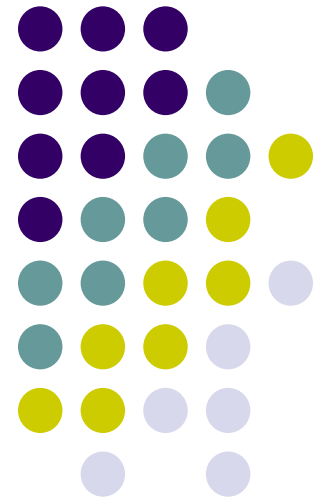


Introduction to C³D

Harris Corporation

May 2014



Introduction

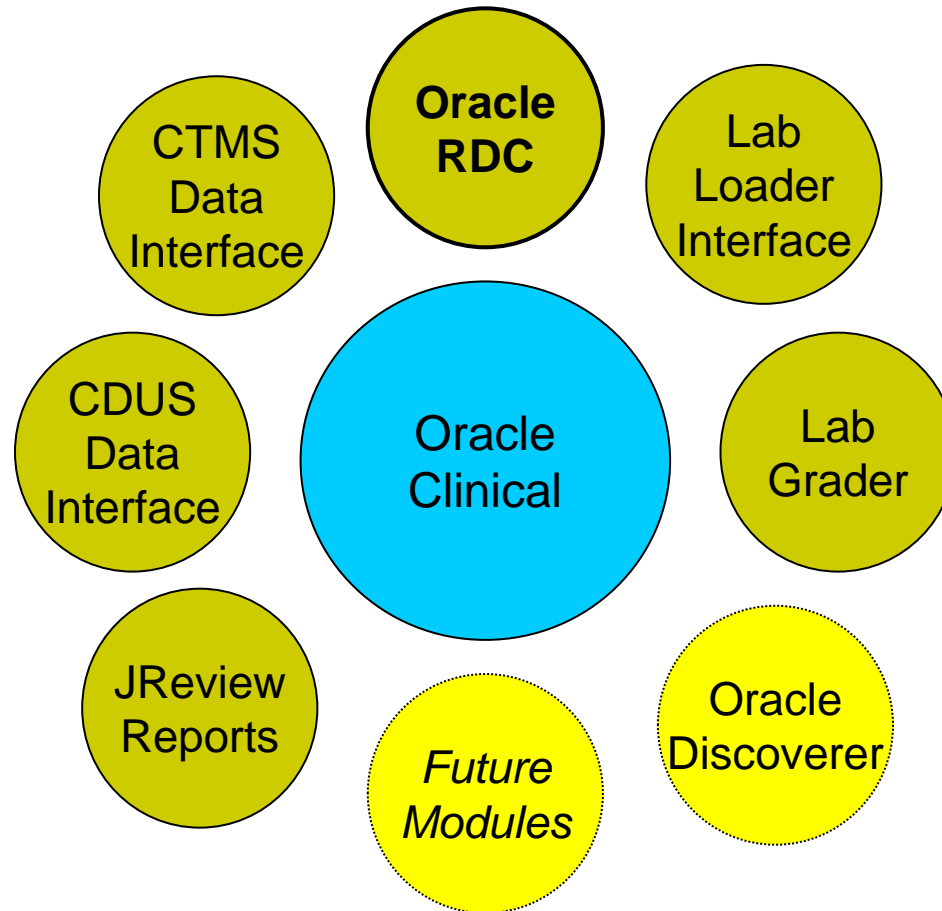
- | C³D - **C**ancer **C**entral **C**linical **D**atabase
- | eCRFs Instructions Manual
- | Support
- | Data Entry
- | Audit-Trail
- | Discrepancy Management
- | Verification
- | Approval
- | Lab Loading

What is C³D

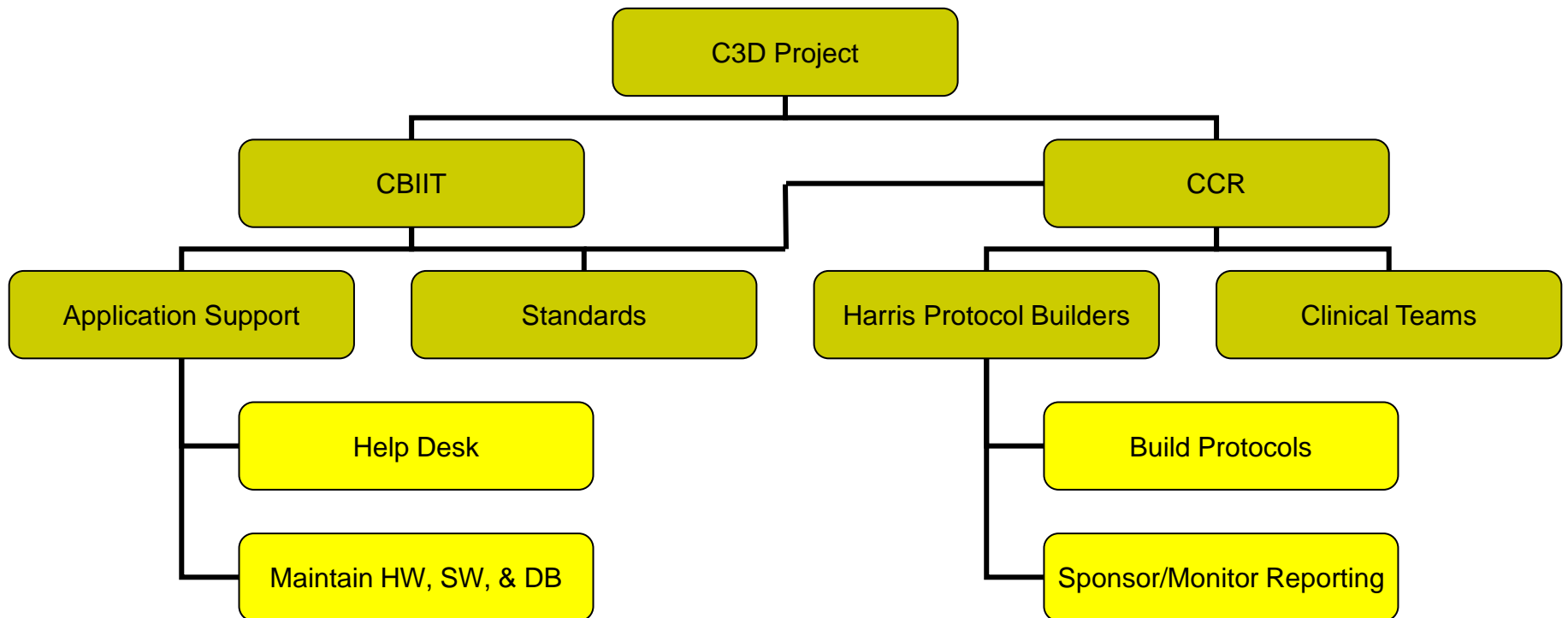


- | Clinical Trials Data Management System
- | RDC (Remote Data Capture) Data Entry
 - q Accessible anywhere in the world (via a Windows computer and Internet Explorer).
 - q **Note for studies prior to 2012:** a Windows XP computer is required at this time. JInitiator will be installed upon first login attempt.
- | C³D supports data standardization, reuse, sharing, and interoperability through electronic Case Report Forms (eCRFs) based on Common Data Elements (CDEs)
- | Based on Industry Standard Technologies

