

Highlight of Oracle Clinical Functionality for Validation Edit Checks



Highlight of Oracle Clinical Functionality for Validation Edit Checks

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Purpose

- Provide basic refresher of Question Group Functionality
- Demonstrate the benefits

Agenda

- Review basic procedure execution
- Review functionality specific to the Question Group Level

Functionality Map

OPA (Julie Lavoie - OPSSLAVOLJ02 at OCP02 on 22-SEP-2010)

Action Edit Move Clear Data Query Special Help Window

Maintain Study Validation Procedure (Study: A3921114)

Alias	DCM	DCM Domain	DCM Question Group	Aggregate?	Primary Refer?	Event Range		Sort Order		First/Last Event Only	Single Repeat Only?	Create Place Holder?	Correlate With			Qualifying Expression	Where Clause Extension
						First	Last	Event	Extension				Alias	Event	Qualif. Quest		
A				<input type="checkbox"/>	<input checked="" type="checkbox"/>			RDCM.VISIT_NI	RES.REPEA		<input type="checkbox"/>	<input type="checkbox"/>					
B				<input type="checkbox"/>	<input type="checkbox"/>			RDCM.VISIT_NI	RES.REPEA		<input type="checkbox"/>	<input checked="" type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					
				<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>					

Back Save Questions Correlating Questions Custom Code

Aggregate Function	Lag Depth	Include Null in Lag?
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

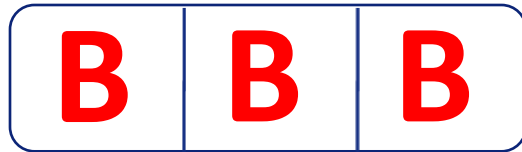
Short Alias for Question Group
Record: 1/2

Anatomy of a Basic Procedure Execution

Records for A Alias



Records for B Alias



Number of
executions
per patient: = 9



Execute Procedure Detail Line

Anatomy of a Basic Procedure (Cont'd)

- 100 patients x 10 records x 10 records
= executed 10,000 times.

As you can see, without using any of OC's built-in functionality, discrepancy checks take a **serious** efficiency hit...

Qualifying Expression

- **Qualifying Expression as a filter.**
 - Limits the processing of data based on any Procedure Question Group question
 - “A.WEIGHT_RAW < 200”

The screenshot shows a software interface with a table. The table has four columns: 'Correlate With', 'Qualif. Quest', 'Qualifying Expression', and 'Where Clause Extension'. The 'Qualifying Expression' column is highlighted with a red rounded rectangle. The table contains several rows of empty input fields. The interface also includes a 'Correlate With' label and a right-pointing arrow above the table.

Correlate With ----->	Qualif. Quest	Qualifying Expression	Where Clause Extension
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		

Where Clauses

- Work in conjunction with Qualifying Expression.
- SQL expression which limits the records retrieved by the procedure on key fields.
 - “RDCM.RECEIVED_DCM_ID = A.RECEIVED_DCM_ID”

The screenshot shows a software interface with a table. The table has four columns: 'Correlate With', 'Qualif. Quest', 'Qualifying Expression', and 'Where Clause Extension'. The 'Where Clause Extension' column is highlighted with a red rounded rectangle. The table contains several rows, each with a checkbox in the 'Qualif. Quest' column and empty text boxes in the other columns. The interface also includes a 'Correlate With' label and a right-pointing arrow above the table.

Correlate With	Qualif. Quest	Qualifying Expression	Where Clause Extension
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		
	<input type="checkbox"/>		

Creating Placeholders

- Creates a null record so that a DCM Question Group which is missing (null) can be evaluated in a procedure. For use in procedures looking for missing data.
 - Ex. **B\$HAS_DATA = 'N'**
 - For example, “Completed the study” and yet was never randomized.
 - A = Subject Summary
 - B = Randomization (Create placeholder is selected)
 - If no Randomization page is collected, B will have no data.

The screenshot shows a data entry form with three columns: 'First/Last Event Only', 'Single Repeat Only?', and 'Create Placeholder?'. The 'Create Placeholder?' column is highlighted with a red box. The second row in this column has a checked checkbox.

