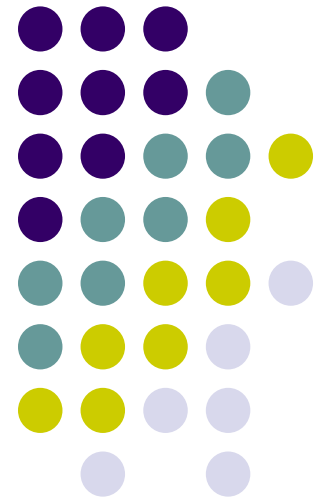


# Introduction to C<sup>3</sup>D

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Harris Corporation

Dec 2016



# Introduction

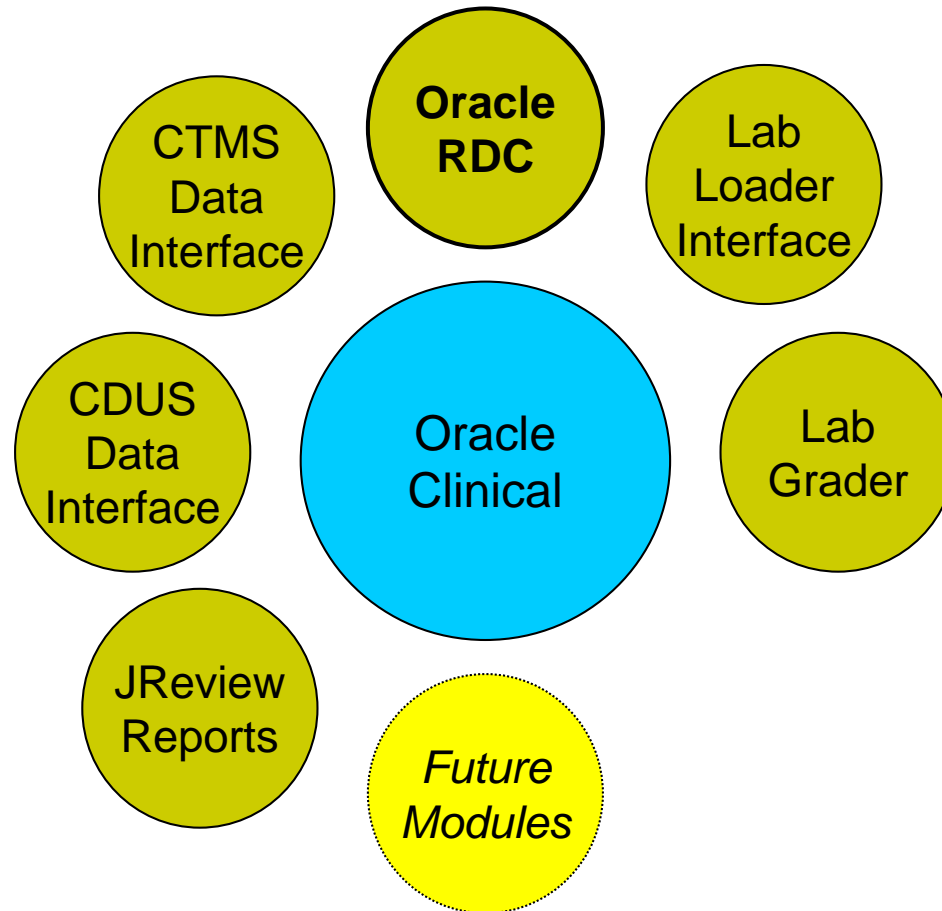
- C<sup>3</sup>D - **C**ancer **C**entral **C**linical **D**atabase
- eCRFs Instructions Manual
- Support
- Data Entry
- Audit-Trail
- Discrepancy Management
- Verification
- Approval
- Lab Loading

# What is C<sup>3</sup>D

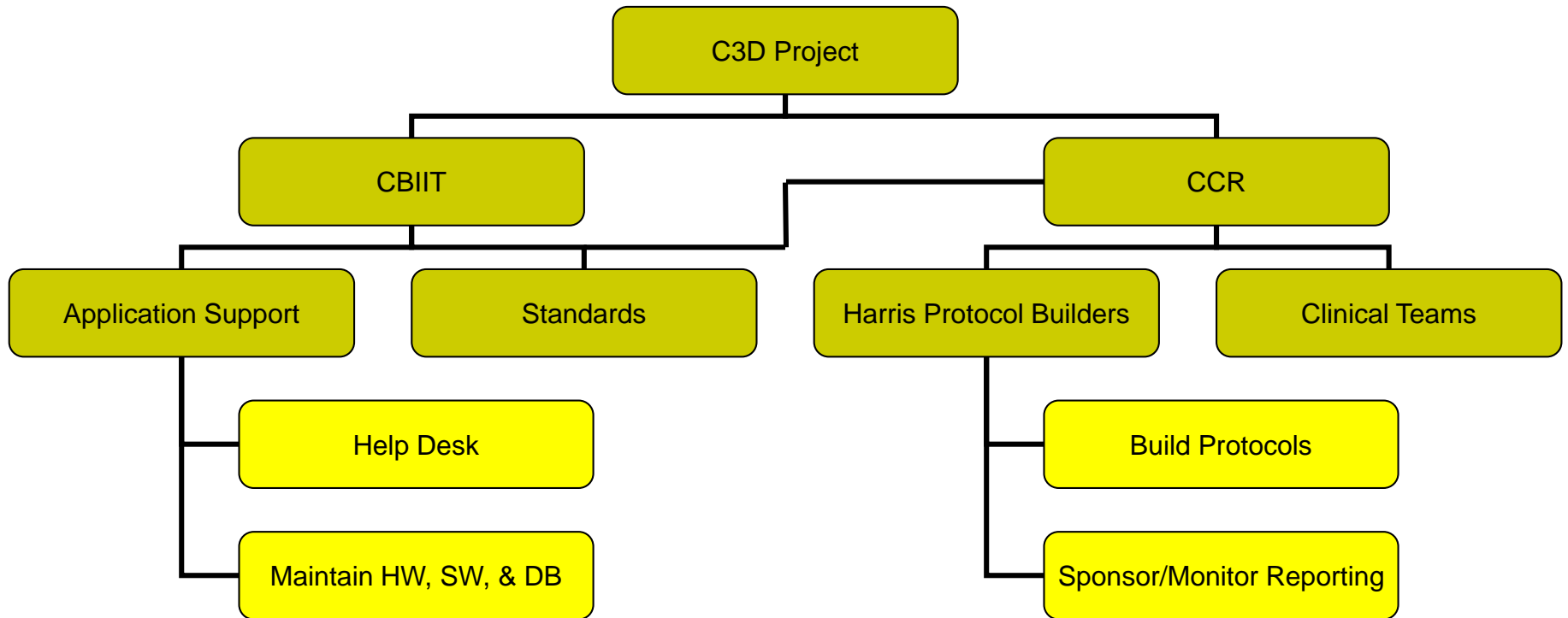


- Clinical Trials Data Management System
- RDC (Remote Data Capture) Data Entry
  - ❑ Accessible anywhere in the world (via a Windows computer and Internet Explorer).
  - ❑ **For studies prior with Clinical Center Number prior to 2012:** The Java Runtime Environment (JRE) version 1.7.0\_45 (or later) is required.
  - ❑ The above requirement will no longer apply by mid-2017, when open studies setup in C3D before 2012 will be converted to a new interface – ‘RDC Onsite’.
- C<sup>3</sup>D supports data standardization, reuse, sharing, and interoperability through electronic Case Report Forms (eCRFs) based on Common Data Elements (CDEs)
- Based on Industry Standard Technologies

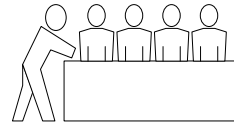
# Cancer Central Clinical Database C<sup>3</sup>D



