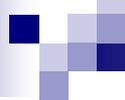


JReview Training

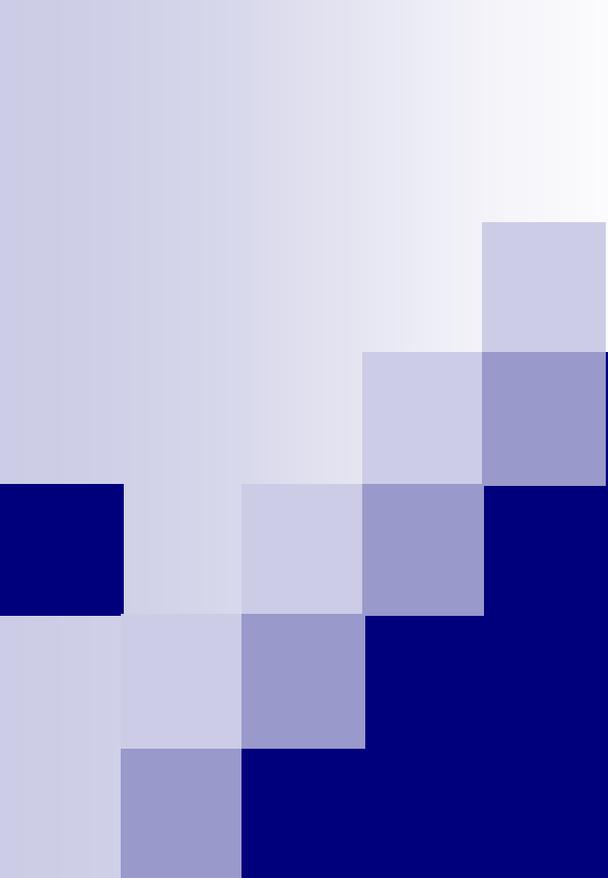
Harris Information Technology Services

(Jan 2015)



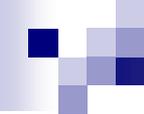
JReview Modules

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



JReview Module 1

Basics and Running Existing Reports



Module 1 Outline

- n Introduction

- n Basics/Navigation

 - .. Login

 - .. Review of the Interface (or user screens) and Reports

 - .. Run existing reports

 - .. Export reports to excel and open it

- n Demo

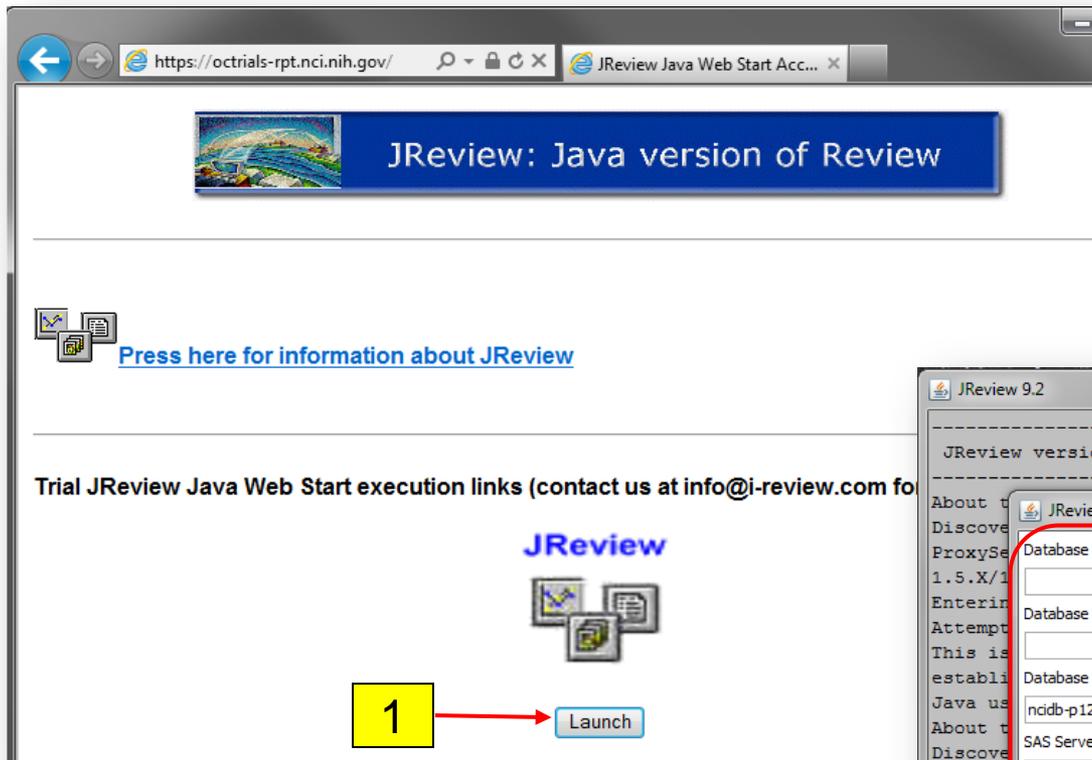
Introduction

- n JReview is the new version of I-Review ("Integrated Review")
- n Companion reporting tool in C3D family
- n Intuitive and user-friendly
- n Allows design of clinical data reports and to perform simple analyses
 - Only allows access to your C3D protocols and Sites
- n Java based application
 - Requires the Java Runtime Environment version 1.7.0_45 or later installed. Do not use version 1.8.xx
- n CCR JReview Reports Instructions/Manual
http://ccrintra.cancer.gov/clin_ops/C3D/iReview_instr.asp
- n Vendor's Manual
<https://ccrod.cancer.gov/confluence/download/attachments/72876079/JReview%20User%20Manual%209.2.6.pdf?api=v2>
- n CBT Training Manual
<http://octrials-train.nci.nih.gov/CBTsubmenu1.html>
- n Contact NCICB for problems/requests
 - 240-276-5541 (Toll free: 888-478-4423) or ncicbiit@mail.nih.gov

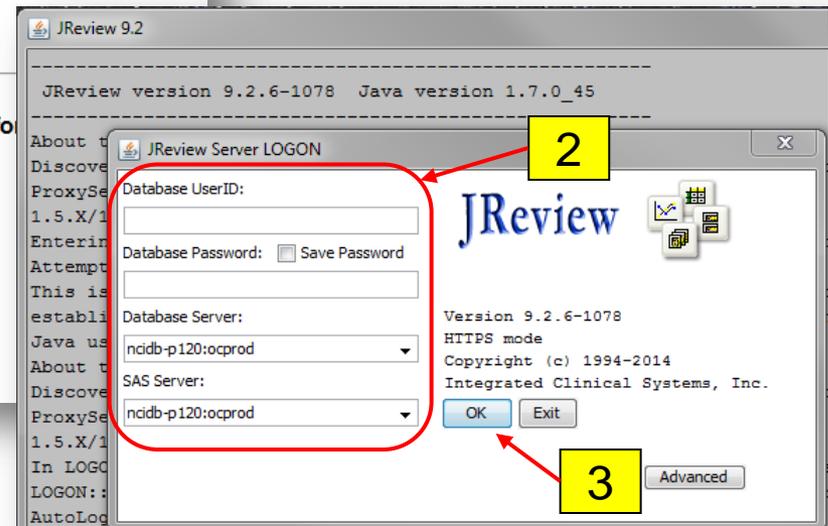
JReview Login

Go to the Login page:

<https://octrails-rpt.nci.nih.gov/>

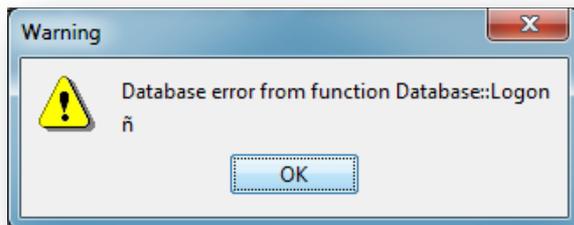


1. Click on the **Launch** button;
2. Enter your C3D:
 1. **UserID**;
 2. **Password**;
 3. **ncidb-p120:ocprod** for the Database and SAS Servers;
3. Click on the **OK** button.

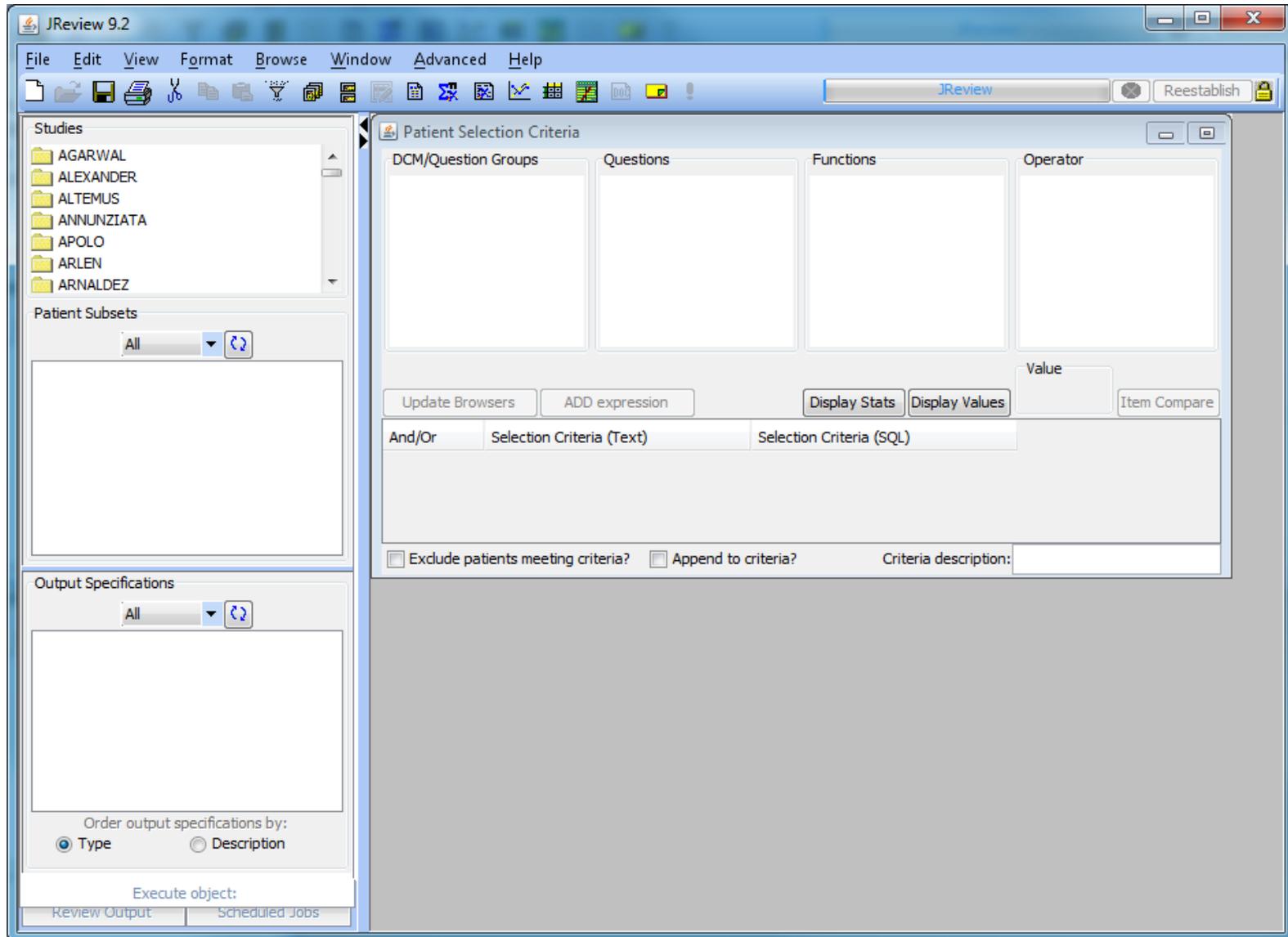


JReview Login

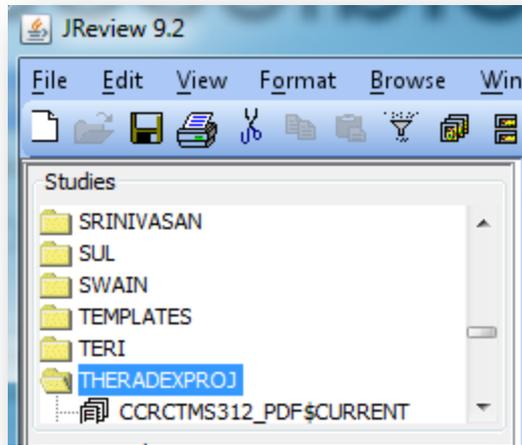
- n If your C3D password is about to expire (a warning is displayed when you log into C3D saying your password is about to expire in xx days), change your C3D password otherwise you will not be able to log into JReview.
- n Three failed logins attempts will your C3D account just like in C3D RDC. You will have to contact the C3D Help Desk to have your account unlocked.
- n The following message is shown if an invalid C3D account and/or password, or if the password is about to expire,