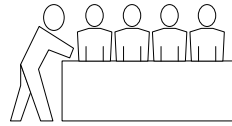
Cancer Central Clinical Database C³D



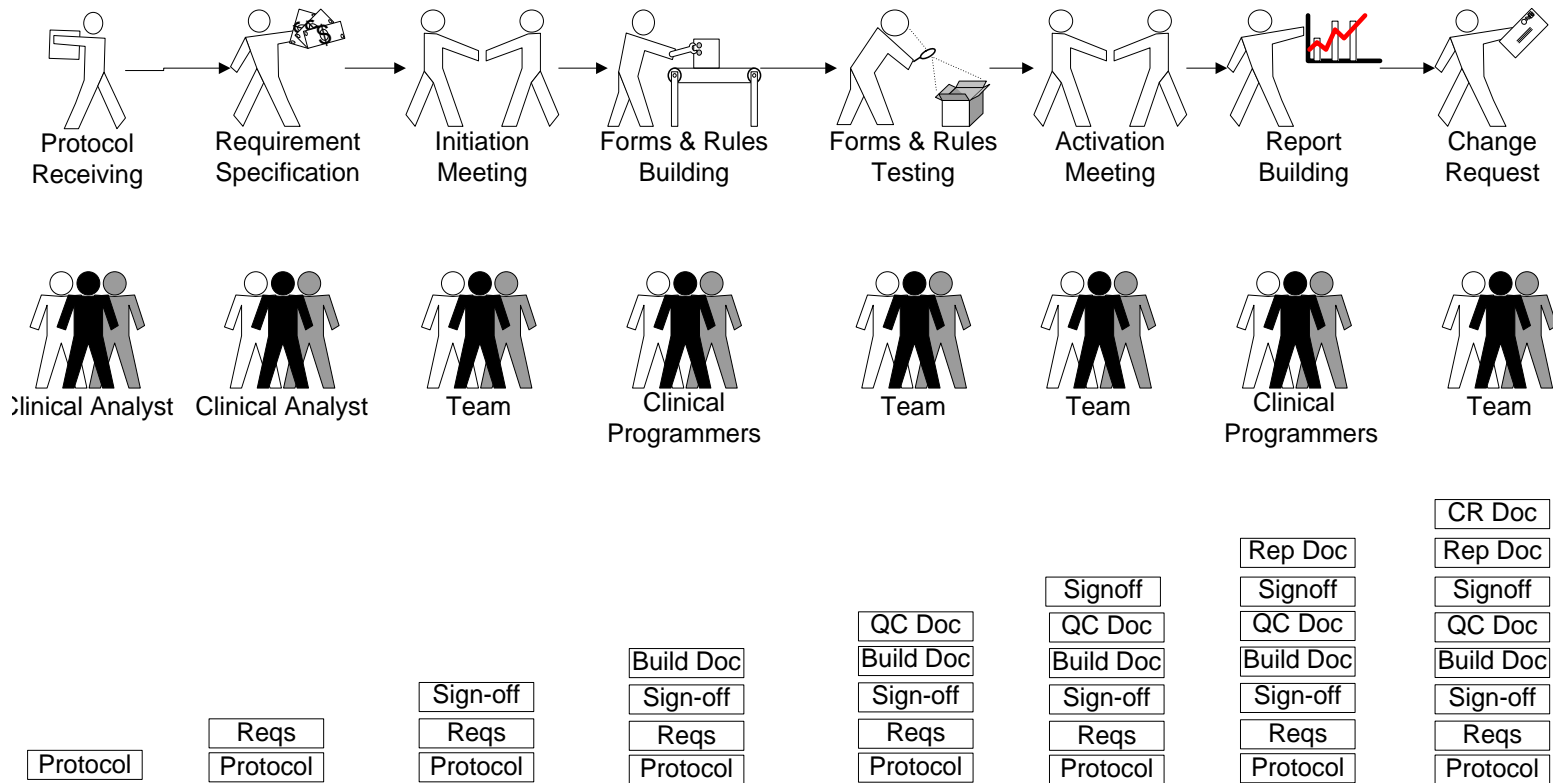
C³D Organization



Designing Protocols in C³D



Control & Configurations Management Group (CCMG)



CCR Standard Case Report Forms

- | Library of Standard Forms & Rules is available as a starting point to build protocol specific forms & rules
- | Detailed Instructions are available for each Standard Form <https://ccrod.cancer.gov/confluence/x/9QiJAw>
- | Each Instructions includes:
 - q General Description
 - q eCRF Screenshot
 - q Field Specific Description (Mandatory, Derived, etc.)
 - q Validation/Derivation Rules

eCRF Instructions Manual

Course Initiation

Home > C3D Portal > [Training and Education](#) > ... > Course Initiation

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

| |
|---|
| Contents |
| <ul style="list-style-type: none"> • Purpose • Course Initiation eCRF • Validations • Derivations |

Purpose

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

Course Initiation eCRF

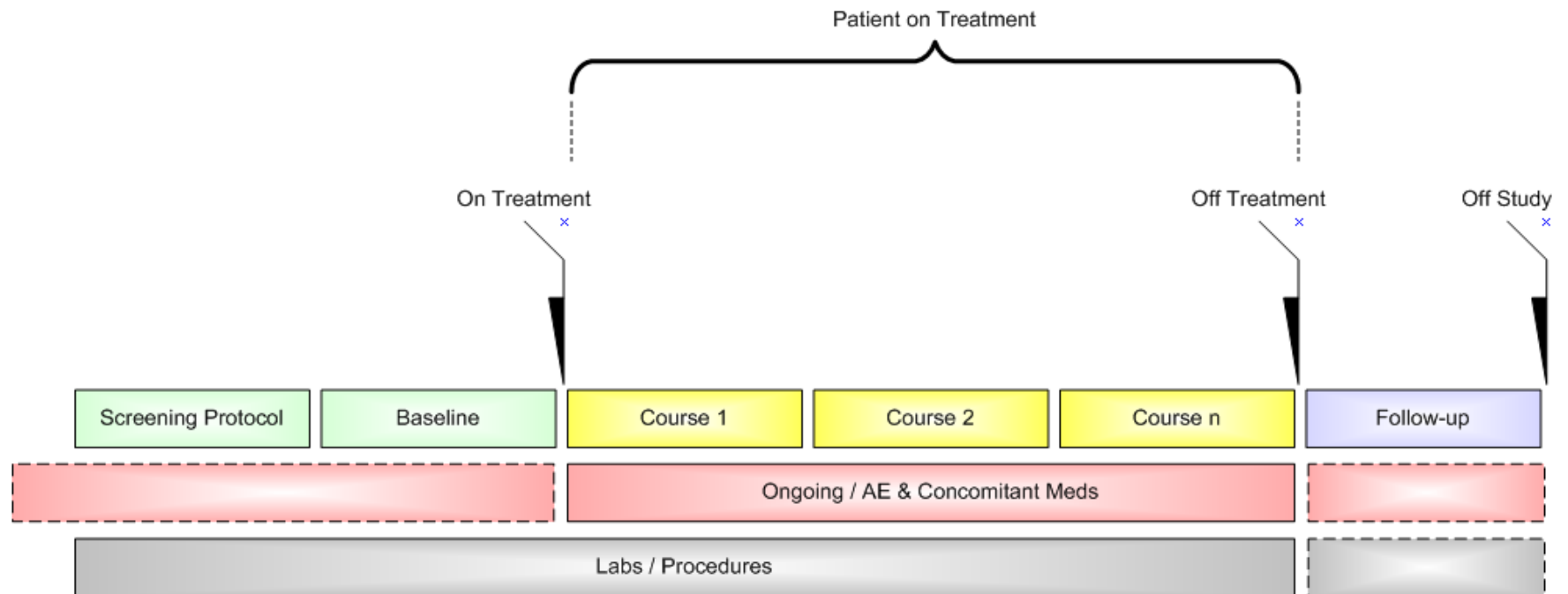
| Field Name | Description / Instructions | Format |
|-------------------------------------|---|-------------|
| Visit Date ^(m) | Enter the date the course started. | DD-MMM-YYYY |
| Course # ^(d) | Sequential number of this course of treatment: first course = 1, second course = 2, etc. | 5 digits |
| 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
 - q Eligibility, Enrollment, PE, Vitals, Baseline Symptoms, Prior Therapies, ...
- | Courses/Cycles
 - q Course Initiation, Study Medication Administration, PK, Course Assessment, PE, ...
- | Labs
 - q Blood Chemistry, Hematology, ...
- | Ongoing
 - q AE, Concomitant Measures, Extent of Disease, ...
- | Off Tx / Follow-Up / Off Study

C³D Protocol Phases

C3D Study Phases



Role Based Access

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

C³D Support

- | CBIIT provides the first line of support for C³D related issues
- | Contact
 - q Email: ncicbiit@mail.nih.gov
 - q Phone: 240-276-5541
 - q 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:
 - q Start with a letter;
 - q Must containing **at least one number and one special characters** (Ex:! #);
 - q Has to be at least 8 characters long;
 - q The following special character could cause problems if used: \$ % & ' ''.
- | Production Database is called **ocprod**
- | About C³D Password:
 - q **Do not share the password with others!**
 - q Password needs to be changed the first time you login.
 - q Passwords expire every 3 months and need to be changed.
 - q **Account gets locked upon three unsuccessful attempts. Contact C³D Help Desk to unlock account and/or get new password.**

