



JReview Training

Peraton, Inc

(March 2018)



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

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

Introduction

- JReview is the new version of I-Review ("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 and Sites
- Java based application
 - Requires the Java Runtime Environment version 1.8.0 later installed.
CCR JReview Reports Instructions/Manual
http://ccrintra.cancer.gov/clin_ops/C3D/iReview_instr.asp
- Vendor's Manual
<https://ccrod.cancer.gov/confluence/download/attachments/72876079/JReview%20User%20Manual%209.2.6.pdf?api=v2>
- CBT Training Manual
<http://octrials-train.nci.nih.gov/CBTsubmenu1.html>
- Contact NCICB for problems/requests
 - 240-276-5541 (Toll free: 888-478-4423) or ncicbiit@mail.nih.gov

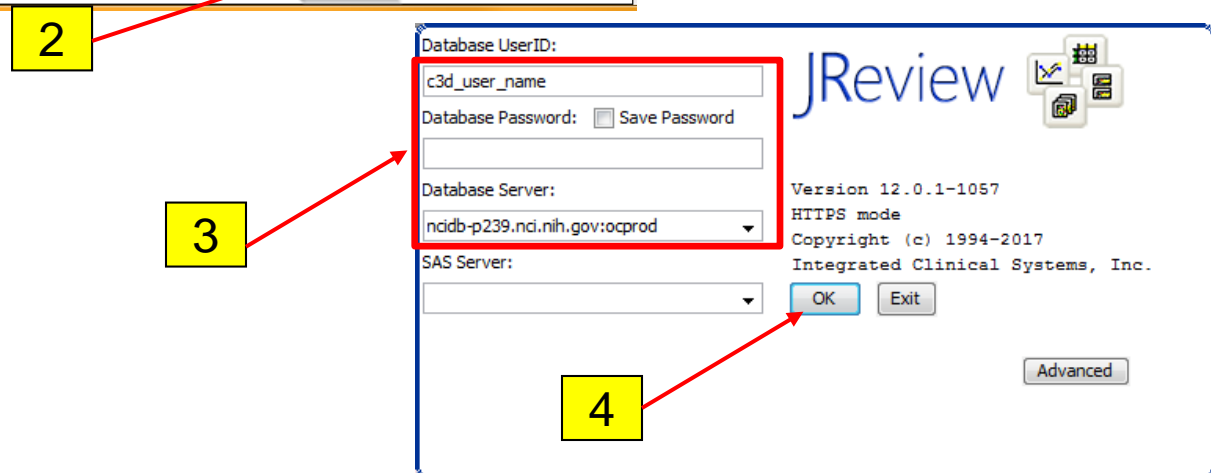
JReview Login

Go to the Login page:

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

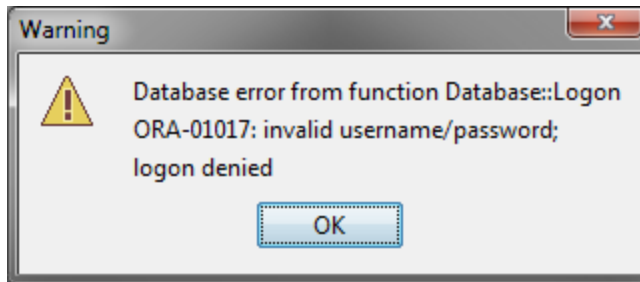


1. Click on the **JReview** button;
2. Click on the **Open** button;
3. Enter your C3D:
 1. **User Name**;
 2. **Password**;
 3. **ncidb-p239.nci.nih.gov:ocprod** for the Database Server (leave SAS Server empty);
4. Click on the **OK** button.

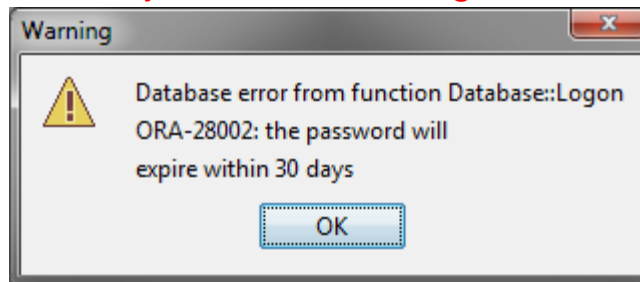


JReview Login

- The following message appears if an invalid C3D account and/or password is used:

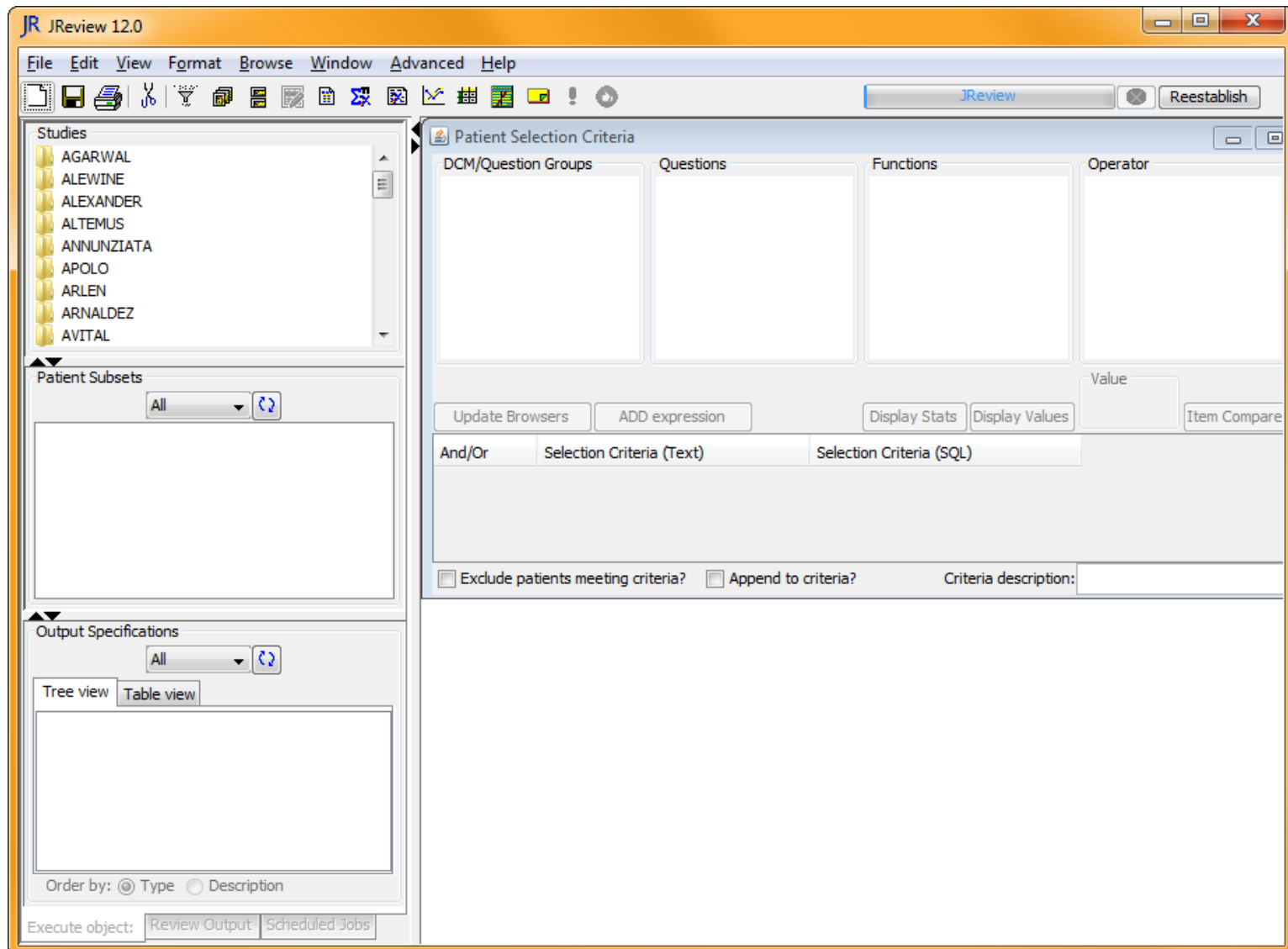


- If your C3D password is about to expire, the warning message below displays when you are logging into JReview saying. **If it is the last day, remember to change the password in C3D, otherwise your account will get locked overnight.**

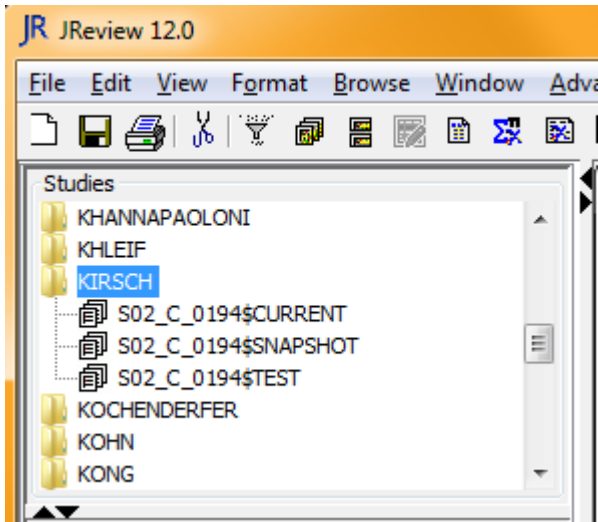


- **Three failed logins attempts will your C3D account just like in C3D RDC. You will have to contact the C3D Help Desk to have your account unlocked.**

JReview Interface



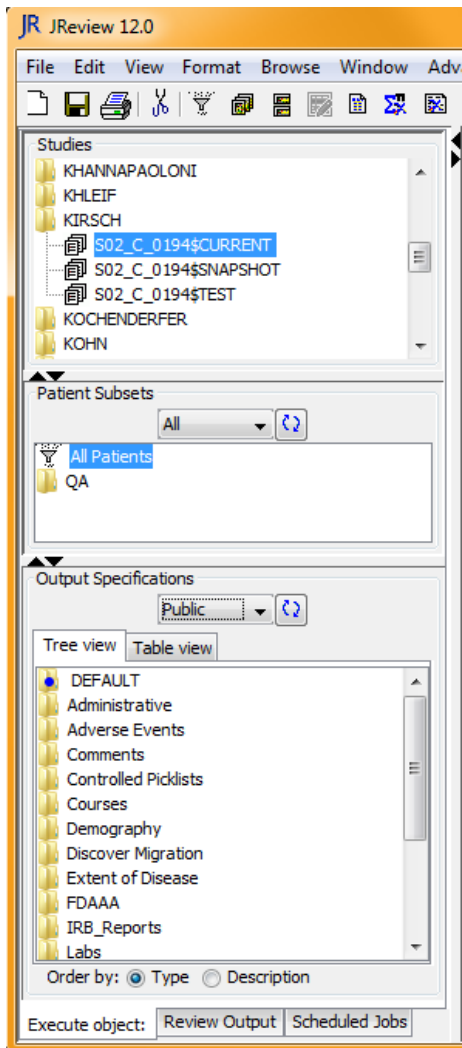
Accessible Studies



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.