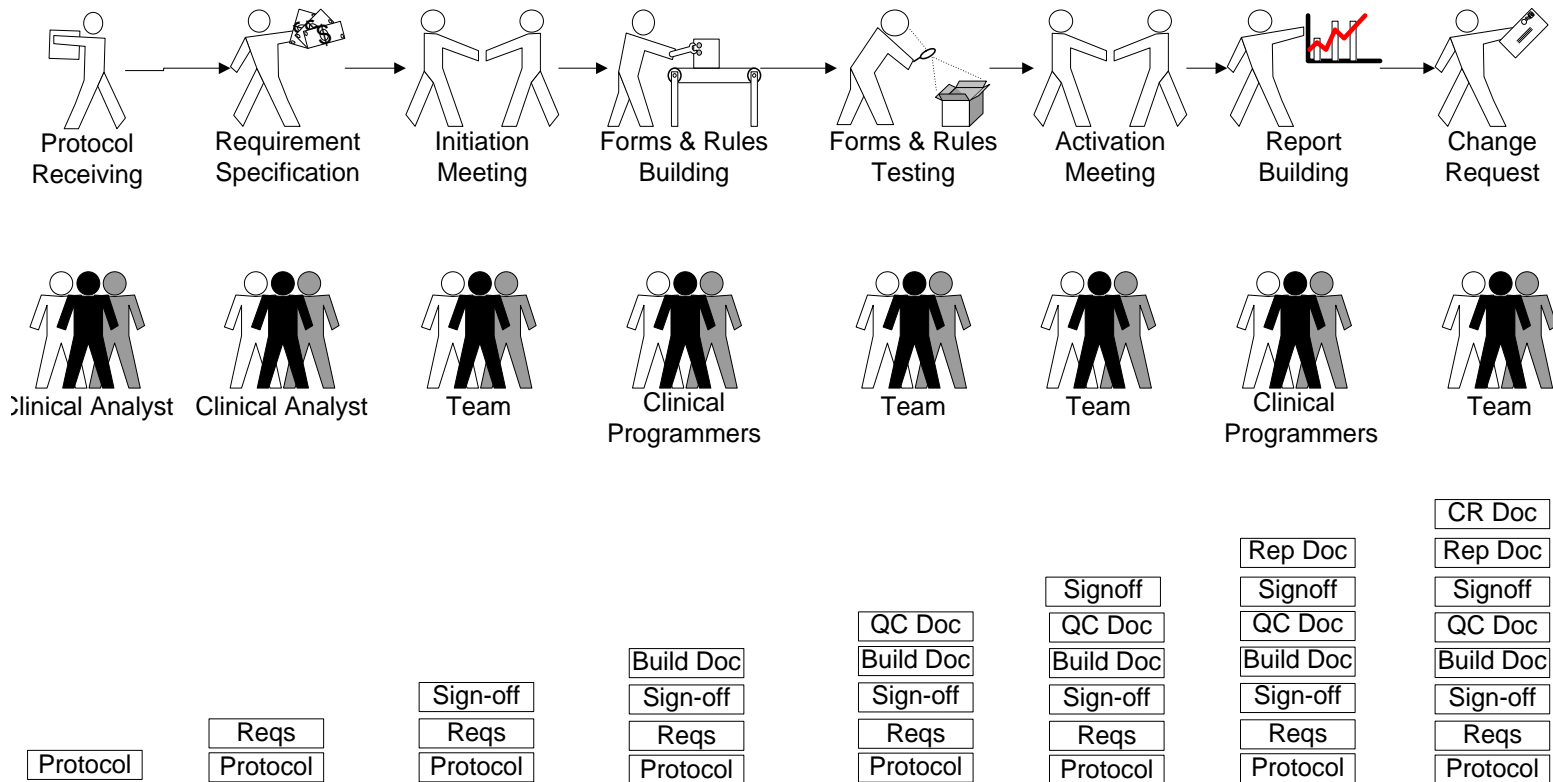
# C<sup>3</sup>D Organization



# Designing Protocols in C<sup>3</sup>D



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:
  - ❑ General Description
  - ❑ eCRF Screenshot
  - ❑ Field Specific Description (Mandatory, Derived, etc.)
  - ❑ Validation/Derivation Rules

# eCRF Instructions Manual

## Course Initiation

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

 Search

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

### Contents

- [Purpose](#)
- [Course Initiation eCRF](#)
- [Validations](#)
- [Derivations](#)

### Purpose

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

### Course Initiation eCRF

Visit Date: [DD-MM-YY] [Blank] [Comment] [Search]

Course #: [5 digits] [Search]

Start Date of Course: [DD-MM-YY]

Arm: [Dropdown]

Treatment Assignment Code: [Dropdown]

Treating Institution: [Dropdown]

Buttons: [Save] [Cancel] [Print] [Close]

Course #: [5 digits]

Start Date of Course: [DD-MM-YY]

Arm: [Dropdown]

Treatment Assignment Code: [Dropdown]

Treating Institution: [Dropdown]

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

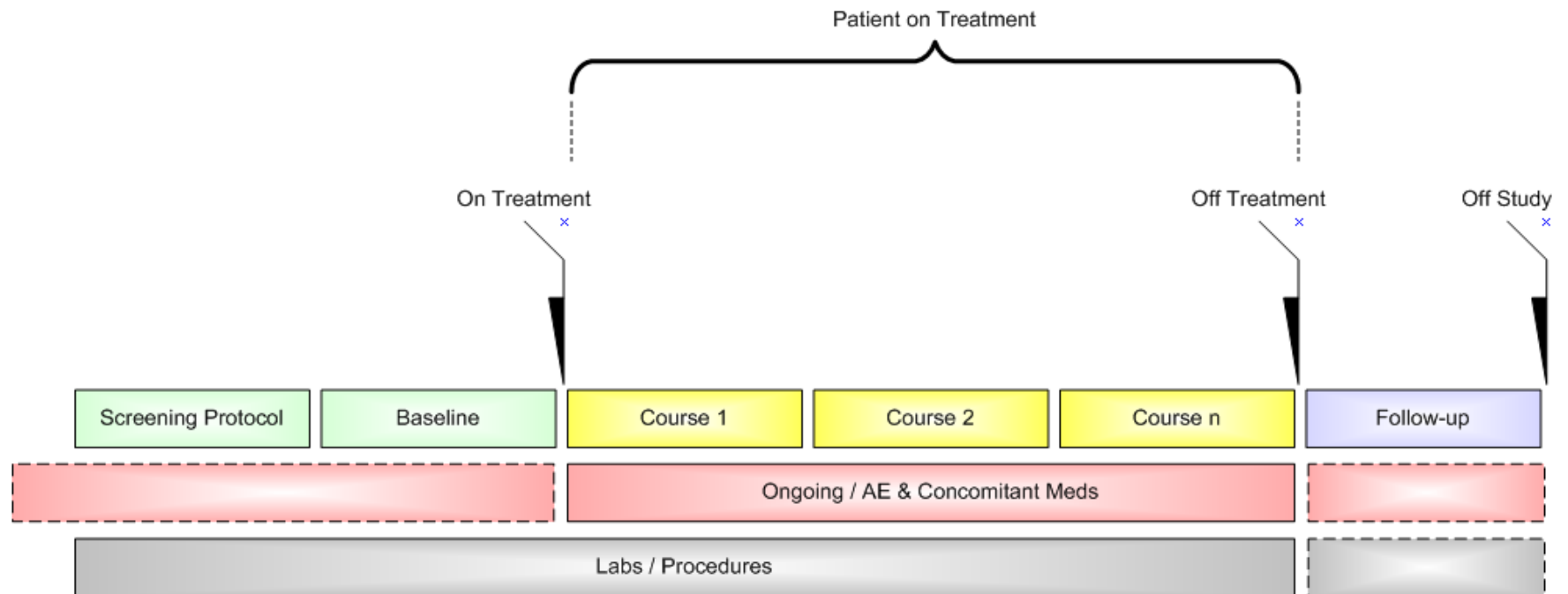


# CCR Standard Case Report Forms

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

# C<sup>3</sup>D 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

# NCI/CCR Confidentiality Agreement – Training Certificate

- At the end of the Training session, print, sign and fax the CCR Confidentiality Agreement to 240-541-4435. You can also scan and e-mail it back to the Trainer.
- Upon receipt of the CCR Confidentiality Agreement:
  - The request for your C3D account, password and access will be submitted. The C3D Help Desk will provision your C3D account within 2 business days.
  - The Certificate you attended the training will e-mailed to you.
  - Keep your signed CCR Confidentiality Agreement and the Training Certificate in your Study's regulatory binder.