C³D Login Web Pages

- | C³D is Accessible Worldwide
- | C³D Production Login Page:
<https://octrials.nci.nih.gov/opa45/rdclaunch.htm>
- | C³D provides a separate Data Entry environment to test protocol design
 - q Test Login page:
<https://octrials.nci.nih.gov/opa45/rdclauncht.htm>

C³D Login Web Page

https://octrials.nci.nih.gov/opa45/rdclaunch.ht Launch Oracle Clinical RDC... x

Oracle Pharmaceutical Applications

RDC 4.5

Login

RDC Onsite

[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

Login

The image shows a screenshot of the Oracle Developer Forms Runtime - Web application. The main window has a title bar that reads "Oracle Developer Forms Runtime - Web" and an "ORACLE" logo in the top right corner. Below the title bar, there is a "Window" menu. In the center of the main window, a "Logon" dialog box is displayed. The dialog box has a title bar with "Logon" and a close button. It contains three input fields: "Username:", "Password:", and "Database:". Below the input fields are two buttons: "Connect" and "Cancel". A yellow callout box with a black border points to the "Connect" button and contains the text: "Enter User, Password, and Database. Then click Connect".

C³D Activity List

The screenshot shows the Oracle C³D Activity List application. The window title is "Deven Shah(Data management role) at OCTRN on 19-JAN-2006 (Study:TRAINING Site:NCI Book:Dci_Book_Jan_2006)". The menu bar includes "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". The toolbar contains icons for user, home, back, forward, search, and help.

The main area is titled "Activity List" and shows a tree view on the left with "TRAINING" selected and "Site: NCI" expanded. A vertical list of numbers from 1 to 15 is visible. Callouts point to various elements:

- Select All Data, Active Discrepancies, etc.** points to a set of links: "Review 1 Active Discrepancies", "Show All Data for TRAINING", and "Review 1 Active Discrepancies for Site NCI".
- Select Data for specific Site or Patient** points to the "Site: NCI" tree view.
- Choose Different Studies** points to the "Change Study" button.
- Specify Search Criteria** points to the "Search" button.
- Study Summary** points to the "Study Information" section.

On the right side, there are buttons: "Load Filter", "Change Study", "Search", "Cancel", and "Help".

At the bottom, there are two sections:

- Study Information:** Name: Training study for template 3.12B, # Sites: 1, Patients: Created 30, Enrolled 0, With Data 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, Clean 0, Approved 0, Locked 0, Not Locked 1.

The status bar at the bottom shows "Record: 1/3" and navigation buttons like "<OSC>".

Selecting Activity

- | Quick Links to View
 - q All Study Data
 - q Discrepant Data
 - q Site Specific or Patient Specific Data
- | Change Study button to choose a Different Study
 - q Default Study is preserved from prior login
 - q Access to study sites and C³D features are controlled by user role
- | Search button used to locate eCRFs based on one or more criterion

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

The screenshot shows the Oracle Clinical Remote Data Capture interface. A 'Change Study' dialog box is open, displaying a list of studies. The dialog has a search field at the top labeled 'Find %'. Below it is a table with two columns: 'Study Name' and 'Title'. The table lists 20 studies. At the bottom of the dialog are three buttons: 'Find', 'OK', and 'Cancel'. A yellow callout box with a black border points to the 'OK' button, containing the text 'Select Study & Click OK'. The background application window shows a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window) and a toolbar with various icons. The status bar at the bottom of the application window displays 'Choices in list: 80' and 'Record: 1/1'.

| 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 Foio |

Study Access

- | Study/Site access and C³D features determined by user role
- | User Roles:
 - q Data Managers (Performs Data Entry)
 - q Research Nurse (Performs Data Entry and Verifies eCRFs)
 - q Monitor (Read-only access and Approves eCRFs)
 - q Principal Investigator (Read-only access)
 - q Reviewer (Read-only access)

Search Criteria

The screenshot displays the Oracle Clinical Remote Data Capture interface. The main window title is "Deven Shah(Data management role) at OCTRN on 19-JAN-2006 (Study:TRAINING Site:NCI Book:Dci_Book_Jan_2006)". The menu bar includes "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". The toolbar contains various icons for navigation and actions. The main area shows a grid of data with columns for "Screening 1 Elig", "Screening 2 Enroll", and "Screening 3 MR". A "Search" dialog box is open, allowing users to specify search criteria. The dialog box includes the following fields and buttons:

- Book:** Dci_Book_Jan_2006 (Default Book)
- Site:** Nci (All Sites)
- Patients:** Patient 1 (All Patients, Specify...)
- Visits/Pages:** All visits and pages (All Visits, Specify...)
- CRF Status:** All CRFs (All Statuses, Specify...)
- Date Window:** All entry and visit dates (All Dates, Specify...)
- Data:** All data (All Data, Specify...)

Buttons at the bottom of the dialog box are "OK", "Load Search", "Cancel", and "Change Study". A yellow callout box labeled "Search Criteria Dialog Box" points to the dialog box.

Search Criteria

I Search options:

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

I **Quick Tip:**

- q Protocol Amendments may require different DCI Book. Latest DCI book is the default one. Use Search option to select a previous book.
- q 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

Oracle Clinical Remote Data Capture

ORACLE

Pull Down to view eCRFs by Phases or Visits
Pull Down to view additional Visits

Tabs: Visit | 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 |
|----------|------------------|--------------------|-----------------|---------------------|---------------------|----------------------|------------------------|-----------------------|------------------------|------------------------|
| 1 (SAH) | | | | | | | | | | |
| 4 (WCW) | | | | | | | | | | |
| 5 (SAH) | | | | | | | | | | |
| 6 (SAH) | | | | | | | | | | |
| 7 (SAH) | | | | | | | | | | |
| 8 (SAH) | | | | | | | | | | |
| 9 (CD) | | | | | | | | | | |
| 10 (SAH) | | | | | | | | | | |

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: All patients, all pages

Activity List: Summary | Discrepancies | Verification | Approval | Audit Trail | Links