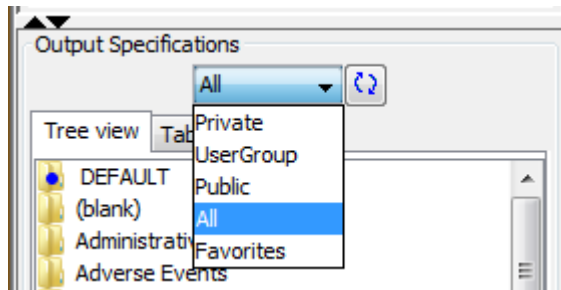
Saved Reports



- 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



- Reports can be saved as **Private** or **Public**.
 - A Private report is only accessible by the user that created it.
- 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.
 - Favorites – Reports marked as Favorites.

Execute a Saved Report

1

2

3

4

Report Output

JReview 12.0

File Edit View Format Browse Window Advanced Help

Studies

- CCR_CTMS_312_B\$SNAPSHOT
- CCR_CTMS_312_B\$TEST
- CCR_CTMS_312_C\$CURRENT
- CCR_CTMS_312_C\$TEST
- CCR_ROS_2011_V1\$CURRENT
- CCR_ROS_2011_V1\$SNAPSHOT
- CCR_ROS_2011_V1\$TEST
- PDMS_CCR\$CURRENT

Patient Subsets

All

All Patients

Output Specifications

Public

Tree view Table view

Template Reports

- Adverse Events - TEMPLATE REPORT
- Adverse Events - Unresolved - TEMPLATE REPORT
- Baseline Medical History -V1 - TEMPLATE REPORT
- Baseline Symptoms - V5 - TEMPLATE REPORT
- Blood Transfusion -V3 - TEMPLATE REPORT
- Chimerism -V3 - TEMPLATE REPORT
- Concomitant Measures -V2 - TEMPLATE REPORT
- Copy of Demographics -V3_AM
- Course Summary - V4 - TEMPLATE REPORT
- Course Summary plus RECIST- V4 - TEMPLATE REPORT

Order by: Type Description

Execute object: Review Output Scheduled Jobs

Patient Selection Criteria - All Patients

Adverse Events - TEMPLATE REPORT - All Patients

Show Filter Refresh

	Study	Site	Patient	Section	Row	Course #	Day in Course
1	CCR_ROS_2011_V1	NCI	1010001	AE1	1	1	376
2	CCR_ROS_2011_V1	NCI	1010001	AE1	2		
3	CCR_ROS_2011_V1	NCI	1010002	AE1	1	1	2
4	CCR_ROS_2011_V1	NCI	1010002	AE1	2		
5	CCR_ROS_2011_V1	NCI	1010003	AE1	1		
6	CCR_ROS_2011_V1	NCI	1010004	AE1	1	-1	-1
7	CCR_ROS_2011_V1	NCI	1010004	AE1	2	1	2
8	CCR_ROS_2011_V1	NCI	1010004	AE1	3	1	2
9	CCR_ROS_2011_V1	NCI	1010004	AE1	4	1	277
10	CCR_ROS_2011_V1	NCI	1010004	AE1	5	1	251
11	CCR_ROS_2011_V1	NCI	1010004	AE1	6	1	188
12	CCR_ROS_2011_V1	NCI	1010004	AE1	7	1	273
13	CCR_ROS_2011_V1	NCI	1010004	AE2	1	1	274
14	CCR_ROS_2011_V1	NCI	1010005	AE1	1		
15	CCR_ROS_2011_V1	NCI	1010006	AE1	1	-1	-32
16	CCR_ROS_2011_V1	NCI	1010006	AE1	2	-1	-29

Operator

Value

Value

Item Compare

description:



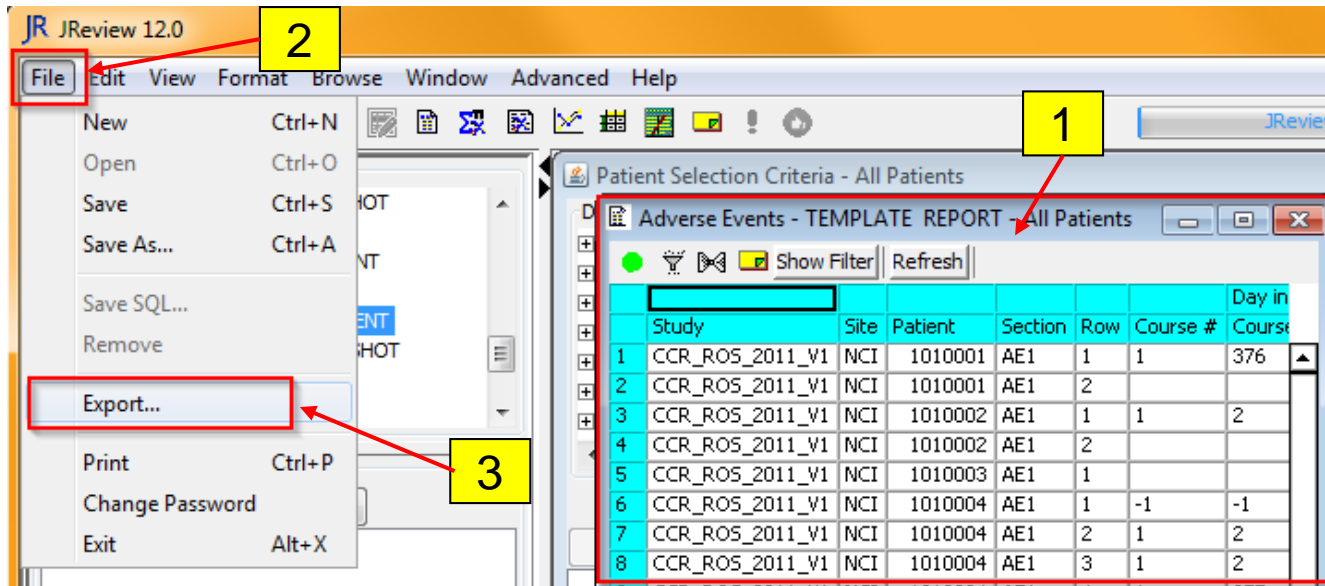
To Execute an Existing Report

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.

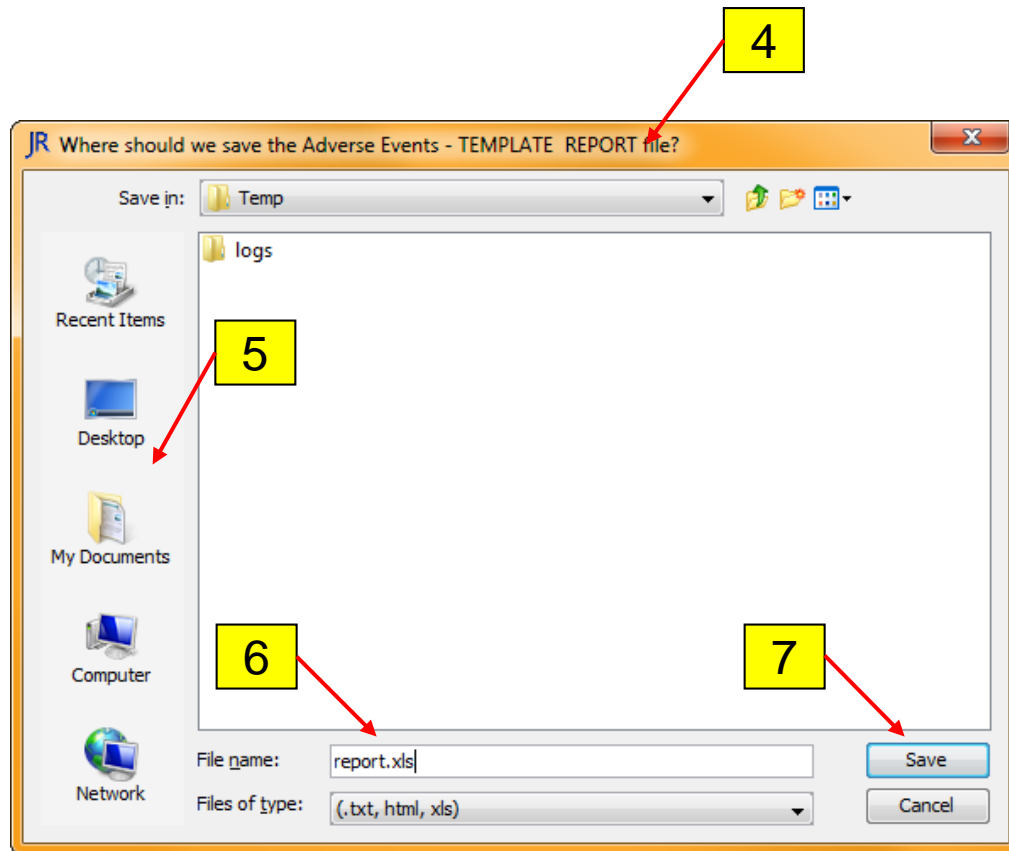
How to Export Reports



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

The screenshot displays the Adobe Acrobat Professional interface with a PDF document open. The document is titled "QA Reports" and contains a section titled "Discrepancy: Discrepancy Type vs Review Status".