JReview Interface



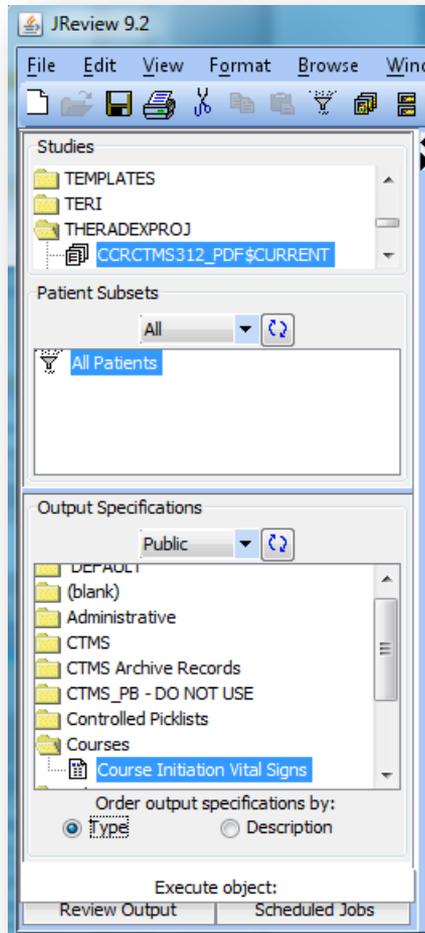
Accessible Studies



Studies you have access to

- Studies that you have access to are listed in a folder with the Principal Investigator's name. "**\$Current**" in name of the study indicates live data.

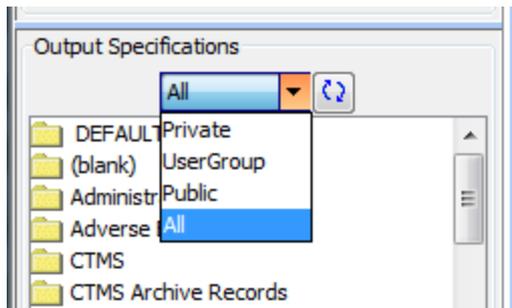
Saved Reports



- The Output Specification area lists the reports, saved by you and other users, that are available for the selected study.
- The reports are organized in folders.

Saved Reports

Output Specifications



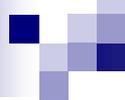
- n Reports can be saved as **Private** or **Public**.
 - .. A Private report is only accessible by the user that created it.
- n Use the **Output Specification** drop-down to choose which reports to show:
 - .. Private – shows only reports created by you and available to you in the study;
 - .. Public – shows reports available to anyone with access to the study (even reports saved by other users);
 - .. All – same as Private and Public combined.

Execute a Saved Report

The screenshot shows the JReview 9.2 software interface. The 'Studies' list on the left contains several entries, with 'CCR_ROS_2011_V1\$CURRENT' highlighted by a red arrow and a yellow box labeled '1'. Below this, the 'Patient Subsets' section shows 'All Patients' selected. The 'Output Specifications' section shows 'All' selected, and the 'Template Reports' list contains 'All AEs - V5 - TEMPLATE REPORT' highlighted by a red arrow and a yellow box labeled '3'. A red arrow and a yellow box labeled '2' point to the 'All' dropdown in the 'Output Specifications' section. A red arrow and a yellow box labeled '4' point to the 'All AEs - V5 - TEMPLATE REPORT' entry in the 'Template Reports' list. The 'Report Output' table in the center-right displays the following data:

Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #
CCR_ROS_2011_V1	1010001	170	0	1	1
CCR_ROS_2011_V1	1010001	170	0	1	2
CCR_ROS_2011_V1	1010002	170	0	1	1
CCR_ROS_2011_V1	1010003	170	0	1	2
CCR_ROS_2011_V1	1010003	170	0	1	1
CCR_ROS_2011_V1	1010004	170	0	1	1
CCR_ROS_2011_V1	1010004	170	0	1	2
CCR_ROS_2011_V1	1010004	170	0	1	3
CCR_ROS_2011_V1	1010004	170	0	1	6
CCR_ROS_2011_V1	1010004	170	0	1	5
CCR_ROS_2011_V1	1010004	170	0	1	7
CCR_ROS_2011_V1	1010004	170	0	1	1
CCR_ROS_2011_V1	1010004	170	0	1	4
CCR_ROS_2011_V1	1010005	170	0	1	1
CCR_ROS_2011_V1	1010006	170	0	1	3
CCR_ROS_2011_V1	1010006	170	0	1	2

A red arrow points from the 'Report Output' table to a yellow box labeled 'Report Output' at the bottom center of the image.



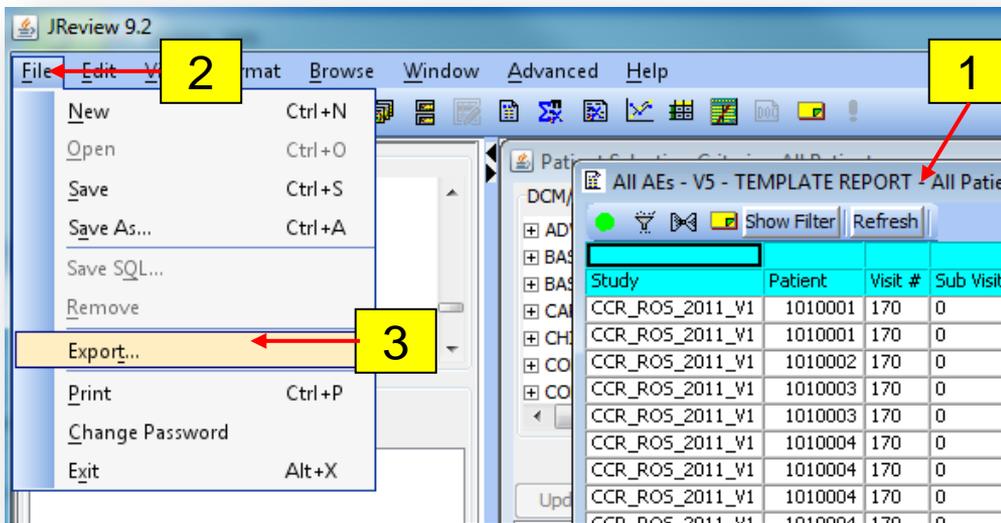
To Execute an Existing Report

1. Click on folder with the PI's name and click on the desired study (use \$CURRENT for live production data);
2. Optionally, change the Output Specification drop-down to Private or Public;
3. Double-click on folder to open and list the reports in it;
4. Double-click on the name of a saved report to execute it.

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

Note: Lab reports on studies with a lot of lab data can take a few minutes to execute.

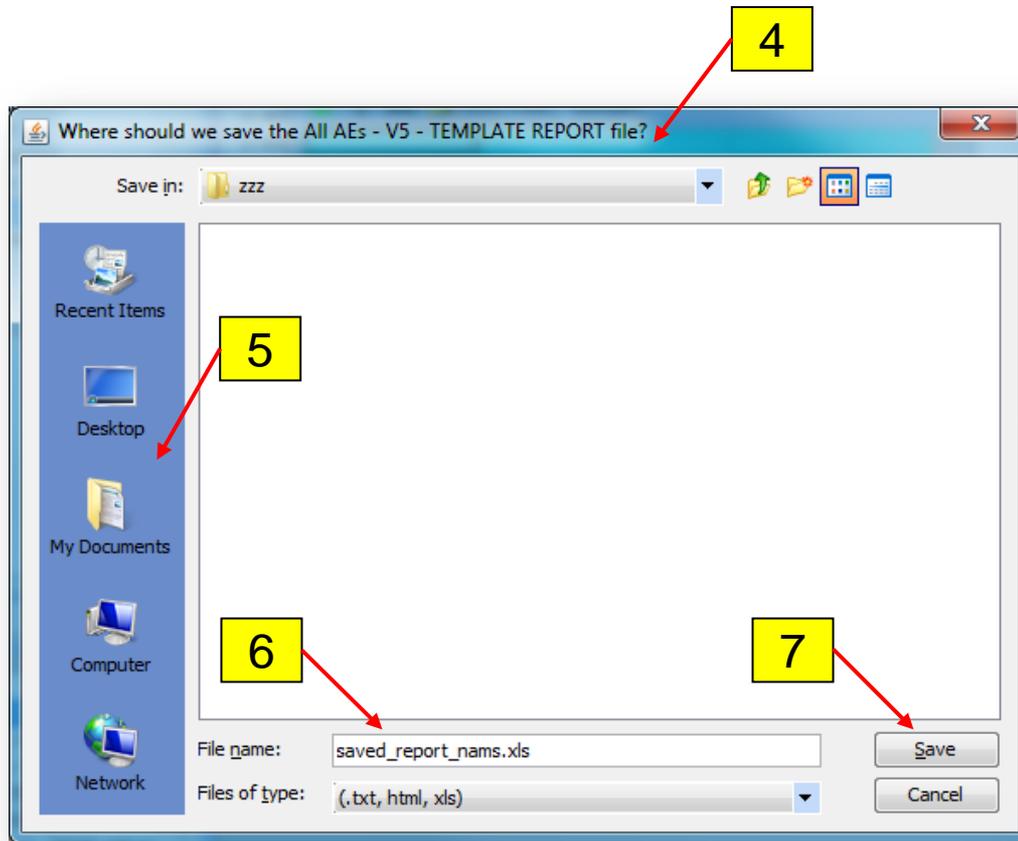
How to Export Reports



Once a report has completed executing:

1. Click on the **Report Output** window;
2. Click on **File** menu item;
3. Select the **Export** menu option;

How to Export Reports



4. Save dialog window will appear;
5. Select a **location** (desktop, my documents..) to save the report;
6. Enter a **file name** with extension (use **.xls** for spreadsheets, **.txt** for text files);
7. Click **Save** button.

CCR JReview Manual

Adobe Acrobat Professional - [CCR IReview Reports_V1.0.pdf]

File Edit View Document Comments Tools Advanced Oracle Clinical RDC Window Help

80%

QA Reports

Discrepancy: Discrepancy Type vs Review Status

Description

This report lists the count of discrepancies categorized by type and review status. The columns displayed depend on the type of discrepancy review status in the selected study.