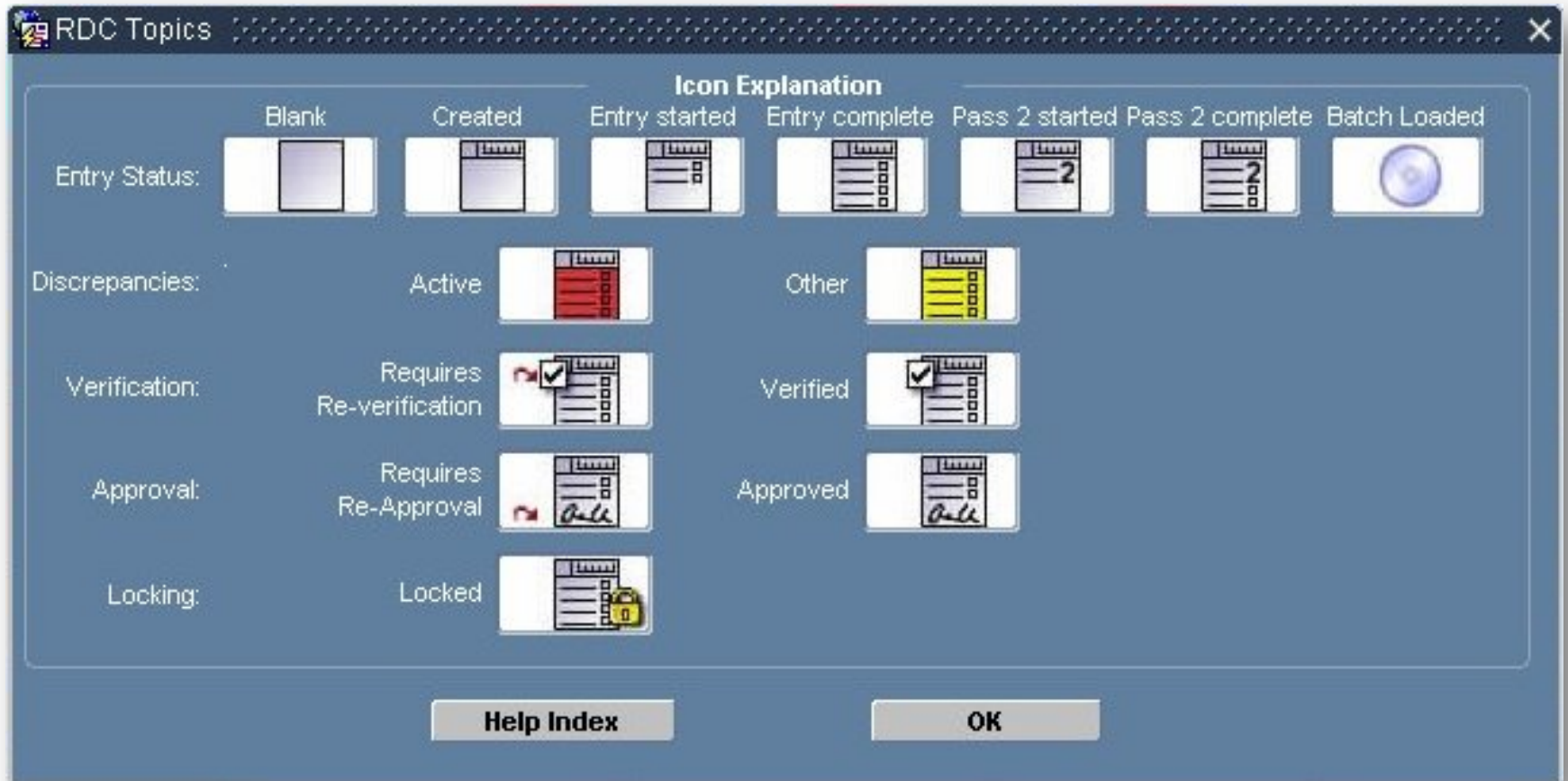
| Summary For | # Patients | Summary of CRFs Retrieved | | | | Summary of CRFs in Current Tab | | | | |
|-------------|------------|---------------------------|-----|----------|----------------------|--------------------------------|----------------------|----|----------------------|----|
| Visit | 17 | Planned | 254 | Awaiting | Not approved | 254 | With active discreps | 24 | Not approved | 93 |
| | | Unplanned | | | Awaiting re-approval | | With other discreps | | Awaiting re-approval | |
| | | Total | 254 | | Approved | | Clean | 69 | Approved | |
| | | With active discreps | 87 | | | | | | | |
| | | With other discreps | | | | | | | | |
| | | Clean | 167 | | | | | | | |
| | | | | | | | | | Not verified | 91 |
| | | | | | | | | | e-verification | 1 |
| | | | | | | | | | Verified | 1 |

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

Navigating RDC Spreadsheet

- | Spreadsheet Layout
 - q Patients along Rows
 - q Phases or Visits Tabs along Columns; pull down for additional visits
 - q eCRF within Tabs
 - q Cells represents an eCRF for the corresponding Patient-Visit
- | Tabs can be organized by Study, Phase, & Visit
 - q 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
 - q Menu
 - q Toolbar
 - q Hot Keys

eCRF Icons



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)

The screenshot displays the Oracle Clinical Remote Data Capture (eCRF) interface. The title bar shows the user 'OPA (Marcelo Fontinha - OPS\$FONTINHMT at OCPROD on 15-JUN-2004)'. The menu bar includes 'File', 'Edit', 'Insert', 'CRF', 'Group Activities', 'Validate', 'Help', and 'Window'. The toolbar contains various icons for file operations and help. The main window is titled 'Patient X2 Page 2 (Enroll for Screening) Page 1 of 1'. The left sidebar shows a list of tabs: X1 (XYZ), X2 (XYZ), X3 (XYZ), X4 (XYZ), X8 (XYZ), X9 (XYZ), and X10 (XYZ). The main form area contains various data entry fields. Annotations in yellow boxes highlight specific features: 'Tabs for eCRF Sections' points to the left sidebar; 'Non-enterable field' points to a field with a red 'X' icon; 'Ellipsis indicates field has a Pick List' points to a dropdown menu; 'Yellow - Univariate Discrepancy' points to a yellow-highlighted field; and 'eCRF Scroll Bar' points to the bottom scroll bar. The form data includes: Visit Date: 10-Jun-2004; Gender: M; Date of Birth: 01-JAN-1973; Age at Entry: [non-enterable]; 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, Asian, American Indian/Alaska Native, Race Not Reported, Race Unknown); Ethnicity: NONHISPANIC; Registering Institution: [non-enterable]; Local Patient ID: [non-enterable]; Patient Subgroup: [non-enterable]; Registering Group: SWOG; Country Code: AR; Postal Code: [non-enterable]; 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: [non-enterable]; Grade of Histology: 2; Date of Diagnosis: [non-enterable]; Planned TAC: ARM A; Date Informed Consent Signed: 01-JAN-2003; Date of Informed Consent Version: 12-DEC-2002. The bottom status bar shows 'Record: 1/1' and '<OSC>'.

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

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

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)

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

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

Activity List All patients, all pages

Summary Discrepancies Verification Approval Audit Trail Links

Allaes COM

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

| Field | Row | Original value | Current value | Changed on | BY | Intervening | |
|-------------------------|-----|----------------|---------------|----------------------|------------|-------------|------|
| Action to adverse event | 1 | 1=NONE | <Row Deleted> | 02-JUN-2004 15:30:46 | Liming Wan | | |
| Action to adverse event | 1 | 2=REDUCED | <Row Deleted> | 02-JUN-2004 15:36:44 | Liming Wan | Update | Show |
| Attribution | 1 | 1=UNRELATED | <Row Deleted> | 02-JUN-2004 15:30:46 | Liming Wan | Update | Show |
| Attribution | 1 | 2=UNLIKELY | <Row Deleted> | 02-JUN-2004 15:36:44 | Liming Wan | Update | Show |
| Date when the episode | 1 | | <Row Deleted> | 02-JUN-2004 15:30:46 | Liming Wan | Update | Show |
| Date when the episode | 1 | | <Row Deleted> | 02-JUN-2004 15:36:44 | Liming Wan | Update | Show |
| Day in course | 1 | | 31 | 02-JUN-2004 15:36:44 | Liming Wan | Resequenced | 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:**
 - q Auditing Begins after Form is marked complete
 - q Do not share user ids and passwords!

Resizing eCRF Window

The screenshot displays the Oracle Clinical Remote Data Capture interface. A window titled "Sizing window for Data Entry" is open over the main application. The window has a title bar with a close button (X) on the right. The main area of the window is light blue. A yellow callout box points to the title bar with the text: "Click Title Bar to enter Resize Mode". A blue callout box points to a button labeled "Done" with the text: "then click the [Done] button". Another yellow callout box points to the bottom-right corner of the window with the text: "Then Click and Drag the Title Bar to move the window or the sides/corners to resize". A third yellow callout box points to the "Done" button with the text: "Click Done when resizing is complete". Below the window, there is a "Summary For" section with a dropdown menu set to "CRF". At the bottom of the application, there is a status bar with the text "Record: 1/1" and "<OSC>".