# C<sup>3</sup>D Support

- CBIIT provides the first line of support for C<sup>3</sup>D related issues
- Contact
  - Email: [ncicbiit@mail.nih.gov](mailto:ncicbiit@mail.nih.gov)
  - Phone: 240-276-5541 (**Toll free**: 888-478-4423)
    - Telephone support is available Monday to Friday, 9:00 a.m. to 5:00 p.m. Eastern Time, excluding government holidays.
  - Additional Information at:  
<https://ccrod.cancer.gov/confluence/x/KwBYB>
- Protocol specific issues are escalated to the Protocol Builder by CBIIT
- Changes to Standards are escalated to Controls & Configuration Management Group (CCMG)

# Username & Password

- Username is typically your last name and first name initial.  
Ex: **smiths**
- Password rules:
  - ❑ Start with a letter;
  - ❑ Must containing **at least one number and one special characters** (Ex:! #);
  - ❑ Has to be at least 8 characters long;
  - ❑ The following special character could cause problems if used: \$ % & ' " /.
- Production Database is called **ocprod**
- About C<sup>3</sup>D Password:
  - ❑ **Do not share the password with others!**
  - ❑ Password needs to be changed the first time you login.
  - ❑ Passwords expire every 4 months and need to be changed.
  - ❑ **Account gets locked upon three unsuccessful attempts. Contact C<sup>3</sup>D Help Desk to unlock account and/or get new password.**

# C<sup>3</sup>D Login Web Pages

- C<sup>3</sup>D is Accessible Worldwide
- C<sup>3</sup>D Production Login Page:  
<https://octrials.nci.nih.gov/opa46/rdlaunch.htm>
- C<sup>3</sup>D provides a separate Data Entry environment to test protocol design
  - Test Login page:  
<https://octrials.nci.nih.gov/opa46/rdlauncht.htm>

# C<sup>3</sup>D Login Web Page

For studies with NCI Clinical Center Number prior to 2012 (ex: 11\_C\_0001, 10\_C\_0002), click on the Login button.

The screenshot shows a web browser window with the URL <https://octrials.nci.nih.gov/opa46/rdclaunch.ht>. The page features the Oracle Health Sciences logo and the title "Oracle Clinical Remote Data Capture 4.6". A central navigation menu includes a "Login" button (highlighted with a red box), "RDC Onsite", "Change Password", and "Login help". A yellow box with the text "Click on Login Button" has an arrow pointing to the "Login" button. On the right side, there are several blue hyperlinks: "Health Sciences Document Online", "RDC Online Help Home", "Downloads", "Oracle Health Sciences", and "Oracle Health Sciences User Group".



# 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".

# C<sup>3</sup>D Activity List

The screenshot shows the Oracle C<sup>3</sup>D Activity List interface. 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 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 for "TRAINING" with "Site: NCI" selected. A list of 15 items is displayed. Callout boxes point to various features:

- Select All Data, Active Discrepancies, etc.**: Points to the top of the list with 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" selection.
- 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.

The bottom section contains "Study Information" and "Study CRF Information".

Study Information			Study CRF Information			
Name	Training study for template 3.12B		Planned	<input type="text" value="1"/>	Not verified	<input type="text" value="1"/>
# Sites	<input type="text" value="1"/>		Unplanned	<input type="text" value="0"/>	Awaiting re-verification	<input type="text" value="0"/>
Created	Enrolled	With Data	Total	<input type="text" value="1"/>	Verified	<input type="text" value="0"/>
Patients <input type="text" value="30"/>	<input type="text" value="0"/>	<input type="text" value="1"/>	With active discreps	<input type="text" value="1"/>	Not approved	<input type="text" value="1"/>
			With other discreps	<input type="text" value="0"/>	Awaiting re-approval	<input type="text" value="0"/>
			Clean	<input type="text" value="0"/>	Approved	<input type="text" value="0"/>
					Locked	<input type="text" value="0"/>
					Not Locked	<input type="text" value="1"/>

Record: 1/3

# Selecting Activity

- Quick Links to View
  - All Study Data
  - Discrepant Data
  - Site Specific or Patient Specific Data
- Change Study button to choose a Different Study
  - Default Study is preserved from prior login
  - Access to study sites and C<sup>3</sup>D features are controlled by user role
- Search button used to locate eCRFs based on one or more criterion
- **Quick Tip:**
  - This screen provides a quick review of open discrepancies in your study
  - **It is strongly recommended to work with one patient at a time when performing data entry to avoid entering data in the wrong patient position.**

# Selecting Study

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 'Find %' search field at the top. The list contains the following entries:

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

At the bottom of the dialog are buttons for 'Find', 'OK', and 'Cancel'. A yellow callout box with an arrow 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), a toolbar, and a main workspace with a 'Visit' tab selected. The status bar at the bottom indicates 'Choices in list: 80' and 'Record: 1/1'.

# Study Access

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

# Search Criteria

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 icons for home, save, print, refresh, search, and help. The main area shows a grid of CRF pages 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

- Search options:
  - ❑ Book - collection of CRFs for a particular version of the protocol (initial version or amendments)
  - ❑ Site
  - ❑ Patients
    - Range of Patients
  - ❑ Visits/Pages
    - Phases, Visits, etc.
  - ❑ CRF Status
    - Complete, Discrepant, Verified, Approved, etc.
  - ❑ CRF Entry Date Window
    - Entry or Modification Date Ranges
  - ❑ Data
    - Data entered in an eCRF
- **Quick Tip:**
  - ❑ Protocol Amendments may require different DCI Book. Latest DCI book is the default one. Use Search option to select a previous book.
  - ❑ Search Criteria Could be saved for future use.

