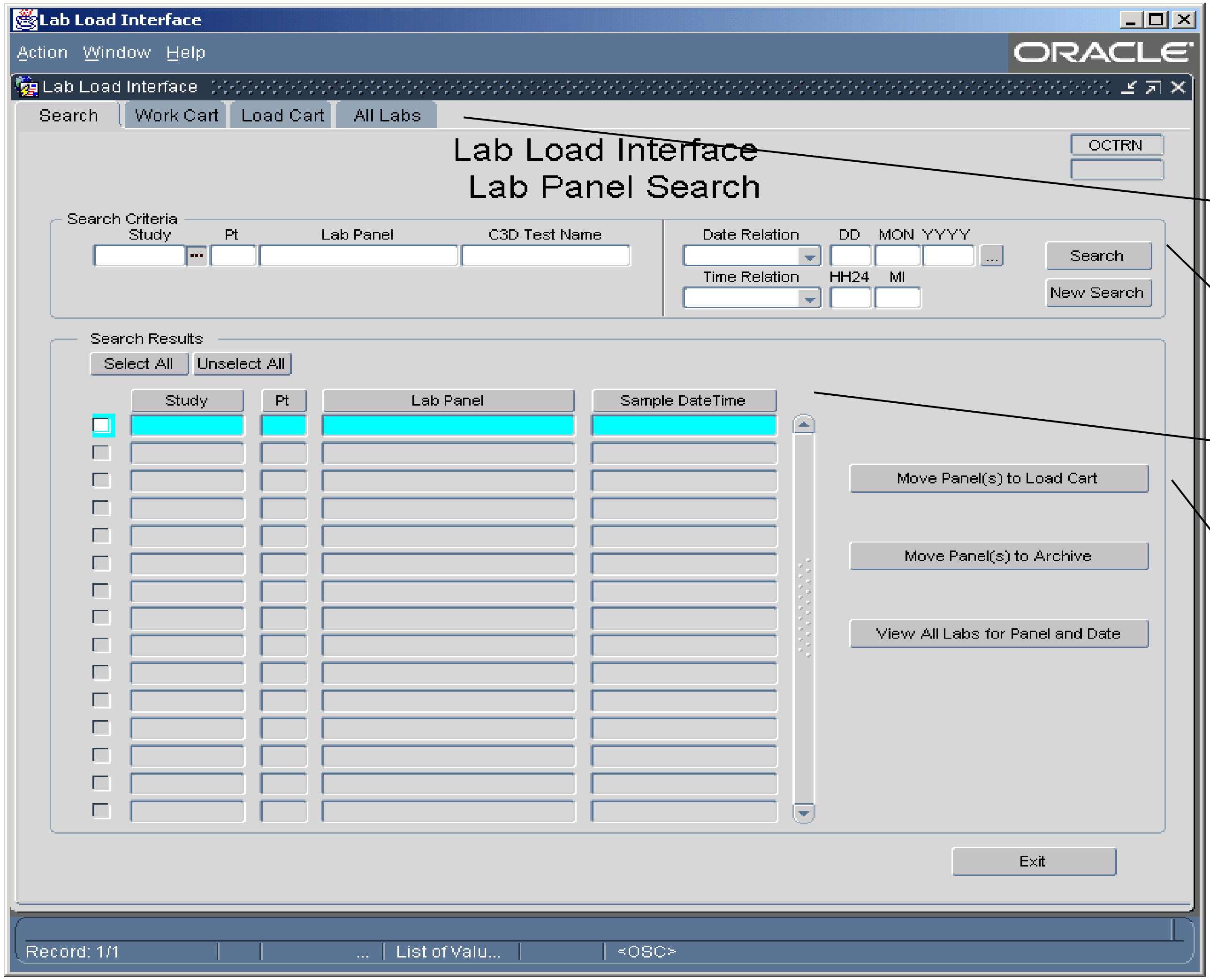
C3D

LLI

# What is LLI?

- LLI is a utility to review and identify specific Lab Test Results to be downloaded from the CRIS/CDW into C3D
- URL: http://octrials.nci.nih.gov/opa45/labloadinter.htm
- Username & Password are same as C3D