Discrepancy Type vs Review Status

1	A	B	C	D	E	F	G	H	I	Total
1	Check	Discrepancy Type	Description	CLOSED	IN REVIEW	IRRESOLVABLE	RESOLVED	UNREVIEWED		
2	DCR CTMS 312 R	1-EVENT 1-DCM	Address Event duplicate check (AE10)						3	3.00
3			Address Event future dates check (AE1)	3						3.00
4			Address Event internal record check (AE3)	3					4	7.00
5			Address Event outcome and date number	28				1	33	63.00
6			Address Event resolve date check (AE04)						7	7.00
7			Address Event valid grade check (AE17)	5					8	13.00
8			Address Event vs Course Initiation check	5					12	18.00
9			Address Event vs Course Initiation date	8	1				16	25.00
10			Address Event vs Lab. Toxicity grading cl.	22	2	1	1		30	65.00
11			Baseline Medical History vs. Init Course	1						1.00
12			Baseline Symptom internal check (BS01)						1	1.00
13									1	1.00
14										
15										
16										
17										
18			Vital Signs vs Course initiation check (VI)	7					5	12.00
19			Vital Signs BSA check - MS Toxicity (VI)	1					2	3.00
20		DATA TYPE	(assess)	7		1			10	18.00
21		DE COMMENT				1	1		2	2.00
22		DVG		4					2	6.00
23		DVG SUBSET		2					2	2.00
24		LENGTH		5					13	18.00
25		LOWERBOUND		2					1	3.00
26		MANDATORY		86	2	4	1		100	275.00
27		PARTIAL DATE							1	1.00
28		THE SAMRIS		16					2	18.00
29		Total		272.00	8.00	7.00	5.00		484.00	790.00

Access

User Level: Public

Study Level: Global

Columns

Field	Description
Study	Protocol Number for which Access is being Queried
Discrepancy Type	1-Event 1-DCM: Multivariate discrepancy. Marked as red on RDC. DATA TYPE: Univariate discrepancy. Response value type is not

8.50 x 11.00 in

21 of 148

CCR JReview Manual

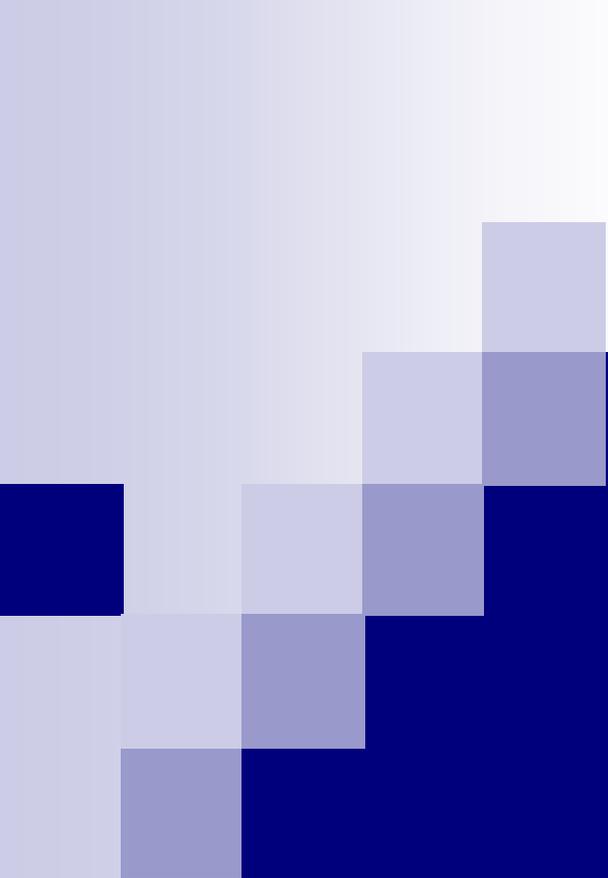
- n Link to JReview Manual:
https://ccrod.cancer.gov/confluence/download/attachments/72876079/IReview%20Reports_v3.0_manual.pdf?version=1&modificationDate=1319117587187&api=v2
- n General Instructions on how to execute saved reports, export output, customize saved reports, create your own reports, set filters and save report.
- n Catalog of template reports that can be used as is or as a starting point for your own custom reports.
- n 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. JReview 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

n DEMO

- Log-in
- Run a Saved Report
- Export output to Excel spreadsheet



JReview Module 2

Modifying Existing Reports



Module 2 Outline

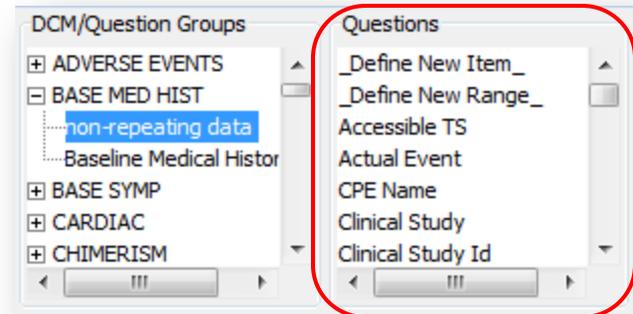
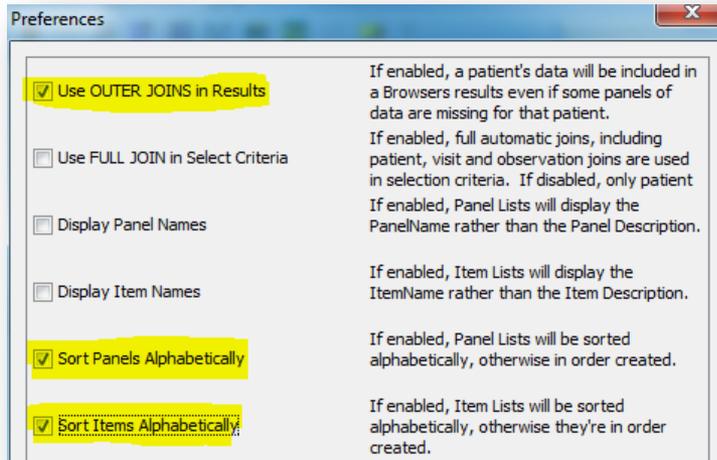
- n C3D Terminology
- n Setting Recommended Preferences
- n Oracle/JReview Relationship
 - .. JReview and C3D Correlation
 - .. F1 function
- n Open and Modify Saved AE report
- n Actual/Decoded, Print change, Sort order
- n Save Report
- n Demo

C3D Oracle Clinical Terminology

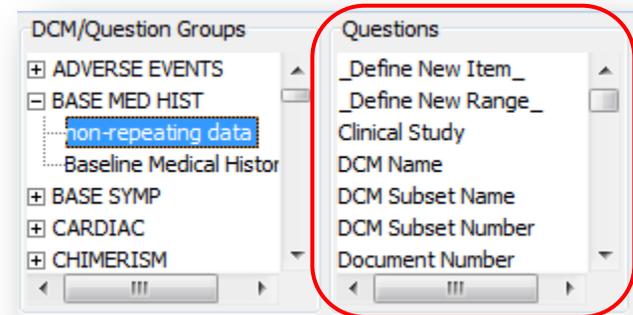
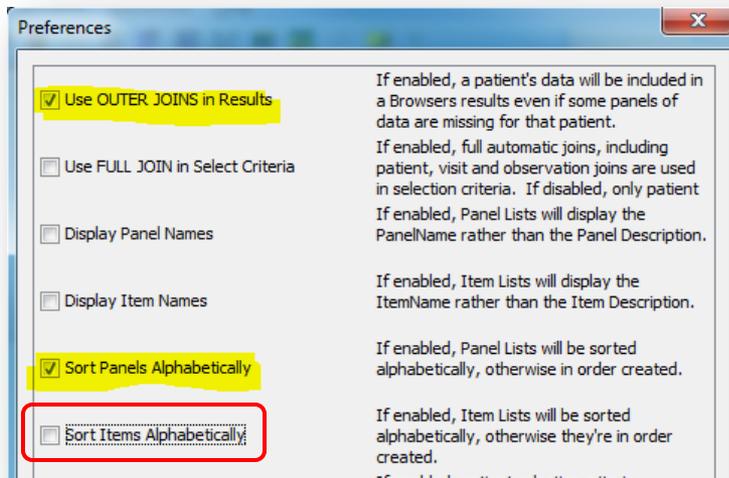
- n **DCI** – Data Collection Instrument (i.e. a CRF!)
- n **DCM** – Data Collection Module (Section or "Tab" of a CRF.)
- n **Question** – a single element of a CRF in which datum ("Response") is entered.
- n **Non-repeating Question Group** – A group of Questions that occurs once – ex: Course Initiation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

Changing Preferences

Default



Recommended



Setting "Preferences"

- n Edit JReview Preferences to change the order the **DCM/Question Groups** and **Questions** are listed.
- n To change preferences:
 1. Click on **Edit** menu item;
 2. Select **Preferences** menu option;
 3. Click on check boxes to enable or disable preferences - See recommendations on previous slide.

C3D and JReview Correlation

The image displays a screenshot of the JReview software interface, illustrating the correlation between C3D and JReview data. The interface is divided into several sections:

- Patient Information:** Patient ID 1010001, Page 4 (Medhist for Screening), Page 1 of 1, Repeat 6 of 18. Visit Date: 19-Apr-2010. Blank Comment.
- DCMs:** A yellow box labeled "DCMs" points to the "COM" tab in the patient information section.
- Non-Repeating Group:** A yellow box labeled "Non-Repeating Group" points to the "Baseline Medical History" section.
- Repeating Group:** A yellow box labeled "Repeating Group" points to the "Patient Selection Criteria - All Patients" section.
- Questions:** A yellow box labeled "Questions" points to the "Questions" section in the Patient Selection Criteria.

The "Patient Selection Criteria - All Patients" section is expanded to show the following groups:

- DCM/Question Groups
 - ADVERSE EVENTS
 - BASE MED HIST
 - non-repeating data
 - Baseline Medical History
 - BASE SYMP
 - CARDIAC
 - CHIMERISM
 - COMMENTS
 - CONCOM MEDS/MEAS
 - CONSULT SPECIAL
 - COURSE ASSESS
 - COURSE INIT
 - DIAGNOSTIC ECG
 - ELIG CHECK
 - ENROLLMENT

The "Questions" section lists the following items:

- _Define New Item_
- _Define New Range_
- 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

The "Baseline Medical History" section shows the following data:

Body System	Finding Results	Medical History If Abnormal
H/E/E/N/T	N	
NECK	N	
RESPIRATORY	N	
CARDIOVASCULAR	N	
GASTROINTESTINAL	N	
MUSCULOSKELETAL	A	Back pain
DERMATOLOGIC	N	

C3D: F1 & Field Help Function

- n Displays Oracle Clinical question name and default prompt for selected data point.
- n Useful in finding out the question's **Default Prompt** as it appears in JReview.
 1. Click on a specific data point on eCRF in C3D:
 - a) On RDC Onsite studies, press the mouse's right button and select the "Field Help" option;
 - b) On non RDC Onsite studies, press the keyboard F1 key.
 2. A pop-up window appears and shows the data point's question name and default prompt .

F1 and Field Help Function

RDC Onsite

BASELINE MEDICAL HISTORY

Date of Examination

Body System	Finding Results	Medical History If Abnormal
H/E/E/N/T		
NECK		
RESPIRATORY		
CARDIOVASCULAR		
GASTROINTESTINAL		
MUSCULOSKELETAL		

Context menu options: Delete Row, Investigator Comment, Add Discrepancy, Show Audit History, Show Full Text, **Field Help**

1

Oracle Clinical Data Collection Help

DCM Question Group Information

Name: MED_HISTORY
Help Text

2

DCM Question Information

Question Name: Finding Results
Occurrence SN
SAS Name: A2213A
Help Text: CDE_ID=2003876/VERSION=3.1
Default Prompt: Finding Results

Mandatory?
Auto Skip?
Indicator?
Sight Verification?
Length: 1
Decimal Places: 0
Lower Bound
Upper Bound

Non RDC Onsite

Patient 1010001 Page 4 (Medhist for Screening) Page 1 of 1, Repeat 1 of 18.