Table of Contents (Left Panel):

- Introduction
- General Instructions
 - Help for I-Review
 - Installing I-Review
 - Logging into I-Review
 - User Interface
 - Running Canned Reports
 - Parameterized Canned Reports
 - Failure of Canned Reports
 - User and Study Access Level
 - Modifying Canned Reports & Resaving
 - Extracting Data to MS Excel
 - Types of Reports
- Administrative Reports
- QA Reports
 - Discrepancy: Discrepancy Type vs Rev
 - Description
 - Access
 - Columns
 - Discrepancy: Manually Closed Discrep
 - Discrepancy: Unreviewed Discrepancie
 - Discrepancy: Unreviewed Discrepancie
 - Discrepancies: Univariate Discrepancy
 - Discrepancies: Discrepancies History

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

Check	A	B	Description	C	D	E	F	G	H	I	Total
		Discrepancy Type			CLOSED	IN REVIEW	IRRESOLVABLE	RESOLVED	UNREVIEWED		
1											
2	DCR CTMS 392 R	1-EVENT 1-DCM	Adverse Event duplicate check (AE/DC)								3.00
3			Adverse Event future dates checks (AE)								3.00
4			Adverse Event internal record check (AG)								4.76
5			Adverse Event outcome and date number		28				1		33.63
6			Adverse Event resolve date check (AE/RA)								7.76
7			Adverse Event valid grade check (AE/17)		5						8.13
8			Adverse Event vs Course Initiation check		5						12.18
9			Adverse Event vs Course Initiation date		8		1				16.25
10			Adverse Event vs Lab Toxicity grading cl		22		2	1			39.65
11			Baseline Medical History vs. Init Course		1						1.00
12			Baseline Symptom internal check (BS/CI)								1.00
13											1.00
14											1.00
15											1.00
16											1.00
17											1.00
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91											1.00
92											1.00
93											1.00
94											1.00
95											1.00
96											1.00
97											1.00
98											1.00
99											1.00
100											1.00
Total					272.00	8.00	7.00	5.00			484.00790.00

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 time is not

CCR JReview Manual

- Link to JReview Manual:
https://ccrod.cancer.gov/confluence/download/attachments/72876079/IReview%20Reports_v3.0_manual.pdf?version=1&modificationDate=1319117587187&api=v2
- 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. 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

- DEMO

- Log-in

- Run a Saved Report

- Export output to Excel spreadsheet



JReview Module 2

Modifying Existing Reports



Module 2 Outline

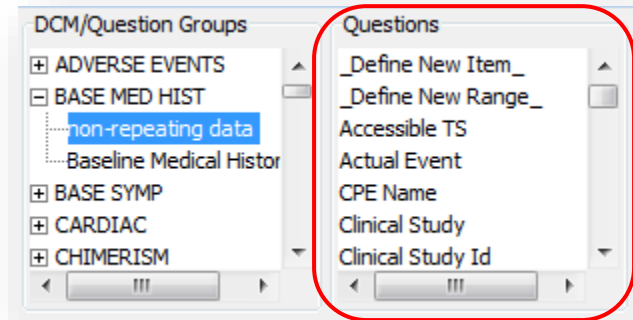
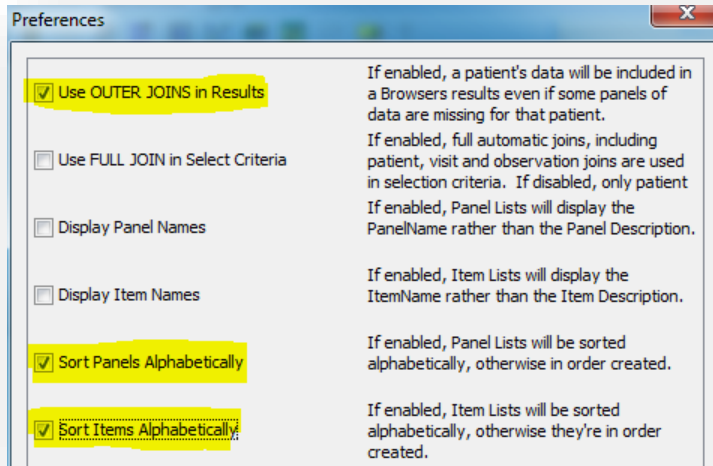
- C3D Terminology
- Setting Recommended Preferences
- Oracle/JReview Relationship
 - JReview and C3D Correlation
 - F1 function
- Open and Modify Saved AE report
- Actual/Decoded, Print change, Sort order
- Save Report
- Demo

C3D Oracle Clinical Terminology

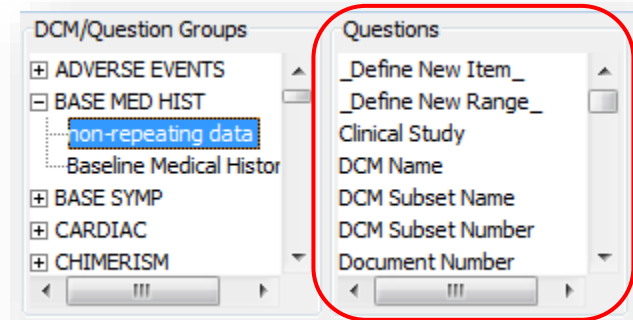
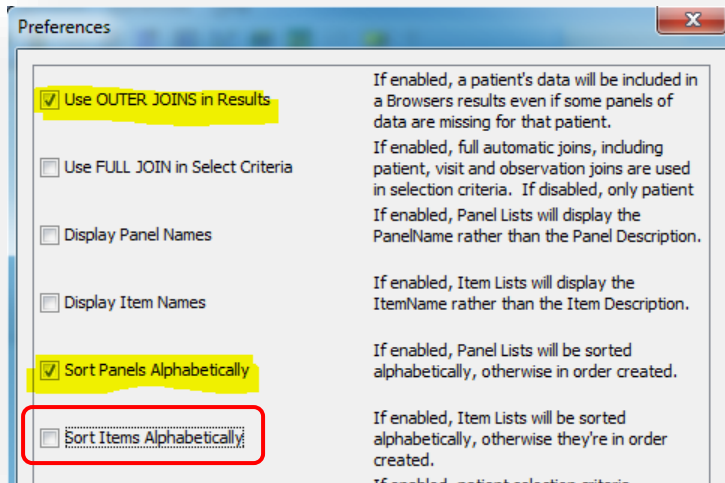
- **DCI** – Data Collection Instrument (i.e. a CRF!)
- **DCM** – Data Collection Module (Section or "Tab" of a CRF.)
- **Question** – a single element of a CRF in which datum ("Response") is entered.
- **Non-repeating Question Group** – A group of Questions that occurs once – ex: Course Initiation CRF.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

Changing Preferences

Default



Recommended



Setting "Preferences"

- Edit JReview Preferences to change the order the **DCM/Question Groups** and **Questions** are listed.
- 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

DCMs

Non-Repeating Group

Repeating Group

Questions

Questions

Patient 1010001 Page 4 (Medhist for Screening) Page 1 of 1, Repeat 6 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
DERMATOLOGIC	N	

File Edit View Format Browse Window Advanced Help

Studies

- CCR_ROS_2011_V1\$CURRENT
- CCR_ROS_2011_V1\$SNAPSHOT
- THERADEX\$CURRENT
- THERADEX\$ROLLSNAP

Patient Selection Criteria - All Patients

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

Questions

- _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

C3D: F1 & Field Help 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 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

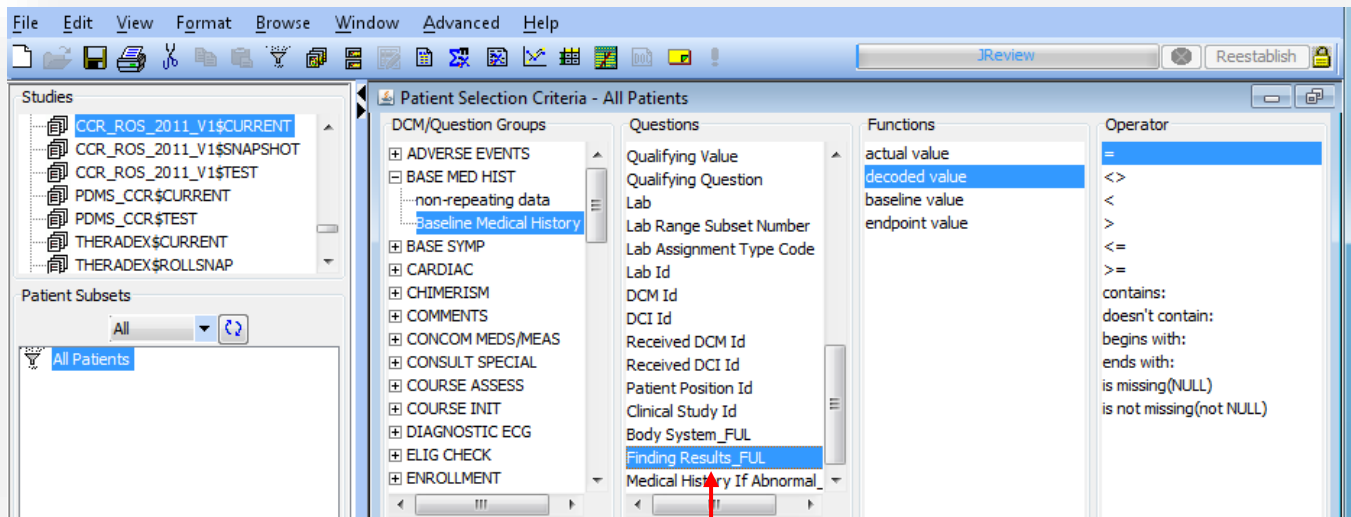
Question Name: NORM_ABNORM_IND
Occurrence Sn: 0
SAS Name: A2213A
Help Text
Default Prompt: Finding Results