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

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

Date 16-Apr-2004 Doc # R11035201 Last modified on 17-May-2004 09:43:10
Status Entry Started Last transaction on 17-May-2004 09:43:10
By Liming Wan

Record: 1/1 <OSC>

Click Title Bar to enter Resize Mode

then click the [Done] button

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

Done

Click Done when resizing is complete

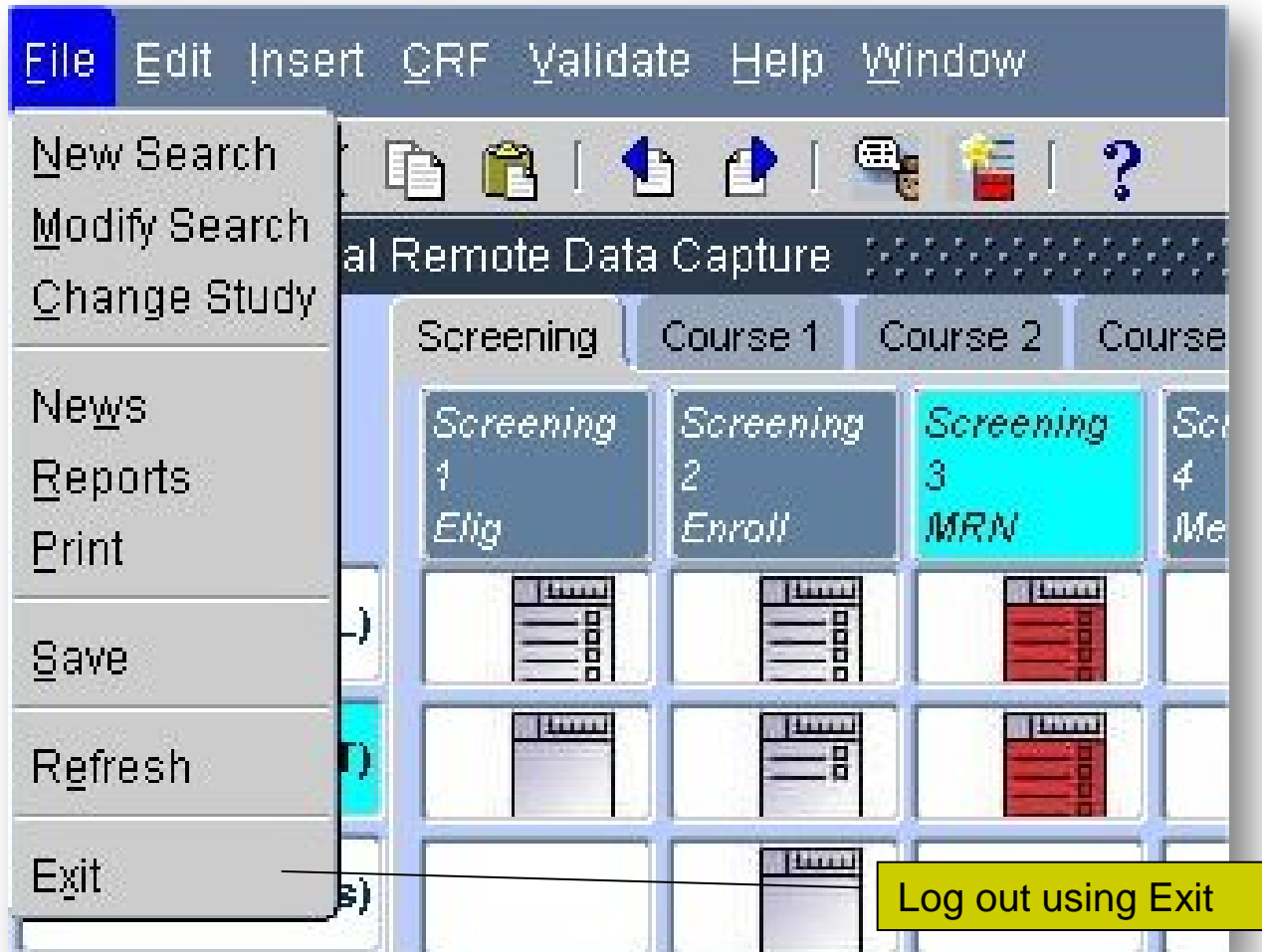
Then Click and Drag the Title Bar to move the window or the sides/corners to resize

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

Log Out



Log Out

- | Exit C³D before closing the Browser
- | Inactivity for more than 30 minutes logs you out automatically. **Any unsaved work is lost!**

Inserting New Patient

The screenshot displays the Oracle Clinical Remote Data Manager interface. The window title is "Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)". The menu bar includes "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". The toolbar contains icons for home, save, delete, copy, paste, and help. The main area shows a patient list with columns for "Visit", "Screen", "Initials", "Hematology", "Urinalysis", "Bone Mar...", "Serology", and "Other Se...". The patient list includes rows for visits 11 through 18, each labeled "(SAH)". A yellow callout box points to the "Insert" icon in the toolbar with the text "Icon to Insert New Patients". Another yellow callout box points to the "Insert" dialog box with the text "Choose Patient Position". The dialog box has a list of numbers from 27 to 34, with 29 selected. The dialog box has "OK" and "Cancel" buttons. The status bar at the bottom shows "Activity List" and "All patients, all pages". The bottom-most bar contains the text "Enter an additional patient into the spreadsheet." and "Record: 1/1".

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 Manager

Insert

27
28
29
30
31
32
33
34

OK Cancel

Choose Patient Position

Icon to Insert New Patients

Activity List All patients, all pages

Summary Discrepancies Verification Approval Audit Trail

Enter an additional patient into the spreadsheet.
Record: 1/1

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

Starting New Planned eCRF

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

Entering Visit Date

The screenshot shows the Oracle Clinical Remote Data Capture interface. At the top, the user is identified as 'Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)'. The main window displays a grid of data entry tabs for various screening activities. The 'Screening 6 Prior Tx' tab is currently selected and highlighted in cyan. Below the grid, a form for 'Patient 4 Page 6 (Prior Tx for Screening)' is visible. The 'Visit Date' field is empty and has a dropdown arrow. To its right is a 'Blank' checkbox and a 'Comment' text box. Below these are 'PTX' and 'COM' buttons. A large instruction box reads: 'Enter date, or T for Today, Y for Yesterday, L for Last entered (required)'. A yellow callout box with a black border points to the 'Visit Date' field, containing the text 'Enter Visit Date and press Tab key'. At the bottom, there is an 'Activity List' section with 'All patients, all pages' selected, and a footer with the text '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>'.

Entering New eCRF

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

Entering Data in eCRF

The screenshot shows the Oracle Clinical Remote Data Capture (eCRF) interface. The title bar indicates the user is OPA (Marcelo Fontinha - OPS\$FONTINHMT) at OCPROD on 15-JUN-2004. The interface includes a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window) and a toolbar. A tabs bar at the top lists various sections: Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Blood Chemistry, Hematology, Urinalysis, Bone Marrow, Serology, Other Serum, and Blood Gas. The main window displays 'Patient X2 Page 2 (Enroll for Screening) Page 1 of 1'. The left sidebar contains a list of tabs (X1 to X10) and buttons for 'Activity List', 'Summary', and 'Summary For'. The main form area contains various data entry fields. Annotations in yellow boxes highlight specific features: 'Tabs for eCRF sections' points to the top tabs bar; 'Non-enterable field' points to a greyed-out 'Age at Entry' field; 'Indicates Pick List' points to a vertical list of race options; 'Yellow - Univariate Discrepancy' points to a yellow-highlighted 'STAGE II A' field; 'Use Tab to move between fields' points to the 'Date of Birth' field; and 'eCRF Scroll Bar' points to the vertical scrollbar on the right. The bottom status bar shows 'Record: 1/1' and '<OSC>'.

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

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

Visit Date: 10-Jun-2004 Blank Comment

Enroll* Init_Vs COM

Blank

Enrollment

Gender: M Date of Birth: 01-JAN-1973 Age at Entry: [Greyed out] 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: [Greyed out]

Local Patient ID: [Greyed out]

Patient Subgroup: [Greyed out]

Registering Group: [Greyed out]

Country Code: AR

Postal Code: [Greyed out]

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: [Greyed out]

Grade of Histology: 2

Date of Diagnosis: 01-JAN-2003

Planned TAC: ARM A

Date of Informed Consent Version: 12-DEC-2002

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

Entering Data in eCRF

- | Navigating between Fields
 - q Use Tab Key to move to Next Field
 - q Use Shift Tab to move to Previous Field
 - q Use Mouse Click to navigate to a Specific Field
- | Fields with Ellipsis indicate a Pick List (Use the Pick List!)
- | Enter Dates as
 - q Complete dates for Current Information (ex: 5/23/2014, 5-23-2014 or 05232014)
 - q MMYYYY for Prior Information is acceptable when complete date cannot be obtained (ex: 05-00-2014, 05/00/2014, 05002014)

Tabular eCRF

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.

