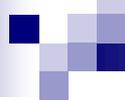


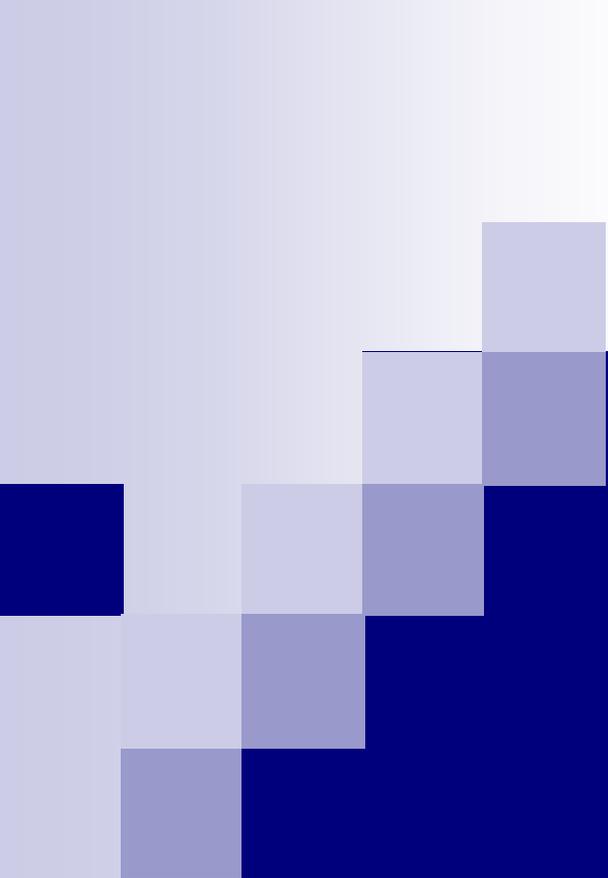
I-Review Training

Harris Information Technology Services
(HITS)



I-Review Modules

1. Basics and Running Existing Reports
2. Modifying Existing Reports
3. Creating ad hoc Reports
4. Filters and Patient Selection Criteria



I-Review Module 1

Basics and Running Existing Reports



Module 1 Outline

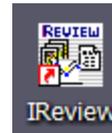
- Introduction
- Basics/Navigation
 - Login
 - Review of the Interface (or user screens) and Reports
 - Run existing reports
 - Export reports to excel and open it
- Demo
- Exercise

Introduction

- I-Review stands for 'Integrated Review'
- Companion reporting tool in C3D family
- Intuitive and user-friendly
- Allows design of clinical data reports and to perform simple analyses
 - Only allows access to your C3D protocols
- Requires installation on your PC using the NAL 
□ NCICB provides installation instructions
- CCR I-Review Reports Instructions
http://ccrintra.cancer.gov/clin_ops/C3D/iReview_instr.asp
- Vendor's PDF Manual
<http://ncicbsupport.nci.nih.gov/sw/content/C3D/ireview8.pdf>
- CBT Training Manual
<http://octrails-train.nci.nih.gov/CBTsubmenu1.html>
- Contact NCICB for problems/requests
 - 301-451-4384 or ncicb@pop.nci.nih.gov

I-Review Login

- Double click on the desktop I-Review Icon
- Use the same login and password as your C3D account
- Database and SAS Server:
 - cbiodb5 (production)
 - cbiodb2:octrn (training)

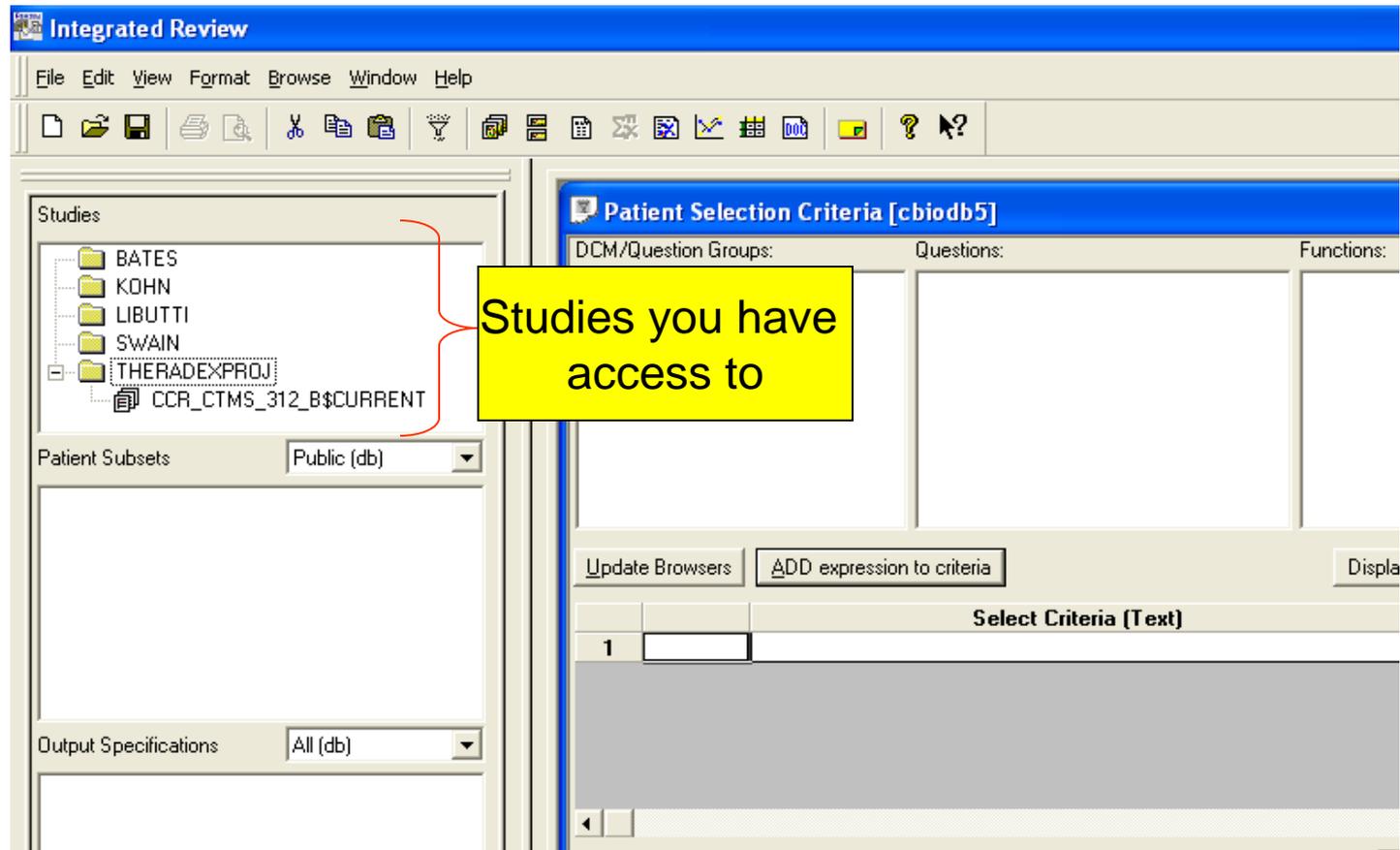
A screenshot of the "Integrated Review Server LOGON" dialog box. The dialog has a title bar with a close button (X) in the top right corner. The main area contains four input fields: "Database UserID" with the value "ops\$ccrrn01", "Database Password" (empty), "Database Server" with a dropdown menu showing "cbiodb2:octrn", and "SAS Server" with a dropdown menu showing "cbiodb2:octrn". To the right of the input fields are "OK" and "Cancel" buttons. Below the input fields, there is a small "REVIEW" icon, the text "Integrated Review version 9.0.9", and the copyright notice "Copyright © 1994-2009 Integrated Clinical Systems, Inc." The dialog box has a light gray background and a blue border.

I-Review Interface

The screenshot shows the 'Integrated Review - [Patient Selection Criteria [cbiodb5]]' window. The interface is divided into several sections:

- Menu Bar:** File, Edit, View, Format, Browse, Window, Help.
- Toolbar:** Contains icons for file operations (open, save, print, copy, paste, delete), navigation (back, forward), and help.
- Left Panel:**
 - Studies:** A tree view showing folders for BATES, KOHN, LIBUTTI, SWAIN, and THE RADEXPBROW. THE RADEXPBROW is selected.
 - Patient Subsets:** A dropdown menu currently set to 'All (db)'.
 - Output Specifications:** A dropdown menu also set to 'All (db)'.
 - Execute:** A button to run the query.
 - Order output specificati:** Radio buttons for 'Type' (selected) and 'Desi'.
 - Execute Objects:** Buttons for 'Execute Objects', 'Review Output', and 'Scheduled'.
- Main Panel:**
 - DCM/Question Groups:** An empty text area.
 - Questions:** An empty text area.
 - Functions:** An empty text area.
 - Operators:** An empty text area.
 - Buttons:** 'Update Browsers', 'ADD expression to criteria', 'Display Stats', 'Display Values', and 'Item Compare'.
 - Value:** A text input field.
 - Table:** A table with two columns: 'Select Criteria (Text)' and 'Select Criteria (SQL)'. It has one row with the number '1' in the first column.
- Bottom Bar:** 'For Help, press F1' and a 'NUM' indicator.