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

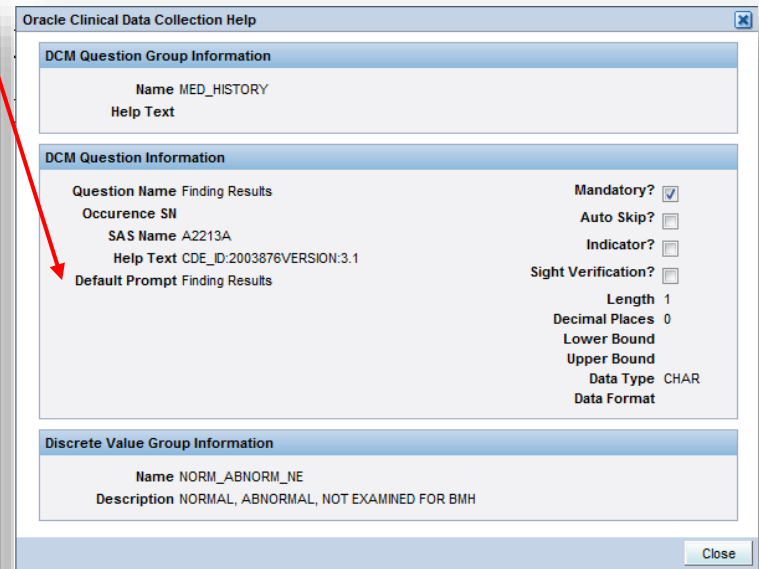
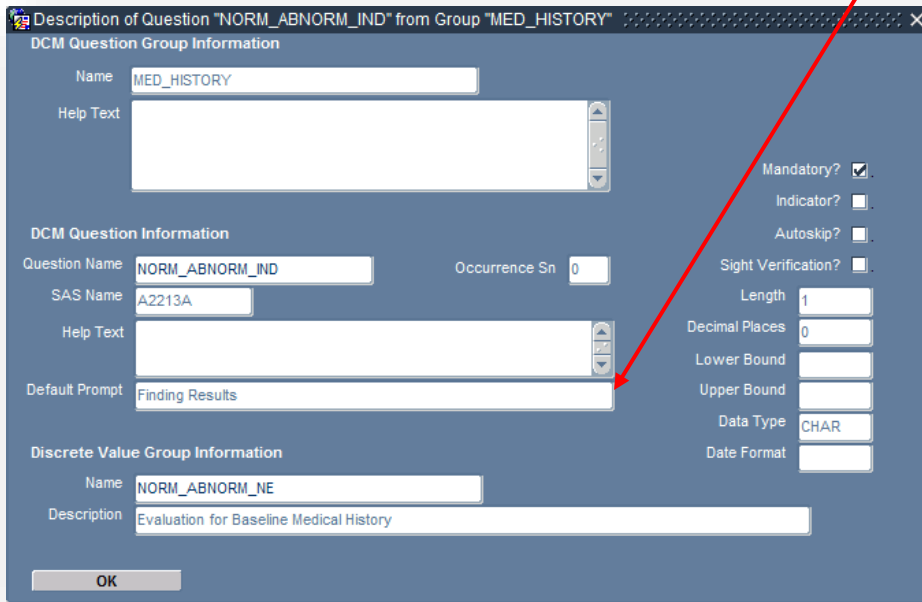
Discrete Value Group Information

Name: NORM_ABNORM_NE
Description: Evaluation for Baseline Medical History

OK



Question's Default Prompt



Open and Modify Reports

Report definition in Report Browser

Right click, then choose open

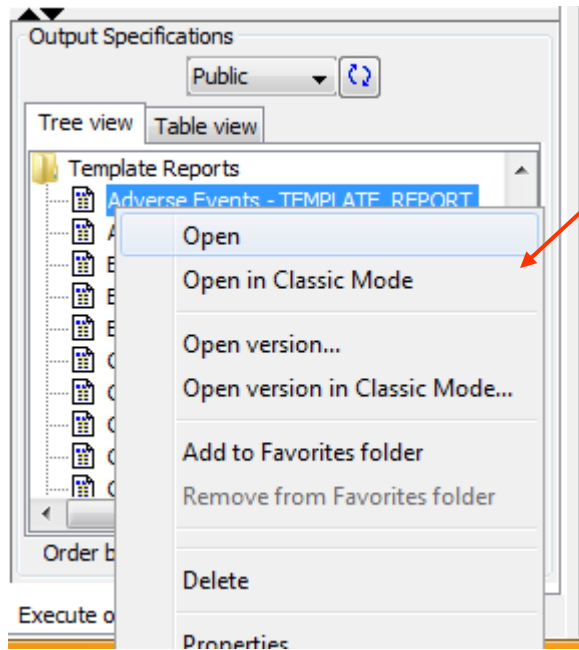
The screenshot shows the JReview 12.0 interface. The 'Report Browser [Object:60502]' window is active, displaying a list of reports under 'Template Reports'. A context menu is open over the 'Adverse Events - TEMPLATE REPORT' report, with the 'Open' option selected. The 'Detail Data Listing' table shows data for the selected report, and the 'General' section shows settings for the report.

	1	2
Col. Head 1		
Col. Head 2	Study	Site
Sort By	1	2
Row Results		
Warn-Low		
Warn-High		
Panic-Low		
Panic-High		
Items	STUDY	INVSITE
Panels	AEAEAE T0,	AEAEAE T0,
Function	actual va...	actual va...

	Study	Site	Patient	Section
1	CCR_RO5_2011_V1	NCI	1010001	AE1
2	CCR_RO5_2011_V1	NCI	1010001	AE1
3	CCR_RO5_2011_V1	NCI	1010002	AE1
4	CCR_RO5_2011_V1	NCI	1010002	AE1
5	CCR_RO5_2011_V1	NCI	1010003	AE1

Name	Value
Direct to Excel?	<input type="checkbox"/>
Enable Editing?	<input type="checkbox"/>
Enable Review Notes?	<input type="checkbox"/>
Heading	Adverse Events - TEMPLATE RE...
Mark New Data?	<input type="checkbox"/>
Suppress duplicate r...	<input type="checkbox"/>

Open and Modify Reports



Right click, then choose open

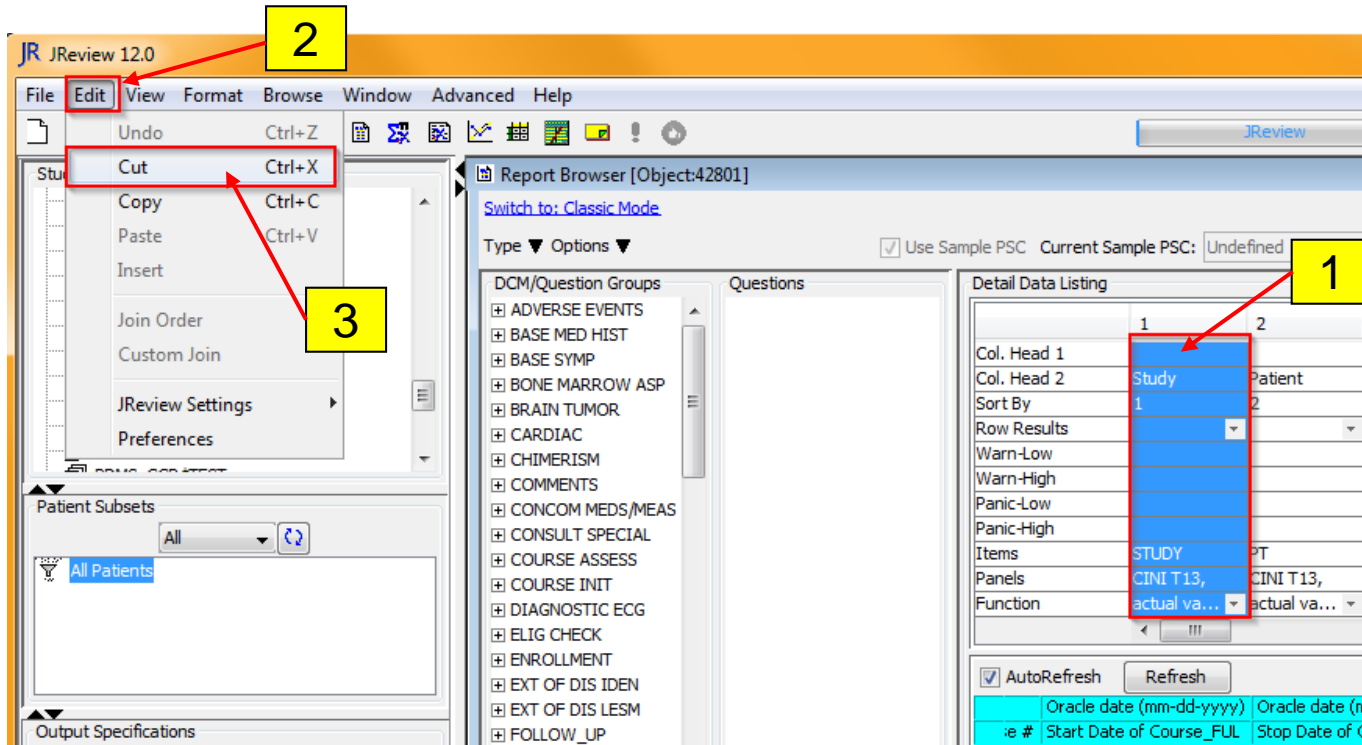
1. Choose **Open in Classic Mode** to open the old interface to edit the report design.
2. Optionally, choose **Open Version** to open a previously saved version




Modifying Saved Reports

- A saved report can be modified to suit your requirements.
- The following changes can be made:
 - Remove **Columns**
 - Rename **Columns Headings**
 - Set **Sort Order**
 - Set **Print Change**
 - Change **Function** (date format, actual/decoded value)
- The modified report can also be saved for later use.