Visit Date: 19-Apr-2010 Blank Comment

Bmeh COM

BASELINE MEDICAL HISTORY

Date of Examination: 01-JAN-2010

Body System	Finding Results	Medical History If Abnormal
H/E/E/N/T	N	
NECK	N	
RESPIRATORY	N	
CARDIOVASCULAR	N	
GASTROINTESTINAL	N	
MUSCULOSKELETAL	A	Back pain

1

Description of Question "NORM_ABNORM_IND" from Group "MED_HISTORY"

DCM Question Group Information

Name: MED_HISTORY
Help Text

2

DCM Question Information

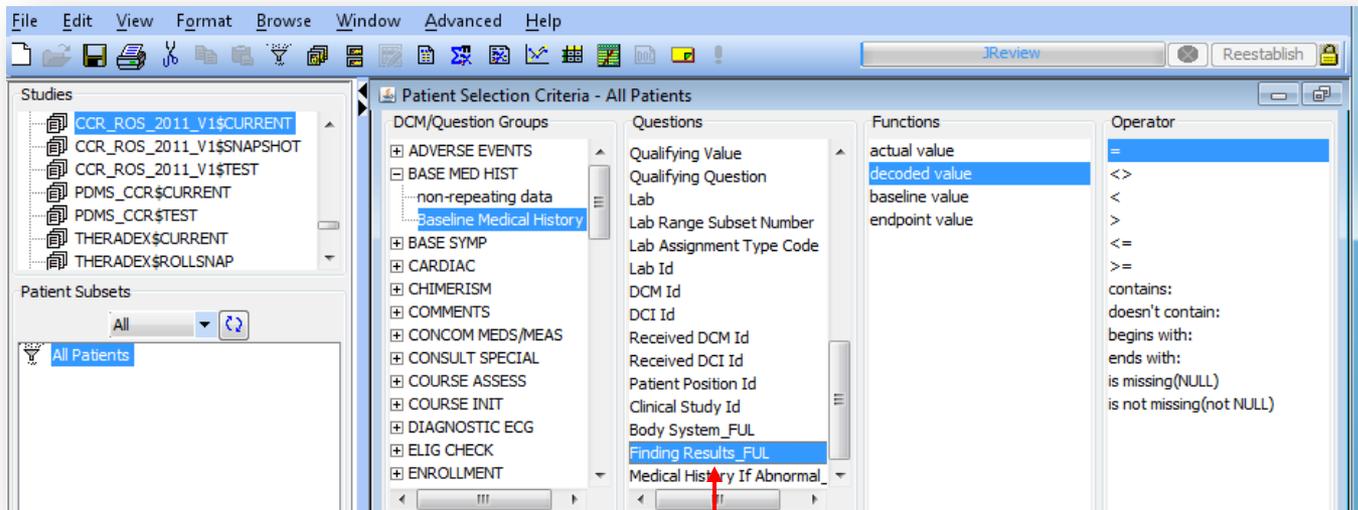
Question Name: NORM_ABNORM_IND
Occurrence Sn: 0
SAS Name: A2213A
Help Text
Default Prompt: Finding Results

Mandatory?
Indicator?
Autoskip?
Sight Verification?
Length: 1
Decimal Places: 0
Lower Bound
Upper Bound
Data Type: CHAR
Date Format

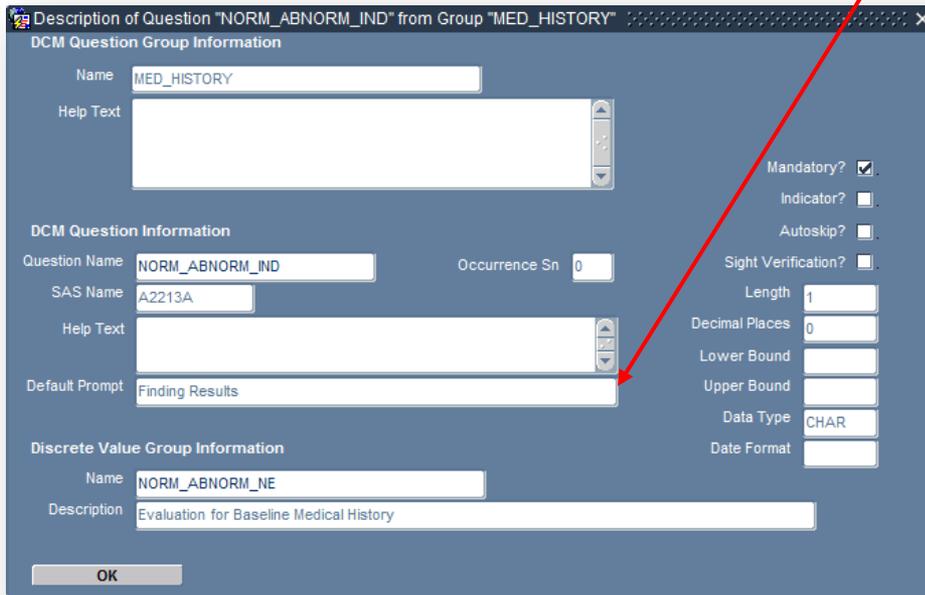
Discrete Value Group Information

Name: NORM_ABNORM_NE
Description: Evaluation for Baseline Medical History

OK



Question's Default Prompt



Open and Modify Reports

Right click, then choose open

Report definition in Report Browser

Output Specifications

All

Template Reports

- All AEs - V5 - TEMPLATE REPORT
- Baseline Medical History -V1 - TEM
- Baseline Symptoms - V5 - TEMPLA
- Blood Transfusion -V3 - TEMPLAT
- Chimerism -V3 - TEMPLATE REPO
- Concomitant Measures -V2 - TEM
- Course Summary - V4 - TEMPLAT
- Discontinuation (Formatted) -V3

Order output specifications by:

Type Description

Open

Open version...

Remove

Properties

Schedule

Report Browser [Object:42802]

Type:

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

DCM/Question Groups

- ADVERSE EVENTS
- BASE MED HIST
- BASE SYMP
- CARDIAC
- CHIMERISM
- COMMENTS
- CONCOM MEDS/MEAS
- CONSULT SPECIAL
- COURSE ASSESS
- COURSE INIT
- DIAGNOSTIC ECG
- ELIG CHECK
- ENROLLMENT
- EXT OF DIS IDEN
- EXT OF DIS LESM
- FOLLOW_UP
- INFECTION EP
- LAB_ALL
- LAB_LL

Questions

Functions

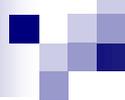
Data Highlighting Custom Join Add Item Add All I... Filter Output Create ...

Header

Adverse Events -V5

Show Details? Suppress duplicate ... Enable Edi... Mark New... Autosize ...

0	1	2	3	4	5	6	7
Col. Head 1							
Col. Head 2	Study	Patient	Visit #	Sub Visit	DCM Subset	Repeat #	Course
Sort Order							
Row results							
Warn -Low							
Warn -High							
Panir-l ow							



Modifying Saved Reports

- n A saved report can be modified to suit your requirements.
- n The following changes can be made:
 - Remove **Columns**
 - Rename **Columns Headings**
 - Set **Sort Order**
 - Set **Print Change**
- n The modified report can also be saved for later use.

Remove Columns

2

3

1

Report Browser [Object:42802]

Type: DCM/Question Groups

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

ADVERSE EVENTS

BASE MED HIST

BASE SYMP

CARDIAC

CHIMERISM

COMMENTS

CONCOM MEDS/MEAS

CONSULT SPECIAL

COURSE ASSESS

COURSE INIT

DIAGNOSTIC ECG

ELIG CHECK

ENROLLMENT

EXT OF DIS IDEN

EXT OF DIS LESM

FOLLOW_UP

INFECTION EP

LAB_ALL

LAB_LL

Output Specifications

All

Template Reports

- All AEs - V5 - TEMPLATE REPORT
- Baseline Medical History - V1 - TEMPL
- Baseline Symptoms - V5 - TEMPLATE
- Blood Transfusion - V3 - TEMPLATE R
- Chimerism - V3 - TEMPLATE REPORT
- Concomitant Measures - V2 - TEMPL
- Course Summary - V4 - TEMPLATE R

Order output specifications by:

Type Description

Execute object:

Review Output Scheduled Jobs

Data Highlighting Custom Join Add Item Ad

Header

Adverse Events -V5

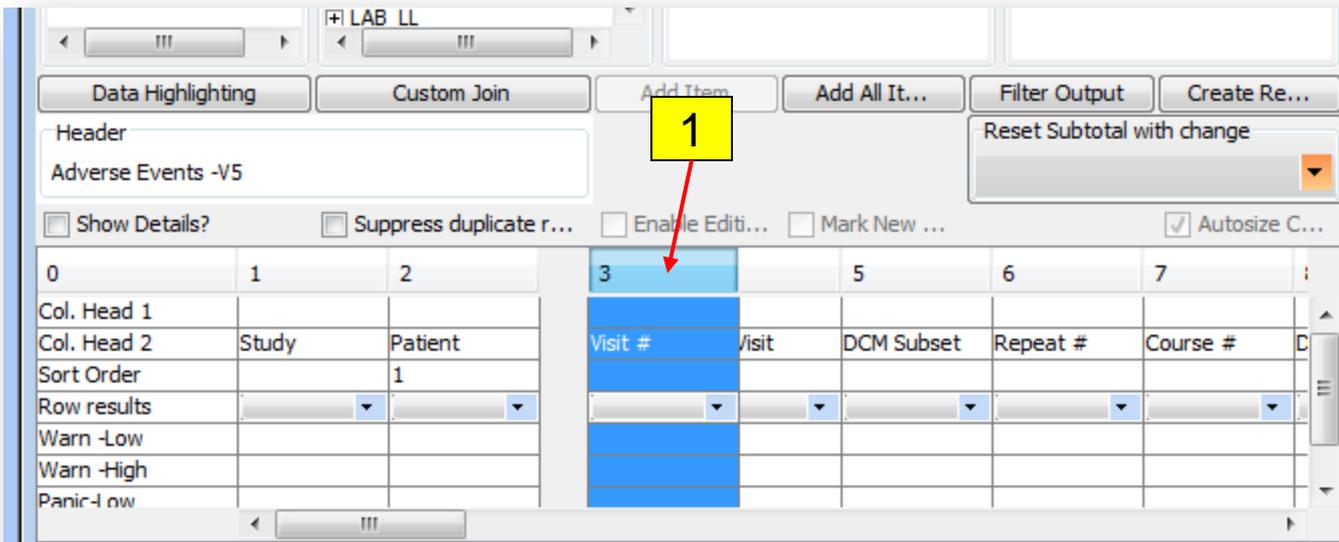
Show Details? Suppress duplicate r... Enable Editi... M

0	1	2	3	4
Col. Head 1				
Col. Head 2	Study	Patient	Visit #	Sub Visit
Sort Order		1		
Row results				
Warn -Low				
Warn -High				
Panic -Low				

1. Click on the cell with a number above the column to remove
2. Select the **Edit** menu item
3. Select the **Cut** menu option

Hint: Use the scissors  on the toolbar instead of steps 2 and 3 to remove the selected column.

Rearrange Report Column Order

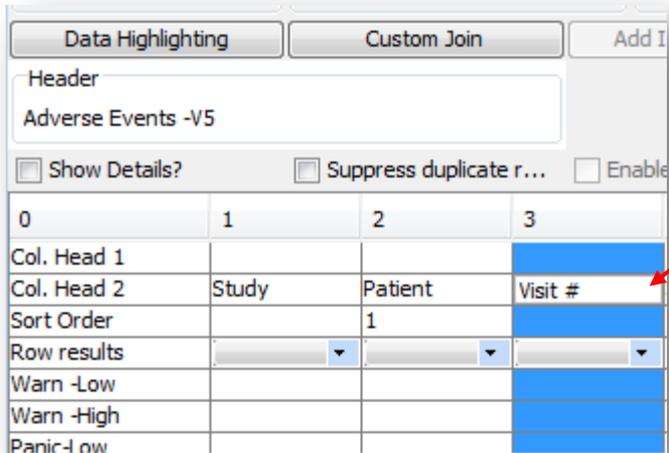


The screenshot shows a report configuration interface. At the top, there are several buttons: "Data Highlighting", "Custom Join", "Add Items", "Add All It...", "Filter Output", and "Create Re...". Below these buttons is a "Header" section with the text "Adverse Events -V5". There are also checkboxes for "Show Details?", "Suppress duplicate r...", "Enable Editi...", "Mark New ...", and "Autosize C...". The main part of the interface is a table with columns numbered 0 through 7. The table has several rows, including "Col. Head 1", "Col. Head 2", "Sort Order", "Row results", "Warn -Low", "Warn -High", and "Panir-1 ow". A yellow box with the number "1" and a red arrow points to the number "3" above the "Visit #" column.

