

Using the Aggregate Functionality when Programming Validation and Derivation Procedures



Using the Aggregate Functionality when Programming Validation and Derivation Procedures

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Purpose

- Provide a guideline on using the Aggregate Function when programming Edit Checks

Agenda

- What is the Aggregate Function?
- Benefits
- Aggregate Function Types
- Calculation Example
- Data Comparison Example
- Aggregate Lag Function Example
- Pitfalls
- Summary
- Questions

What is the Aggregate Function?

Functionality of Validation/Derivation Procedures that allow more efficient programming when in need of mathematical calculations or data retrieval



Benefits of the Aggregate Function

- Avoids the need for custom code in order to perform...
 - Mathematical Operations
 - Counts
 - Numerical or Date Comparisons
- Aggregate Lag Function allows for use of function for a number of sequential occurrences of a question
- Creates easy references during programming

Aggregate Function Types

- Calculations
 - AVG
 - SUM
 - COUNT
- Data Comparisons
 - MAX
 - MIN
- Combinations
 - AVG, MAX, SUM
- Aggregate Lag Function

Calculations (Average)

Specification: Average Systolic BP is not between 70 and 180

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Definitions

Procedure Name	Domain	Version	Status	Exec Context	Description	Category	Ver 3.1 Style?	Lab Range Dependent?
TEST_AGGREGATE_AVG	TEST_ARS	0	P	ON-LINE/DCM	Average Systolic BP not between 70 and 180	1-EVENT 1-DCM	<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"/>

Exit Save Change Study Q-Grps Details Sys Vars User Vars Custom Code

Calculations (Average)

Aggregate Function for the question must be selected

Question Name	Occ #	DCM Derived Question?	Report?	Aggregate Function	Include Lab Range?	Include Thesaurus terms?	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
VTLS_SYS_BP	0	<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"/>	<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

Calculations (Average)

Beyond just the Average Function, the MAX, MIN, SUM, and COUNT Functions are also available

The screenshot shows a software interface for defining procedure questions. A dialog box titled "Procedure Questions for Alias A" is open, displaying a list of aggregate functions. A yellow callout box highlights the text "Custom Combinations can be manually entered" over the "Question Name" field. Another yellow callout box highlights "Length Restriction of 15" over the function list. The function list includes MIN, MAX, SUM, COUNT, AVG, MIN, MAX, and AVG. The MAX and SUM rows are highlighted with a red box. To the right of the list is a table with columns for "Lag Depth", "Include Null in Lag?", "Aggregate Lag Function", and "Include Current Event in Aggregate Lag?".

Question Name	Rel_CodeList_value_...	Description	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
VT			<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	MIN	Minimum	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	MAX	Maximum	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	SUM	Sum	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	COUNT	Count	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	AVG, MIN, MAX	Average, Minimum, Maximum	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
	AVG	Average	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>

Calculations (Average)

The selected Average Aggregate Function will populate in the Aggregate Function field

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Questions for Alias A

Question Name	Occ #	DCM Derived Question ?	Report?	Aggregate Function	Include Lab Range?	Include Thesaurus terms?	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
VTLS_SYS_BP	0	<input type="checkbox"/>	<input type="checkbox"/>	AVG	<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"/>		<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>

Back Save

Calculations (Average)

Setup the Remainder of the Aliases

Use same Question Group that was used for Aggregate Alias

Filter Primary Alias to occur at to Last Event only

Maintain Study Validation Procedure (Study: TEST_ARS)

Question Groups for TEST_AGGREGATE_AVG

Alias	DCM	DCM Domain	DCM Question Group	Aggregate?	Primary Refer?	Event Range		Sort Order		First/Last Event Only	Single Repeat Only?	Create Place Holder?
						First	Last	Event	Extension			
A	VITALS	TEST_ARS	VITALS	<input checked="" type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
B	VITALS	TEST_ARS	VITALS	<input type="checkbox"/>	<input checked="" type="checkbox"/>			RDCM.VISIT_NI	RES.REPEA	LAST	<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"/>						<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



