

Implementation and Benefits of Sort Order Functionality for Validation and Derivation Procedures



Implementation and Benefits of Sort Order Functionality for Validation and Derivation Procedures

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Purpose

- Purpose of this presentation is to highlight the benefits and correct use of Sort Order functionality in procedures.
- Provide guidance and examples on using the Sort Order Event and Extension sections in procedures.

Agenda

- Present problem Sort Order is intended to solve.
- Review the looping structure of a procedure.
- Explain the difference between the Event and Extension Sort Order.
- Provide examples where the use of the sort order is highly effective.
- Overview of Sort Order.

Problem

- Data entry in Log or Dosing type pages often is not in chronological order.

DOSING RECORD:

NOT DONE

Start date (dd-MMM-yyyy): 15-JAN-2011 Stop date (dd-MMM-yyyy): 20-JAN-2011

Number of tabs taken per day: 2

NOT DONE

Start date (dd-MMM-yyyy): 20-JAN-2011 Stop date (dd-MMM-yyyy): 30-JAN-2011

Number of tabs taken per day: 3

NOT DONE

Start date (dd-MMM-yyyy): 10-JAN-2011 Stop date (dd-MMM-yyyy): 15-JAN-2011

Number of tabs taken per day: 1

Sort Order Solution

- When Properly applied, Sort Order can pre-sort data.

Pre-Sort

15-JAN-2011

20-JAN-2011

10-JAN-2011

Post-Sort

- This streamlines/simplifies procedure logic

Looping structure for procedure with more than one Question Group

- In this example procedure retrieves records from two QGs.

QG A Visit 1 → **QG A loop open**

 QG B Visit 1 → **QGB loop open**

 Detail Expression(s) executed

 QG B Visit 2

 Detail Expression(s) executed → **QGB loop close**

QG A Visit 2 →

 QG B Visit 1 → **QGB loop open**

 Detail Expression(s) executed

 QG B Visit 2

 Detail Expression(s) executed → **QGB loop close**

→ **QG A loop close**

Sort Order: Event and Extension

- Defines the order in which data will be retrieved and evaluated.
- Sort Order Event section (inner most Sort Order).
- Sort Order Extension section used for additional sorting of data.

Maintain Study Validation Procedure (Study: GR546)

Question Groups for V_ADVERSE_EVENT_COMMENT

| Alias | Event Range | | Sort Order | | First/Last Event Only | Single Repeat Only? |
|-------|-------------|------|--------------|-----------|-----------------------|--------------------------|
| | First | Last | Event | Extension | | |
| S | | | RDCM.VISIT_N | RES.REPEA | | <input type="checkbox"/> |
| D | | | RDCM.VISIT_N | RES.REPEA | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |
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| | | | | | | <input type="checkbox"/> |
| | | | | | | <input type="checkbox"/> |

Back Save Questions Correlating Questions Custom Code

Example Procedures using EVENT Sort Order

- Create a procedure to fire if **stop date of current visit is not equal to start date of next visit** for a dosing module.

The screenshot shows a software interface for configuring a procedure. It consists of several tables and a correlation section.

| Alias | DCM | DCM Domain | DCM Question |
|-------|--------|------------|--------------|
| A | DOHING | TEST_ARS | DOSE |
| B | DOHING | TEST_ARS | DOSE |

Below the tables are buttons: **Back**, **Save**, **Questions**, **Correlating Questions**, and **Custom C**.

The correlation section is titled "Correlate With" and includes the following fields:

| Single Repeat Only? | Create Place Holder? | Alias | Event | Qualif. Quest | Qualifying Expression |
|-------------------------------------|--------------------------|-------|-------|--------------------------|-----------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | | | <input type="checkbox"/> | A.STOP_DATE is not N |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A | NEXT | <input type="checkbox"/> | B.START_DATE is not |

Yellow callouts provide additional context:

- Ensures only Highest and Lowest value**: Points to the DCM Domain and DCM Question columns.
- Previous (A) visit Stop Date is compared to NEXT (B) visit Start Date**: Points to the correlation row where Alias is 'A' and Event is 'NEXT'.
- Both values are NOT NULL**: Points to the 'Qualifying Expression' column.

Example Procedures using EVENT Sort Order

- Sort the data in the ascending order of DCM_DATE and DCM_TIME using Sort Event function of the procedure.

RDCM.DCM_DATE ASC,RDCM.DCM_TIME ASC,

| Question Group | Aggregate? | Primary Refer? | Event Range | | Sort Order | |
|----------------|------------|----------------|-------------|------|--------------------------------------|-----------|
| | | | First | Last | Event | Extension |
| GR | | | | | RDCM.DCM_DATE ASC | RES.REPEA |
| GR | | | | | RDCM.DCM_DATE ASC,RDCM.DCM_TIME ASC, | RES.REPEA |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Example Procedures using EVENT Sort Order

- Data in OC before applying Event Sort Order:

Sub event 0 : DCM DATE = 01-JAN
(Start Date: 01-JAN, Stop Date: 05-JAN)

Sub event 1 : DCM DATE = 10-JAN
(Start Date: 10-JAN, Stop Date: 15-JAN)