0	1	2	3	5	6	7	:
Col. Head 1			Visit #	Visit	DCM Subset	Repeat #	Course #
Col. Head 2	Study	Patient					
Sort Order		1					
Row results							
Warn -Low							
Warn -High							
Panir-1 ow							

1. Click and drag the cell with a number above the column to move to the desired location and release the mouse button.

Edit Column Heading



Data Highlighting Custom Join Add I

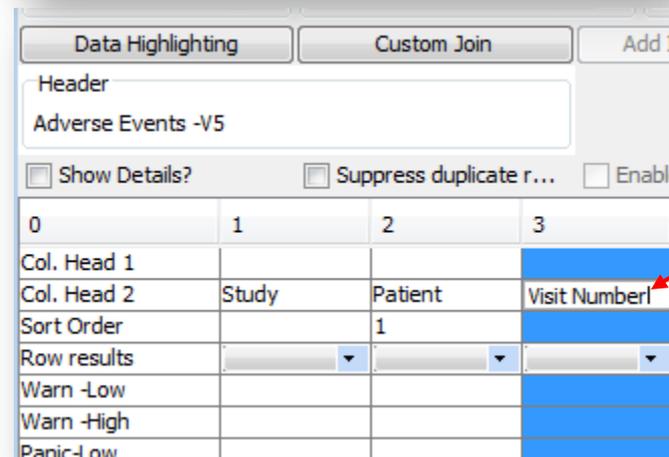
Header
Adverse Events -V5

Show Details? Suppress duplicate r... Enable

0	1	2	3
Col. Head 1			Visit #
Col. Head 2	Study	Patient	
Sort Order		1	
Row results			
Warn -Low			
Warn -High			
Panic-Low			

1. Double-click on the Column Header 1 or 2 to enter edit mode
2. Type in the desired new text

Note: Press the **Enter** or **Tab** key or click on another cell when done.



Data Highlighting Custom Join Add I

Header
Adverse Events -V5

Show Details? Suppress duplicate r... Enable

0	1	2	3
Col. Head 1			Visit Number1
Col. Head 2	Study	Patient	
Sort Order		1	
Row results			
Warn -Low			
Warn -High			
Panic-Low			

Setting Sort Order

- n Enter numbers in the Sort Order cells that correspond to the way the report output data is to be sorted. In this example, the output is sorted first on the patient position ID and then on the patient initials alphabetically.

Header		
Detail Data Listing		
<input type="checkbox"/> Show Details? <input type="checkbox"/> Suppress dup		
0	1	2
Col. Head 1		
Col. Head 2	Patient	Patient Initials
Sort Order	1	2
Row results		
Warn -Low		

Chosen Order

Detail Data Listing - Subset of patients	
<input type="checkbox"/> Show Filter Refresh	
Patient	Patient Initials
1010001	CDG
1010002	AS
1010003	ROMC
1010004	RJP
1010005	DMB
1010006	DGT

Report Output

- n In this example, the sort order numbers were reversed and now the output is sorted first on the patient initials alphabetically and then by patient position ID.

Header		
Detail Data Listing		
<input type="checkbox"/> Show Details? <input type="checkbox"/> Suppress du		
0	1	2
Col. Head 1		
Col. Head 2	Patient	Patient Initials
Sort Order	2	1
Row results		
Warn -Low		

Chosen Order

Detail Data Listing - Subset of patients	
<input type="checkbox"/> Show Filter Refresh	
Patient	Patient Initials
1010002	AS
1010001	CDG
1010006	DGT
1010005	DMB
1010004	RJP
1010003	ROMC

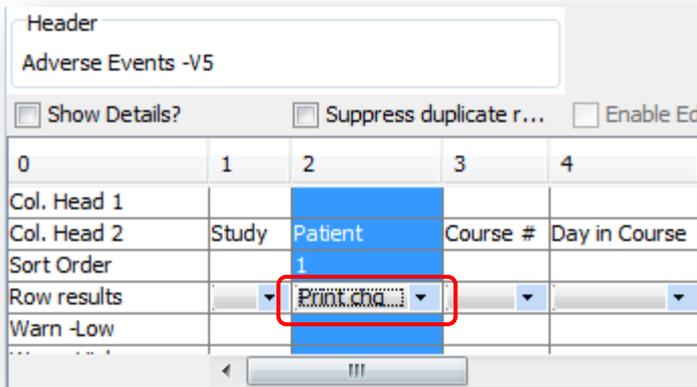
Report Output

Hints: Optional descending sort is specified by a trailing " D" after the sort order number.
Do not repeat numbers.

Print Change Enabled

- n On columns that have a sort order number, it is possible to select the "Print Change" option from the drop-down list as shown below.
- n Data will only display on the output when the value differs from the contents of the cell above.

Warning: Although it is a nice visual cue, sometimes this feature could misled the user into thinking a value is missing simply because its display was suppressed since it was the same and the one above. The other issue is that an empty cell is exported to the Excel spreadsheet making it hard to sort and filter in the data.



The screenshot shows a data table titled 'Adverse Events -V5 - Subset of patients'. The table has 7 columns: Study, Patient, Course #, Day in Course, Course, Date of Onset, and Date Resolved. The 'Patient' column is highlighted in red. The table contains 18 rows of data. The 'Patient' column values are 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010003, 1010004, 1010004, and 1010004. The 'Date of Onset' and 'Date Resolved' columns are in MM-DD-YYYY format.

Study	Patient	Course #	Day in Course	Course	Date of Onset	Date Resolved
12_C_0047	1010003	101	6	N	02-28-2012	03-04-2012
12_C_0047		101	22	N	03-15-2012	04-05-2012
12_C_0047		101	22	N	03-15-2012	04-05-2012
12_C_0047		102	28	Y	04-19-2012	05-03-2012
12_C_0047		102	28	Y	04-19-2012	05-03-2012
12_C_0047		102	28	Y	04-19-2012	05-03-2012
12_C_0047		103	2	N	04-20-2012	04-23-2012
12_C_0047		103	28	N	05-16-2012	05-24-2012
12_C_0047		104	4	N	05-20-2012	05-27-2012
12_C_0047		104	28	N	06-13-2012	08-08-2012
12_C_0047		105	28	N	07-11-2012	09-05-2012
12_C_0047		106	28	N	08-08-2012	09-05-2012
12_C_0047				N	12-05-2012	--
12_C_0047	1010004	101	2	N	03-16-2012	04-05-2012
12_C_0047		101	3	N	03-17-2012	03-29-2012
12_C_0047		101	3	N	03-17-2012	04-05-2012

Print Change Disabled

- n To disable the Print Change feature, select the empty option from the drop-down as shown below.
- n The output will always show the contents of the cell and not suppress it.

The screenshot shows a configuration window for 'Adverse Events -V5'. It includes a header field, a 'Show Details?' checkbox, and a 'Suppress duplicate r...' checkbox. Below these are several rows for column headers and sort orders. A red box highlights a dropdown menu in the 'Row results' row, which is currently set to an empty option.



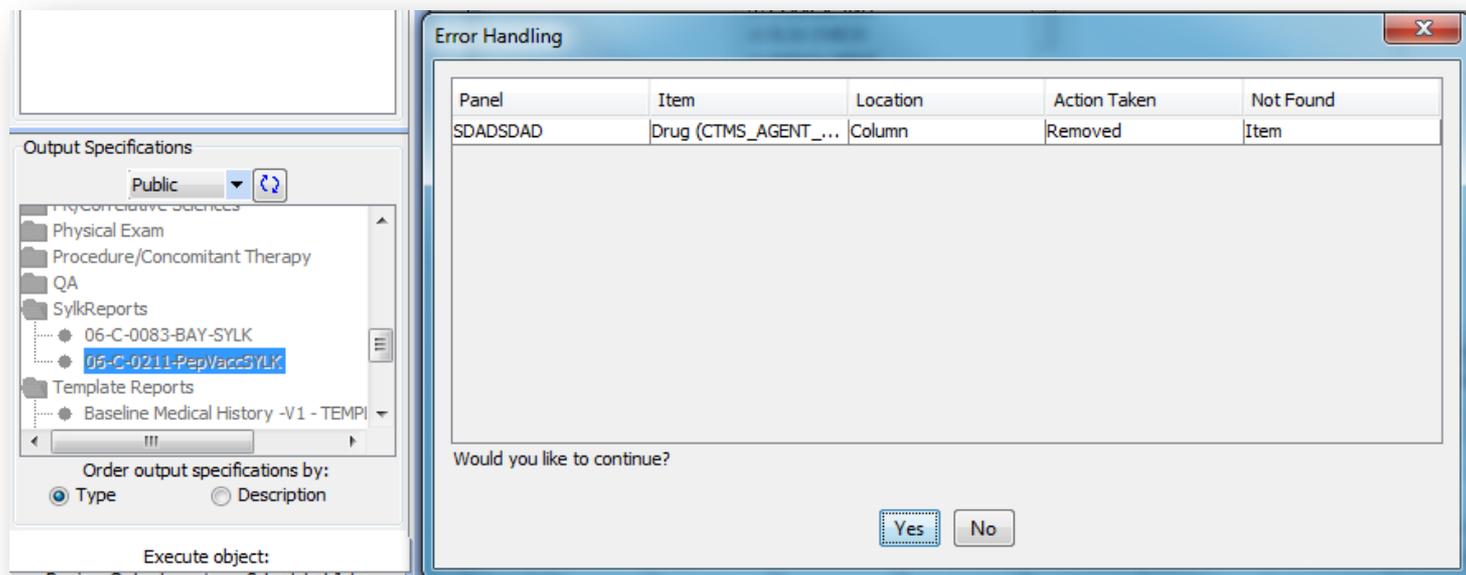
The screenshot shows a data table titled 'Adverse Events -V5 - Subset of patients'. The table has columns for Study, Patient, Course #, Day in Course, Course, Date of Onset, and Date Resolved. A red box highlights the 'Patient' column, showing that the values are not suppressed.

Study	Patient	Course #	Day in Course	Prior	(MM-DD-YYYY)	(MM-DD-YYYY)
12_C_0047	1010003	101	6	N	02-28-2012	03-04-2012
12_C_0047	1010003	101	22	N	03-15-2012	04-05-2012
12_C_0047	1010003	101	22	N	03-15-2012	04-05-2012
12_C_0047	1010003	102	28	Y	04-19-2012	05-03-2012
12_C_0047	1010003	102	28	Y	04-19-2012	05-03-2012
12_C_0047	1010003	102	28	Y	04-19-2012	05-03-2012
12_C_0047	1010003	103	2	N	04-20-2012	04-23-2012
12_C_0047	1010003	103	28	N	05-16-2012	05-24-2012
12_C_0047	1010003	104	4	N	05-20-2012	05-27-2012
12_C_0047	1010003	104	28	N	06-13-2012	08-08-2012
12_C_0047	1010003	105	28	N	07-11-2012	09-05-2012
12_C_0047	1010003	106	28	N	08-08-2012	09-05-2012
12_C_0047	1010003			N	12-05-2012	--
12_C_0047	1010004	101	2	N	03-16-2012	04-05-2012
12_C_0047	1010004	101	3	N	03-17-2012	03-29-2012
12_C_0047	1010004	101	3	N	03-17-2012	04-05-2012