Accessible Studies



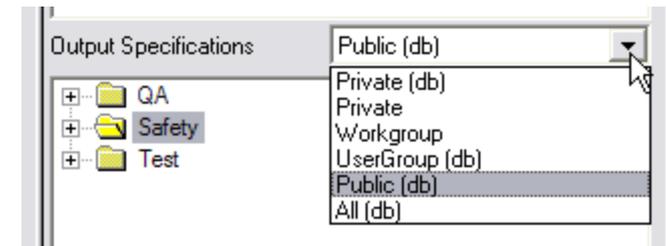
Note: Studies you have access to are listed in a folder per Principal Investigator. “Current” in name of the study indicates live data.

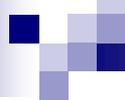
Saved Reports

The screenshot displays a software interface for patient selection criteria. On the left, a 'Studies' tree shows a hierarchy including 'BATES', 'KOHN', 'LIBUTTI', 'SWAIN', 'THERADEXPROJ', and 'CCR_CTMS_312_B\$CURRENT'. Below this, 'Patient Subsets' is set to 'Public (db)' with 'All patients' selected. 'Output Specifications' is set to 'All (db)'. A list of specifications is shown, including 'Administrative', 'Adverse Event', 'AppsSupport', 'CDUS', 'CDUS Archive', 'CDUS Data Set', 'CTMS', 'CTMS Archive Records', 'CTMS_PB - DO NOT USE', 'Comments', 'Course Assessment', 'Courses', 'Demographics', 'Demography', 'Extent of Disease', 'IRB_Reports', 'Labs', 'My Reports', and 'Objects'. A red bracket on the right side of this list is labeled 'Saved Reports'. The main window, titled 'Patient Selection Criteria [cbiodb5]', contains 'DCM/Question Groups' and 'Questions' sections. The 'DCM/Question Groups' list includes 'ADVERSE EVENTS', 'BASE MED HIST', 'BASE SYMP', 'CARDIAC', 'CHIMERISM', 'COMMENTS', 'CONCOM MEDS/MEAS', 'COURSE ASSESS', and 'COURSE INIT'. Below these are buttons for 'Update Browsers' and 'ADD expression to criteria'. A 'Select Criteria (Text)' table is visible with a single row containing the number '1'. At the bottom, there are checkboxes for 'Exclude patients meeting criteria?' and 'Append to criteria?'. A yellow box with the text 'Saved Reports' is overlaid on the bottom right of the interface.

Output Specifications

- This section lists saved reports organized in folders (which I-Review calls categories).
- Saved reports can be Private or Public.
- Use the drop-down to choose which reports to show:
 - Private (db) – shows only reports created by you and available to you in the study;
 - Public (db) – shows reports available to anyone with access to the study (even reports saved by other users);
 - All (db) – same as Private and Public combined.





To Execute an Existing Report

1. Select the study you want (\$CURRENT has the live production data);
2. Use the Output Specification drop-down to select Private (db) Public (db) or All (db) – only if needed;
3. Click on + sign left of the Output Specification folder to show the reports in it;
4. Double click on the name of a saved report to execute it;

The report executes for a few second and the output will be presented in a separate tab labeled with the report title.

Execute a Saved Report

1 → CCR_CTMS_312_B\$CURRENT

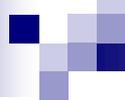
2 → All (db)

3 → Execute

4 → All AEs

Adverse Events Report Data:

	A	B	C	D	E	F	G
1	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course #
2	CCR_CTMS_312_B	1	24	0	2	1	
3	CCR_CTMS_312_B	1	24	0	1	2	
4	CCR_CTMS_312_B	1	24	0	2	2	
5	CCR_CTMS_312_B	1	24	0	1	1	
6	CCR_CTMS_312_B	1	24	0	3	1	
7	CCR_CTMS_312_B	1	24	0	1	5	
8	CCR_CTMS_312_B	1	24	0	1	3	
9	CCR_CTMS_312_B	1	24	0	1	4	
10	CCR_CTMS_312_B	1	24	0	1	6	
11	CCR_CTMS_312_B	1	24	0	2	3	
12	CCR_CTMS_312_B	1	24	0	2	4	
13	CCR_CTMS_312_B	2	24	0	1	5	-1
14	CCR_CTMS_312_B	2	24	0	1	4	-1
15	CCR_CTMS_312_B	2	24	0	1	1	1
16	CCR_CTMS_312_B	2	24	0	2	2	1
17	CCR_CTMS_312_B	2	24	0	2	3	1
18	CCR_CTMS_312_B	2	24	0	1	2	1
19	CCR_CTMS_312_B	2	24	0	2	1	1
20	CCR_CTMS_312_B	2	24	0	2	4	1
21	CCR_CTMS_312_B	2	24	0	2	5	1
22	CCR_CTMS_312_B	2	24	0	2	6	
23	CCR_CTMS_312_B	2	24	0	1	3	
24	CCR_CTMS_312_B	2	24	0	1	6	
25	CCR_CTMS_312_B	3	24	0	1	3	
26	CCR_CTMS_312_B	3	24	0	1	1	
27	CCR_CTMS_312_B	3	24	0	1	1	



How to Export Reports

Once a report has completed executing:

1. Select the report output tab;
2. Click on File menu option;
3. Select the Export menu item;
4. Save dialog window will appear;
5. Select location (desktop, my documents..);
6. Enter a file name;
7. Click Save button;

How to Export Reports

The screenshot illustrates the steps to export a report in the Integrated Review application. The main window displays the 'Patient Selection Criteria [cbiodb5]' interface with a table of data. A yellow box labeled '1' highlights the 'Report' button in the bottom taskbar. A yellow box labeled '2' points to the 'File' menu, and a yellow box labeled '3' points to the 'Export...' option within that menu. A yellow box labeled '4' points to the 'Save As' dialog box, which is open over the main window. A yellow box labeled '5' points to the 'Save in' field, which is set to 'Desktop'. A yellow box labeled '6' points to the 'File name' field, which contains 'All AEs'. A yellow box labeled '7' points to the 'Save' button in the dialog box. The 'Save as type' is set to 'Excel Files (*.xls)'. The background window shows a table with columns A through G and rows 22 through 27.

	A	B	C	E	F	G
22	CCR_CTMS_312_B	2	24	0	2	5
23	CCR_CTMS_312_B	2	24	0	2	6
24	CCR_CTMS_312_B	2	24	0	1	3
25	CCR_CTMS_312_B	2	24	0	1	6
26	CCR_CTMS_312_B	3	24	0	1	3
27	CCR_CTMS_312_B	3	24	0	1	1

How to Open/Modify the Exported Report Output

- Double click on exported report output (spreadsheet on desktop, My Documents, etc.)
 - File will open in Excel
- To make any changes to the spreadsheet you must first unprotect it following these steps:
 1. Click on Tools Menu option
 2. Select Protection
 3. Select Unprotect Sheet

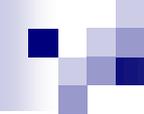
How to Open/Modify the Saved Report Output

The screenshot shows the Microsoft Excel interface with a spreadsheet. The header row (row 2) is highlighted in cyan. Three yellow callout boxes are present: '1' points to the 'Tools' menu, '2' points to the 'Unprotect Sheet...' option in the 'Protection' dropdown, and '3' points to the 'Protection' dropdown menu itself.

	A	B	C	D	E	F	G	H	I	J	K	
1										Prior	(MM-DD-YYYY)	(MM-DD-YYY
2	Study	Patient	Vi	ub Visit	DCM Subset	Repeat #	Course #	Day in Course	Course	Date of Onset	Date Resolve	
3	CCR_CTMS_312_B	1	24	0	2	1			Y	03-03-2003	03-02-2003	
4	CCR_CTMS_312_B	1	24	0	1	2			N	07-21-2003	--	
5	CCR_CTMS_312_B	1	24	0	2	2			N	02-02-2004	02-03-2004	
6	CCR_CTMS_312_B	1	24	0	1	1			Y	05-05-2004	05-10-2004	
7	CCR_CTMS_312_B	1	24	0	3	1			N	06-06-2004	06-07-2004	
8	CCR_CTMS_312_B	1	24	0	1	5			Y	03-06-2005	--	
9	CCR_CTMS_312_B	1	24	0	1	3			Y	05-05-2005	--	
10	CCR_CTMS_312_B	1	24	0	1	4			N	05-05-2005	--	
11	CCR_CTMS_312_B	1	24	0	1	6			Y	05-05-2005	--	
12	CCR_CTMS_312_B	1	24	0	2	3			N	09-03-2005	--	
13	CCR_CTMS_312_B	1	24	0	2	4			N	10-06-2005	--	
14	CCR_CTMS_312_B	2	24	0	1	5	-1	-446	Y	12-12-2001	01-02-2001	
15	CCR_CTMS_312_B	2	24	0	1	4	-1	-58	N	01-04-2003	--	
16	CCR_CTMS_312_B	2	24	0	1	1	1	552	N	09-04-2004	--	
17	CCR_CTMS_312_B	2	24	0	2	2	1	563	N	09-15-2004	09-20-2004	
18	CCR_CTMS_312_B	2	24	0	2	3	1	573	N	09-25-2004	10-10-2004	
19	CCR_CTMS_312_B	2	24	0	1	2	1	574	N	09-26-2004	09-30-2004	
20	CCR_CTMS_312_B	2	24	0	2	1	1	620	N	11-11-2004	12-12-2004	
21	CCR_CTMS_312_B	2	24	0	2	4	1	675	N	01-05-2005	--	
22	CCR_CTMS_312_B	2	24	0	2	5	1	676	N	01-06-2005	--	
23	CCR_CTMS_312_B	2	24	0	2	6			N	05-05-2005	--	
24	CCR_CTMS_312_B	2	24	0	1	3			N	11-12-2005	--	
25	CCR CTMS 312 B	2	24	0	1	6			N	06--3030	--	

CCR I-Review Manual

- General Instructions on how to execute saved reports, export output, customize saved reports, create your own reports, set filters and save report.
- Catalog of template reports that can be used as is or as a starting point for your own custom reports.
- Since studies have their peculiarities and sometimes deviate from the CCR Standard eCRFs, some of the saved template reports might contain items that are not applicable to a study. I-Review shows a prompt indicating which items are not compatible and remove them from the report. If the item exists in the study, it most likely has a different name, but it still can be added to the report. Module 2 covers modifying reports.