Calculations (Average) – Procedure Execution

Execution Path of Procedure with Aggregate Alias

Aggregate Alias
Records



Perform Aggregate Calculation

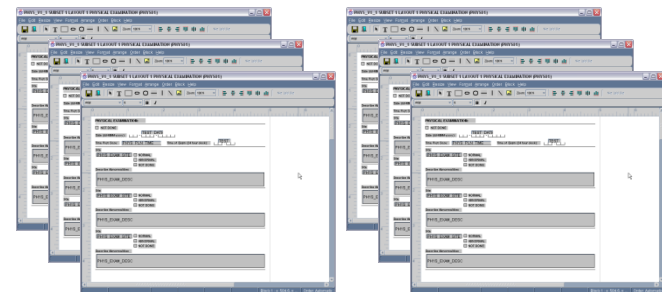


Primary Alias
Record



Existing
Records

Create Discrepancy if expression in Detail is true



Calculations (Average) – Procedure Execution

Execution Path of Procedure with Aggregate Alias

Aggregate Alias
Records

--	--	--

Calculate Average



= 69.5

Primary Alias
Record

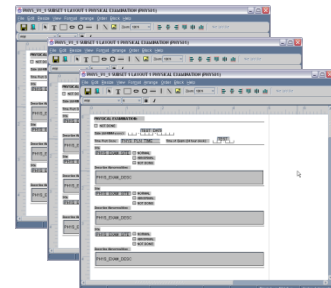
--	--	--

Existing
Records

Create Discrepancy if expression in Detail is true

69

70



PREMIER
RESEARCH

Calculations (Average)

Review of the output file shows the execution path of the procedure

```
Processing Patient: A100  
A.VTLS_SYS_BP$AV = 69.5
```

Average is 69.5 as expected

```
B.VISIT_NUMBER = 2  
B.DCM_DATE = 20010101  
B.REPEAT_SN = 1  
B.VTLS_ND = DONE
```

```
Discrepancy found for Detail 1 - Average Systolic BP is not between 70 and 180
```

Discrepancy is created as per detail logic

Data Comparison (Max)

Specification: Last Dosing Date on Dosing Page is after Last Dosing Date on End of Study Page

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Definitions

Procedure Name	Domain	Version	Status	Exec Context	Description	Category	Ver 3.1 Style?	Lab Range Dependent?
TEST_AGGREGATE_MAX	TEST_ARS	0	P	ON-LINE/DCM	Last Dosing Date on Dosing Page after Last Dosing Date on E	1-EVENT 1-DCM	<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"/>

Exit Save Change Study Q-Grps Details Sys Vars User Vars Custom Code

Data Comparison (Max)

Aggregate Alias: Dosing DCM used for Dosing Page collection

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Questions for Alias A

Question Name	Occ #	DCM Derived Question?	Report?	Aggregate Function	Include Lab Range?	Include Thesaurus terms?	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
DOSE_DATE	0	<input type="checkbox"/>	<input type="checkbox"/>	MAX	<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"/>		<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>

Select MAX as the Aggregate Function

Back Save

Data Comparison (Max)

Expression Logic:

A.DOSE_DATE\$MX > B.LAST_DOSE_DATE

Maintain Study Validation Procedure (Study: TEST_ARS)

Details for Procedure TESTAggregate_MAX

Order#	Cont if Discrep?	Cont at Detail#	Test Not Null only?	Failure Type	Description	Expression
1	<input checked="" type="checkbox"/>		<input type="checkbox"/>	NORMAL	Last Dosing Date on Dosing Page after Last Dosing Date on End of Study Page	A.DOSE_DATE\$MX > B.LAST_DOSE_DATE
	<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 Variables

Data Comparison (Max)

Data Entry Results in the Following

Baseline Visit

Visit 3

Visit 4

Dosing
Page

Doc#	R00101	Visit Name	R01Z001	DCI Date	01/01/2011
Study Name	R0C_TRAN2	Visit#	01	DCI Time	
Patient	R001001	Subevent#	0	Status	Created
Site	R0C_T01E1	DCI ShortName	DOSING	Investigator	R0C_T01E1
DCI Name	DOSING RECORD	Is Blank	<input checked="" type="checkbox"/>		