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

File Edit Insert **CRF** Group Activities Validate Help Window

Oracle Clinical

Previous
Next
Insert Row
Delete Row
Lock
Unlock

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)

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

Visit Date **16-Apr-2004** Blank Comment

Allaes* COM

Activity List
Summary
Summary For
CRF

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

Using Pick List

The screenshot displays the Oracle Clinical Remote Data Capture interface. At the top, the title bar reads "Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)". The menu bar includes "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". The toolbar contains various icons for file operations and help. The main window shows a patient record for "Patient 1 Page 35 (Adv Event for Ongoing) Page 1 of 1, Repeat 1 of 4." The "Visit Date" is "07-Jul-2004". A yellow callout box points to the "Type" field, which is currently set to "AE1". The callout text reads: "Click on Field Ellipsis or Hit F9 to show Pick List". A pick list dialog box is open, showing a search field with "bi%" and a list of results: "AE_SELECT", "Bicarbonate, serum-low", and "Bilirubin (hyperbilirubinemia)". The "Bicarbonate, serum-low" option is highlighted. The dialog box has "Find", "OK", and "Cancel" buttons. The background interface includes a table with columns for "Date", "Resolved", "CTC Term", "CTC Category", "Adverse Event Description", "Filed", and "Grac". The "CTC Term" column has a yellow highlight. Other interface elements include "Activity List", "Summary", "Discrepancies", and "Audit Trail". The status bar at the bottom shows "Choices in list: 2 (Choices in full list: 1000)" and "Record: 1/1".

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:
 - q Start typing in some letter and the list is filtered as you type or;
 - q 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.
 - q **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:
 - o CTCAE Term (version 3.0) pick list on the Adverse Events and Baseline Symptoms;
 - o Agents in the Concomitant Measures and Medications;
 - o Enrollment eCRF Disease Term (only when using comprehensive CTEP list of Diseases);
 - o Enrollment eCRF Registering Institute;
 - o Course Initiation eCRF Treating Institute.
- | **Quick Tips:**
 - q 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

The screenshot displays the Oracle Clinical Remote Data Capture interface. At the top, the user is identified as Deven Shah (Data management role) at OCTRN on 01-MAR-2005, working on Study: TRAINING, Book: Dci Book. The main window shows a patient record for Patient 5, Page 2 (Enroll for Screening), with a visit date of 03-Nov-2004. A yellow callout box labeled "Marking entire eCRF Blank" points to the "Blank" checkbox in the top right of the form area. Below this, a large blue area contains the text "This section has been marked as blank", with a second yellow callout box labeled "Marking Section Blanks" pointing to this area. The interface includes a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window), a toolbar, and a tabbed interface for different data sections like Screening, Course 1, Course 2, Blood Chem..., Hematology, Urinalysis, Bone Mar..., Serology, Other Se..., and Blood Gas. At the bottom, there is a summary section for Patient 5, Visit Screening, created on 03-Nov-2004 12:44:30, and a status bar indicating "Checked if there is no data for this section of the CRF" and "Record: 1/1".

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:**
 - q It is a good practice to mark Sections that will not have data entered as Blank.
 - q 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

The screenshot displays a software interface for data management. At the top, a status bar shows the user 'Abu Muyeen(Data management role)' at 'OCPROD' on '23-FEB-2010' for 'Study:10_C_0056 Site:NCIMB Book:Book_0_11dec2009'. A menu bar includes 'File', 'Edit', 'Insert', 'CRF', 'Group Activities', 'Validate', 'Help', and 'Window'. A 'Patient' menu is open, showing options: 'Patient', 'CRF', 'Visit', 'Discrepancy (manual) F11', 'Section Discrepancy', and 'Investigator Comment F12'. The main area is a grid with columns for 'Cycle 2' through 'Cycle 6', 'Blood Chemistry', 'Hematology', 'Urinalysis', 'Serology', 'Other Serums', 'Other Uri...', and 'Coagula...'. The first row shows '1010001 (SES)' with 'Blood Ch. 2' through 'Blood Ch. 6' and 'Hide unplanned pages'. A yellow box labeled 'Add Unplanned' points to a cell in the grid. Another yellow box labeled 'Show/Hide Unplanned' points to the 'Hide unplanned pages' cell. Below the grid is an 'Activity List' for 'Site NCIMB, Patient 1010001'. At the bottom, a summary table shows data for 'Visit' and 'Summary of CRFs Retrieved'.

| Summary For | # Patients | Planned | Unplanned | Total | Not verified | Awaiting re-verification | Verified |
|-------------|------------|---------|-----------|-------|--------------|--------------------------|----------|
| Visit | 1 | 25 | 12 | 37 | 37 | | |

| Summary of CRFs in Current Tab | Planned | Unplanned | Total | Not verified | Awaiting re-verification | Verified |
|--------------------------------|---------|-----------|-------|--------------|--------------------------|----------|
| | 1 | 6 | 7 | 7 | | |

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:
 - q Select the appropriate Lab Visit;
 - q Open the patient's last Lab eCRF on the selected visit;
 - q Then select the menu option Insert -> Visit
 - o **Do not select Insert -> CRF**

Saving eCRF

The screenshot displays the Oracle Clinical Remote Data Capture interface. The window title is "Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)". The menu bar includes File, Edit, Insert, CRF, Group Activities, Validate, Help, and Window. The Oracle logo is in the top right corner. The main area shows a patient enrollment form for "Patient 5 Page 2 (Enroll for Screening) Page 1 of 1". The form includes fields for Visit Date (03-Nov-2004), Blank checkbox, Comment, Enroll, Init_Vs, and COM buttons. A yellow box labeled "Save Icon" points to a save icon in the top right of the form area. Below the form is an ENROLLMENT section with fields for Gender (M), Date of Birth (13-APR-1995), Age at Entry (9.2), Patient Initials (SAH), Date of Registration (22-JUN-2004), and Date from which to Start Including labs (18-JUN-2004). The bottom status bar shows "Record: 1/1" and "List of Valu...".

Saving eCRF

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

- | **Quick Tip:**
 - q Save Often!! Especially while entering Ongoing Information such as AEs and ConMeds.
 - q C³D session terminates without warning if there is no activity for 30 minutes.

Data Entry Change Reason

The screenshot displays the Oracle Clinical Remote Data Capture interface. The main window shows patient information for "Patient 5 Page 2 (Enroll for Screening) Page 1". The "ENROLLMENT" section includes fields for Gender (M), Date of Birth (01011967), Date of Registration (22-JUN-2004), and Date from which to Start Including labs (18-JUN-2004). A yellow box labeled "Data Changed" points to the Date of Registration field. An "Audit Information for Data Change" dialog box is open, showing the Change Reason as "DATA ENTRY ERR" and the Description as "Data Entry Error". The dialog box also has a "Comment" field and "Save" and "Cancel" buttons.

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

Patient 5 Page 2 (Enroll for Screening) Page 1

1 - 1

Visit Date 03-Nov-2004

Enroll Init_Vs COM

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

Record: 1/1 <OSC>

Audit Information for Data Change

Change Reason: DATA ENTRY ERR

Description: Data Entry Error

Comment:

Save Cancel

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:**
 - q 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 C³D.
- | C³D validation checks are defined based on the definition of the fields, logical rules, protocol specifications, and sponsor requirements.
- | Discrepancies are tools to assist teams in identifying potential data inconsistencies and facilitate real-time QA of data.

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

C³D Discrepancy Types

I Univariate

- q 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.)

I Multivariate

- q Based on a condition on one or more questions as defined in a validation rule
- q Generated on-line or when validation rules are run (eCRF must be saved as Complete.)

I Manual

- q 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

The screenshot shows a web application interface. At the top, a blue header bar contains the text: "Deven Shah(Data management role) at OCPROD on 18-JUN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)". Below this is a menu bar with items: "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". A toolbar with various icons is located below the menu bar. The main content area features a window titled "My Activity List" with a tree view on the left and a list of links on the right. The tree view shows a folder icon next to "THER_STD" and a sub-item "Site: SITE_01". The list of links includes: "[Review 49 Active Discrepancies](#)", "[Show All Data for THER_STD](#)", and "[Review 49 Active Discrepancies for Site SITE_01](#)". On the right side of the window, there are four buttons: "Change Study", "Search", "Cancel", and "Help". At the bottom of the window, there are two tabs: "Summary" and "Links".