Handling a Panel Items Not Found in Saved Reports

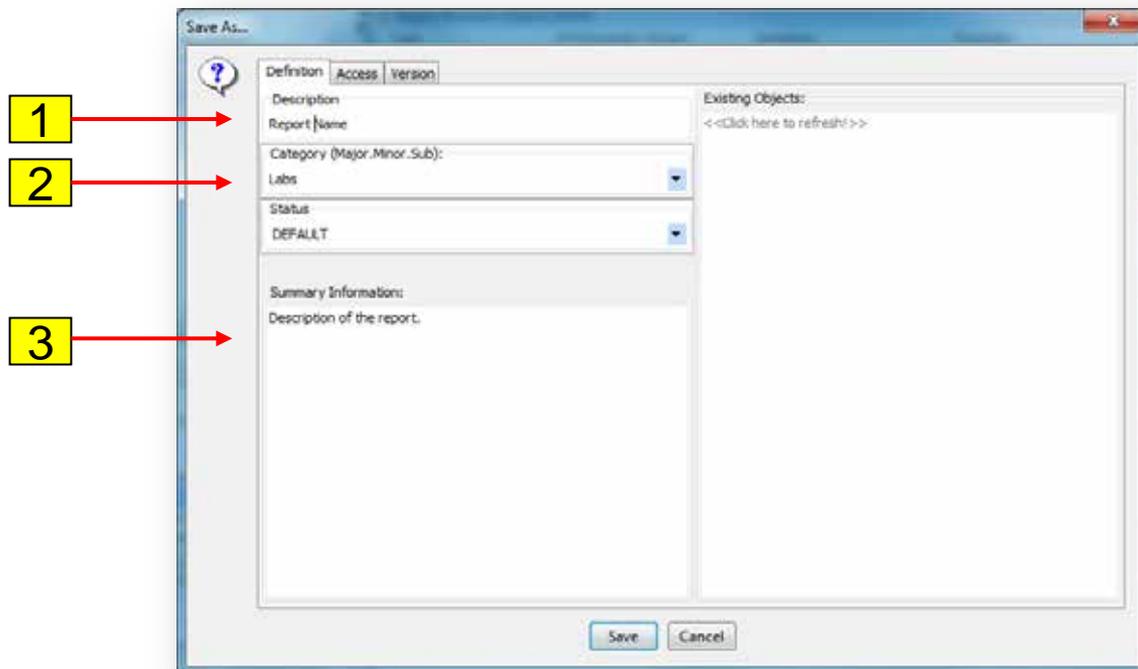
- n Some saved reports may contain items (questions) that are not applicable to a study.
- n When you try to execute or open such saved report, a warning message (see below) indicates which items are not found. These items are automatically removed.
 - Click **"Yes"** to proceed and load the rest of the report's items.
 - Click **"No"** to abort and not load/execute the report.
- n Optionally, these items can be replaced with the appropriate ones for your study.

Note: Review Filters and Patient Selection Criteria as well since items are also present there and could affect the result of the report.



Saving a Report

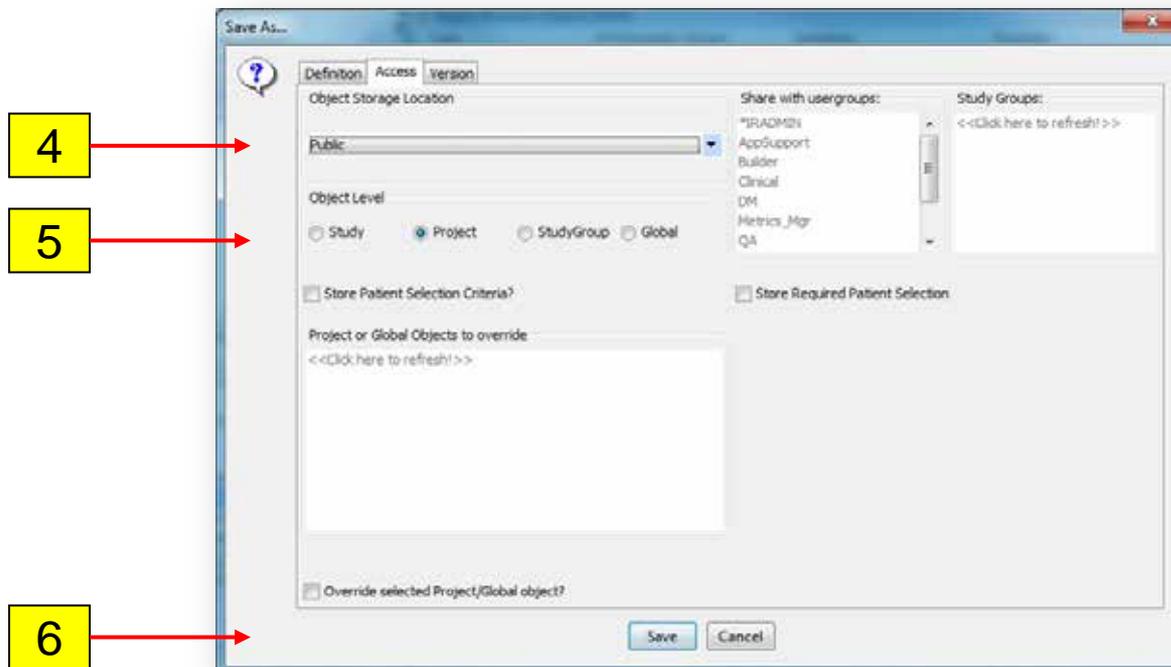
- n After making changes to the saved report, you are able to save it as a new report (necessary if you did not create the saved report) or update it (if you created it).
- n Click on the **File** menu item and then choose the **Save As** menu option to save the current report definition as a new report. Use the menu item **Save** to update the existing report.
- n Click on the **Definition** tab and enter:
 1. The report name in the **Description** box;
 2. Select a folder from the **Category** drop-down list (or type in the name of a new folder);
 3. Enter a brief description about the report in the **Summary Information** box.



Saving a Report

- n Click on the **Access** tab and select:
 - 4. Choose whether the report will be **Private** (only accessible by you) or **Public** (accessible to all user with access to the study) from the **Object Storage Location** drop-down list;
 - 5. Choose the **Object Level** radio button **Study** to make the report only be available in the currently selected study; or choose **Project** to make the report available to all studies associated with the current **PI** selected;
 - 6. Click on the **Save** button.

Hint: After saving a new report that was based on an existing report, it is advisable to open the newly saved report if you will continue modifying it.

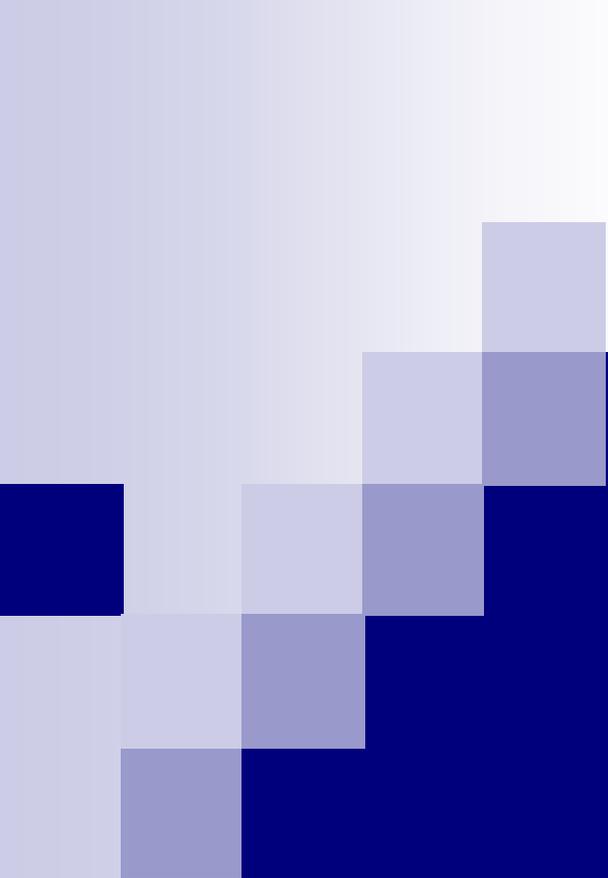




Module 2 Demo

n DEMO

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



JReview Module 3

Creating ad hoc Reports



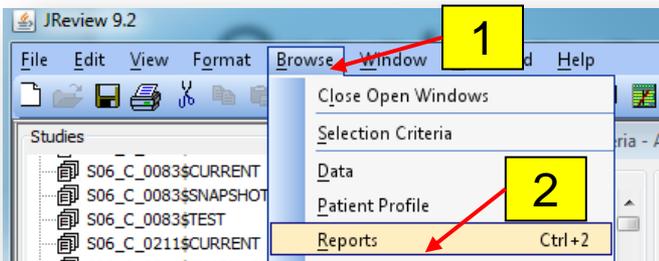
Module 3 Outline

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

Report Browser

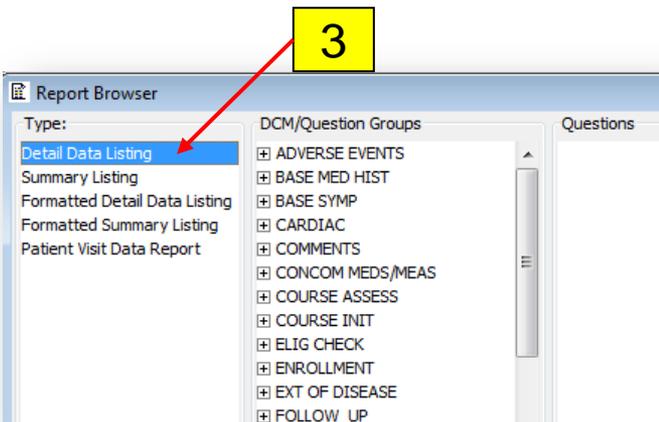
- n Report Browser has two basic report types:
 - Detail Data Listing – Lists details of selected questions from one of more CRFs.
 - Summary Data Listing – Allows for displaying counts, averages, minimum and maximum values without the details.
- n Output of these reports are shown in a grid layout and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

Creating a Detail Data Listing Report



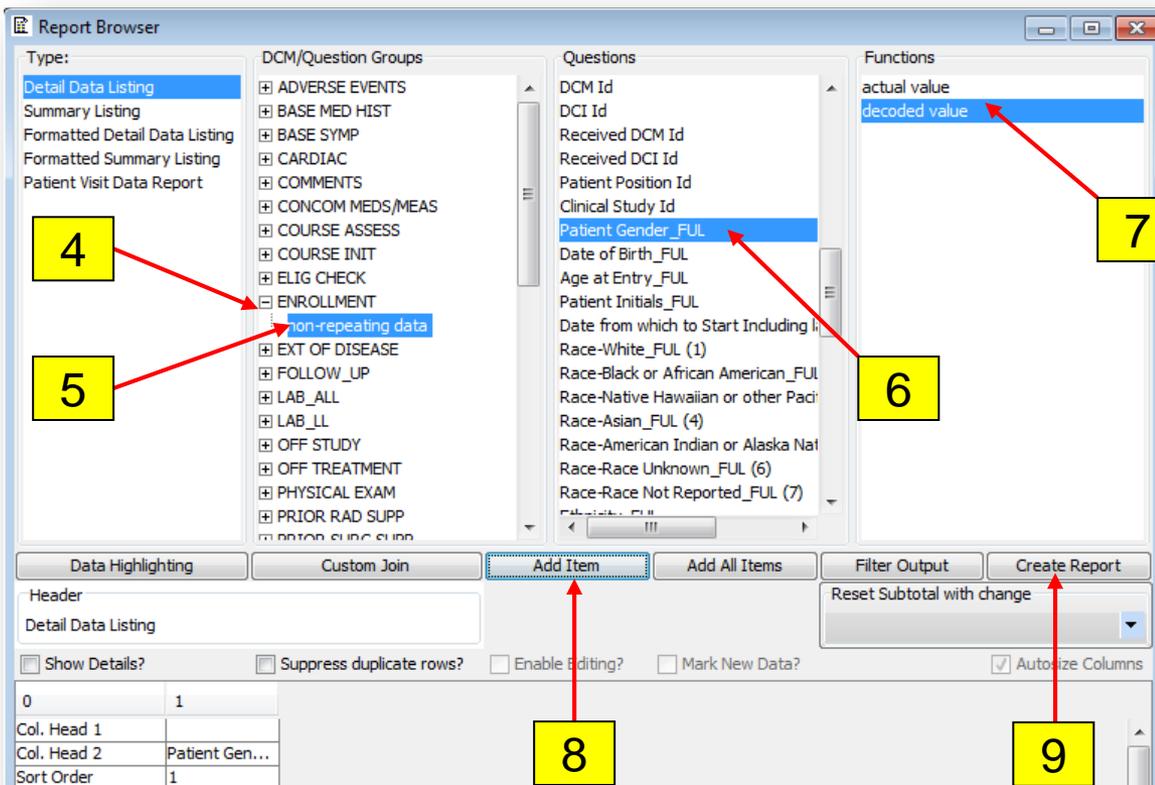
1. Click on the **Browse** menu item;
2. Click on the **Reports** menu option.