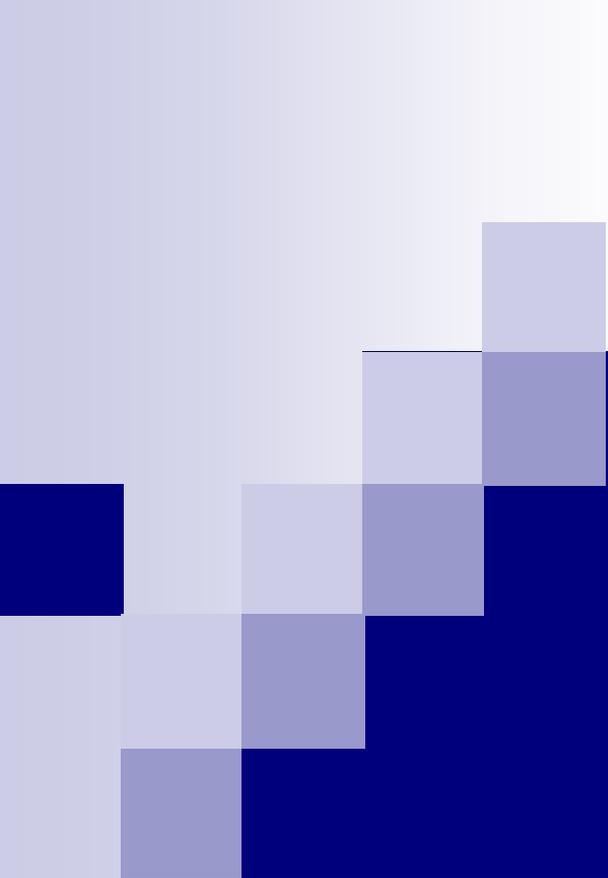
Module 1 Demo and Exercises

- DEMO

- Exercise

- Log-in

- Run All AEs saved report (unformatted)



I-Review Module 2

Modifying Existing Reports



Module 2 Outline

- C3D Terminology
- Setting Recommended Preferences
- Oracle/I-Review Relationship
 - I-Review and C3D Correlation
 - F1 function
- Open and Modify Saved AE report
- Actual/Decoded, Print change, Sort order
- Save Report
- Demo
- Exercises

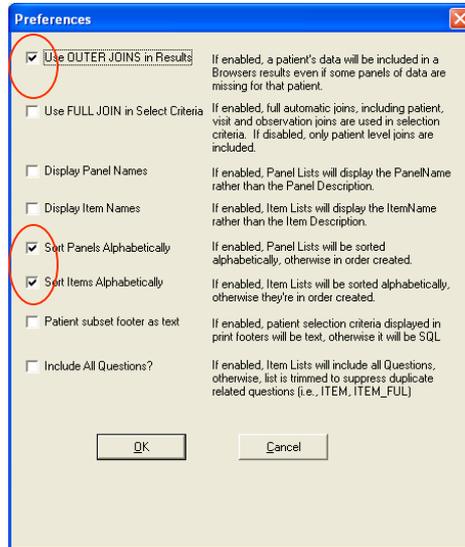


C3D Oracle Clinical Terminology

- DCI – Data Collection Instrument (CRF!)
- DCM – Data Collection Module (Section or ‘Tab’ of a CRF.)
- Question – a single element of a CRF in which datum (‘Response’) is entered.
- Non-repeating Question Group – A group of Questions that occurs once – ex: Course Initiation.
- Repeating Question Group - A group of Questions that occurs more than once – ex: Adverse Events.

Changing Preferences

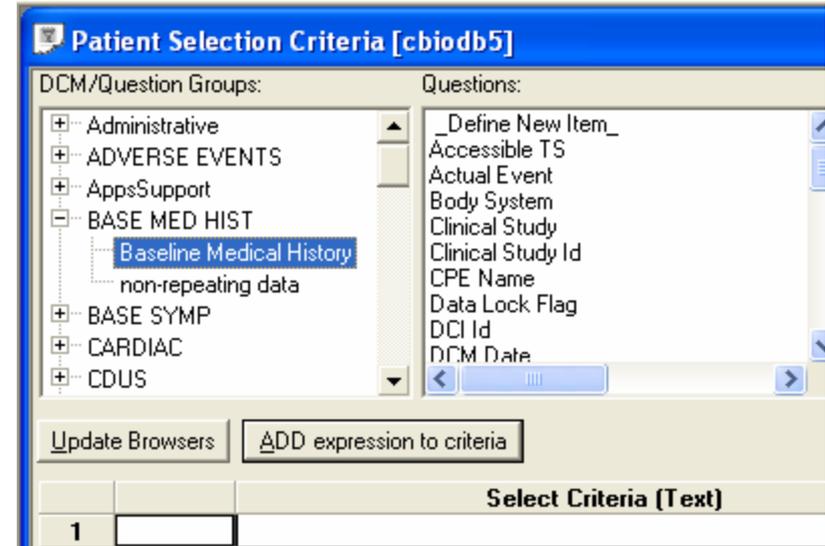
Default



Preferences

- Use OUTER JOINS in Results
- Use FULL JOIN in Select Criteria
- Display Panel Names
- Display Item Names
- Sort Panels Alphabetically
- Sort Items Alphabetically
- Patient subset footer as text
- Include All Questions?

OK Cancel



Patient Selection Criteria [cbiodb5]

DCM/Question Groups:

- Administrative
- ADVERSE EVENTS
- AppsSupport
- BASE MED HIST
 - Baseline Medical History
 - non-repeating data
- BASE SYMP
- CARDIAC
- CDUS

Questions:

- _Define New Item_
- Accessible TS
- Actual Event
- Body System
- Clinical Study
- Clinical Study Id
- CPE Name
- Data Lock Flag
- DCI Id
- DCM Date

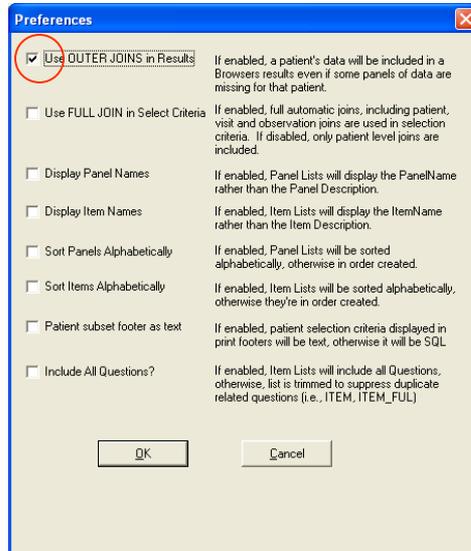
Update Browsers ADD expression to criteria

Select Criteria (Text)

1



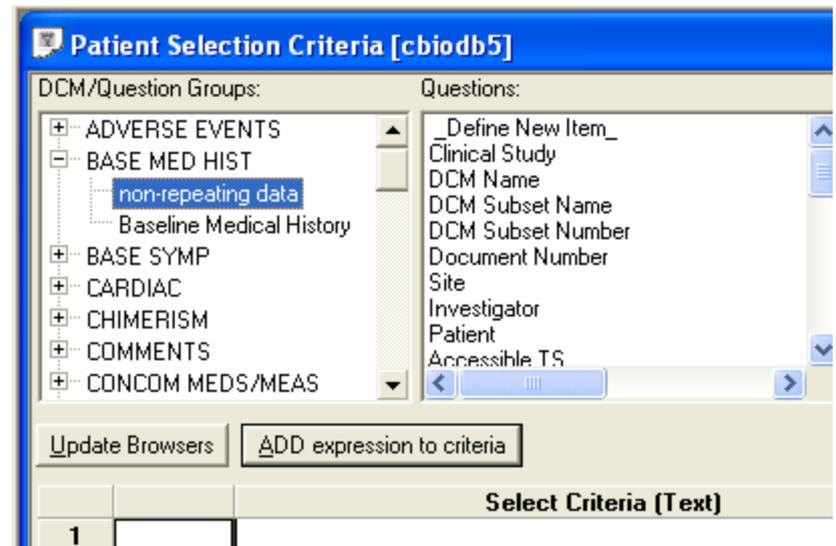
Recommended



Preferences

- Use OUTER JOINS in Results
- Use FULL JOIN in Select Criteria
- Display Panel Names
- Display Item Names
- Sort Panels Alphabetically
- Sort Items Alphabetically
- Patient subset footer as text
- Include All Questions?