First/Last Event Only	Single Repeat Only?	Create Placeholder ?
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

Possible Data

Protocol ID: <input type="text"/>	Center: <input type="text"/>	Subject ID: <input type="text"/>
Visit: <input type="text"/>	Date of Visit: <input type="text" value="01-JAN-2001"/> (dd-MMM-yyyy)	Page: <input type="text"/>

CONCOMITANT DRUG TREATMENT - FOR OTHER THAN PRIMARY DIAGNOSIS:

NONE

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date

(dd-MMM-yyyy): 04-APR-2004

Stop Date

(dd-MMM-yyyy): 05-MAY-2005

Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date

(dd-MMM-yyyy): 01-JAN-2001

Stop Date

(dd-MMM-yyyy): 06-JUN-2006

Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date

(dd-MMM-yyyy): 07-JUL-2007

Stop Date

(dd-MMM-yyyy): 08-AUG-2008

Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date

(dd-MMM-yyyy): 09-SEP-2009

Stop Date

(dd-MMM-yyyy): 10-OCT-2010

Ongoing

Repeat 1

Repeat 2

Repeat 3

Repeat 4

Single Repeat

- First repeat of the first qualified record
- For multiple repeats are collected on the page and it is desired to evaluate only one.
 - For example, 12 discrepancies vs. 1

The screenshot shows a data entry form with three columns: 'First/Last Event Only', 'Single Repeat Only?', and 'Create Place Holder?'. The 'Single Repeat Only?' column is highlighted with a red box. The 'Create Place Holder?' column has a checked checkbox in the second row.

First/Last Event Only	Single Repeat Only?	Create Place Holder ?
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

Example

Protocol ID:	Center:	Subject ID:
<input type="text"/>	<input type="text"/>	<input type="text"/>
Visit:	Date of Visit:	Page:
<input type="text"/>	<input type="text" value="01-JAN-2001"/> (dd-MMM-yyyy)	<input type="text"/>

CONCOMITANT DRUG TREATMENT - FOR OTHER THAN PRIMARY DIAGNOSIS:

NONE

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 04-APR-2004 Stop Date (dd-MMM-yyyy): 05-MAY-2005 Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 01-JAN-2001 Stop Date (dd-MMM-yyyy): 06-JUN-2006 Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 07-JUL-2007 Stop Date (dd-MMM-yyyy): 08-AUG-2008 Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 09-SEP-2009 Stop Date (dd-MMM-yyyy): 10-OCT-2010 Ongoing

Check if the Visit Date is before Screening:

- **Without** Single Repeat Checked, evaluates on every retrieved repeat. Firing once per repeat.
- **With** Single Repeat checked, evaluates only once. Firing only once.

Repeat 1

Repeat 2

Repeat 3

Repeat 4

Sort Order

- Log style events with multiple repeats
 - For instance, Concomitant medication or Dosing Records.
 - Sort Order Extension of “START_DATE ASC” evaluates each date in the order of earliest date to latest.
 - Combined with Single Repeat, Evaluates the earliest dose against Study Start

<----- Sort Order ----->

Event	Extension	First/Last Event Only
RDCM.VISIT_NI	RES.REPEA	
RDCM.VISIT_NI	RES.REPEA	

Sort Order

Protocol ID:	Center:	Subject ID:
<input type="text"/>	<input type="text"/>	<input type="text"/>
Visit:	Date of Visit:	Page:
<input type="text"/>	<input type="text" value="01-JAN-2001"/> (dd-MMM-yyyy)	<input type="text"/>

CONCOMITANT DRUG TREATMENT - FOR OTHER THAN PRIMARY DIAGNOSIS:

NONE

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): Stop Date (dd-MMM-yyyy): Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): Stop Date (dd-MMM-yyyy): Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): Stop Date (dd-MMM-yyyy): Ongoing

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): Stop Date (dd-MMM-yyyy): Ongoing

Order evaluated:

01-JAN-2001

04-APR-2004

07-JUL-2007

09-SEP-2009

Repeat 1

Repeat 2

Repeat 3

Repeat 4

Ex. checking the earliest Concomitant Drug Treatment against the first study dose.

Event Ranges

- Narrows the scope to only particular events.
 - For example, DAY1 would be entered for “First” and DAY26 would be entered as the parameter for “Last”.

The screenshot shows a data entry form with two main sections. The first section, titled "<----- Event Range ----->", contains two columns: "First" and "Last". The second section, titled "<----- Sort O", contains a column labeled "Event". The "Event" column has two rows with the text "RDCM.VISIT_NI". The "Event Range" section is highlighted with a red rounded rectangle.

<----- Event Range ----->		<----- Sort O
First	Last	Event
<input type="text"/>	<input type="text"/>	RDCM.VISIT_NI
<input type="text"/>	<input type="text"/>	RDCM.VISIT_NI
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

First/Last Event Only

- Similar to Single Repeat with Sort Order.
- For log style records that contain only a single repeat.
- For example, Last dose event recorded before End of Study or first dose to Study Start.