# RDC Spreadsheet

Deven Shah(Data management role) at OCTRN on 02-MAR-2005 (Study:TRAINING Book:Dci Book)

File Edit Insert CRF Group

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

Activity List: All patients, all pages

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 verified	91	Not approved	93	
		Unplanned			e-verification	1	With active discreps	24	
		Total	254		Verified	1	With other discreps		
		With active discreps	87	Not approved	254		Awaiting re-approval		
		With other discreps		Awaiting re-approval			Clean	69	
		Clean	167	Approved			Approved		

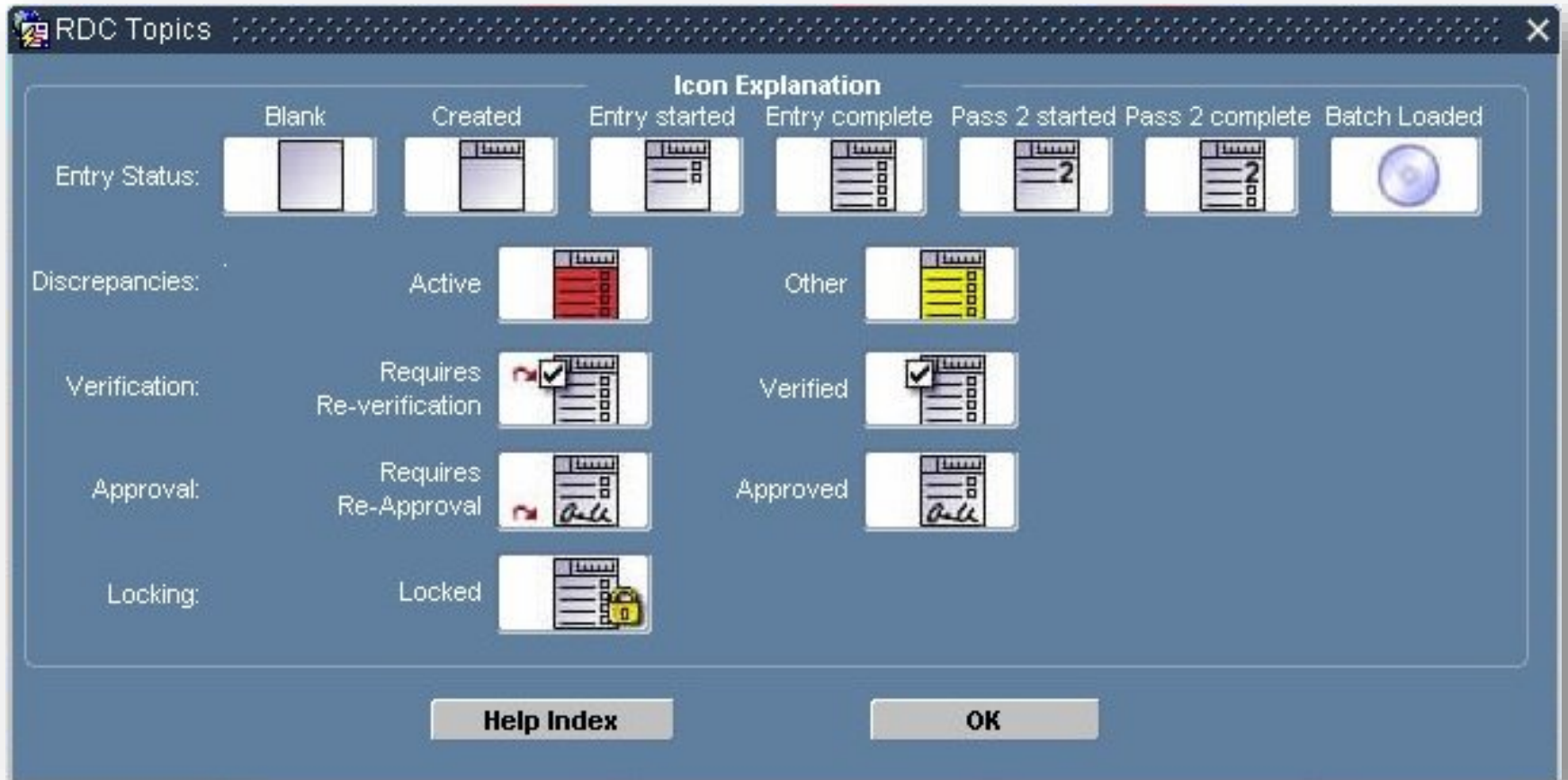
Display summary information about a Visit, a Patient, a Planned eCRF or the selected eCRF.



# Navigating RDC Spreadsheet

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

# eCRF Icons



# 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 interface is divided into several sections:

- Left Panel:** A vertical list of tabs labeled 'X1 (XYZ)', 'X2 (XYZ)', 'X3 (XYZ)', 'X4 (XYZ)', 'X8 (XYZ)', 'X9 (XYZ)', and 'X10 (XYZ)'. Below these are 'Activity List', 'Summary', and 'Summary For' sections.
- Main Form:** A data entry form with fields for 'Visit Date' (10-Jun-2004), 'Enroll\*' (Init\_Vs, COM), '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' (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), and 'Date Informed Consent Signed' (01-JAN-2003), 'Date of Informed Consent Version' (12-DEC-2002).

Annotations highlight specific features:

- Tabs for eCRF Sections:** Points to the vertical list of tabs on the left.
- Non-enterable field:** Points to a field with a red 'X' icon, indicating it cannot be edited.
- Ellipsis indicates field has a Pick List:** Points to an ellipsis icon next to the 'Date of Birth' field.
- Yellow – Univariate Discrepancy:** Points to the 'STAGE II A' field, which is highlighted in yellow.
- eCRF Scroll Bar:** Points to the vertical scroll bar on the right side of the form.

The status bar at the bottom shows 'Record: 1/1', 'List of Valu...', 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	
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

The screenshot displays the Oracle Clinical Remote Data Capture interface. A window titled "Sizing window for Data Entry" is open, and several callout boxes provide instructions on how to resize it:

- Click Title Bar to enter Resize Mode** (yellow box)
- then click the [Done] button** (blue box)
- A future alternative is to use the right mouse on the title bar** (blue box)
- Then Click and Drag the Title Bar to move the window or the sides/corners to resize** (yellow box)
- Click Done when resizing is complete** (yellow box)

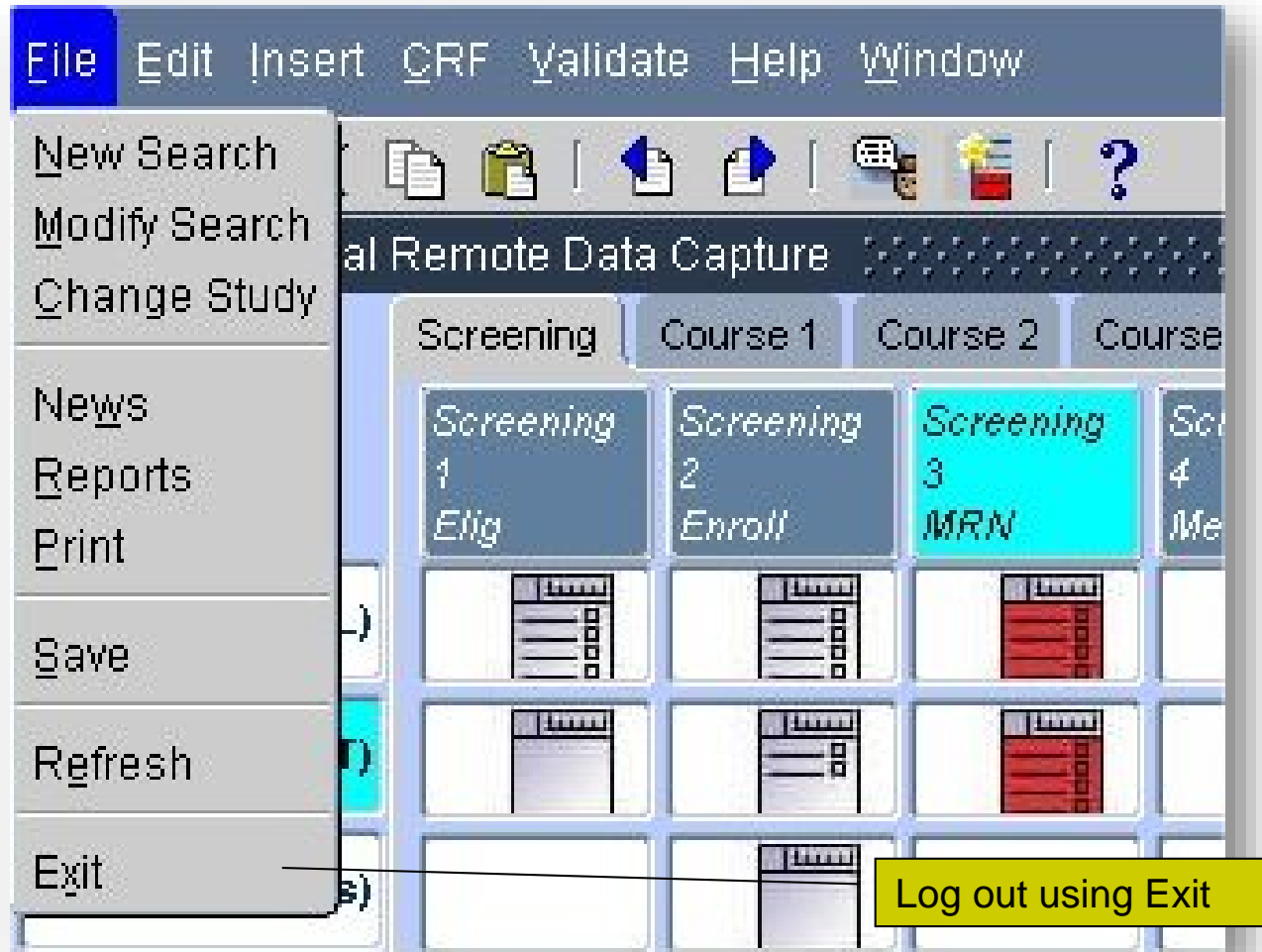
The interface includes a menu bar (File, Edit, Insert, CRF, Group Activities, Validate, Help, Window), a toolbar, and a tabbed interface with tabs for Urinalysis, Bone Marrow, Serology, Other Serum, Blood Gas, Red Cell In..., Other Ur..., Immune P..., Serum El..., Urine El..., Flow Cyt..., and Other Labs. A sidebar on the left contains a list of activities (X1 to X10) and a summary section for CRF. At the bottom, there are fields for 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), and By (Liming Wan). The status bar at the bottom shows "Record: 1/1" and "<OSC>".