OK Cancel



Patient Selection Criteria [cbiodb5]

DCM/Question Groups:

- ADVERSE EVENTS
- BASE MED HIST
 - non-repeating data
 - Baseline Medical History
- BASE SYMP
- CARDIAC
- CHIMERISM
- COMMENTS
- CONCOM MEDS/MEAS

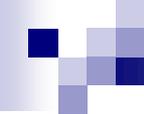
Questions:

- _Define New Item_
- Clinical Study
- DCM Name
- DCM Subset Name
- DCM Subset Number
- Document Number
- Site
- Investigator
- Patient
- Accessible TS

Update Browsers ADD expression to criteria

Select Criteria (Text)

1



Setting 'Preferences'

- Editing preferences changes the order the DCM/Question Groups and Questions are listed
- To change preferences:
 1. Click on Edit Menu Option
 2. Select Preferences (A dialog box will appear)
 3. Click on check boxes to enable or disable preferences- See recommendations on next slide

C3D and I-Review Correlation

Patient 1 Page 10 (Phys Scrn for Screening) Page 1 of 1.

Visit Date **07-Jun-2004** Blank Comment

Scrp* COM **DCMs**

PHYSICAL EXAM - SCREENING

Date of Examination **02-FEB-2002**

Body System	Finding Results	Comment
H/E/E/NT	N	
NECK	N	
RESPIRATORY	N	
CARDIOVASCULAR	N	
GASTROINTESTINAL	N	
MUSCULOSKELETAL	A	BACK PAIN
DERMATOLOGIC	A	MULTIPLE AREAS OF KE

Questions

Repeating Group

The screenshot shows a patient screening form. A yellow box labeled 'DCMs' points to the 'Scrp*' field. Another yellow box labeled 'Non-Repeating Group' points to the 'Date of Examination' field. A third yellow box labeled 'Questions' points to the table of body systems and findings. A fourth yellow box labeled 'Repeating Group' points to the table's header row.

Integrated Review - [Patient Selection Criteria [cbiodb5]]

File Edit View Format Browse Window Help

Studies

- BATES
- KOHN
- LIBUTTI
- SWAIN
- THERADEXPROJ
- CCR_CTMS_312_B\$CURRENT

Patient Subsets: Public (db)

- All patients

Output Specifications: All (db)

Administrative

DCM/Question Groups:

- ADVERSE EVENTS
- BASE MED HIST
 - non-repeating data
 - Baseline Medical History
- BASE SYMP
- CARDIAC
- CHIMERISM
- COMMENTS
- CONCOM MEDS/MEAS
- COURSE ASSESS
- COURSE INIT
- ELIG CHECK
- ENROLLMENT
- EXT OF DISEASE
- FOLLOW_UP
- INFECTION EP
- LAB_ALL
- IAR 11

Questions:

- _Define New Item_
- Clinical Study
- DCM Name
- DCM Subset Name
- DCM Subset Number
- Document Number
- Site
- Investigator
- Patient
- Accessible TS
- Login TS
- LstChg Ts
- CPE Name
- Entered By
- Data Lock Flag
- DCM Date
- DCM Time
- Repeat #
- Actual Event
- Sub Event

DCMs

Non-Repeating Group

Questions

Repeating Group

The screenshot shows the I-Review interface. A yellow box labeled 'DCMs' points to the 'BASE MED HIST' group. Another yellow box labeled 'Non-Repeating Group' points to the 'non-repeating data' sub-group. A third yellow box labeled 'Questions' points to the 'Baseline Medical History' item. A fourth yellow box labeled 'Repeating Group' points to the 'BASE MED HIST' group's parent level.

C3D: F1 Function

- Displays Oracle Clinical question name and default prompt for selected data point
- Useful in finding out the question's default prompt as it appears in I-Review
- To use F1 function:
 1. Using the cursor, click on a specific data point on eCRF in C3D
 2. Press F1 on keyboard to display, in pop-up window, the data point's question default prompt

F1 Function

Patient 3 Page 3 (MRN for Screening) Page 1 of 1, Repeat 1 of 2.

Visit Date **22-Sep-2004** Blank Comment

PATIENT IDENTIFICATION

Institution	Patient Medical Record Number
NCIETI	20-30-45-56
ABCDEFG	3456789

1

Description of Question "PT_ID" from Group "PATIENT_ID"

DCM Question Group Information

Name:

Help Text:

Mandatory? Indicator? Autoskip? Sight Verification?

DCM Question Information

Question Name: Occurrence Sn:

SAS Name: Length:

Help Text: Decimal Places:

Default Prompt: Lower Bound: Upper Bound:

Data Type: Date Format:

Discrete Value Group Information

Name:

Description:

OK

2

Patient Selection Criteria [cbiodb5]

DCM/Question Groups:	Questions:	Functions:	Operators:
<ul style="list-style-type: none"> INFECTION EP LAB_ALL LAB_LL OFF TREATMT STDY PATIENT_ID <ul style="list-style-type: none"> Patient Identification PHARMACOK PHYSICAL EXAM PRIOR RAD SUPP 	<ul style="list-style-type: none"> Lab Id DCM Id DCI Id Received DCM Id Received DCI Id Patient Position Id Clinical Study Id Institution Patient Medical Record Number 	<ul style="list-style-type: none"> actual value baseline value endpoint value 	<ul style="list-style-type: none"> = <> < > <= >= contains: doesn't contain: begins with: ends with:

Update Browsers ADD expression to criteria Display Stats Display Values Value: Item Compare

Select Criteria (Text) Select Criteria (SQL)

Question's Default Prompt

Description of Question "PT_ID" from Group "PATIENT_ID"

DCM Question Group Information

Name: PATIENT_ID

Help Text:

Mandatory? Indicator? Autoskip? Sight Verification?

DCM Question Information

Question Name: PT_ID Occurrence Sn: 0

S&S Name: ABC1223 Length: 12

Help Text: CDE_ID:2003301 VERSION:3.0 Decimal Places: 0

Default Prompt: Patient Medical Record Number

Lower Bound: Upper Bound: Data Type: CHAR Date Format:

Discrete Value Group Information

Name: Description:

OK

Open and Modify Reports

Right click, then choose open

Report definition
in Report Browser

Output Specifications

- Administrative
- Adverse Event
 - AE Summary - Counts by CTC Term
 - AEs Grade 3-5 V1
 - AEs Grade 3-5 V2
 - All AEs
 - All AEs
 - Baseline
 - Baseline
 - Open AEs
- AppsSupport
- CDUS
- CDUS Archi

Execute

Execute Objects Review Output Scheduled

Report Browser

Type: DCM/Question Groups: Questions: Functions:

- Detail Data Listing
- Summary Listing
- Formatted Detail Data Listing
- Formatted Summary Listing
- Patient Visit Data Report

- ADVERSE EVENTS
- BASE MED HIST
- BASE SYMP
- CARDIAC
- CHIMERISM
- COMMENTS
- CONCOM MEDS/M
- COURSE ASSESS
- COURSE INIT
- ELIG CHECK
- ENROLLMENT
- EXT OF DISEASE
- FOLLOW_UP
- INFECTION EP
- LAB_ALL
- LAB_LL
- OFF TREATMT STI

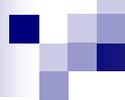
Heading: Adverse Events

Layout: Show Details? Suppress duplicate rows? AutoSize Columns?

	A	B	C	D	E	F	G	H
Col.Head 1								
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course #	Day in Cours
Sort Order		1	2	3				
Row results	Print chg							
Warn -Low								
Warn -High								
Panic-Low								
Panic-High								

Execute

Execute Objects Review Output Scheduled



Modifying Saved Reports

- A saved report can be modified to suit your requirements
- The following changes can be made:
 - Remove columns
 - Rename column headings
 - Change sort order
 - Set Print Change
- The modified report can also be saved for later use.

Remove Columns

The screenshot shows a software interface with a menu bar (File, Edit, View, Format, Browse, Window, Help) and a toolbar. The 'Edit' menu is open, showing options like Cut, Copy, Paste, Insert, Select All, Find, Replace, Go To, Join Order, Custom Join, Edit Defined Item, Edit Range Variable, Edit Imported SQL, Remove Pivot Panel, and Preferences. A yellow box labeled '3' points to the 'Edit' menu. A yellow box labeled '2' points to the 'Cut' option. A yellow box labeled '1' points to the 'Sub Visit' column in a table.

The table below shows a data grid with columns A through E. The 'Sub Visit' column (D) is highlighted, and a yellow box labeled '1' points to it. The table content is as follows:

Heading	A	B	C	D	E
Adverse Events					
Layout:					
<input type="checkbox"/> Show Details?					
Col.Head 1					
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset
Sort Order		1	2	3	
Row results	Print chg				
Warn -Low					
Warn -High					
Panic-Low					
Panic-High					
Include? prompt					

Remove Columns

To remove a column:

1. Click on the header (capital letter, “D”) of the column you want to remove
2. Select Edit from the menu option
3. Select the menu item Cut 

Rearrange Report Column Order

Heading
Adverse Events

Layout:
 Show Details?