DOSING RECORD
 NOT DONE
Start Date: _____ Stop Date: _____
Reason for Dose Change: _____

01 - JAN - 2011

Doc#	R00201	Visit Name	R01Z001	DCI Date	05/05/2011
Study Name	R0C_TRAN2	Visit#	02	DCI Time	
Patient	R001001	Subevent#	0	Status	Created
Site	R0C_T01E1	DCI ShortName	VITALS	Investigator	R0C_T01E1
DCI Name	VITALS	Is Blank	<input checked="" type="checkbox"/>		

VITAL SIGNS
 NOT DONE
Weight: _____ LBS KG
Height: _____ IN CM
Temperature: _____ F C
Pulse: _____

DOSING RECORD
 NOT DONE
Start Date: _____ Stop Date: _____
Reason for Dose Change: _____

05 - MAY - 2011

Doc#	R00301	Visit Name	R01Z001	DCI Date	05/01/2011
Study Name	R0C_TRAN2	Visit#	03	DCI Time	
Patient	R001001	Subevent#	0	Status	Created
Site	R0C_T01E1	DCI ShortName	DOSING	Investigator	R0C_T01E1
DCI Name	DOSING RECORD	Is Blank	<input checked="" type="checkbox"/>		

DOSING RECORD
 NOT DONE
Start Date: _____ Stop Date: _____
Reason for Dose Change: _____

01 - MAY - 2011

End of
Study Page

Doc#	R00401	Visit Name	R01Z001	DCI Date	05/04/2011
Study Name	R0C_TRAN2	Visit#	04	DCI Time	
Patient	R001001	Subevent#	0	Status	Created
Site	R0C_T01E1	DCI ShortName	DOSING	Investigator	R0C_T01E1
DCI Name	DOSING RECORD	Is Blank	<input checked="" type="checkbox"/>		

DOSING RECORD
 NOT DONE
Start Date: _____ Stop Date: _____
Reason for Dose Change: _____

04 - MAY - 2011



Latest Dosing Date

05 - MAY - 2011

Data Comparison (Max)

Execution and Review of the output file yields the following:

Max Date is May 5th, 2011 as expected

Processing Patient: A95
A. DOSE_DATE\$MX = 20110505

B. VISIT_NUMBER = 7
B. DCM_DATE = 20010101
B. REPEAT_SN = 1

B. EOS_LAST_DOSE_DATE = 20110504
Discrepancy found for Detail 1 - Last Dosing Date on Dosing Page after Last Dosing

**Procedure creates discrepancy as expected as
Max Dosing Date is after Date of Last Dose**

Aggregate Lag Function (What is it?)

- Similar to Aggregate function but for a set number of sequential occurrences of a question
- Records must be a specific number of events/occurrences sequentially prior to the current compared question creating a 'lag' effect

Aggregate Lag Function

Specification: Average Heart Rate > 100 over last three visits

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Definitions

Procedure Name	Domain	Version	Status	Exec Context	Description	Category	Ver 3.1 Style?	Lab Range Dependent?
TEST_AGGREGATE_LAG	TEST_ARS	0	P	ON-LINE/DCM	Heart Rate Average greater than 100 over last three visits	1-EVENT 1-DCM	<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"/>

Exit Save Change Study Q-Grps Details Sys Vars User Vars Custom Code

Aggregate Lag Function

Only a single Alias is required to program this procedure

Ensure that the Aggregate function checkbox is NOT checked

Maintain Study Validation Procedure (Study: TEST_ARS)

Question Groups for TESTAggregate_LAG

Alias	DCM	DCM Domain	DCM Question Group	Aggregate?	Primary Refer?	Event Range		Sort Order		First/Last Event Only	Single Repeat Only?	Create Place Holder?
						First	Last	Event	Extension			
A	VITALS	TEST_ARS	VITALS	<input type="checkbox"/>	<input checked="" 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"/>
				<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 Lag Function