# LLI Search 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>

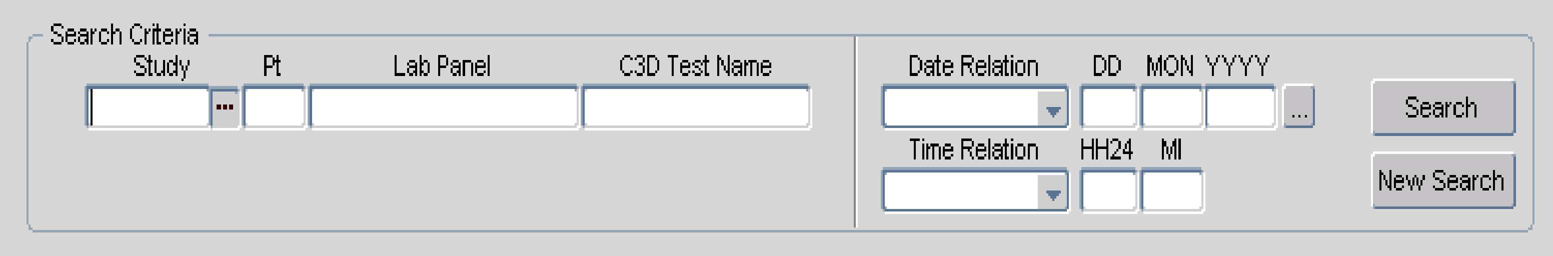
Workflow

Search Criteria

Selected Panels

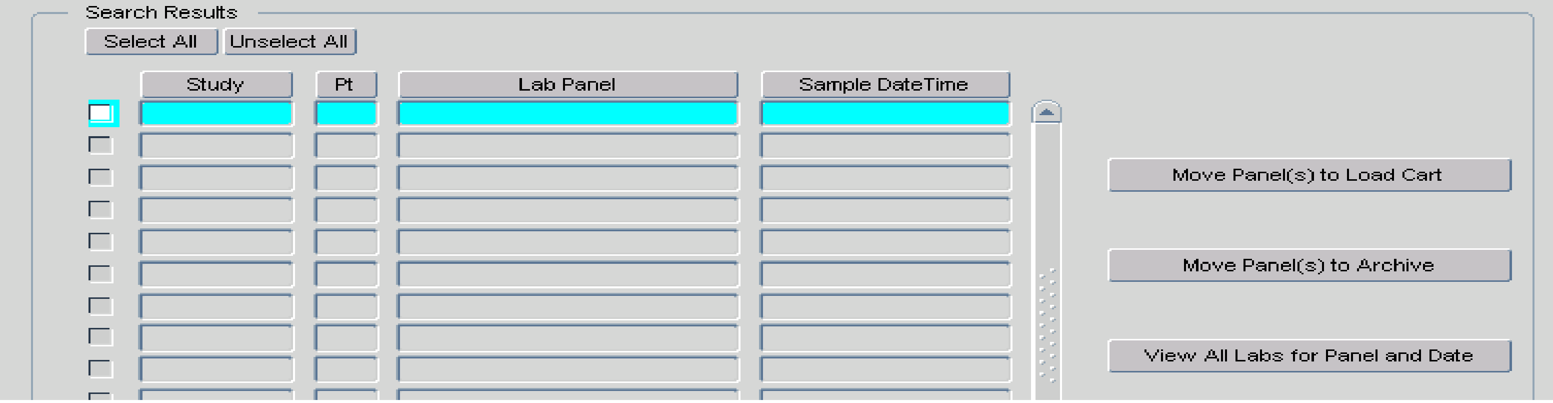
Action Buttons

# LLI Search Criteria


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

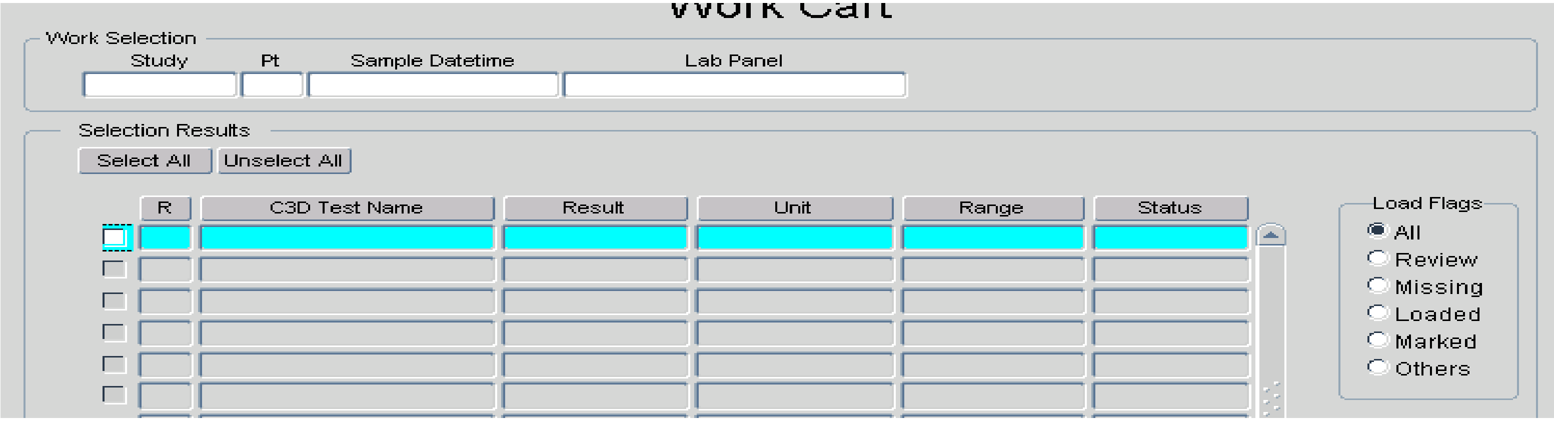
- **Searching**
  - Can search by Study, Patient Number, Lab Panel, OC Lab Question, Date and/or Time
    - Each search field contains Pick List.
    - Date and Time allows the ‘%’ wild card
    - Date and Time provide the additional option of:
      - “On or Before”, “On or After” and “LIKE” comparisons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

# Question & Answer