Hint: Optionally, click on the  toolbar icon to open the Report browser.



3. Click on the **Detail Data Listing** Type.

Creating a Detail Data Listing Report

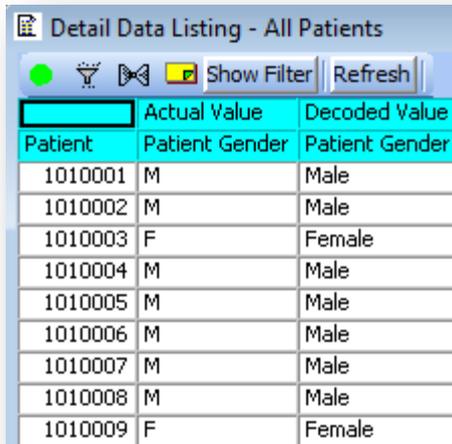


4. Expand the **Enrollment** DCM;
5. Click on the **non-repeating data** Question Group;
6. Click on a desired **Question**;
7. Click in one of the **Functions**;
8. Click on the **Add Item** button to add the Question to the report;
 - 9. Repeat steps 4-8 to add additional questions to the report;
9. Click on the **Create Report** button to run the report and view the output.

Note: "Actual Value" should be highlighted under function unless the question:

- a) is a date question, then choose desired date format;
- b) has a pick list in C3D CRF, then "Decoded Value" is automatically selected.

Actual versus Decoded value

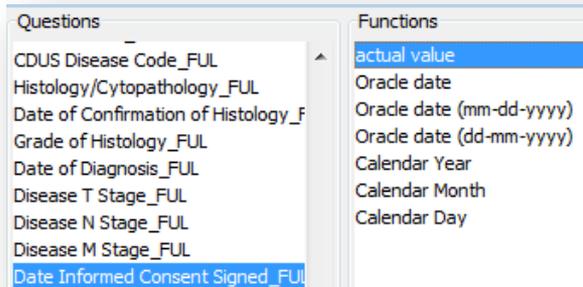


	Actual Value	Decoded Value
Patient	Patient Gender	Patient Gender
1010001	M	Male
1010002	M	Male
1010003	F	Female
1010004	M	Male
1010005	M	Male
1010006	M	Male
1010007	M	Male
1010008	M	Male
1010009	F	Female

- n **Actual Value:** is the actual representation of a data point entered in a C3D CRF and stored in the database.
- n **Decoded Value:** is the long description of the actual value. It is available for questions which have pick lists in C3D.
- n JReview selects the decoded value by default.

Date Formats

Available Date Functions



0	1	2	3	4	5
Col. Head 1		Actual Value	Oracle date	Oracle date ...	Oracle date ...
Col. Head 2	Patient Initials	Date Inform...	Date Inform...	Date Inform...	Date Inform...
Sort Order	1				
Row results					
Warn -Low					
Warn -High					
Panic-Low					

Sample output

The screenshot shows a window titled 'Detail Data Listing - All Patients'. It has a toolbar with icons for search, filter, and refresh, along with 'Show Filter' and 'Refresh' buttons. Below the toolbar is a table with the following data:

	Actual Value	Oracle date	Oracle date (mm-dd-yyyy)	Oracle date (dd-mm-yyyy)
Patient Initials	Date Informed Consent Signed			
BAF	20110819	19-AUG-11	08-19-2011	19-08-2011
BFD	20110527	27-MAY-11	05-27-2011	27-05-2011
BJD	20110708	08-JUL-11	07-08-2011	08-07-2011
CAF	20110502	02-MAY-11	05-02-2011	02-05-2011

- n Actual value (yyyymmdd) (ex: 20060422)
 - .. Use this when date sort is needed.
- n Oracle Date (dd-mon-yy) (ex: 22-APR-06)
 - .. If used and partial dates exist for the question, then JRreview will show an error message.
 - .. Note: Same format shown in C3D RDC.
- n Oracle Dates (mm-dd-yyyy (ex: 04-22-2006) and dd-mm-yyyy (22-04-2006))
 - .. Allows for date calculations in Excel.
 - .. **Note:** Do not use this format when sorting dates.

Important Reports Considerations

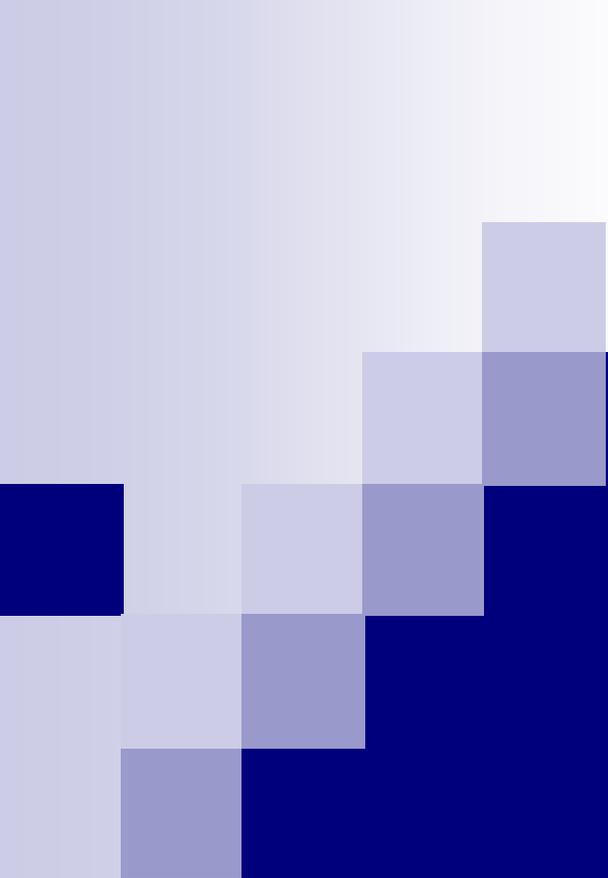
- n When using multiple CRFs in a report, select CRFs in the same chronological order as they would have been filled out according to the protocol schema.
 - For example: Enrollment, Course initiation, AE, Course Assessment, Off-Treatment
- n JReview "knows" how to put together data from different CRFs
 - By patient position and sometimes by course as well.
- n Watch out when combining questions from two or more repeating groups
 - **Results in a Cartesian Product!**
- n Note on reports with Course End Date for patients still on treatment:
 - C3D defaults the current (ongoing) course End Date to "August 15 3501" date.



Module 3 Demo

n DEMO

- Create a Detail Data Listing with questions from different CRFs and using Actual/Decoded value and the various Date Formats.
- Save the report.



JReview Module 4

Filters and Patient Selection Criteria



Module 4

- n JReview Terminology
- n Patient Selection Criteria
- n Filters
- n Demo

JReview Terminology

- n Patient Selection Criteria – Specification of how to subset the patient population based on their data.
Ex: (Female Patients) Gender = "F"
 - Can be saved as part of the report or independently (Patient Subset).
- n Patient Subsets – Saved Patient Selection Criteria! Re-usable across reports.
 - Listed between studies and output specification sections
- n Filter – Criteria specified as part of a report and used to include or excludes data (rows or records).
Ex: AE Grade >= 3
 - Automatically saved with the report.

Note:

- n If you do not use a patient selection criteria, or patient subset, your reports will include data from all the patients for the Study Sites you have access to.

Create a Patient Selection Criteria

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

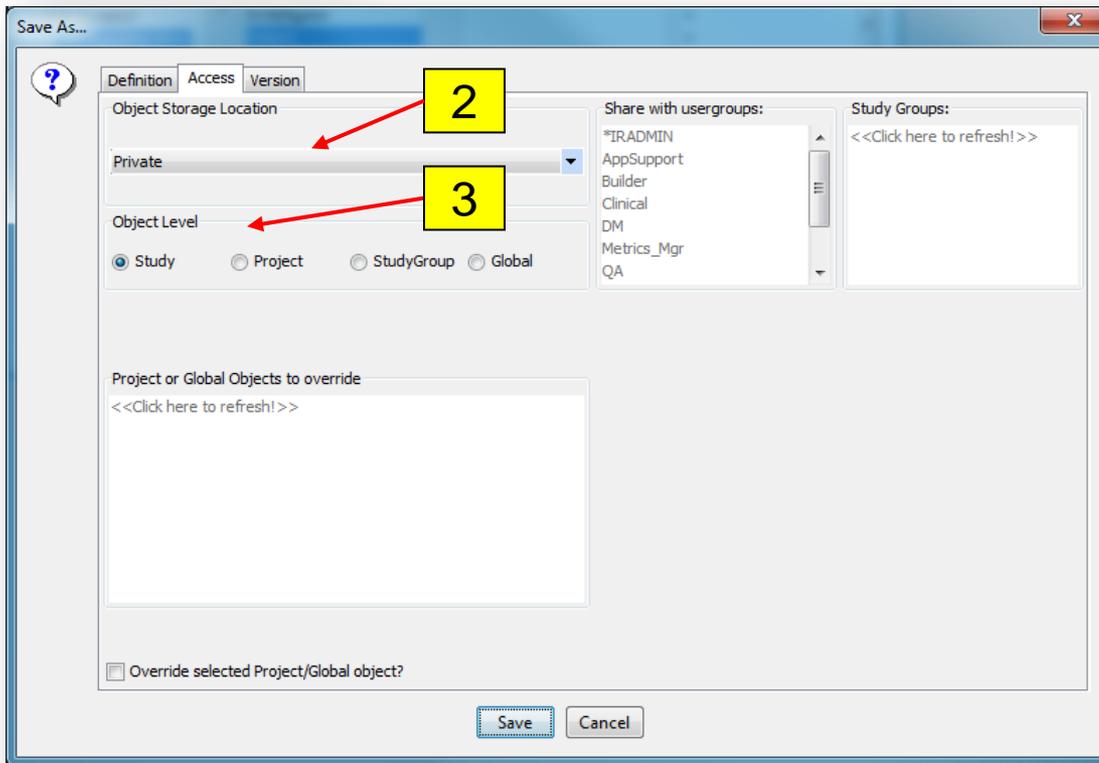
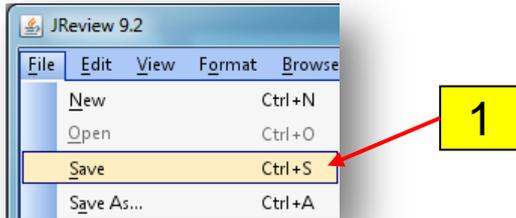
- 1**: DCM/Question Groups list (ENROLLMENT, non-repeating data, etc.)
- 2**: Questions list (Clinical Study Id, Patient Gender_FUL, etc.)
- 3**: Functions list (actual value, decoded value)
- 3**: Operator list (=, <>, <, >, <=, >=)
- 4**: Display Values button
- 5**: Display Values pop-up window showing a table with 'decoded value' and 'Code' columns. The 'Female' row is selected.
- 6**: ADD expression button
- 7**: OK button
- 8**: Update Browsers button

A yellow box labeled 'Selection pop up window' points to the Display Values window.