Reset Subtotal with change

	A	B	C	D	E	F
Col.Head 1						
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #
Sort Order		1	2	3		
Row results	Print chg					
Warn -Low						
Warn -High						
Panic-Low						
Panic-High						
Include? prompt						

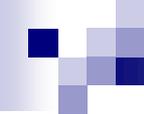
2

1

←

→

Patient Sele... Report Bro... Adverse Ev...



Rearrange Report Column Order

To move a column:

1. Click on the header (capital letter, “D”) of the column you want to move
2. Use the directional arrow buttons to place the highlighted column in the columnar position(s) you would like.

Edit Column Heading

	A	B	C
Col.Head 1			
Col.Head 2	Study	Patient	Visit #
Sort Order		1	2
Row results	Print chg		
Warn -Low			
Warn -High			
Panic-Low			
Panic-High			
Include? prompt			

1

←

⏪

⏩ Patient Sele... Report Bro... Adverse Ev...

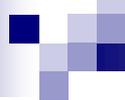
	A	B	C
Col.Head 1			
Col.Head 2	Study	Patient	Visit Number
Sort Order		1	2
Row results	Print chg		
Warn -Low			
Warn -High			
Panic-Low			
Panic-High			
Include? prompt			

2

←

⏪

⏩ Patient Sele... Report Bro... Adverse Ev...



Edit Column Heading

You can edit the column headings in 2 locations, the column heading 1 and column heading 2.

To edit a column heading:

1. Double-click on the column heading text to edit
2. Edit the text
3. Press Enter or Tab (note that the cursor will not go to the next heading! Repeat steps 1-3 to edit the next heading.)

Changing Sort Order Before

The screenshot shows a software interface with a list of test categories on the left and a data table on the right. The list includes:

- PHARMACOK
- PHYSICAL EXAM
- PRIOR RAD SUPP
- PRIOR SURG SUPP
- PRIOR THRPY SUPP
- PRIOR TREAT SUMM
- SCINTIGRAPHY

The data table has two columns, A and B, and six rows:

	A	B
1		
2	Patient Initials	Local Patient ID
3	CTM	99-99-99-99
4	LAB	12-34-56-9
5	MF	99-99-91-91
6	TEST	

A yellow callout box labeled "Choose Order" points to the "Sort Order" column in the table, which has values 1 and 2. An arrow points from the "Reset Subtotal with change" button to the table.

Changing Sort Order After

OFF TREATMT STDY
PATIENT_ID
PHARMACOK
PHYSICAL EXAM
PRIOR RAD SUPP

Detail Data Listing
Layout: Show Details? Reset Subtotal with change

	A	B
Col.Head 1		
Col.Head 2	Patient In	Local Pa
Sort Order	2	1
Row results		
Warn -Low		
Warn -High		
Panic-Low		
Panic-High		
Include? prompt		

Choose Order

	A	B
1		
2	Patient Initials	Local Patient ID
3	LAB	12-34-56-9
4	MF	99-99-91-91
5	CTM	99-99-99-99
6	TEST	

RENT

Edit Report Sort Order

- A sort order controls how the report output rows are organized.
- The sort order 1 will be the item in which the primary sort will take place, sub-sorted by sort order 2, and so on.
- To make changes to the sort order:
 1. Place cursor on the default sort order values
 2. Delete, replace, edit or add sort order values
 3. Optional descending sort is specified by a trailing 'D' after the sort order number

Print Change Before

LAB_LL
OFF TREATMT STDY
PATIENT_ID
PHARMACOK
PHYSICAL EXAM
PRIOR RAD SUPP
PRIOR SURG SUPP

Heading
Adverse Events
Layout: Show Details? Reset Subtotal with change

	A	B	C	D	E	F
Col.Head 1						
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #
Sort Order		1	2	3		
Row results						
Warn -Low						
Warn -High						
Panic-Low						
Panic-High						
Include? prompt						



	A	B	C	D
1				
2	Study	Patient	Visit #	Sub Visit
3	CCR_CTMS_312_B	1	24	0
4	CCR_CTMS_312_B	1	24	0
5	CCR_CTMS_312_B	1	24	0
6	CCR_CTMS_312_B	1	24	0
7	CCR_CTMS_312_B	1	24	0
8	CCR_CTMS_312_B	1	24	0
9	CCR_CTMS_312_B	1	24	0
10	CCR_CTMS_312_B	1	24	0
11	CCR_CTMS_312_B	1	24	0
12	CCR_CTMS_312_B	1	24	0
13	CCR_CTMS_312_B	1	24	0
14	CCR CTMS 312 B	2	24	0

Print Change After

LAB_LL
OFF TREATMT STDY
PATIENT_ID
PHARMACOK
PHYSICAL EXAM
PRIOR RAD SUPP
PRIOR SURG SUPP

Heading
Adverse Events
Layout: Show Details? Reset Subtotal with change

	A	B	C	D	E	F
Col.Head 1						
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #
Sort Order		1	2	3		
Row results		Print chg				
Warn -Low						
Warn -High						
Panic-Low						
Panic-High						
Include? prompt						



	A	B	C	D	
1					
2	Study	Patient	Visit #	Sub Visit	DCM Subset
3	CCR_CTMS_312_B	1	24	0	
4	CCR_CTMS_312_B		24	0	
5	CCR_CTMS_312_B		24	0	
6	CCR_CTMS_312_B		24	0	
7	CCR_CTMS_312_B		24	0	
8	CCR_CTMS_312_B		24	0	
9	CCR_CTMS_312_B		24	0	
10	CCR_CTMS_312_B		24	0	
11	CCR_CTMS_312_B		24	0	
12	CCR_CTMS_312_B		24	0	
13	CCR_CTMS_312_B		24	0	
14	CCR CTMS 312 B	2	24	0	

Print Change

- Suppresses the display of the content of a cell for which the value is same as that of the cell above
- Only works with columns which are being sorted
- To use:
 1. Click on the cell below the sort order number
 2. Select Print change from pick list

	A	B
Col.Head 1		
Col.Head 2	Study	Patient
Sort Order		1
Row results		<input type="text"/>
Warn -Low		
Warn -High		
Panic-Low		Print c
Panic-High		

Handling a Panel Items Not Found in Saved Reports

The screenshot displays a software interface with a 'Report Browser' window and a 'WARNING: Panels Items Not Found' dialog box. The 'Report Browser' window shows a tree view of 'Patient Subsets' (All patients, Gender, Misc, QA) and 'Output Specifications' (Private (db), DEFAULT, Administrative: Tracking, Adverse Events, AE x Grade with Frequency Distribution, Labs, Safety, SAMPLE - Clinic Report - V1 Lab Test, Study Drug Administration). The 'Report Browser' window also shows a table with columns: Type, DCM/Question Groups, Questions, Functions, and a list of items including 'ADVERSE EVENT' and 'BASE MED HIST'.

The 'WARNING: Panels Items Not Found' dialog box contains the following text:

Warning!! Panels/Items defined in Output Specifications are not found in current study.
Unexpected results may occur.

	Not Found	Panel Name	Item(s)	Location	Action Taken
1	Item	SDADSDAD	START_TM_FUL	Obs Item	Removed

Do you wish to continue?

Yes No

Handling a Panel Items Not Found in Saved Reports

- Some saved reports may contain items (questions) that are not applicable to a study
- When you try to execute or open such saved report, a warning message indicates which report items are not found. These items are automatically removed.
- Click 'Yes' to proceed and load the rest of the report's items (and execute the report if you double-clicked on the report's name) or click 'No' to abort and not load/execute the report.
- Optionally, these items can be replaced with the appropriate ones for your study.
- Review Filters and Patient Selection Criteria as well since items are also present there and could affect the result of the report.



Saving a Modified Saved Report

- After making changes to the saved report, you are able to save it as a new report or update it (if owned by you).
- Click on the File menu option
- Click on the Save As menu item to save the current report definition as a new report.
- Or click on the Save menu item to update a report previously saved by you. I-Review remembers the report's information.
- You cannot update or delete a report that was not created by you.