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:**
 - q 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

Visit

Screening Course 1 Course 2 Course 3 Course 4 Course 5 Blood Chemistry Hematology Urinalysis Bone Marrow

| 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 |
|----------------|------------------|--------------------|-----------------|---------------------|---------------------|------------------------|----------------------|-----------------------|------------------------|-------------------|
| 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

The screenshot displays the 'Discrepancies Tab' in a clinical trial data management system. The interface is divided into several sections:

- Top Navigation:** Tabs for various data entry sections: Screening, Course 1-5, Blood Chemistry, Hematology, Urinalysis, Bone Marrow, Serology, Other Serum, Blood Gas, and Re.
- Screening Grid:** A grid showing the status of different screening pages for multiple patients. The 'Screening 5 Symptom' page for Patient 1 is highlighted in blue.
- Patient List:** A list of patients on the left, including Patient 1 (L), Patient 2 (PT), Patient 5 (No inits), Patient 9 (No inits), and Patient 10 (ABC).
- Form View:** A detailed view of the selected eCRF page (Patient 1 Page 5). It includes fields for Visit Date (25-Mar-2003), Bsym* (COM), Onset Date (00-SEP-2002), CTC Term (HEPATIC:: BILIRUBIN), and Symptom Description (ABC).
- Discrepancies Tab:** A tab at the bottom showing a list of discrepancies. The first entry is highlighted in red and reads: "Value of hdfhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus".

Two yellow callout boxes provide additional context:

- Top Callout:** "Discrepancies in the selected eCRF are summarized in Discrepancies Tab" (with an arrow pointing to the Discrepancies tab).
- Bottom Callout:** "First tab enumerates all discrepancies. Additional tabs provide individual discrepancies details." (with an arrow pointing to the first discrepancy entry).

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)

File Edit Insert Go Validate Data Entry Help Window

Oracle Clinical Remote Data Capture

Tabs Visit Unanalysis Bone Marrow Serology Oth

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

Visit Date 25-Mar-2003 Blank Comment

Oasm* 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

Each Discrepancy Detail is in following tabs

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 Status Discrepancy not reviewed by Id : 8375801

Comments Action History Resolution Comments and Reason

Disc History is available via this button

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

Discrepancy Details

- | Subsequent tabs show details for each discrepancy
- | Open Discrepancies are displayed first and are followed by Closed Discrepancies
- | **Quick Tip:**
 - q 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

Univariate Validation Failure

Univariate Failure Reason: THESAURUS

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

Comments

OK Cancel

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

| Visit Page CRF | Screening 1 Elig | Screening 2 Enroll | Screening 3 MRN |
|----------------|------------------|--------------------|-----------------|
| 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

How are Univariate Disc. Created?

- | Univariate Discrepancies pop-up is presented during data entry when the entered value does not match the field definition.
 - q Mandatory field left empty
 - q Text entered in a Date or Numeric Field
 - q Too many characters entered
 - q Value is not on the Pick List
 - q Partial Date entered when a complete date is required
- | Data Entry operator can:
 - q Cancel the pop-up and fix the value
 - q Or accept the discrepancy
- | **Quick Tip:**
 - q Univariate Discrepancies are reassessed during Batch Validation for Design Changes.

How is a Univariate Disc. Displayed?

The screenshot displays the Oracle Clinical Remote Data Capture interface. The main window shows a patient list on the left and a data entry grid for various screening visits. A pop-up window titled "Patient 1 Page 5 (Symptom for Screening) Page 1 of 1, Repeat 1 of 2." is open, showing a table of symptom data. The value "HDFHDFH" in the CTC-Term column is highlighted in yellow, indicating a univariate discrepancy. A yellow callout box points to this value with the text "Data Values with Univariate Discrepancies is highlighted".

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

Below the data entry grid, a "Discrepancies" tab is active, showing a list of discrepancies. The first entry is highlighted in red and yellow, with a yellow callout box pointing to it, stating "Data Values with Univariate Discrepancies is highlighted".

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

How is a Univariate Disc. Displayed?

- | Discrepant data is highlighted in Yellow
- | Discrepancy text provides the details
- | **Quick Tip:**
 - q 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
 - q Example 1: Create Discrepancy if the entered BSA is not within 10% of the calculated BSA
 - q Example 2: Create Discrepancy if Date of Histological Confirmation is before Date of Diagnosis

- | **Quick Tip:**
 - q Rules available as a standard on each eCRF are summarized in the eCRFs Instructions Manual.
 - q 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:
 - q on-line validation rules are evaluated upon completion of a CRF **Saved as Complete**
 - q 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:**
 - q Complex rules run overnight.

How is a Multivariate Disc. displayed?

The screenshot displays the Oracle Clinical Remote Data Capture interface. At the top, the user is identified as Deven Shah (Data management role) at OCTRN on 07-MAR-2005, working on the TRAINING study. The interface includes a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window) and a toolbar. Below the menu is a tabbed interface for various data capture forms, with 'Screening 2 Enroll' currently active. A pop-up window titled 'Patient 10 Page 2 (Enroll for Screening) Page 1 of 1' is open, showing patient details such as Visit Date (03-Nov-2004), Primary Disease Site (BONE MARROW), and Disease Term (ACUTE LYMPHOCYTIC LEUKE). A discrepancy is highlighted in a red box: 'Date of Histology Confirmation 01-JUN-1999 is before Date of Diagnosis 01-DEC-2000 . Please verify'. The status of this discrepancy is 'Discrepancy not reviewed by Id : 45113401'. Below the discrepancy message is a 'History' section with a 'Resolution Comments and Reason' field. At the bottom, a table shows related data:

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

Three yellow callout boxes with arrows point to specific elements: 'Discrepancy tab' points to the discrepancy message, 'Discrepancy Description' points to the status and history area, and 'Related Data' points to the table at the bottom.

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
 - q Discrepancy Text
 - q Involved Clinical Data in the evaluation of the Discrepancy
- | **Quick Tip:**
 - q 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

The screenshot shows the Oracle Clinical Remote Data Capture interface. At the top, it displays the user 'Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER_STD Site:SITE_01 Book:Whole Book)'. The main window is titled 'Oracle Clinical Remote Data Capture' and shows a grid of data entry fields for various screening visits. A yellow callout box points to a specific data field containing 'hdfhdfh' and says 'Choose Go to Data Field from Pull Down Menu'. Another yellow callout box points to the discrepancy text in the table below and says 'Fix Data as indicated in the Discrepancy Text'. A context menu is open over the discrepancy, with 'Go to data field' highlighted in blue.

Oracle Clinical Remote Data Capture

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

Patient 1 (L) 2 (PT) 5 (No inits) 9 (No inits) 10 (ABC)

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 Scm

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

Visit Date 25-Mar-2003 Blank Comment

Bsym* COM Blank

00-SEP-2002 HEPATIC:: Bilirubin ABC 2=M

20-JUL-2002 hdfhdfh XYZ 1=M

Search Site SITE_01

Summary Discrepancies Verification Approval Audit Trail

List 1 - Active

Seq Text Status Comments

1 Value of hdfhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus Discrepancy not reviewed by

New History

Send to site
Send for classification
Close - resolved
Closed - no resolution
Go to data field

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:
 - q Consulting Source Documentation and;
 - q Modifying incorrect data and specifying change reason;
 - q Requesting eCRF Design and/or Validation Rule Change.

- | **Quick Tip:**
 - q System obsoletes univariate discrepancy automatically when data is corrected and complies with design/rules.
 - q 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

- | C³D 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)

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 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

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

Visit Date 20-May-2004 Blank Comment

Enroll* Init_Vs COM

Blank

ENROLLMENT

Gender M Date of Birth 24-OCT-1953 Age at Entry
Date of Registration 19-MAY-2004 Date from wh

Race: Select all that apply

Summary Discrepancies **Verification** Approval Audit Trail Links



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

Comment Keep comment between verifications

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

1 - 8

| | Screening 1 <i>Elig</i> | Screening 2 <i>Enroll</i> | Screening 3 <i>MRN</i> | Screening 4 <i>Medhist</i> | Screening 5 <i>Symptom</i> | Screening 6 <i>Prior Tx</i> | Screening 7 <i>Prior Thrp</i> | Screening 8 <i>Prior Rad</i> |
|---------|----------------------------|------------------------------|---------------------------|-------------------------------|-------------------------------|--------------------------------|----------------------------------|---------------------------------|
| 1 (BJS) | | | | | | | | |
| 2 (SB) | | | | | | | | |
| 3 (SKY) | | | | | | | | |
| 4 (GB) | | | | | | | | |
| 5 (FB) | | | | | | | | |
| 6 (WC) | | | | | | | | |

Re-verification Required

Verified eCRF

Verification

The screenshot shows the Oracle Clinical Remote Data Capture interface. At the top, the user is identified as Deven Shah (Data management role) at OCTRN on 19-SEP-2005. The interface includes a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window) and a toolbar. Below the menu is a tabbed interface with tabs for various data capture activities: Visit, Screening, Course 1, Course 2, Blood Chem..., Hematology, Urinalysis, Bone Mar..., Serology, Other Se..., Blood Gas, Pulmonar..., Red Cell..., and Other Ur... The 'Screening' tab is active, showing a grid of patient records. The first patient, 1 (BJS), is highlighted in cyan. A pop-up window titled 'Patient 1 Page 2 (Enroll for Screening) Page 1 of 1.' is open, displaying patient details: Visit Date 20-May-2004, Blank checkbox, Comment field, and buttons for Enroll, Init_Vs, and COM. Below the pop-up, the 'Activity List' shows 'All patients, all pages'. At the bottom, the 'Verification' tab is selected, showing a table of verification activities. A yellow box highlights the 'Re-verify Button' in the bottom right corner of the verification table.