# Resizing eCRF Window

- Click on the eCRF title bar to enter resize mode
- Click and drag title bar to move window
- Click and drag window edge to expand/reduce window size
- Click OK when Done
  
- **Quick Tip:**
  - Right mouse click on the eCRF title bar to show a pop-up menu with options to move/resize the eCRF window.

# Log Out



# Log Out

- Exit C<sup>3</sup>D 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 main 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 various icons, including a person icon for inserting a new patient. A dialog box titled "Insert" is open, showing a list of patient positions from 27 to 34, with position 29 selected. The dialog has "OK" and "Cancel" buttons. A yellow callout box points to the person icon in the toolbar with the text "Icon to Insert New Patients". Another yellow callout box points to the "Insert" dialog with the text "Choose Patient Position". The main window shows a list of patients (11-18) and a grid of data entry fields for various tests like Hematology, Urinalysis, Bone Mar..., Serology, and Other Se... The status bar at the bottom indicates "All patients, all pages" 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

Icon to Insert New Patients

Choose Patient Position

11 (SAH)  
12 (SAH)  
13 (SAH)  
14 (SAH)  
15 (SAH)  
16 (SAH)  
17 (SAH)  
18 (SAH)

Activity List All patients, all pages

Summary Discrepancies Verification Approval Audit Trail

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

# Inserting New Patient

- Click Patient Icon or Select Insert -> Patient from the menu bar
- Choose a Patient Position Number from the pick list
- New Patient Row is Created
- **Quick Tips:**
  - The total number of Patients available for entry are governed by protocol ceiling accrual. Request additional patient numbers if protocol is amended.
  - It is a good practice to use the patient numbers in sync with those assigned by Central Registration Office (CRO)

# Starting New Planned eCRF

The screenshot displays the Oracle Clinical Remote Data Capture application. The window title is "Deven Shah(Data management role) at OCTRN on 01-MAR-2005 (Study:TRAINING Book:Dci Book)". The interface includes a menu bar with "File", "Edit", "Insert", "CRF", "Group Activities", "Validate", "Help", and "Window". Below the menu bar is a toolbar with various icons. The main area is a grid of data cells. The first column is labeled "Visit" and contains the value "20". The second column is labeled "Course 1" and contains the value "Physical". The third column is labeled "Course 2" and contains the value "Pharmacok.". The fourth column is labeled "Blood Chem..." and contains the value "Study Med". The fifth column is labeled "Hematology" and contains the value "Assess". The sixth column is labeled "Urinalysis". The seventh column is labeled "Bone Mar...". The eighth column is labeled "Serology". The ninth column is labeled "Other Se...". A yellow callout box with the text "Click on empty Cell to insert eCRF and begin data entry" points to an empty cell in the second row, second column. The bottom of the interface shows a navigation bar with "Activity List", "All patients, all pages", "Summary", "Discrepancies", "Verification", "Approval", and "Audit Trail". The status bar at the bottom left shows "Record: 2/5" and a "<OSC>" button.

Visit	Course 1	Course 2	Blood Chem...	Hematology	Urinalysis	Bone Mar...	Serology	Other Se...
20	Course 1 11 Initiation	Course 1 12 Physical	Course 1 13 Pharmacok.	Course 1 14 Study Med	Course 1 15 Assess			
20 (HHC)								

Click on empty Cell to insert eCRF and begin data entry

# Starting New Planned eCRF

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

# Entering Visit Date

The screenshot shows the Oracle Clinical Remote Data Capture interface. The title bar indicates the user is Deven Shah (Data management role) at OCTRN on 01-MAR-2005, working on a study named TRAINING. 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 of the window, there is an 'Activity List' section showing 'All patients, all pages' 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
  - ❑ **Visit Date is the Lab Sample Collection Date for Lab eCRFs!**
  - ❑ Visit Date is mandatory except for Ongoing Visit eCRFs.
  - ❑ Partial dates are not acceptable.
  - ❑ Consult eCRFs Instructions Manual for eCRF specific guidance:
    - Usually Evaluation Date, Administration Date, Initiation Date, Lab Date, Course Start Date, etc.

# Entering Data in eCRF

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

File Edit Insert CRF Group Activities Validate Help Window

Oracle Clinical Remote Data Capture

Tabs: Visit | Screening | Course 1 | Course 2 | Course 3 | Course 4 | Course 5 | Blood Chemistry | Hematology | Urinalysis | Bone Marrow | Serology | Other Serum | Blood Gas

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

Visit Date: 10-Jun-2004 Blank  Comment:

Enroll\* Init\_Vs COM

**Tabs for eCRF sections**

Blank

**Enrollment**

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 **Indicates Pick List**

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

**Yellow – Univariate Discrepancy**

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: 01-JAN-2003

Planned TAC: ARM A

Date of Informed Consent Version: 12-DEC-2002

**Use Tab to move between fields**

**eCRF Scroll Bar**

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

# Entering Data in eCRF

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

# Tabular eCRF

**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.**

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	
		Y	01-MAY-2004	10-MAY-2004	Anorexia	GASTROINTESTINAL	
1	64	Y	05-MAY-2003	10-MAY-2003	Palpitations	CARDIAC ARRHYTHMIA	
		Y	05 UNK 2004	00-MAY-2004	Alkalosis (metabolic or respi	METABOLIC/LABORATORY	
-1	-61	Y	01-JAN-2003	10 UNK 2003	Palpitations	CARDIAC ARRHYTHMIA	
-1	-30	N	01-FEB-2003	02-FEB-2003	Dental: dentures or prosthe	GASTROINTESTINAL	

# Tabular eCRF

- Fields shown in a grid layout
- Scroll up and down the rows of the table using arrow keys (No Scroll Bars!!)
- **Quick Tips:**
  - Use the menu option CRF -> Insert Row to insert a row between two rows (below the currently selected row).
  - **A row cannot be left blank and must be deleted before proceeding to another row.**
    - Select the menu option CRF -> Delete Row.