Select the Patient Selection Criteria window and then:

1. Expand the **DCM** in the **DCM/Question Groups** list and select the **non-repeating data** Question Group;
2. Click on a **Question** to select it;
3. Click on an **Operator**;
4. Click on the **Display Values** button;
 - Window shows up listing values for the selected question
5. Click on the **desired value** to select it;
 - To choose multiple values, hold down ctrl key when selecting values
6. Click on the **ADD expression** button;
7. Click on the **OK** button when done
 - Repeat steps 1-6 to add criterion using other questions.
8. Click on the **Update Browser** button to activate Patient Selection Criteria

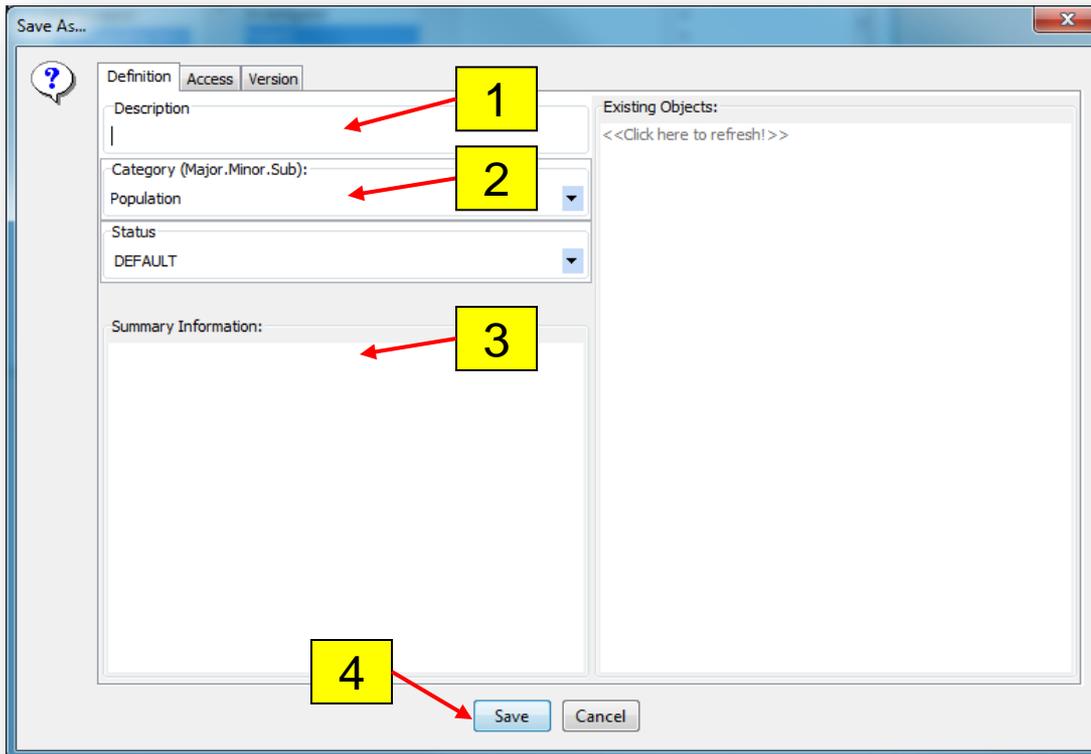
Save a Patient Selection Criteria



Select the Patient Selection Criteria window and then:

1. Select the **File** menu item and then the **Save** menu option.
2. On the **Access** tab, select a **Project Storage Location** drop-down list:
 - a) **Private** – Only you will have access to the saved Patient Selection Criteria.
 - b) **Public** – Everyone with access to the selected study will have access to the saved Patient Selection Criteria.
3. Then select the **Object Level**:
 - a) **Study** – Patient Selection Criteria will only be available to the selected study
 - b) **Project** – Patient Selection Criteria will be available to all the studies associated with the PI (folder that groups the studies.).

Save a Patient Selection Criteria



Then click on the **Definition** tab and:

1. Enter the **Name** of the Patient Selection Criteria being saved in the **Description** area.
2. Select a **Category** from the drop-down list. Category is the folder name where the criteria will be saved. A new Category can be created by typing in a new folder name.
3. Optionally, enter a brief description of the Patient Selection Criteria in the **Summary Information** area.
4. Click on the **Save** button.

Note: You cannot update or delete a Patient Subset that was not created by you.

Saving Patient Selection Criteria with a Report

Save

Definition Access Version

Object Storage Location

Public

Object Level

Study Project StudyGroup Global

Share with usergroups:

*TRADMIN
AppSupport
Builder
Clinical
DM
Metrics_Mgr
QA

Study Groups:

<<Click here to refresh! >>

Store Patient Selection Criteria? Store Required Patient Selection

Project and Global overrides are not available while saving over an existing object

Save Cancel

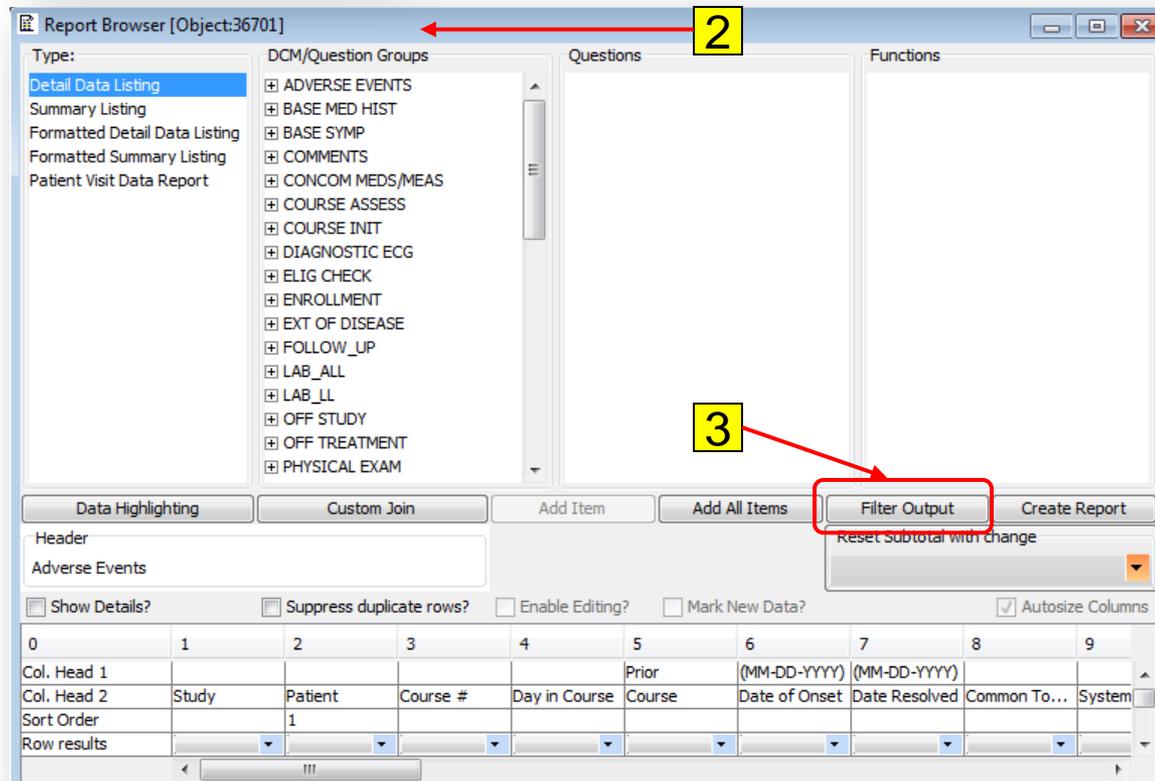
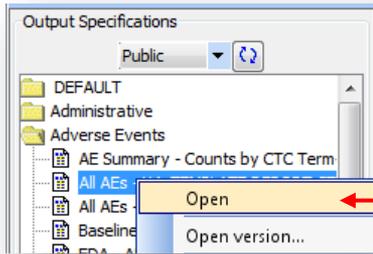
- n While Filters are automatically saved with the Report, a Patient Selection Criteria is not.
- n When saving a Report, check the **Store Patient Selection Criteria?** option on the **Access** tab to save the Criteria as part of the report.
- n Next time the Report is opened or run, the Patient Selection Criteria loads and the report only runs for the patients that satisfied the criteria.



Filter Output

- n Filter Output is a criteria used to select which data from a CRF should be included in the Report's output (undesired rows are not included in the report output)
- n Filter Output is always saved as a part of the report.
- n The Patient Selection Criteria and Filter Output can be used together or individually to meet your needs.

Create and Save a Filter



1. If the Report you want to set the Filter Output is not open, locate the report in the **Output Specification** area, right-click on the report's name and select the **Open** option.
2. If the Report is already open, then select the **Report Browser** window.
3. Click on the **Filter Output** button.

Create and Save a Filter

1. Select a **DCM/Question Group**;

2. Select a **Question**;

3. Select a **Function**;

4. Select an **Operator**;

5. Click on **Display Values** button to show the list of values stored in the database for this study;

6. Click on the desired value to select it;

- To choose multiple values, hold down ctrl key when selecting values

7. Click on the **ADD expression** button;

8. Click on the **OK** button when done;

- Repeat steps 1-6 to add criterion using other questions

9. Click on the **Save Filter** button to enable the filter.

Note: On the **Report Browser** window the **Filter Output** window has now changed to **Filter is On** indicating a filter has been set on the report.

1. Select a **DCM/Question Group**;
 2. Select a **Question**;
 3. Select a **Function**;
 4. Select an **Operator**;
 5. Click on **Display Values** button to show the list of values stored in the database for this study;
 6. Click on the desired value to select it;
 - o To choose multiple values, hold down ctrl key when selecting values 7. Click on the **ADD expression** button;
 8. Click on the **OK** button when done;
 - q Repeat steps 1-6 to add criterion using other questions 9. Click on the **Save Filter** button to enable the filter.
- Note:** On the **Report Browser** window the **Filter Output** window has now changed to **Filter is On** indicating a filter has been set on the report.

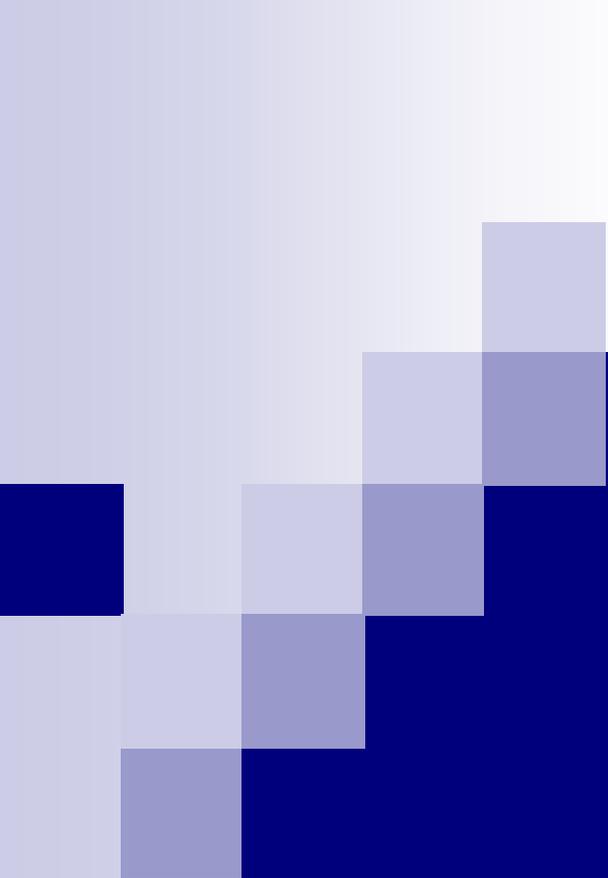
Patient Selection versus Filter

- n Patient Selection Criteria = Patient positions selected
 - .. Ex: Patients with Arm A in Course Initiation CRF. Patients 1, 7 and 22, which have Arm A are selected and report runs only for these Patients.
- n Filter Output = Observation level subset
 - .. Ex: Patient with Serious AEs. Only patients that have at least one Serious AE are selected and report runs only for these Patients.

Module 4 Demo and Exercises

n Demo

- .. Using the previously created report with enrollment and AE questions create the following:
 - n Create a filter for AEs \geq grade 3
 - n Create Patient selection criteria for "Male"
 - n Generate report for "Male" patients with AE \geq grade 3



Questions???