Configuring questions for the aggregate lag function is completed differently

Maintain Study Validation Procedure (Study: TEST_ARS) for Alias A

Question Name	Occ #	Question ?	Report?	Aggregate Function	Include Lab Range?	Include Thesaurus terms?	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
VTLS_HEART_RATE	0	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2	<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"/>
		<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

Select the Heart Rate Question

Update the Lag Depth

Select the Aggregate LAG Function

Aggregate Lag Function

Note: Despite only being able to select one option from the LOV, multiple functions can be manually entered

Select the Average Aggregate Lag Function

The screenshot shows a software interface for maintaining study validation procedures. The main window is titled "Maintain Study Validation Procedure (Study: TEST_ARS)" and displays "Procedure Questions for Alias A". A table lists questions with columns for Occ #, DCM Derived, Question?, Report?, Aggregate Function, Include Lab Range?, Include Thesaurus terms?, Lag Depth, Include Null in Lag?, Aggregate Lag Function, and Include Current Event in Aggregate Lag?. The first row shows "VTLS_HEART_RATE" with Occ # 0, Lag Depth 2, and an empty Aggregate Lag Function field.

An "Aggregate Lag Function" dialog box is open, showing a search field and a list of functions. The "AVG" function is highlighted with a red box.

Ref_Codelist_Value_...	Description
MIN	Minimum
MAX	Maximum
SUM	Sum
COUNT	Count
AVG MIN MAX	Average Minimum,Maximum
AVG	Average

Aggregate Lag Function

Depending on the lag depth, this step is optional

Check 'Include Current Event in Aggregate Lag?'

Maintain Study Validation Procedure (Study: TEST_ARS)

Procedure Questions for Alias A

Question Name	Occ #	DCM Derived Question ?	Report?	Aggregate Function	Include Lab Range?	Include Thesaurus terms?	Lag Depth	Include Null in Lag?	Aggregate Lag Function	Include Current Event in Aggregate Lag?
VTLS_HEART_RATE	0	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2	<input type="checkbox"/>	AVG	<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"/>		<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

Aggregate Lag Function

Programming of the Expression Logic

Referencing aggregate lag variables through the F9 feature is recommended

Maintain Study Validation Procedure (Study: TEST_ARS)

Details for Procedure TEST_AGGREGATE_LAG

Order#	Cont if Discrep?	Cont at Detail#	Test Not Null only?	Failure Type	Description	Expression
1	<input checked="" type="checkbox"/>		<input type="checkbox"/>	NORMAL	Heart Rate Average greater than 100 over last three vitals sign visits	
	<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 Variables

Aggregate Lag Function

Naming convention = Alias\$QuestionName\$AggregateSuffix

Referencing aggregate function variables through the F9 feature is recommended

The screenshot displays the 'Maintain Study Validation Procedure' window. On the left, a list of 'Variable Name' entries is shown, with four instances of '\$VTLS_HEART_RATE' highlighted in red boxes. The main area contains three 'Editor' windows, each showing a variable name with an aggregate function suffix: '\$VTLS_HEART_RATE\$AV', '\$VTLS_HEART_RATE\$L1', and '\$VTLS_HEART_RATE\$L2'. To the right of these editors, three yellow callout boxes point to the respective variable names: 'Heart Rate Average', 'Heart Rate Lag 1 Variable', and 'Heart Rate Lag 2 Variable'. The bottom of the window features buttons for 'Back', 'Select', 'DVG', 'QG Vars', and 'Std Vars'.