# Using Pick List

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. <Univ>". The "Visit Date" is "07-Jul-2004". Below this, there are tabs for "AE1\*", "AE2", "AE3", "AE4", "AE5", and "COM". The "Type" field is set to "AE1". A yellow callout box with a black border points to the "Type" field, containing the text: "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
- Bilirubin (hyperbilirubinemia)

The "Bicarbonate, serum-low" option is highlighted in blue. The dialog box has "Find", "OK", and "Cancel" buttons. At the bottom of the screen, a status bar 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:
  - Start typing in some letter and the list is filtered as you type or;
  - Click on the Find box, enter a some letters surrounded by the wildcard % character (ex: %ypo% ) and click on the Find button. Select one of the values.
  - **If the Pick List has more than 1,000 items, items beyond 1,000 cannot be searched after the Pick List is shown.** Close the Pick List and use the wildcard find shown above then press the F9 key or click on the ellipsis. This way the entire list will be searched and matched items shown. The following Pick Lists have more than 1,000 items:
    - CTCAE Term (version 3.0) pick list on the Adverse Events and Baseline Symptoms;
    - Agents in the Concomitant Measures and Medications;
    - Enrollment eCRF Disease Term (only when using comprehensive CTEP list of Diseases);
    - Enrollment eCRF Registering Institute;
    - Course Initiation eCRF Treating Institute.
- **Quick Tips:**
  - If a value is not in the pick list enter it, consult your DM Supervisor. Entering a value that is not on the pick list will create a discrepancy.

# Marking eCRF Blank

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 another yellow callout box labeled "Marking Section Blanks" pointing to it. 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:**
  - ❑ It is a good practice to mark Sections that will not have data entered as Blank.
  - ❑ Once all sections of a CRF are 'addressed' (by entering data or marking it as blank) the overall status of the eCRF becomes Entry Complete.

# Entering/Viewing Laboratory Data

Abu Muyeen(Data management role) at OCPROD on 23-FEB-2010 (Study:10\_C\_0056 Site:NCIMB Book:Book\_0\_11dec2009)

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

Oracle  
 Patient  
 CRF  
**Visit**  
 Discrepancy (manual) F11  
 Section Discrepancy  
 Investigator Comment F12

1010001 (SES)

	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Blood Chemistry	Hematology	Urinalysis	Serology	Other Serums	Other Uri...	Coagula...
1	Blood Ch..2	Blood Ch..3	Blood Ch..4	Blood Ch..5	Blood Ch..6	Blood Ch..6	Hide unplanned pages					
	Blood Chem	Blood Chem	Blood Chem	Blood Chem	Blood Chem	Blood Chem						

Activity List Site NCIMB, Patient 1010001

Summary Discrepancies Verification Approval Audit Trail Links

Summary For	# Patients	Summary of CRFs Retrieved				Summary of CRFs in Current Tab			
Visit	1	Planned	25	Not verified	37	Planned	1	Not verified	7
		Unplanned	12	Awaiting re-verification		Unplanned	6	Awaiting re-verification	
		Total	37	Verified		Total	7	Verified	

Annotations:  
 - Yellow box: Show/Hide Unplanned (points to 'Hide unplanned pages' cell)  
 - Yellow box: Add Unplanned (points to empty cell in Cycle 2)

# Entering/Viewing Laboratory Data

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

# Saving eCRF

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, COM, 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). A yellow box labeled "Save Icon" points to a save icon in the top right of the form area. The bottom status bar shows "Record: 1/1" and "List of Valu...".

# Saving eCRF

- eCRF can be saved using
  - Toolbar Save Icon (yellow floppy disk)
  - F10 Key
  - File -> Save menu option
- **Quick Tip:**
  - Save Often!! Especially while entering Ongoing Information such as AEs and ConMeds.
  - C<sup>3</sup>D 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 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 various icons for navigation and editing. The main content area shows a patient record for "Patient 5 Page 2 (Enroll for Screening) Page 1". The patient's visit date is "03-Nov-2004". The "ENROLLMENT" section shows the patient's gender as "M" and date of birth as "01011967". The date of registration is "22-JUN-2004", and the date from which to start including labs is "18-JUN-2004". A dialog box titled "Audit Information for Data Change" is open, showing a "Change Reason" of "DATA ENTRY ERR" and a "Description" of "Data Entry Error". The dialog box also has a "Comment" field and "Save" and "Cancel" buttons. A yellow box labeled "Data Changed" is positioned below the dialog box, with an arrow pointing to the "Date from which to Start Including labs" field.

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

Audit Information for Data Change

Change Reason: DATA ENTRY ERR

Description: Data Entry Error

Comment:

Save | Cancel

Data Changed

Record: 1/1 | <OSC>

# Data Entry Change Reason

- Change Reason needs to be specified while changing data on completed eCRF
- Change Reason becomes part of the Audit Trail along with date of change and user name
- Comments can be provided in the change reason to further explain
- **Quick Tip:**
  - ❑ Do not use personnel/patient names or identifiers in the comments.

# What is a Discrepancy?

- A discrepancy is the failure of entered data to pass a validation check as applied by C<sup>3</sup>D.
- C<sup>3</sup>D validation checks are defined based on the definition of the fields, logical rules, protocol specifications, and sponsor requirements.
- Discrepancies are tools to assist teams in identifying potential data inconsistencies and facilitate real-time QA of data.
- **Quick Tips:**
  - ❑ Discrepancies do not cover 100% of possible data inconsistencies.
  - ❑ Clinical judgment may supersede discrepancy logic.



# C<sup>3</sup>D Discrepancy Types

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

# Some Typical Discrepancies

Types	Example:	Resolutions
Data Type	Text entered in numeric or date field.	Review Source Document and enter appropriate data.
Length Problems	Too many characters entered.	Use NIH accepted Abbreviations.
Value not on the Pick List	Generic Agent not present in Concomitant Agent Pick List and user typed in an Agent not found on the Pick List.	Search for alternates. Consult Team Lead. Request value to be added to Pick List.
Mandatory Value	Required Field left empty.	Refer to Source Document. Design modification.
Partial/Invalid Dates	00-10-2010 entered, but field requires a full data such as 01-01-2010	Refer to Source Documents. Check Day Month Year order. Check that date is not in the future.

# Outstanding Discrepancies in a Study

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 options: "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", with "Links" being the active tab.

Deven Shah(Data management role) at OCPROD on 18-JUN-2004 (Study:THER\_STD Site:SITE\_01 Book:Whole Book)

File Edit Insert CRF Group Activities Validate Help Window

My Activity List

- THER\_STD
  - Site: SITE\_01

[Review 49 Active Discrepancies](#)

[Show All Data for THER\\_STD](#)

[Review 49 Active Discrepancies for Site SITE\\_01](#)

Change Study

Search

Cancel

Help

Summary Links

# Outstanding Discrepancies in a Study

- Total number of Discrepancies in a study are shown in the Activity List
- Clicking on the 'Review xx Active Discrepancies' link will present only the Discrepant eCRFs
- **Quick Tip:**
  - Data Managers should manage their discrepancies every morning to help ongoing QA of data.