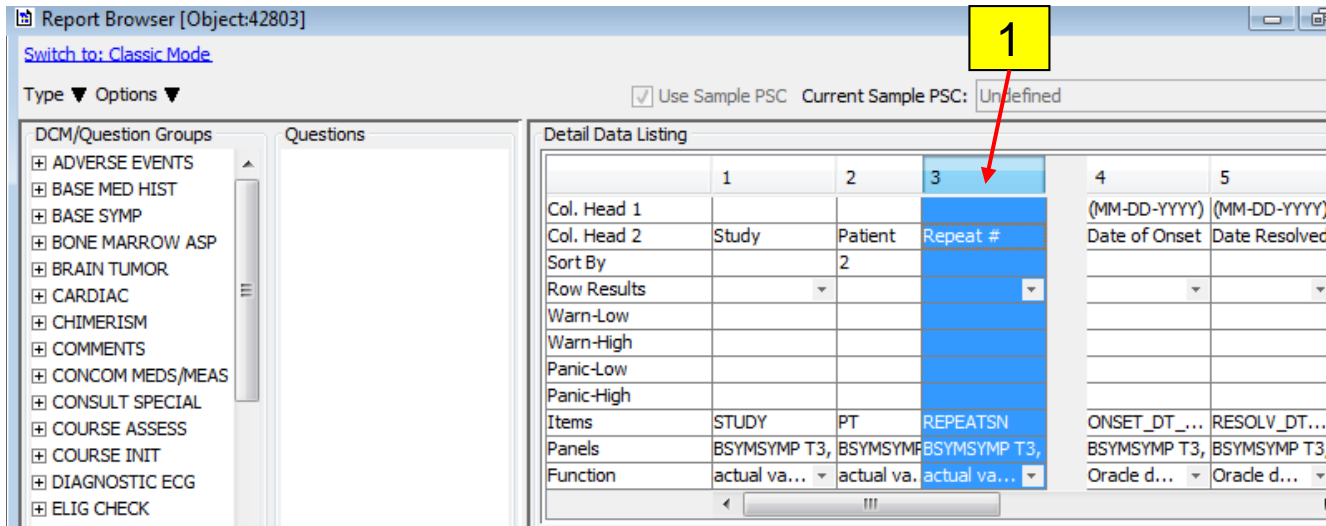
Remove Columns



1. Click on the Column Header 1 or 2 to select/highlight the column
2. Select the **Edit** menu item
3. Select the **Cut** menu option

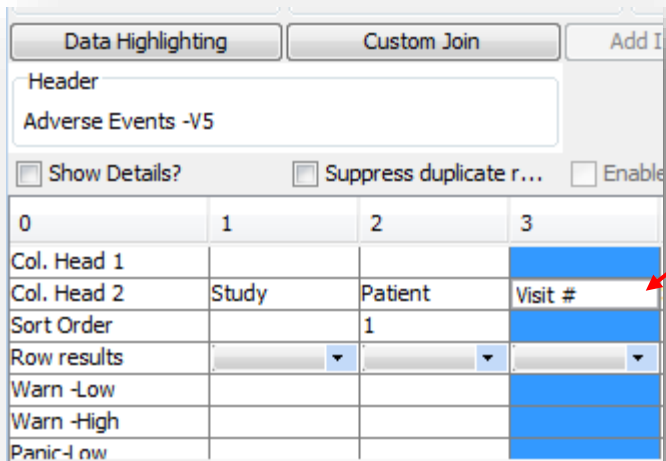
Hint: Use the scissors  on the toolbar instead of steps 2 and 3 to remove the selected column.

Rearrange Report Column Order



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

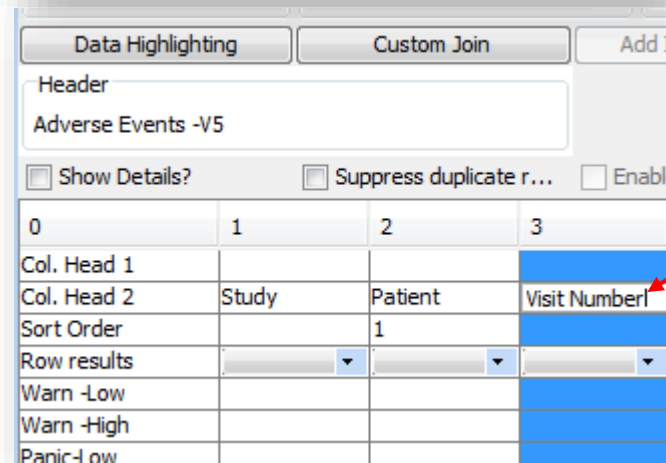
Header
Adverse Events -V5

Show Details? Suppress duplicate r... Enable

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

Setting Sort Order

- 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	2l
Row results		
Warn -Low		

Chosen Order

Patient	Patient Initials
1010001	CDG
1010002	AS
1010003	ROMC
1010004	RJP
1010005	DMB
1010006	DGT

Report Output

- 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	1l
Row results		
Warn -Low		

Chosen Order

Patient	Patient Initials
1010002	AS
1010001	CDG
1010006	DGT
1010005	DMB
1010004	RJP
1010003	ROMC

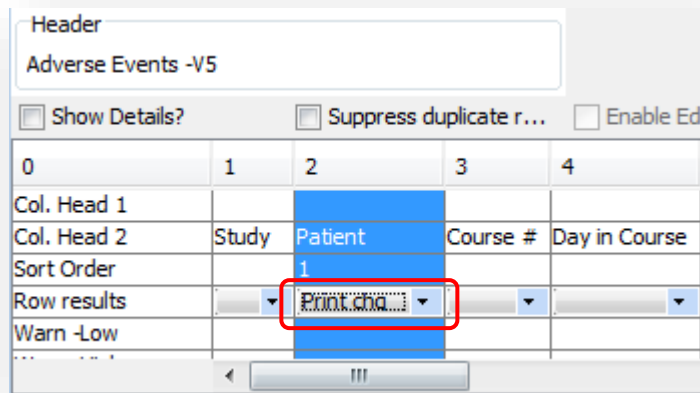
Report Output

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

Print Change Enabled

- 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.
- 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 columns: Study, Patient, Course #, Day in Course, Prior, Course, Date of Onset, and Date Resolved. The 'Patient' column is highlighted with a red box. The data rows show various adverse events for different patients and courses.

Study	Patient	Course #	Day in Course	Prior	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

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

Data Highlighting Custom Join Add

Header
Adverse Events -V5

Show Details? Suppress duplicate r... Enable

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

Adverse Events -V5 - Subset of patients

Show Filter Refresh

Study	Patient	Course #	Day in Course	Prior	(MM-DD-YYYY)	(MM-DD-YYYY)
				Course	Date of Onset	Date Resolved
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

Change Function

- In the “New Mode” Report Designer interface, it is possible to change a question’s function and choose a different date format or toggle between actual/decoded value without the need to remove the question and add it again.

Click on the Function Drop-down

The screenshot shows the 'Report Browser' interface. On the left is a 'DCM/Questi...' sidebar with a list of questions. The main area is titled 'Detail Data Listing' and contains a table with columns 4 and 5. The table headers are '(MM-DD-YYYY)' and '(MM-DD-YYYY)'. The table body contains data for 'Study', 'Patient', and 'Repeat #'. Below the table is a 'Function' dropdown menu that is open, showing options like 'actual value', 'Orade date', and 'Orade date (mm-dd-yyyy)'. A red box highlights the 'actual value' option in the dropdown.

Col. Head 1	4	5
Col. Head 2	peat #	Date of Onset
Sort By		Date Resolved
Row Results		
Warn-Low		
Warn-High		
Panic-Low		
Panic-High		
Items	PEATSN	ONSET_DT_...
Panels	YMSYMP T3,	BSYMSYMP T3,
Function	tual va...	Orade d...