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

Buttons: **Re-verify** (highlighted), Undo Verify



Approval

The screenshot displays the Oracle Clinical Remote Data Capture interface. At the top, the user is identified as Deven Shah (Data management role) at OCTRN on 19-SEP-2005. The main window shows a grid of patient records with columns for different screening activities. A pop-up window for 'Patient 1 Page 4 (Medhist for Screening) Page 1 of 1' is open, showing a 'Re-Approval required' status and a 'BASELINE MEDICAL HISTORY' section with a date of examination of 20-MAY-2004. The 'Approval' tab is selected, and a 'Type password and press Enter to approve this CRF' field is visible. A 'Keep comment between approvals' checkbox is also present. The bottom status bar shows 'Record: 1/1'.

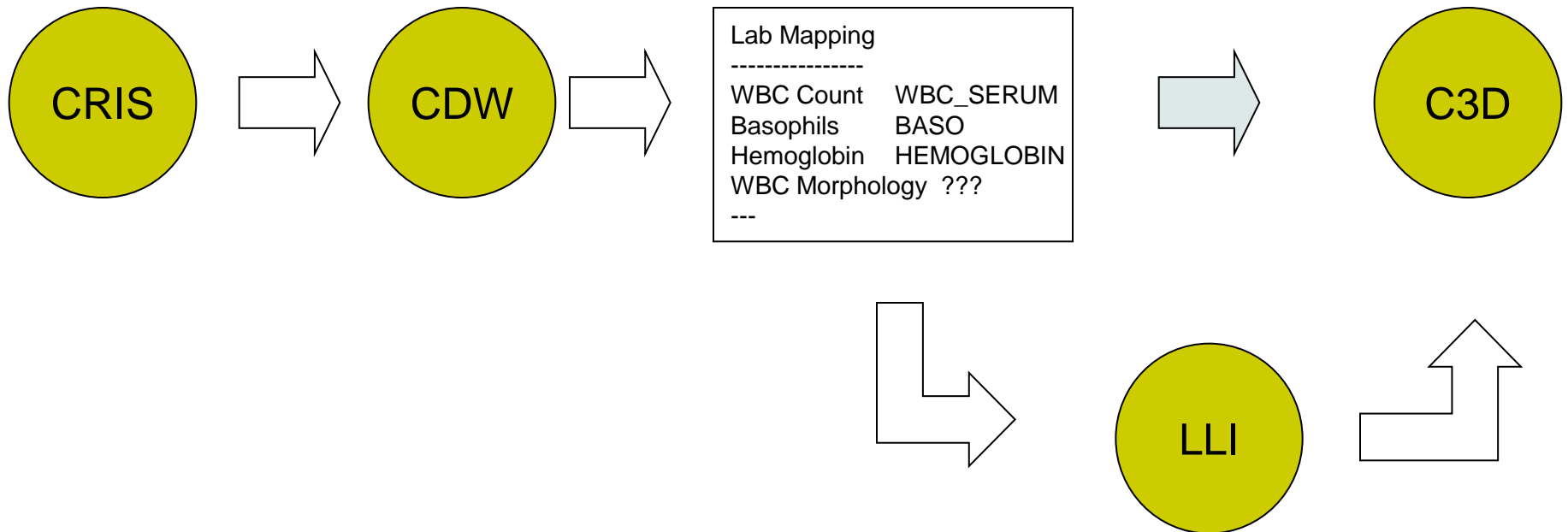
Annotations in yellow boxes:

- Verified & Approved**: Points to the 'Screening 4 Medhist' tab in the grid.
- Approved**: Points to the 'Screening 5 Symptom' tab in the grid.
- Re-Approval required**: Points to the status of the patient record in the pop-up window.
- Approval Tab**: Points to the 'Approval' tab in the bottom navigation bar.
- Approval Password**: Points to the password input field in the 'Approval' tab.

Approval

- | Each eCRF can be approved clicking on the Approve button and providing your C³D 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 C³D Lab Data Flow



What is LLI?

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

LLI Search Criteria

Search Criteria

Study Pt Lab Panel C3D Test Name

Date Relation DD MON YYYY

Time Relation HH24 MI

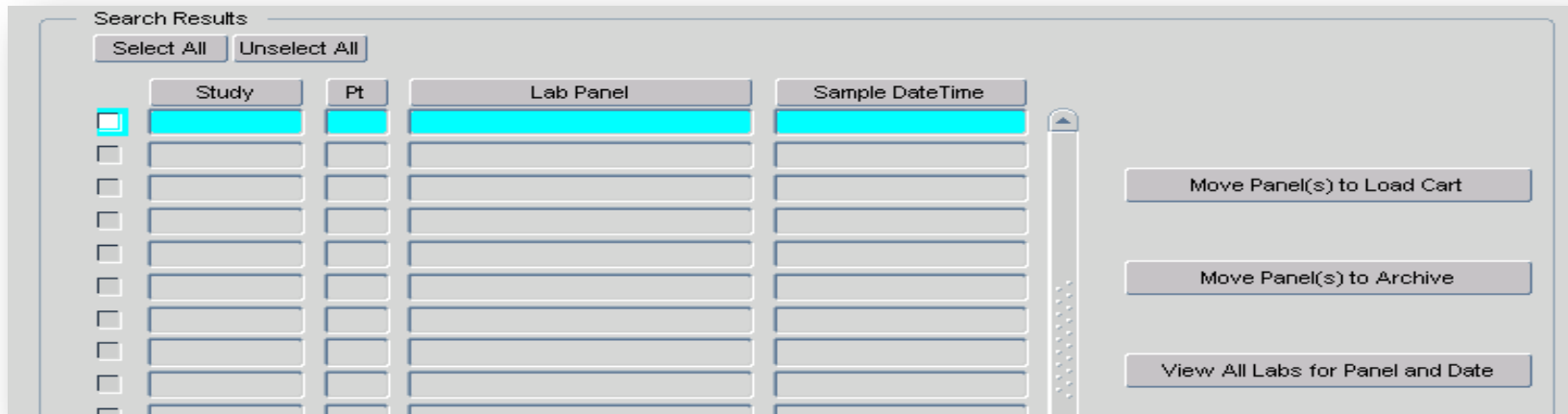
Search

New Search

- **Searching**

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

LLI Search Screen Results



- **Search Results**
 - The result set lists Lab Panels that have at least one lab test available for loading that meet the criteria entered into the search fields.
 - The sort order can be changed using the column headings.
 - Results can be selected/deselected for processing by using the individual select check box or Select Buttons.
 - Entire panels of lab tests can then be moved to the Load Cart or Marked for Archive.
 - Clicking “View All...” button or by double clicking the record presents the Work Cart with specific Lab Test Results for that panel.

LLI Work Cart

WORK CART

Work Selection

Study Pt Sample Datetime Lab Panel

Selection Results

Select All Unselect All

| R | C3D Test Name | Result | Unit | Range | Status |
|-------------------------------------|---------------|--------|------|-------|--------|
| <input checked="" type="checkbox"/> | | | | | |
| <input type="checkbox"/> | | | | | |
| <input type="checkbox"/> | | | | | |
| <input type="checkbox"/> | | | | | |
| <input type="checkbox"/> | | | | | |
| <input type="checkbox"/> | | | | | |

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?