# eCRFs Containing Discrepancies

Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER\_STD Site:SITE\_01 Book:Whole Book)

File Edit Insert Go Validate Data Entry Help Window

Oracle Clinical Remote Data Capture

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 a clinical trial data management system interface. At the top, there are tabs for various data entry sections: Screening, Course 1, Course 2, Course 3, Course 4, Course 5, Blood Chemistry, Hematology, Urinalysis, Bone Marrow, Serology, Other Serum, and Blood Gas. Below these, a grid shows the status of eCRF pages for multiple patients. Patient 1 (L) is selected, and the 'Screening 5 Symptom' page is highlighted. A detailed view of this page is shown, including fields for Visit Date (25-Mar-2003), Bsym\* (COM), and a table of symptoms. The table has columns for Onset Date, CTC Term, Symptom Description, and Grade. Two symptoms are listed: 'HEPATIC:: BILIRUBIN' with onset date '00-SEP-2002' and grade '2=M', and 'HDFHDFH' with onset date '20-JUL-2002' and grade '1=M'. A yellow callout box points to the 'Discrepancies' tab in the bottom navigation bar, stating: "Discrepancies in the selected eCRF are summarized in Discrepancies Tab". Below the navigation bar, a list of discrepancies is shown. The first entry is highlighted in red and contains the text: "Value of hdfhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus". A second yellow callout box points to this list, stating: "First tab enumerates all discrepancies. Additional tabs provide individual discrepancies details." At the bottom, there are buttons for 'New' and 'History'.

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

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		

# 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 **Offstudy 105 Offstudy** Urinalysis Bone Marrow Serology Oth

Visit Page CRF

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 Status : Discrepancy not reviewed by Id : 8375801

Comments Action  **History** 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 tabs

Disc History is available via this button

# Discrepancy Details

- Subsequent tabs show details for each discrepancy
- Open Discrepancies are displayed first and are followed by Closed Discrepancies
- **Quick Tip:**
  - ❑ Double Clicking on the Discrepancy Text brings up a pop-up box with the entire message

# How are Univariate Disc. Created?

Deven Shah(Data management role) at OCTRN on 20-JAN-2004 (Study:THER\_STD Site:SITE\_01 Book:Whole Book)

File Edit Insert Go Validate Data Entry Help Window

Oracle Clinical Remote Data Capture

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:

Alternatively, operator can accept to create univariate disc

Operator can cancel to not create the discrepancy

Univariate Disc Pop-up

Description

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

# How is a Univariate Disc. Displayed?

The screenshot displays the Oracle Clinical Remote Data Capture interface. The main window shows a data entry form for Patient 1 (L) at Site SITE\_01. The form is divided into several sections: a patient list on the left, a grid of data points for various screening visits, and a detailed data entry form for the current visit (Screening 5 Symptom). The detailed form includes fields for Onset Date, CTC Term, Symptom Description, and Grade. The CTC Term field contains the value 'HDFHHDFH', which is highlighted in yellow. A yellow callout box points to this field 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=MC	
20-JUL-2002	HDFHHDFH	XYZ	1=MI	

Below the main data entry form, there is a 'Discrepancies' tab. The 'Discrepancies' list shows one active discrepancy:

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		

A yellow callout box points to this discrepancy with the text: "Data Values with Univariate Discrepancies is highlighted".

# How is a Univariate Disc. Displayed?

- Discrepant data is highlighted in Yellow
- Discrepancy text provides the details
- **Quick Tip:**
  - Double Click on the Discrepancy Message Text to view the entire message in a window.

# How are Multivariate Disc. Created?

- Multivariate Discrepancies are created based on validation rules programmed in a study
  - ❑ Example 1: Create Discrepancy if the entered BSA is not within 10% of the calculated BSA
  - ❑ Example 2: Create Discrepancy if Date of Histological Confirmation is before Date of Diagnosis
- **Quick Tip:**
  - ❑ Rules available as a standard on each eCRF are summarized in the eCRFs Instructions Manual.
  - ❑ Though several standard rules are implemented for each eCRF as specified on the eCRFs Instructions Manual, clinical teams can request them to be turned off or modified to comply with the Protocol.

# Evaluation of Multivariate Rules

- Validation Rules are evaluated:
  - ❑ on-line validation rules are evaluated upon completion of a CRF **Saved as Complete**
  - ❑ during an overnight batch validation session for CRFs **Saved as Complete**
- Multivariate Discrepancies are displayed in the same manner as Univariate Discrepancies. The Discrepancy Details panel indicates the type of Discrepancy.
- **Quick Tip:**
  - ❑ Complex rules run overnight.



# How is a Multivariate Disc. displayed?

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

File Edit Insert CRF Group Activities Validate Help Window

ORACLE

Oracle Clinical Remote Data Capture

Tabs: Visit, Screening, Course 1, Course 2, Blood Chem..., Hematology, Urinalysis, Bone Mar..., Serology, Other Se..., Blood Gas, Pulmonar..., Red Cell..., Other Ur...

1 (SAH)

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

Visit Date: 03-Nov-2004

Enroll\* Init\_Vs COM

Primary Disease Site: BONE MARROW Disease Term: ACUTE LYMPHOCYTIC LEUKE Disease Stage at t

Histology/Cytopathology: Persistent Recurrent Acute Lymphocytic 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:

Activity List: All patients, all pages

Summary Discrepancies Verification Approval

List: 1 - Active 2 - Active 3 - Closed 4 - Closed 5 - Closed 6 - Closed

Date of Histology Confirmation 01-JUN-1999 is before Date of Diagnosis 01-DEC-2000 . Please verify Status: Discrepancy not reviewed by Id: 45113401

Comments Action History 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

Record: 2/6 <OSC>

Discrepancy tab

Discrepancy Description

Related Data

# How is a Multivariate Disc. displayed?

- Discrepancy is based on one or more fields and is NOT highlighted in Yellow
- Discrepancy tab provides the details
  - Discrepancy Text
  - Involved Clinical Data in the evaluation of the Discrepancy
- **Quick Tip:**
  - The Action pull-down “Go to Data Field” does not work as the discrepancy could be based on more than one field.

# How to Address a Discrepancy

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 20-JAN-2004, working on Study: THER\_STD, Site: SITE\_01, and Book: Whole Book. The interface includes a menu bar (File, Edit, Insert, Go, Validate, Data Entry, Help, Window) and a toolbar. Below this is a tabbed interface with tabs for Screening, Course 1 through Course 5, Blood Chemistry, Hematology, Urinalysis, Bone Marrow, Serology, Other Serum, Blood Gas, and Red Cell Ind. The current view is for Patient 1 (L) at Visit Page CRF 5 (Symptom). The data entry form shows fields for Visit Date (25-Mar-2003), Bsym\* (COM), and a table of symptoms. One symptom entry is highlighted in yellow: 20-JUL-2002, hdfhdfh, XYZ, 1=MI. A yellow callout box points to this entry with the text "Fix Data as indicated in the Discrepancy Text". Another yellow callout box points to a pull-down menu that is open, showing options: "Send to site", "Send for classification", "Close - resolved", "Closed - no resolution", and "Go to data field". The "Go to data field" option is highlighted in blue. Below the data entry form is a "Discrepancies" section with a table showing a list of discrepancies. The first discrepancy is highlighted in red and reads: "Value of hdfhdfh for The Common Toxicity Criteria Term is not in the lookup thesaurus". The status is "Discrepancy not reviewed by" and the comments are empty. A pull-down menu is also open for this discrepancy, showing the same options as the one above. The interface also includes a "Search" field with "Site SITE\_01" and buttons for "New" and "History".

Choose Go to Data Field from Pull Down Menu

Fix Data as indicated in the Discrepancy Text

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

# How to Address a Discrepancy

- Review Discrepancy Details
- Whenever possible, use the Action pull down 'Go to Data Field' to jump to the Discrepant Field
- Resolve the discrepancy by:
  - Consulting Source Documentation and;
  - Modifying incorrect data and specifying change reason;
  - Requesting eCRF Design and/or Validation Rule Change.
- **Quick Tip:**
  - System obsoletes univariate discrepancy automatically when data is corrected and complies with design/rules.
  - Multivariate Discrepancies are only re-evaluated during overnight Batch Validation.