Study	Patient	Repeat #	Calendar Year
1	CCR_ROS_2011_V1	1010001	1
2	CCR_ROS_2011_V1	1010002	1
3	CCR_ROS_2011_V1	1010002	2

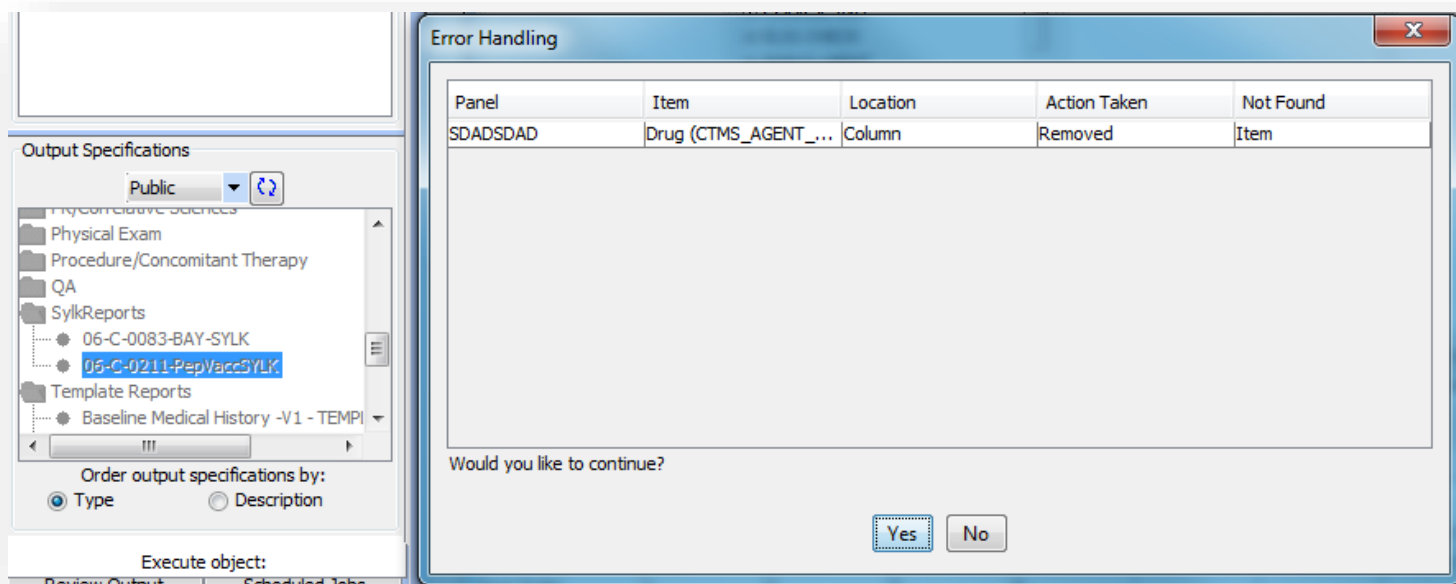
This is a close-up of the function dropdown menu. The 'actual value' option is highlighted with a red box. Other options include 'Orade date', 'Orade date (mm-dd-yyyy)', 'Orade date (dd-mm-yyyy)', 'actual value', 'decoded value', 'baseline value', and 'endpoint value'.

6	7
CTCAE Term	Grade
AE_CTCAEV...	AE_SEV_GD_FUL
BSYMSYMP T3,	BSYMSYMP T3,
actual va...	actual value
	actual value
	decoded value
	baseline value
	endpoint value

Handling a Panel Items Not Found in Saved Reports

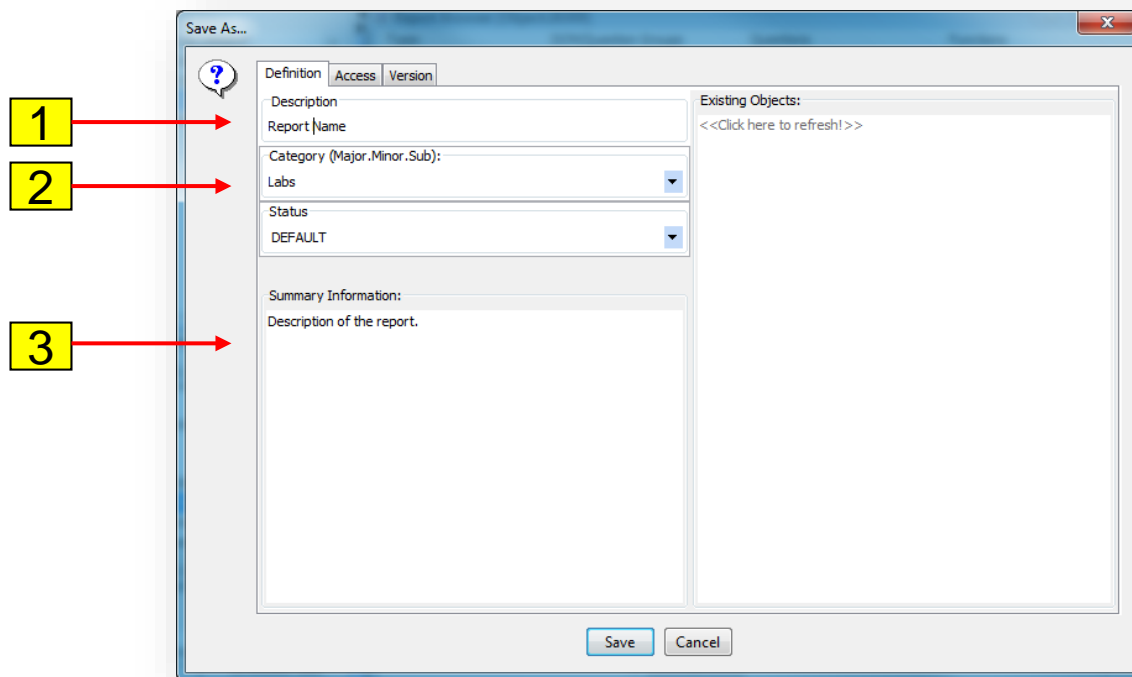
- Some saved reports may contain items (questions) that are not applicable to a study.
- When you try to execute or open such saved report, a warning message (see below) indicates which items are not found. These items are automatically removed.
 - Click **"Yes"** to proceed and load the rest of the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

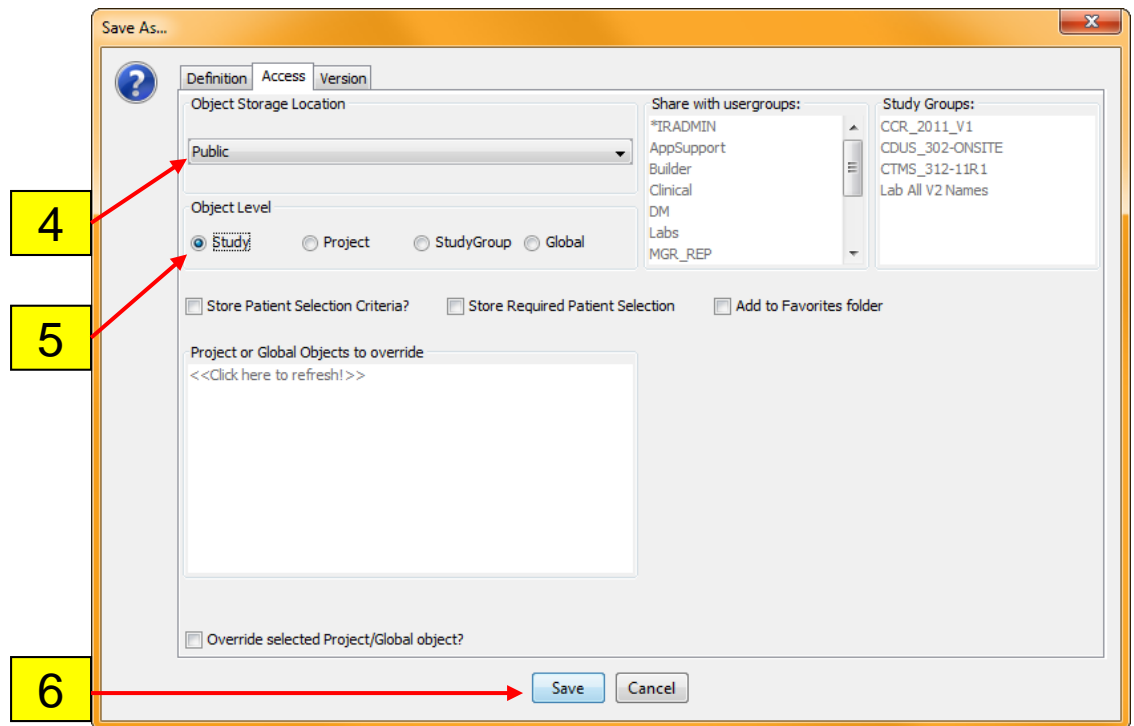
- After making changes to the saved report, you are able to save it as a new report (necessary if you did not create the saved report) or update it (if you created it).
- Click on the **File** menu item and then choose the **Save As** menu option to save the current report definition as a new report. Use the menu item **Save** to update the existing report.
- 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

- 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

■ 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



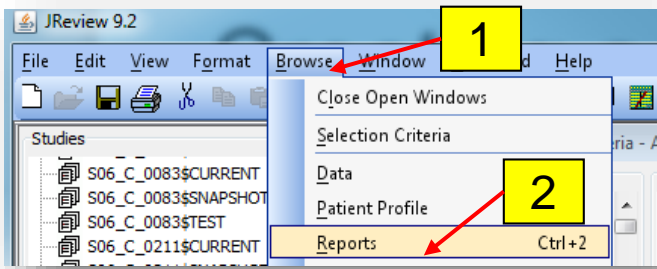
Module 3 Outline

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


Report Browser

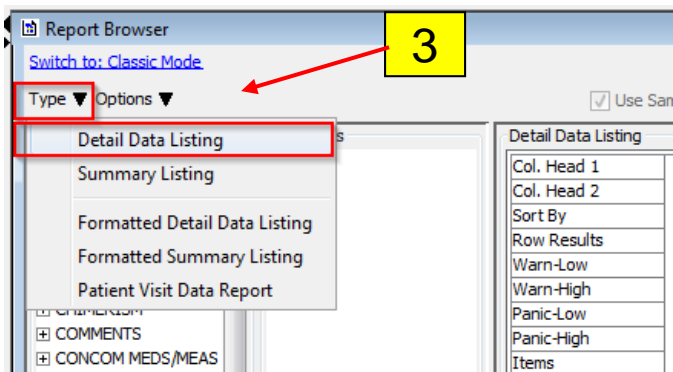
- Report Browser has two basic report types:
 - Detail Data Listing – Lists details of selected questions from one of more CRFs.
 - Summary Data Listing – Allows for displaying counts, averages, minimum and maximum values without the details.
- Output of these reports are shown in a grid layout and can 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