Saving a Modified Saved Report

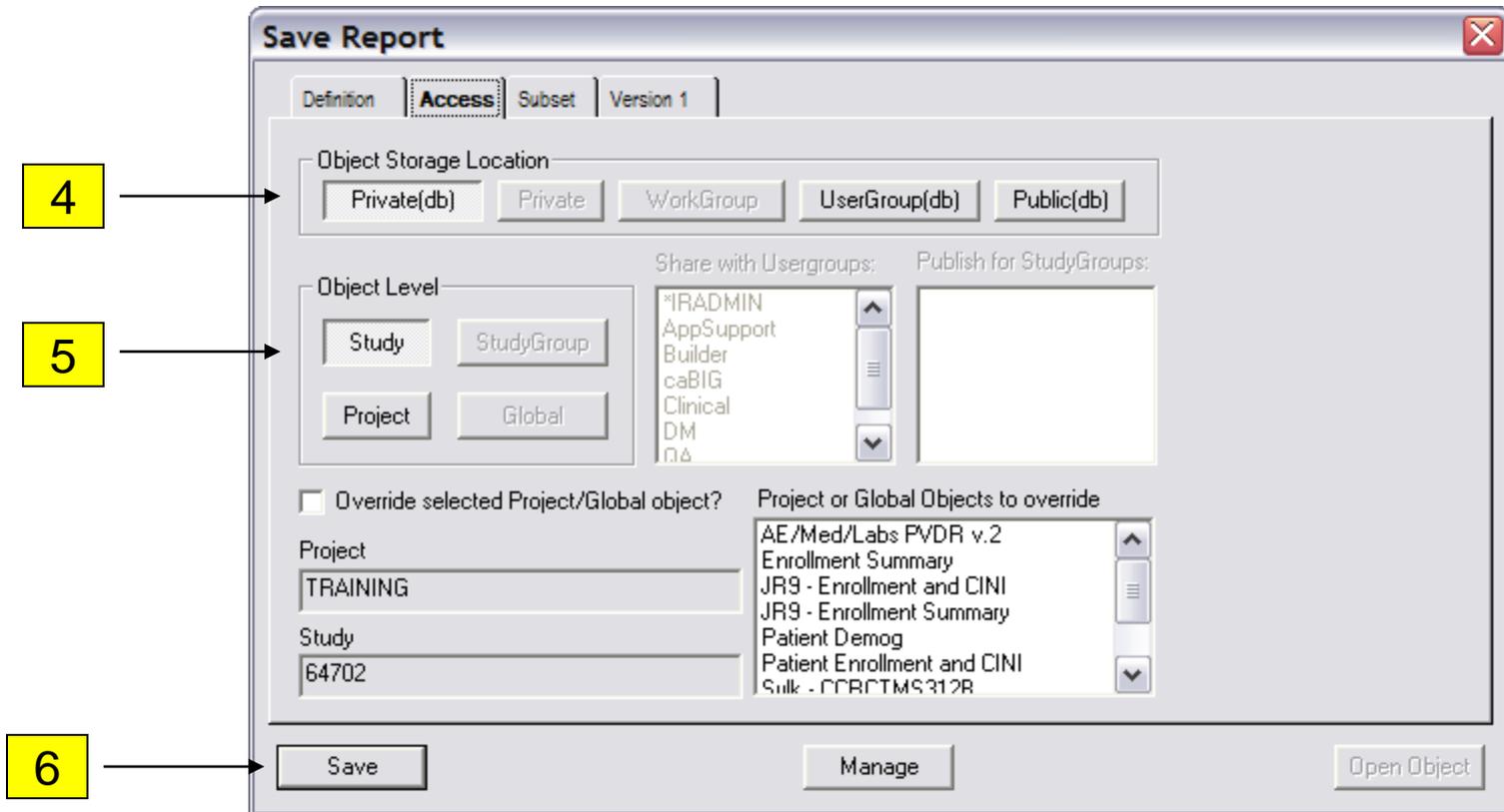
The image shows a 'Save Report' dialog box with the following fields and controls:

- 1**: Points to the 'Description' text input field.
- 2**: Points to the 'Category (Major.Minor.Sub):' dropdown menu, which currently shows 'DEFAULT'.
- 3**: Points to the 'Summary Information' text area, which is currently empty.

Other fields and controls include:

- 'Access', 'Subset', and 'Version 1' tabs.
- 'Existing Objects' text area.
- 'Status:' dropdown menu, currently showing 'DEFAULT'.
- 'ID Number:' text input field.
- 'Save', 'Manage', and 'Open Object' buttons at the bottom.

Saving a Modified Saved Report



Saving Cont'd

Under the 'Definition' tab:

1. Enter the report's Description (that is the report name shown in the Output Specification section);
2. Enter the Category or select an existing one from the drop-down list (that is the folder name shown in the Output Specifications section);
3. Summary Information – Briefly describe the purpose of the report;

Under the 'Access' tab:

4. Select the Object Storage Location – Reports can be saved either as Private (only you have access) or Public (shared with anyone who can access the study);
5. Select the Object Level – Reports can be saved under Project (accessible in all of the PI's studies) or under Study (a specific study);
6. Click on the Save button.

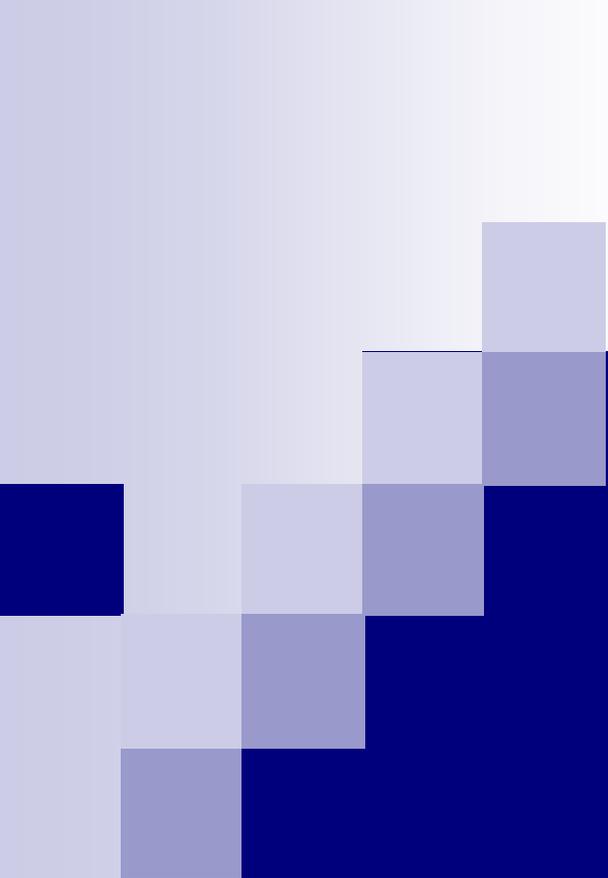


Module 2 Demo and Exercises

- DEMO

- Exercise

- Set Preferences
- Open Saved Report
- Edit Column Order, Remove Questions, Change Sort Order and Set Print Change
- Save report



I-Review Module 3

Creating ad hoc Reports



Module 3 Outline

- Report Browser
- Creating New Reports
- Difference Between Actual and Decoded Values
- Choosing Date Format
- Demo
- Exercise



Report Browser

- Report Browser has two basic report types:
 - Detail Data Listing – Lists details of selected questions from one of more CRFs.
 - Summary Data Listing – Allows for displaying counts, averages, minimum and maximum values without the details.
- Output of these reports are shown in a grid layout and can be exported to an Excel spreadsheet.
- Their ‘Formatted’ counterparts show data in a layout that can be exported to a PDF file.
- Detail Data Listing is the most used report type.

Creating a Detail Data Listing Report

The screenshot shows a software interface for creating a report. The main window is titled "Report Browser" and displays a list of report types and question groups. Three numbered callouts are present:

- 1**: Points to the "Report" menu icon in the top toolbar.
- 2**: Points to the "Report Browser" window title bar.
- 3**: Points to the "Detail Data Listing" option in the "Type:" column of the report browser.

The "Report Browser" window is divided into several sections:

- Type:** A list of report types, with "Detail Data Listing" selected.
- DCM/Question Groups:** A list of question groups, including "ADVERSE EVENTS", "BASE MED HIST", "BASE SYMP", "CARDIAC", "CHIMERISM", "COMMENTS", "CONCOM MEDS/M", "COURSE ASSESS", "COURSE INIT", "ELIG CHECK", "ENROLLMENT", "EXT OF DISEASE", "FOLLOW_UP", "INFECTION EP", "LAB_ALL", "LAB_LL", "OFF TREATMT STI", "PATIENT_ID", "PHARMACOK", and "PHYSICAL EXAM".
- Questions:** An empty column for selecting specific questions.
- Functions:** An empty column for selecting specific functions.

Below the list, there are buttons for "ADD Item", "Add All Items", "Filter Output", and "Create Report". There are also checkboxes for "Show Details?", "Suppress duplicate rows?", and "AutoSize Columns?".

At the bottom, there is a table with the following columns and rows:

	A
Col.Head 1	
Col.Head 2	
Sort Order	
Row results	
Warn -Low	
Warn -High	
Panic-Low	
Panic-High	

Creating a Detail Data Listing Report

The screenshot shows a software interface for creating a report. The interface is divided into several sections:

- Type:** A list of report types, with "Detail Data Listing" selected.
- DCM/Question Groups:** A tree view of data categories. "ENROLLMENT" is expanded, and "non-repeating data" is selected. Callout 4 points to "ENROLLMENT" and callout 5 points to "non-repeating data".
- Questions:** A list of data fields. "Patient Initials" is selected. Callout 6 points to "Patient Initials".
- Functions:** A list of functions. "actual value" is selected. Callout 7 points to "actual value".

Below the main panels, there are several controls and a preview table:

- Heading:** A text field containing "Detail Data Listing".
- Layout:** Includes "Show Details?" (unchecked), "Reset Subtotal with change", "Suppress duplicate rows?" (unchecked), and "AutoSize Columns?" (checked).
- Buttons:** "ADD Item" (callout 8), "Add All Items", "Filter Output", and "Create Report" (callout 9).
- Preview Table:** A table with columns for "Col.Head 1", "Col.Head 2", "Sort Order", "Row results", "Warn -Low", "Warn -High", "Panic-Low", "Panic-High", and "Include? prompt".