Aggregate Lag Function

Expression Logic = A\$VTLS_HEART_RATE\$AV > 100

Maintain Study Validation Procedure (Study: TEST_ARS)

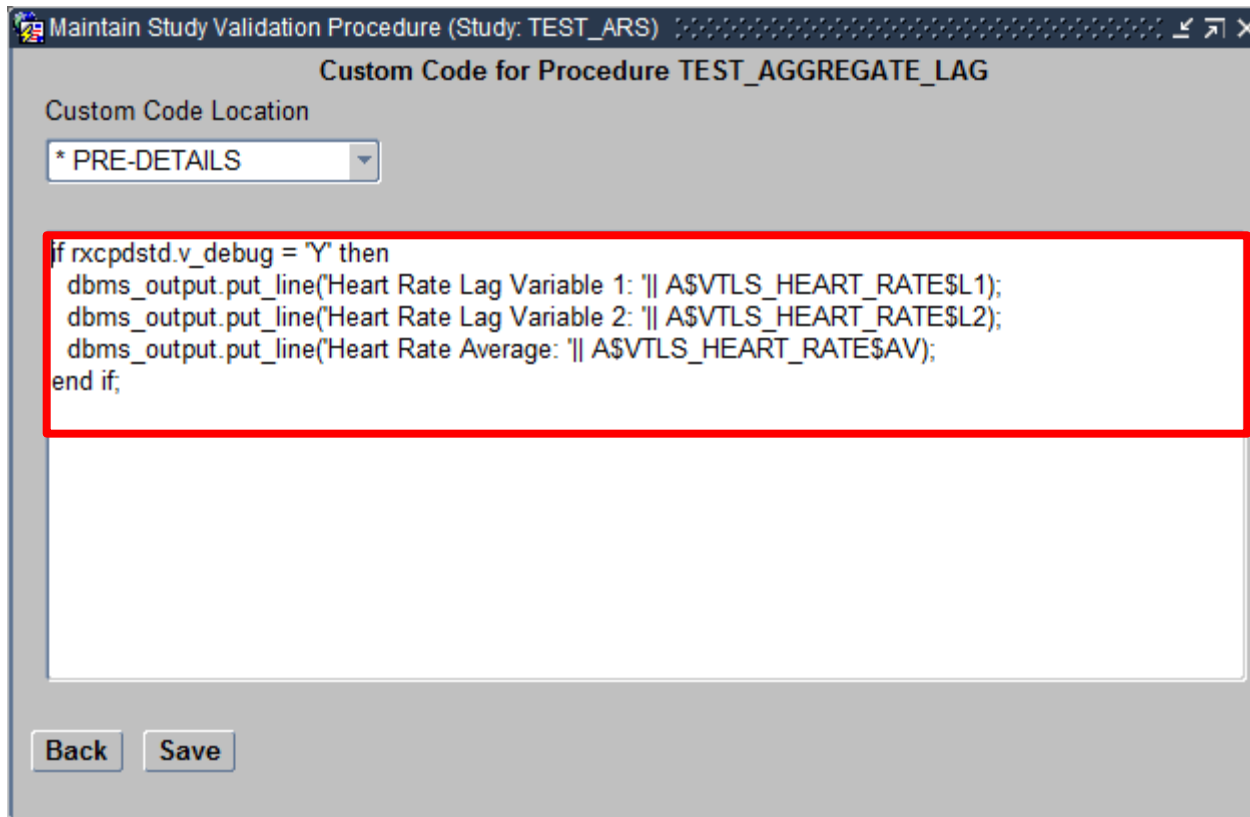
Details for Procedure TEST_AGGREGATE_LAG

Order#	Cont if Discrep?	Cont at Detail#	Test Not Null only?	Failure Type	Description	Expression
1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NORMAL	Heart Rate Average greater than 100 over last three vitals sign visits	A\$VTLS_HEART_RATE\$AV > 100
	<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 Variables

Aggregate Lag Function

Hint: Add Custom Code to print out Aggregate Variables for testing purposes



The screenshot shows a window titled "Maintain Study Validation Procedure (Study: TEST_ARS)". Inside the window, there is a section for "Custom Code for Procedure TEST_AGGREGATE_LAG". A dropdown menu labeled "Custom Code Location" is set to "* PRE-DETAILS". Below this, a text area contains the following PL/SQL code, which is highlighted with a red border:

```
if rxcpstd.v_debug = 'Y' then
  dbms_output.put_line('Heart Rate Lag Variable 1: '|| A$VTLS_HEART_RATE$L1);
  dbms_output.put_line('Heart Rate Lag Variable 2: '|| A$VTLS_HEART_RATE$L2);
  dbms_output.put_line('Heart Rate Average: '|| A$VTLS_HEART_RATE$AV);
end if;
```

At the bottom of the window, there are "Back" and "Save" buttons.