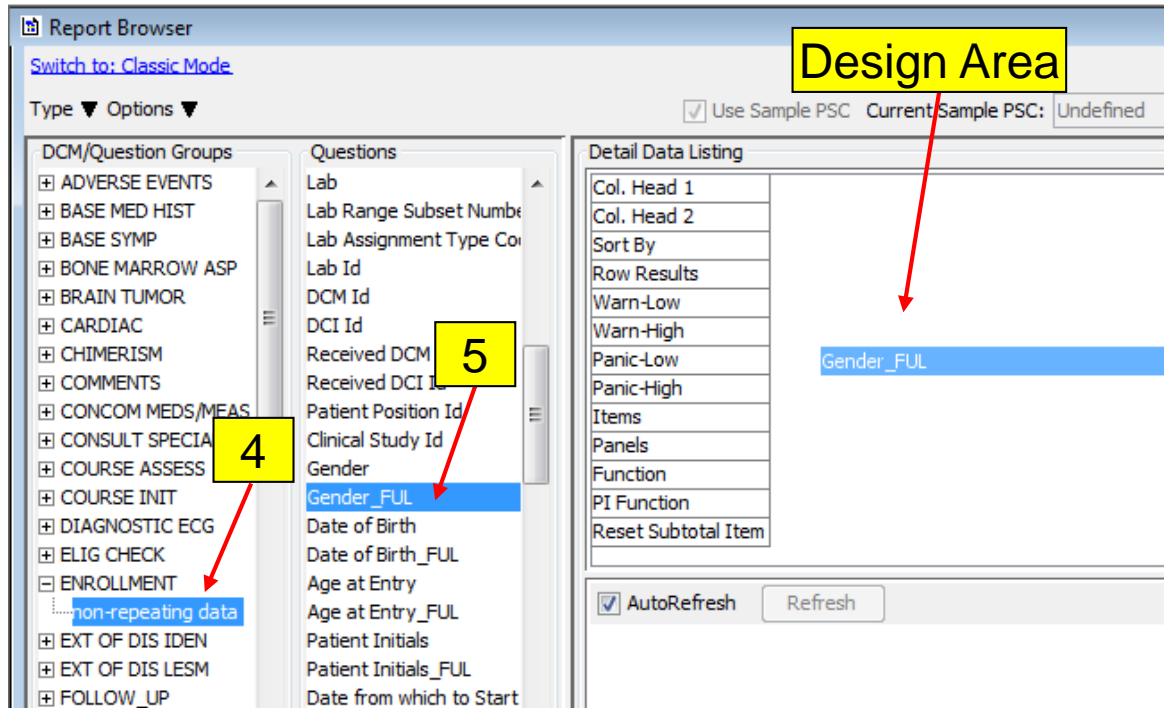
1. Click on the **Browse** menu item;
2. Click on the **Reports** menu option.

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



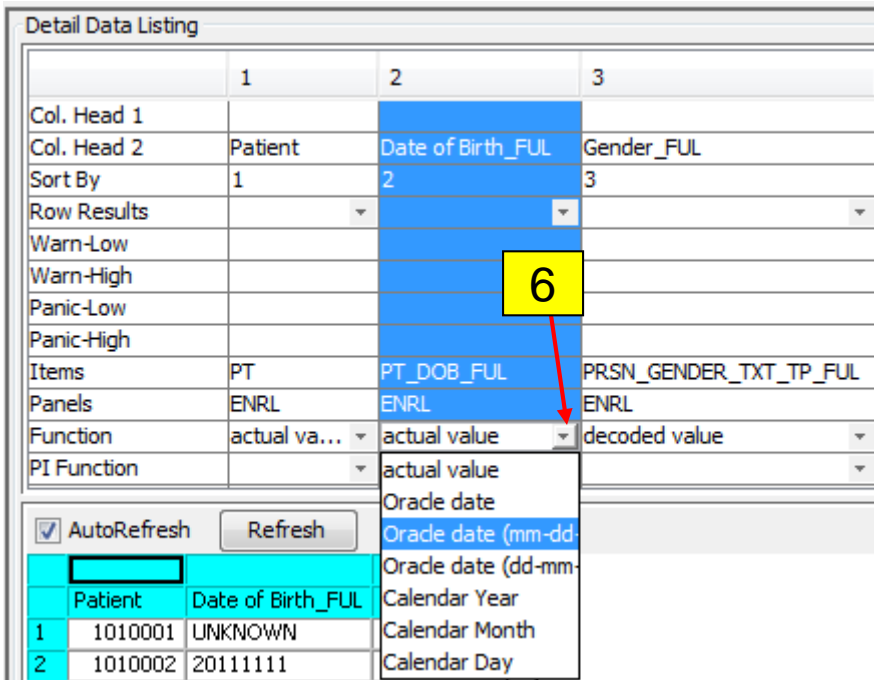
3. Click on the **Type** drop-down, then click on **Detail Data Listing**

Creating a Detail Data Listing Report



4. Expand the **Enrollment** DCM and click on the **non-repeating data** Question Group;
5. Click and drag the desired **Question** to the design area.

Creating a Detail Data Listing Report



Detail Data Listing

	1	2	3
Col. Head 1			
Col. Head 2	Patient	Date of Birth_FUL	Gender_FUL
Sort By	1	2	3
Row Results			
Warn-Low			
Warn-High			
Panic-Low			
Panic-High			
Items	PT	PT_DOB_FUL	PRSN_GENDER_TXT_TP_FUL
Panels	ENRL	ENRL	ENRL
Function	actual va...	actual value	decoded value
PI Function		actual value	

AutoRefresh Refresh

	1	2
	Patient	Date of Birth_FUL
1	1010001	UNKNOWN
2	1010002	20111111

- Optionally, click on the **Function** drop-down and change the date format or actual/decoded value.

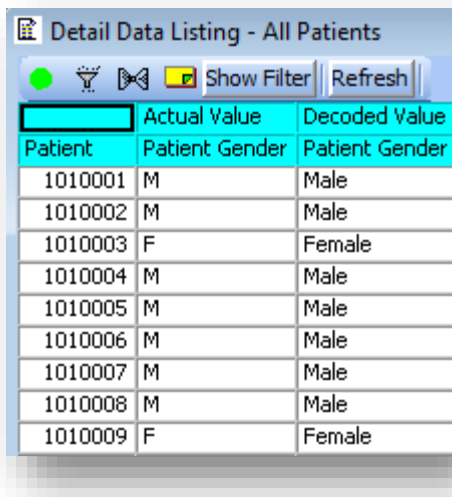
Note:

- Date Questions** have a default **Function** of **Actual Value** which displays in YYYYMMDD Format.
- Questions** that have a Pick-list have a default **Function** of **Decoded Value** which is the description of the pick-list item. Choose **Actual Value** to display the pick-list item code or abbreviation

Hint:

- Uncheck the **AutoRefresh** checkbox if the report's output preview is taking a long time to complete.
- Use the **Refresh** button to manually refresh the report's output preview.

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

- **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 pick lists in C3D.
- JReview selects the decoded value by default.

Date Formats

Detail Data Listing

	1	2	3	4	5
Col. Head 1			Oracle date	Oracle date (mm-dd-yyyy)	Oracle date (dd-mm-yyyy)
Col. Head 2	Patient	Date Informe...	Date Informe...	Date Informed Consent Sig...	Date Informed Consent Sig...
		2	3	4	
Warn-Low					
Warn-High					
Panic-Low					
Panic-High					
Items	FT	CONS_DT_FUL	CONS_DT_FUL	CONS_DT_FUL	CONS_DT_FUL
	ENRL	FNRI	FNRI	FNRI	FNRI
Function	actual va...	actual value	Oracle date	Oracle date (mm-dd-yyyy)	Oracle date (dd-mm-yyyy)
			value	value	value

AutoRefresh Refresh

	Oracle date	Oracle date (mm-dd-yyyy)	Oracle date
Patient	Date Informed Consent Signed_FUL	Date Informed Consent Signed_FUL	Date Informe
1	1010001 20140901	01-SEP-2014	09-01-2014
2	1010002		--
3	1010003 20130505	05-MAY-2013	05-05-2013
4	1010004 19990401	01-APR-1999	04-01-1999

Available Date Functions

Sample Output

- Actual value (yyyymmdd) (ex: 20060422)
 - Use this when date sort is needed.
- 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.
- 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

- 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
- JReview "knows" how to put together data from different CRFs
 - By patient position and sometimes by course as well.
- Watch out when combining questions from two or more repeating groups
 - **Results in a Cartesian Product!**
- 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

■ 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

- JReview Terminology
- Patient Selection Criteria
- Filters
- Demo

JReview Terminology

- 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).
- Patient Subsets – Saved Patient Selection Criteria! Re-usable across reports.
 - Listed between studies and output specification sections
- 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:

- 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 elements highlighted by numbered callouts:

- 1**: DCM/Question Groups list (non-repeating data selected)
- 2**: Questions list (Patient Gender_FUL selected)
- 3**: Operator list (= selected)
- 4**: Display Values button
- 5**: 'Female' value in the Display Values pop-up window
- 6**: ADD expression button
- 7**: OK button
- 8**: Update Browsers button