Creating a Detail Data Listing Report

1. Click the Report Browser icon  on the toolbar, or from the Browse menu option select Reports.
2. Click on  to maximize Report Browser window.
3. Click on “Detail Data Listing” in the Type listbox
4. Double click on a DCM in the “DCM/Question Groups” listbox to reveal the available Question Groups
5. Click on a Question Group to review the available Questions
6. Scroll down Questions listbox until the desired Questions are listed;
7. “Actual Value” should be highlighted under function unless the question
 - is for a date, then choose correct date format
 - has a pick list in C3D, the “Decoded Value” is automatically selected
8. Click on the Add Item button to add Question to the report
9. Repeat steps 4 through 8 to add Questions from other CRFs
10. Click on “Create Report” to run the report and view the output

Actual vs. Decoded value

	A	B	C
1		Actual Value	Decoded Value
2	Patient Initials	Patient Gender	Patient Gender
3	MF	M	Male
4	LAB	F	Female
5	CTM	F	Female
6	TEST		



Actual vs.. Decoded Value

- Actual Value is the ‘Actual’ representation of a data point entered in a C3D CRF and stored in the database.
- Decoded Value is the ‘long’ description of the ‘Actual’ value. It is available for questions which have picklists.
- I-Review selects the decoded value by default.

Selecting a Date Format

	A	B	C	D	E
Col.Head 1		Actual Date	Oracle date	Oracle date (mm-dd-yyyy)	Oracle date (dd-mm-yyyy)
Col.Head 2	Patient Initials	Date of Registration	Date of Registration	Date of Registration	Date of Registration
Sort Order					
Row results					
Warn -Low					
Warn -High					
Panic-Low					
Panic-High					
Include? prompt					

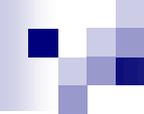
	A	B	C	D	E
1		Actual Date	Oracle date	Oracle date (mm-dd-yyyy)	Oracle date (dd-mm-yyyy)
2	Patient Initials	Date of Registration	Date of Registration	Date of Registration	Date of Registration
3	MF	20060801	01-AUG-06	08-01-2006	01-08-2006
4	LAB	20060305	05-MAR-06	03-05-2006	05-03-2006
5	CTM	20051011	11-OCT-05	10-11-2005	11-10-2005
6	TEST			--	--

Selecting a Date Format

- Oracle dates (mm-dd-yyyy (04-22-2006) and dd-mm-yyyy (22-04-2006))
 - Allows for date calculations in Excel
 - Do not use this format when sorting dates
- Actual value (yyymmdd) (20060422)
 - Use this when date sort is needed
- Oracle Date (dd-mon-yy)(22-APR-06)
 - Do not use if partial dates exist for the question – I-Review crashes – Known bug!
 - Note: Same format shown in C3D RDC

Important Reports Considerations

- When using multiple CRFs in a report, select CRFs in the same chronological order as they would have been filled out according to the protocol schema.
 - Enrollment, Course initiation, AE, Course Assessment, Off-Treatment
- I-Review 'knows' how to put together data from different CRFs
 - By patient position and sometimes by course start date as well.
- Watch out when combining questions from two or more repeating groups which do not have a common question!
 - Results in a Cartesian Product
- Watch out for reports on current patients (pts still on treatment) with no end date of course!
 - IReview defaults to "August 15 3001" date. Meaning patient is current with no course end date. Since the actual date is derived as day -1 of start date of next cycle.

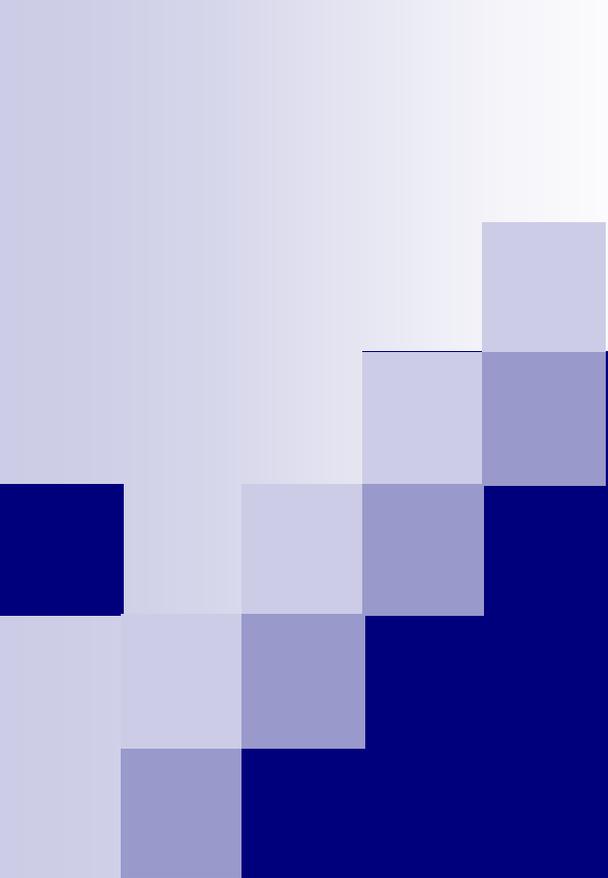


Module 3 Demo and Exercises

- DEMO

- Exercise

- Create an ad hoc Report with Enrollment and AE Questions



I-Review Module 4

Filters and Patient Selection Criteria



Module 4

- I-Review Terminology
- Patient Selection Criteria
- Filters
- Demo
- Exercise

I-Review Terminology

- Patient Selection Criteria – Specification of how to subset the patient population based on their data. **Ex: Female Patients – Gender = 'F'**
- Patient Subsets – Saved Patient Selection Criteria! Re-usable across reports.
- Filter – Part of a report used to include or excludes data (rows or records). **Ex: AE Grade>=3**

Patient Selection Criteria

- Allows one to specify a subset of a protocol's patient population based on any CRF's questions.
 - For example: by gender, by Arm, by registering Institution, etc.
- It can be saved as part of a report or by itself for re-use in any existing saved report.
- Patient Subsets are stand alone saved Patient Selection Criteria.
 - Re-usable across reports
 - Listed between studies and output specification sections

Note:

- If you do not use a patient selection criteria, your reports will include data from the entire protocol's patient population.

Create a Patient Selection Criteria

The screenshot shows the 'Patient Selection Criteria' window with the following components and callouts:

- 1**: DCM/Question Groups list (includes COURSE ASSESS, COURSE INIT, ELIG CHECK, ENROLLMENT, non-repeating data, EXT OF DISEASE, FOLLOW_UP, INFECTION EP)
- 2**: Arrow pointing to 'non-repeating data' in the DCM/Question Groups list
- 3**: Questions list (includes DCM Subset Name, DCM Subset Number, Document Number, Site, Investigator, Patient, Accessible TS, Login TS, LstChg Ts, CPF Name)
- 4**: Operators list (includes =, <, <=, >, >=, contains:, doesn't contain:, begins with:, ends with:)
- 5**: Functions list (includes actual value)
- 6**: Arrow pointing to the 'ADD expression' button in the 'Unique Values for non-repeating data.Patient' pop up window
- 7**: Arrow pointing to the 'Update Browsers' button

The main window displays the following criteria:

Select Criteria (Text)	Select Criteria (SQL)
1 non-repeating data.Patient =10	T13.PT ='10'

The 'Unique Values for non-repeating data.Patient' pop up window displays the following table:

	Value
1	10
2	12
3	9
4	SB00001

Other interface elements include 'Update Browsers', 'ADD expression to criteria', 'Display Stats', 'Display Values', 'Value:', and 'Item Compare' buttons.

Selection pop up window

Create a Patient Selection Criteria

With the Patient Selection Criteria tab selected:

1. Click on Enrollment under DCM/Question Groups
2. Click on non-repeating data
3. Choose Question to determine patient selection (eg. Patient initials, Patient Gender, etc.)
 - “actual value” or “decoded value” should be highlighted
4. Choose Operator
5. Click on “display values” button
 - Window shows up listing values for the selected question
6. Highlight choice and click on “ADD expression”
 - To choose multiple hold down ctrl and click on other values
7. Click on “Update Browser” button to activate Patient Selection Criteria

Save a Patient Selection Criteria

The screenshot shows a dialog box titled "Save Patient Selection Criteria" with a close button (X) in the top right corner. The dialog has four tabs: "Definition" (selected), "Access", "Subset", and "Version 1".