The screenshot shows a data entry interface with a table and a checkbox column. The table has three columns: 'Event', 'Extension', and 'First/Last Event Only'. The 'Event' column contains 'RDCM.VISIT_NI' in the first two rows, followed by empty cells. The 'Extension' column contains 'RES.REPEA' in the first two rows, followed by empty cells. The 'First/Last Event Only' column contains empty text boxes for all rows. To the right of the table is a column of checkboxes labeled 'Single Repeat Only?'. A red box highlights the 'First/Last Event Only' column.

<----- Sort Order ----->			Single Repeat Only?
Event	Extension	First/Last Event Only	<input type="checkbox"/>
RDCM.VISIT_NI	RES.REPEA		<input type="checkbox"/>
RDCM.VISIT_NI	RES.REPEA		<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

Aggregate

- Retrieve summarized response data for a subject.
- By default, the aggregation will be performed across all visits, subevents, qualifying values, and QG repeats.
- Can be limited using the Event Range and/or Where Clause Extension.
- Aggregate functions available are:
 - **Maximum:** The highest value.
 - **Minimum:** The lowest value.
 - **Sum:** A running total.
 - **Average:** The average of all specified responses.
 - **Count:** The number of specified responses collected.

The screenshot shows a software interface with a table. The table has three columns: 'Report?', 'Aggregate Function', and 'Include Lab Range?'. The 'Aggregate Function' column is highlighted with a red rounded rectangle. The table contains 10 rows, each with a checkbox in the 'Report?' column, an empty text box in the 'Aggregate Function' column, and a checkbox in the 'Include Lab Range?' column. The interface is light gray with a blue header bar.

Example of Aggregate and Event Ranges

Check: Difference between Maximum recorded weight and the weight at Screening is more than 10%

Visit: Date of Visit:
(dd-MMM-yyyy)

VITAL SIGNS:

NOT DONE

Weight: LB KG
 Height: IN CM
 Temperature: F C

Position: SITTING
 Blood Pressure: / mmHg
Systolic Diastolic
 Heart Rate: beats/minute
 Respiratory Rate: resp/minute

Waist Circumference:

IN CM

Event Range on the A Alias is from WEEK1 to UNPLANNED and on the B Alias from SCREENING to SCREENING

Visit: Date of Visit:
(dd-MMM-yyyy)

VITAL SIGNS:

NOT DONE

Weight: LB KG
 Height: IN CM
 Temperature: F C

Position: SITTING
 Blood Pressure: / mmHg
Systolic Diastolic
 Heart Rate: beats/minute
 Respiratory Rate: resp/minute

Waist Circumference:

IN CM

Lag Variables - A\$STOP_DATE\$L1

Retrieve the previous n responses to a question

- **Lag Depth:** the number of previous responses to store.
- **Include Null in Lag:** Similar to the 'Create Placeholder' functionality.

Lag Depth	Include Null in Lag?	Aggregate Lag Function
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

Example of Lag

Protocol ID:	Center:	Subject ID:
<input type="text"/>	<input type="text"/>	<input type="text"/>
Visit:	Date of Visit:	Page:
<input type="text"/>	01-JAN-2001 (dd-MMM-yyyy)	<input type="text"/>

Check: Start Date is before the previous Stop Date

Using Lag Depth of 1

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NONE

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 04-APR-2004	Stop Date (dd-MMM-yyyy): 05-MAY-2005	<input type="checkbox"/> Ongoing
--	---	----------------------------------

Repeat 1

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 01-JAN-2001	Stop Date (dd-MMM-yyyy): 06-JUN-2006	<input type="checkbox"/> Ongoing
--	---	----------------------------------

Repeat 2

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 07-JUL-2007	Stop Date (dd-MMM-yyyy): 08-AUG-2008	<input type="checkbox"/> Ongoing
--	---	----------------------------------

Repeat 3

Drug Name (Generic preferred but use brand name for combination product):

TYLENOL

Start Date (dd-MMM-yyyy): 09-SEP-2009	Stop Date (dd-MMM-yyyy): 10-OCT-2010	<input checked="" type="checkbox"/> Ongoing
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Repeat 4

Conclusion

- Use of Innate Functionality:
 - Reduces record retrieval and processing time
 - Reduces the amount of programming errors
 - Overall saves time

Questions?

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