Aggregate Lag Function

Execution and Review of the output file yields the following

Processing Patient: A98

A.VISIT_NUMBER = 1
A.DCM_DATE = 20010101
A.REPEAT_SN = 1
A.VTLS_HEART_RATE = 101
Heart Rate Lag Variable 1:
Heart Rate Lag Variable 2:
Heart Rate Average: 101
Discrepancy found for Detail 1 - Heart Rate Average greater than 100 over last three

Heart Rate:101
Heart Rate Lag 1: Null
Heart Rate Lag 2: Null
Heart Rate Average: 101
Discrepancy Status: Created

A.VISIT_NUMBER = 2
A.DCM_DATE = 20010101
A.REPEAT_SN = 1
A.VTLS_HEART_RATE = 97
Heart Rate Lag Variable 1: 101
Heart Rate Lag Variable 2:
Heart Rate Average: 99

Heart Rate:97
Heart Rate Lag 1: 101
Heart Rate Lag 2: Null
Heart Rate Average: 99
Discrepancy Status: Not Created

A.VISIT_NUMBER = 3
A.DCM_DATE = 20010101
A.REPEAT_SN = 1
A.VTLS_HEART_RATE = 105
Heart Rate Lag Variable 1: 97
Heart Rate Lag Variable 2: 101
Heart Rate Average: 101
Discrepancy found for Detail 1 - Heart Rate Average greater than 100 over last three

Heart Rate:105
Heart Rate Lag 1: 97
Heart Rate Lag 2: 101
Heart Rate Average: 101
Discrepancy Status: Created

Aggregate Lag Function

Execution and Review of the output file yields the following

```
A.VISIT_NUMBER = 2  
A.DCM_DATE = 20010101  
A.REPEAT_SN = 1  
A.VTLS_HEART_RATE = 97  
Heart Rate Lag Variable 1: 101  
Heart Rate Lag Variable 2:  
Heart Rate Average: 99
```

```
A.VISIT_NUMBER = 3  
A.DCM_DATE = 20010101  
A.REPEAT_SN = 1  
A.VTLS_HEART_RATE = 105  
Heart Rate Lag Variable 1: 97  
Heart Rate Lag Variable 2: 101  
Heart Rate Average: 101  
Discrepancy found for Detail 1 - Heart Rate Average greater than 100 over last three
```

```
A.VISIT_NUMBER = 4  
A.DCM_DATE = 20010101  
A.REPEAT_SN = 1  
A.VTLS_HEART_RATE = 89  
Heart Rate Lag Variable 1: 105  
Heart Rate Lag Variable 2: 97  
Heart Rate Average: 97
```

Heart Rate:89
Heart Rate Lag 1: 105
Heart Rate Lag 2: 97
Heart Rate Average: 97
Discrepancy Status: Not Created

Pitfalls

- Where Clause Extension and Qualifying Expression do not filter retrieved data records
- Difficult to program procedures when certain criteria is required for the specification of the edit check
- Multiple Aggregate Aliases will lead to more complex procedures

Summary

- It is recommended to use the integrated functionality of OC rather than using Custom Code
- Programmers should make sure they are aware of the limitations of the Aggregate Function prior to using them
- Aggregate Lag Function is an effective way to reduce aliases in procedures and reference Lag Variables
- Aggregate Functions can be utilized for procedures that required mathematical operations or data comparisons, resulting in more efficient programming

Thank You

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More About Oliver...

Oliver Ho is an Associate Manager at Premier Research Group Limited and has been in the Clinical Trial Industry since 2004. He has experience with managing Database Development, Data Management and Clinical Projects. Oliver has been a member of OHSUG since 2007 and has presented at the conferences in Atlanta, New Orleans, and San Antonio.