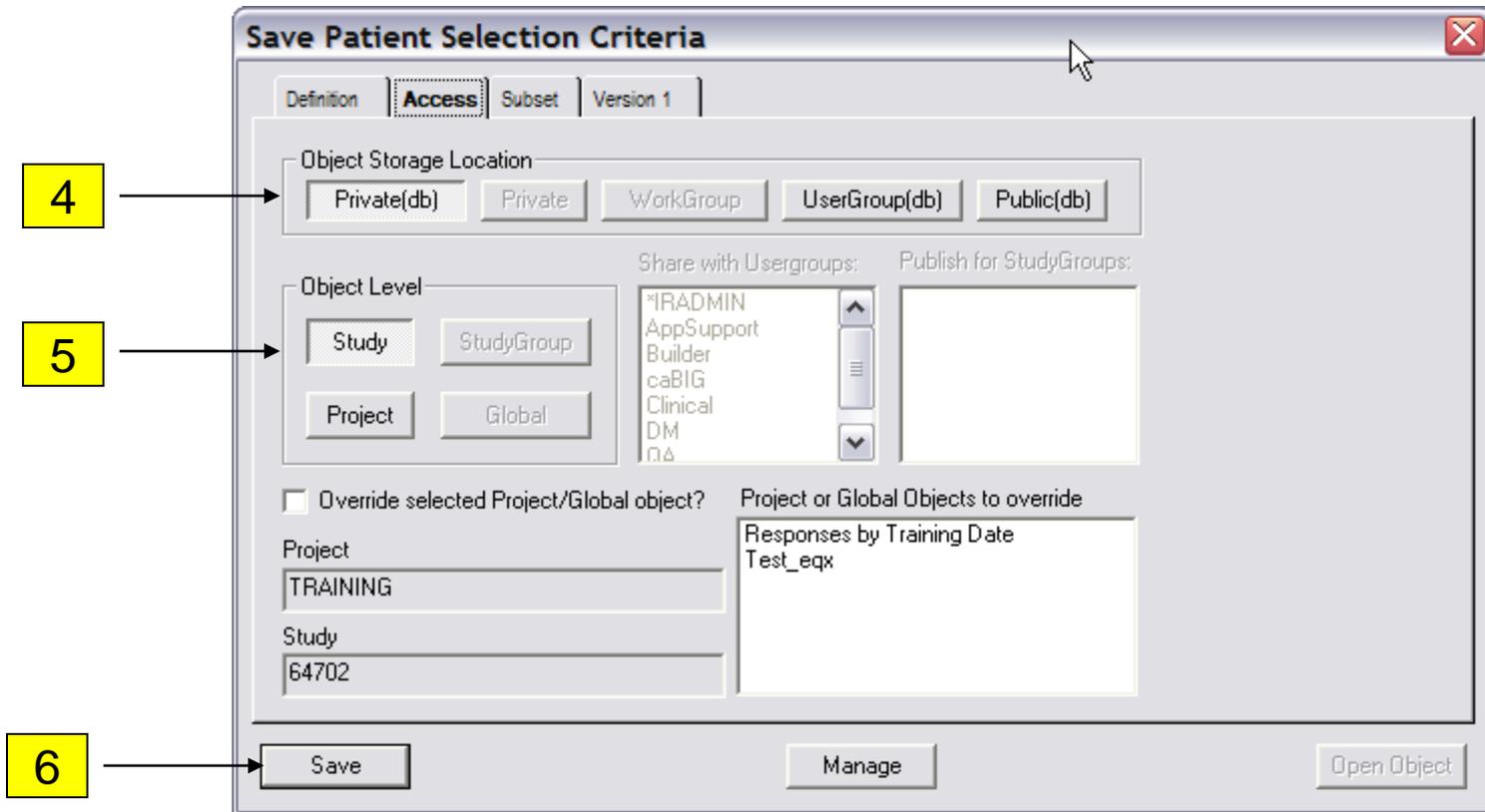
On the left side, three yellow boxes with numbers 1, 2, and 3 have arrows pointing to specific fields:

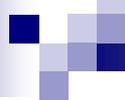
- 1 points to the "Description:" text input field.
- 2 points to the "Category (Major.Minor.Sub):" dropdown menu, which currently shows "DEFAULT".
- 3 points to the "Summary Information:" text area, which is empty and has a vertical scrollbar.

Other fields and elements include:

- "Existing Objects:" text area on the right side.
- "Status:" dropdown menu showing "DEFAULT".
- "ID Number:" text input field at the bottom center.
- Buttons at the bottom: "Save", "Manage", and "Open Object".

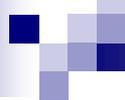
Save a Patient Selection Criteria





Save a Patient Selection Criteria

- After making changes to the Patient Selection Criteria, you are able to save it as a new Patient Subset or update it (if owned by you).
- Click on the File menu option
- Click on the Save As menu item to save the current Criteria as a new Patient Subset.
- Or click on the Save menu item to update a Patient Subset previously saved by you. I-Review remembers the criteria's information.
- You cannot update or delete a Patient Subset that was not created by you.



Save a Patient Selection Criteria

Under the 'Definition' tab:

1. Enter the Patient Selection Criteria Description (that is the Patient Criteria name shown in the Patient Subset section);
2. Enter the Category or select an existing one from the drop-down list (that is the folder name shown in the Patient Subset section);
3. Summary Information – Briefly describe the purpose of the Patient Selection Criteria;

Under the 'Access' tab:

4. Select the Object Storage Location – Patient Subsets can be saved either as Private (only you have access) or Public (shared with anyone who can access the study);
5. Select the Object Level – Patient Subsets can be saved under Project (accessible in all of the PI's studies) or under Study (a specific study);
6. Click on the Save button.



Filter Output

- Filter output is used to select CRFs' desired portions of data they contain. (undesired rows are not included in the report output)
- Filter output is always saved as a part of the report.
- The Patient Selection criteria and filter output can be used together or individually to meet your needs.

Create and Save a Filter

Heading
Adverse Events

Layout: Show Details? Suppress duplicate rows? AutoSize Columns?

Reset Subtotal with change

ADD Item Add All Items **Filter Output** Create Report

	A	B	C	D	E	F	G	H	I	J	K
Col.Head 1									Prior	(MM-DD-YYYY)	(MM-DD-YYYY)
Col.Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course #	Day in Course	Course	Date of Onset	Date Resolved
Sort Order		1	2	3							
Row results	Print chg										
Warn -Low											
Warn -High											
Panic-Low											
Panic-High											
Include? prompt											

Patient Sele... Report Bro...

Create and Save a Filter

Report Output Filter

DCM/Question Groups: ADVERSE EVENTS, Adverse Events, BASE MED HIST, BASE SYMP, CARDIAC, CHIMERISM, COMMENTS

Questions: Therapy, Attribution, Dose Limiting Toxicity, Common Toxicity Criteria Term, Serious, **Grade**, Day in course, Prior Course, CTC Category

Functions: decoded value, baseline value, endpoint value

Operators: =, <>, <, >, <=, >=, is missing(NULL), is not missing(not NULL)

Buttons: Save Filter, ADD expression, Display Stats, Display Values, Value:, Item Compare, Define Parameter

Result Filter (Text): 1 Adverse Events.Grade =Fatal

Result Filter (SQL): TO.CTC_GRADE_FUL = '5'

Unique Values for Adverse Events.Grade

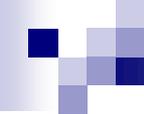
	Decode Text	Cc
1	Fatal	5
2	Mild	1
3	Moderate	2
4	Severe	3
5	Threat	4

Subset using Select Criter

ADD expression

Create and Save a Filter

- To create a filter:
 1. Under Report Browser tab Click on Filter output button
 - Filter output tab will open
 2. Select DCM, DCM Question Group
 3. Select a Question
 4. Select Function
 5. Select an Operator
 6. Click on display values button
 - Double click on a value in popup window or type in a value next to the button
 7. Click Save filter button to enable filter



Patient Selection vs. Filter

- Patient Selection Criteria = Patient positions selected
 - E.g.. Arm A patients = Patients 1, 7, 22 will be listed in output
- Filter Output = Observation level subset
 - E.g.. Resolved AEs = Only AEs with resolved date and outcome will be listed in output

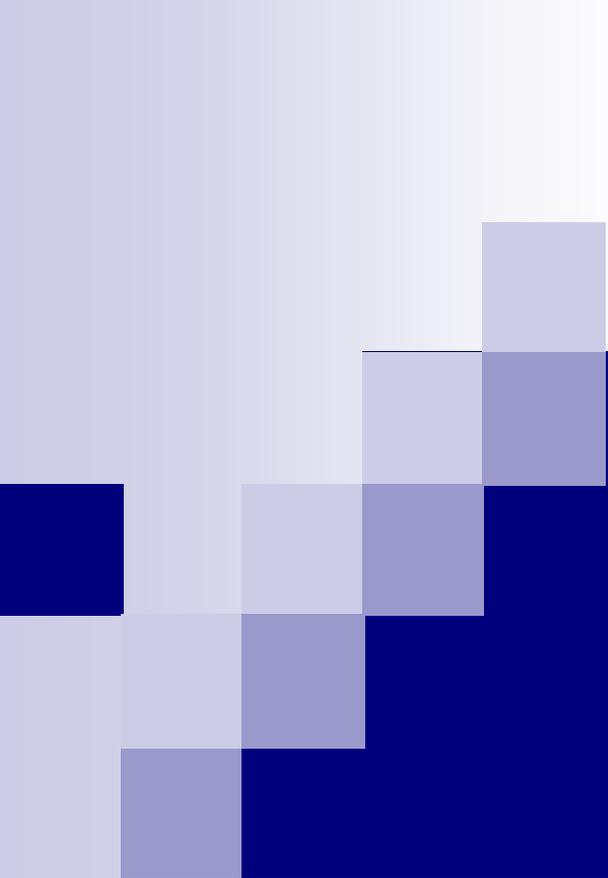
Module 4 Demo and Exercises

- Demo

- Exercise

- Using the previously created report with enrollment and AE questions create the following:

- Create a filter for AEs \geq grade 3
 - Create Patient selection criteria for “male”
 - Generate report for “Male” patients with AE \geq grade 3



Questions???