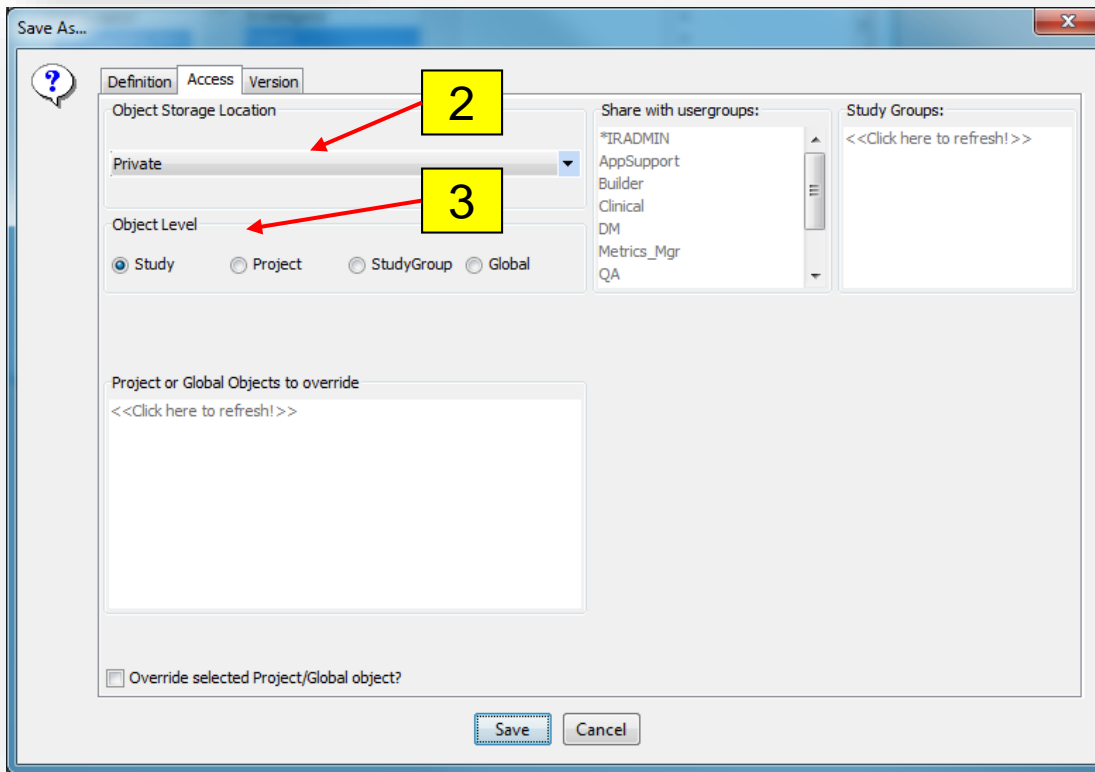
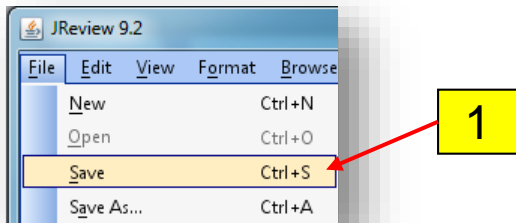
The 'Display Values' pop-up window shows a table with the following data:

decoded value	Code
Female	F
Male	M

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

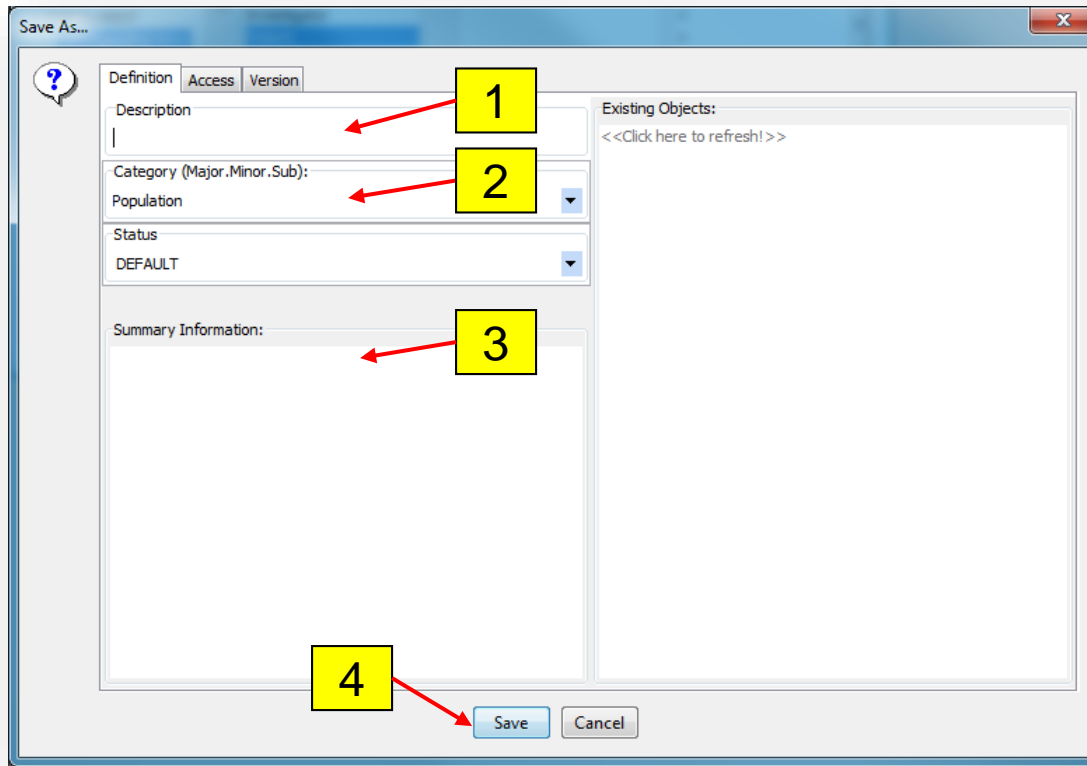
Save a Patient Selection Criteria



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

The screenshot shows a 'Save As...' dialog box with three tabs: 'Definition', 'Access', and 'Version'. The 'Access' tab is active. It contains several sections:

- Object Storage Location:** A dropdown menu set to 'Public'.
- Object Level:** Radio buttons for 'Study' (selected), 'Project', 'StudyGroup', and 'Global'.
- Share with usergroups:** A list of usergroups including *IRADMIN, AppSupport, Builder, Clinical, DM, Labs, and MGR_REP.
- Study Groups:** A list of study groups including CCR_2011_V1, CDUS_302-ONSITE, CTMS_312-11R 1, and Lab All V2 Names.
- Checkboxes:** Three checkboxes are present: 'Store Patient Selection Criteria?' (checked and highlighted with a red box), 'Store Required Patient Selection', and 'Add to Favorites folder'.
- Text Area:** A text area labeled 'Project or Global Objects to override' with the text '<<Click here to refresh!>>'.
- Bottom:** A checkbox for 'Override selected Project/Global object?' and 'Save' and 'Cancel' buttons.

- While Filters are automatically saved with the Report, a Patient Selection Criteria is not.
- When saving a Report, check the **Store Patient Selection Criteria?** option on the **Access** tab to save the Criteria as part of the report.
- 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

- 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)
- 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

Report Browser [Object:60502]
Switch to: Classic Mode
Type ▼ Options ▼ Use Sample PSC Current Sample PSC: Undefined

DCM/Questi... Questions
ADVERSE Disease N S
BASE MEI Disease M S
BASE SYM Disease M S
BONE MA Date of Cor
BRAIN TU Date of Cor
CARDIAC Grade of Hi
CHIMERIS Grade of Hi
COMMENT Date of Dia
CONCOM Date of Dia
CONSULT Date Inform
COURSE Date Inform
COURSE Treatment /
DIAGNOS Treatment /
ELIG CHE Date of Inf
ENROLLM Date of Inf
Extension-rep Informed Co
EXT OF D NI CTMS R
EXT OF D NI CTMS E
FOLLOW_ NI Screeni
INFECTIC NI Age - G
LAB_ALL

Detail Data Listing

	1	2	3	4	5	6
Col. Head 1						
Col. Head 2	Study	Site	Patient	Section	Row	Course #
Sort By	1	2	3	4	5	
Row Results						
Warn-Low						
Warn-High						
Panic-Low						
Panic-High						
Items	STUDY	INVSITE	PT	QUALIFYIN...	REPEATSN	COURS_
Panels	AEAEAE TO,	AEAEAE TO,	AEAEAE TO,	AEAEAE TO,	AEAEAE TO,	AEAEAE
Function	actual va...	actual va...	actual va...	actual va...	actual va...	actual va

AutoRefresh Refresh

Study	Site	Patient	Section	Row	Course #	Day in	Prior	Course AE?	Date of Onset	Date
1	CCR_ROS_2011_V1	NCI	1010002	AE1	1	1	2	N	10-02-2011	10-03
2	CCR_ROS_2011_V1	NCI	1010002	AE1	2			N	01-01-2001	--
3	CCR_ROS_2011_V1	NCI	1010016	AE1	1				11-11-2011	--

Output Filter
Edit... ← 1

Create Report

1. From the Report's Designer window, click on the **Edit** button located in the **Output Filter** area.

Create and Save a Filter

The screenshot shows the JR Output Filter interface with the following components and annotations:

- 1**: DCM/Question Groups pane, with 'Adverse Events' selected.
- 2**: Questions pane, with 'Grade_FUL' selected.
- 3**: Functions pane, with 'decoded value' selected.
- 4**: Operator pane, with '>=' selected.
- 5**: 'Display Values' button in the main interface.
- 6**: 'Severe Adverse Event' value selected in the 'Display Values' dialog.
- 7**: 'ADD expression' button in the 'Display Values' dialog.
- 8**: 'OK' button in the 'Display Values' dialog.
- 9**: 'Save Filter' button in the main interface.

The 'Display Values' dialog box contains the following table:

decoded value	Code
Death Related to Adverse Event	5
Mild Adverse Event	1
Moderate Adverse Event	2
Severe Adverse Event	3

The main interface shows the following filter expression:

```
Adverse Events.Grade_FUL >=Sever... T0.AE_SEV_GD_FUL >='3'
```

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;
 - o Repeat steps 1-6 to add criterion using other questions
 9. Click on the **Save Filter** button to enable the filter.
- Note:** The filter specified is then displayed on the **Output Filter** area.

Patient Selection versus Filter

- 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.
- 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

■ Demo

- 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???