# Verification & Approval

RDC Topics

**Icon Explanation**

	Blank	Created	Entry started	Entry complete	Pass 2 started	Pass 2 complete	Batch Loaded
Entry Status:							
Discrepancies:		Active		Other			
Verification:		Requires Re-verification		Verified			
Approval:		Requires Re-Approval		Approved			
Locking:		Locked					

Help Index      OK

# Verification & Approval

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

# Verification

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

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 Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology

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)								

1 (BJS)

2 (SB)

3 (SKY)

4 (GB)

5 (FB)

6 (WC)

Verified eCRF

Re-verification Required

# 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

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Screening Course 1 Course 2 Blood Chem... Hematology Urinalysis Bone Mar... Serology Other Se... Blood Gas Pulmonar... Red Cell... Other Ur...

1 - 8

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 50.6 Patient Initials BJS

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

Select all that apply

Summary Discrepancies Verification Approval Links

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

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

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

Comment   Keep comment between verifications

Re-verify Undo Verify

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

**Re-verify Button**

# 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 activities across various screening courses. A pop-up window for 'Patient 1 Page 4 (Medhist for Screening) Page 1 of 1' is open, showing a 'Re-Approval required' status. The 'Approval Tab' is selected, and the 'Approval Password' field is highlighted. The current status is 'Not approved'.

**Verified & Approved**

**Approved**

**Re-Approval required**

**Approval Tab**

**Approval Password**

Oracle Clinical Remote Data Capture

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 Pulmonar... Red Cell... Other Ur...

Screening 1 Elig Screening 2 Enroll Screening 3 MRN Screening 4 Medhist Screening 5 Symptom Screening 6 Prior Tx Screening 7 Prior Surg Screening 10 Phys Scrn

1 - 8

1 (BJS) 2 (SB) 3 (SKY) 4 (GB) 5 (FB) 6 (WC) 7 (FH) 8 (TL)

Activity List All patients, all pages

Summary Discrepancies Verification Approval Audit Trail Links

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

Visit Date 20-May-2004 Blank  Comment

Brmh COM

Blank

BASELINE MEDICAL HISTORY

Date of Examination 20-MAY-2004

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



NECK

Comment   Keep comment between approvals

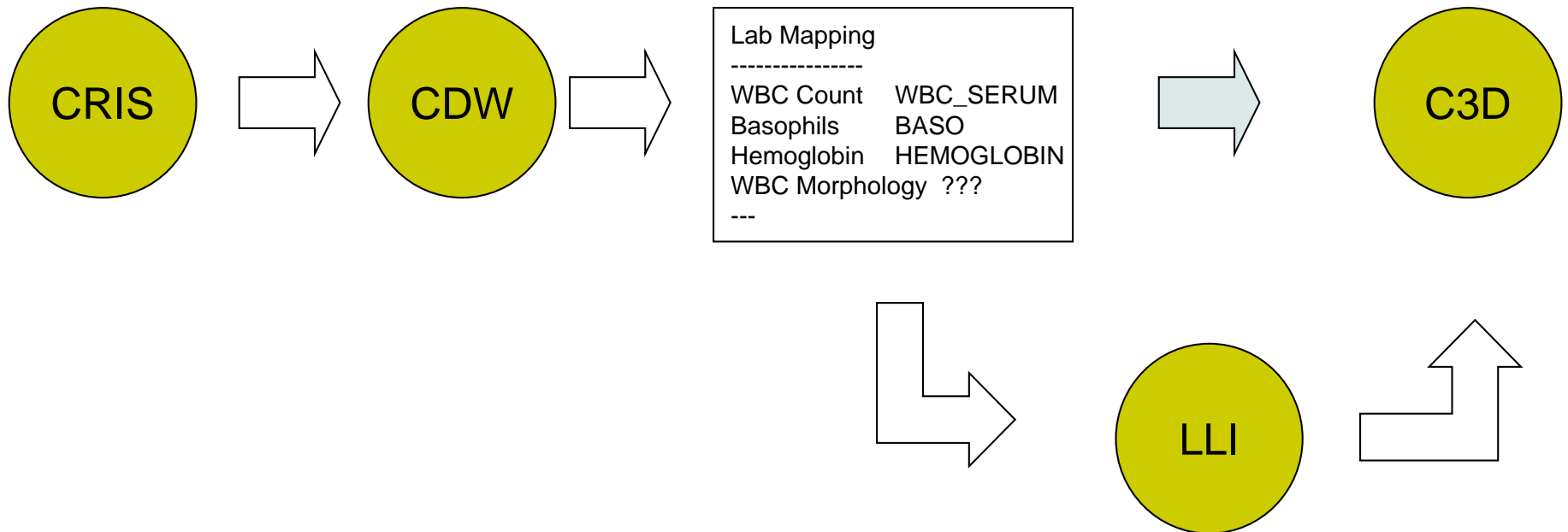
Type password and press Enter to approve this CRF

Record: 1/1 <OSC>

# Approval

- Each eCRF can be approved clicking on the Approve button and providing your C<sup>3</sup>D password
- Approved eCRF Icon has a Signature An icon representing an approved eCRF, showing a document with a signature and a red checkmark.
- Editing an approved eCRF changes its icon to a Re-Approve status An icon representing a re-approve status, showing a document with a signature and a red checkmark.
- Edited eCRF can be re-approved
- eCRF Approval Change History is maintained in the Approval pop-up Window

# CRIS to C<sup>3</sup>D Lab Data Flow



# What is LLI?

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

# LLI Search Screen

Lab Load Interface

ORACLE

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
<input checked="" type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
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<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				
<input type="checkbox"/>				

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

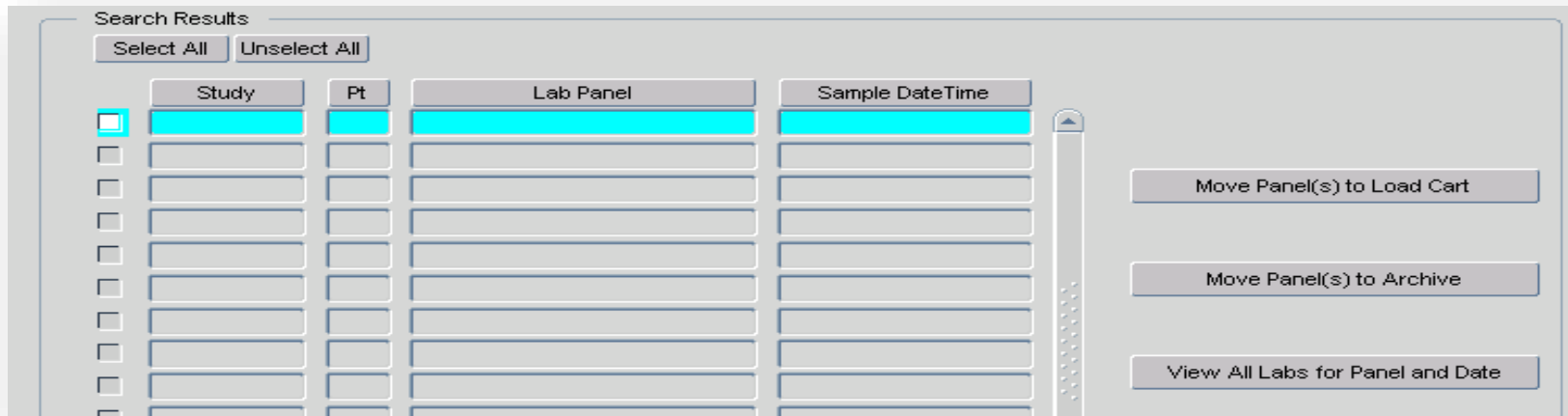
New Search

- **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**
  - 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?