Sub event 2 : DCM DATE = 20-JAN
(Start Date: 20-JAN, Stop Date: 25-JAN)

Sub event 3 : DCM DATE = 05-JAN
(Start Date: 05-JAN, Stop Date: 10-JAN)

Sub event 4 : DCM DATE = 15-JAN
(Start Date: 15-JAN, Stop Date: 20-JAN)

Application of Sort Order

Sub event 0 : DCM DATE = 01-JAN

(Start Date: 01-JAN, Stop Date: 05-JAN)

Sub event 1 : DCM DATE = 10-JAN

(Start Date: 10-JAN, Stop Date: 15-JAN)

Sub event 2 : DCM DATE = 20-JAN

(Start Date: 20-JAN, Stop Date: 25-JAN)

Sub event 3 : DCM DATE = 05-JAN

(Start Date: 05-JAN, Stop Date: 10-JAN)

Sub event 4 : DCM DATE = 15-JAN

(Start Date: 15-JAN, Stop Date: 20-JAN)

Example Procedures using EVENT Sort Order

- Sort Order along with Correlation of visits would result in the following.
- QG A - Subevent 0 (Stop Date = 05-JAN)
 - QG B - Subevent 3 (Start Date = 05-JAN)
 - Detail executed (No Discrepancy)
- QG A - Sub event 3 (Stop Date = 10-JAN)
 - QG B - Subevent 1 (Start Date = 10-JAN)
 - Detail executed (No Discrepancy)
- QG A - Subevent 1 (Stop Date = 15-JAN)
 - QG B - Subevent 4 (Start Date = 15-JAN)
 - Detail executed (No Discrepancy)

Sort Order: Extension

Question Groups for VH_LAB_URIN_LBL3_MICROSCOPIC

| Group | Aggregate? | Primary Refer? | Event Range | | Sort Order | | First |
|-------|--------------------------|-------------------------------------|-------------|------|---------------|-----------|-------|
| | | | First | Last | Event | Extension | |
| | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | | RDCM.VISIT_NI | RES.REPEA | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | RDCM.VISIT_NI | RDCM.QUAL | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | RDCM.VISIT_NI | RDCM.QUAL | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | | | |
| | <input type="checkbox"/> | <input type="checkbox"/> | | | | | |

Find R%

Default Value

RES.REPEAT_SN ASC
RES.REPEAT_SN DESC

Repeat Number ONLY

Qualifying Value AND Repeat Number

RDCM.QUALIFYING_VALUE ASC,RES.REPEAT_SN ASC
RDCM.QUALIFYING_VALUE ASC,RES.REPEAT_SN DESC
RDCM.QUALIFYING_VALUE DESC,RES.REPEAT_SN ASC
RDCM.QUALIFYING_VALUE DESC,RES.REPEAT_SN DESC

Find OK Cancel

Back Save Questions Correlating Questions Custom Code

- The Extension Sort Order adds additional sort criteria to the inner most sort by selecting one of the options from the pick list.

Lowest/highest value from a repeating QG.

- Example : Create a procedure that compares if the latest Stop Date of this visit is before earliest Start Date from the next visit.

Stop date (Visit 1 = QG A)

PREVIOUS DRUG TREATMENT FOR PRIMARY DIAGNOSIS

NONE

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>02-JAN-2008</u> | Stop Date (dd-MMM-yyyy): | <u>10-JAN-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>10-OCT-2008</u> | Stop Date (dd-MMM-yyyy): | <u>14-OCT-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>04-APR-2008</u> | Stop Date (dd-MMM-yyyy): | <u>15-APR-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>03-MAR-2008</u> | Stop Date (dd-MMM-yyyy): | <u>08-MAR-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

Start date (Visit 2 = QG B)

PREVIOUS DRUG TREATMENT FOR PRIMARY DIAGNOSIS :

NONE

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>11-NOV-2008</u> | Stop Date (dd-MMM-yyyy): | <u>15-NOV-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>18-OCT-2008</u> | Stop Date (dd-MMM-yyyy): | <u>22-OCT-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>12-DEC-2008</u> | Stop Date (dd-MMM-yyyy): | <u>16-DEC-2008</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

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

TYLENOL

| | | | |
|------------------------------|--------------------|-----------------------------|--------------------|
| Start Date (dd-MMM-yyyy): | <u>01-JAN-2009</u> | Stop Date (dd-MMM-yyyy): | <u>05-JAN-2009</u> |
|------------------------------|--------------------|-----------------------------|--------------------|

Lowest/highest value from a repeating QG.

Highest Stop Date (Select the first value from Descending list)

| Event | Extension | Sort Order | First/Last | Single Repeat Only? | Create Place Holder? | Correlate With Alias | Correlate With Event |
|--------------|------------|------------|------------|-------------------------------------|--------------------------|----------------------|----------------------|
| CM.VISIT_N | STOP_DATE | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | | |
| RDCM.VISIT_N | START_DATE | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> | A | NEXT |
| | | | | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | | | | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | | | | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | | | | <input type="checkbox"/> | <input type="checkbox"/> | | |

Lowest Start Date (Select first value from Ascending list)

Editor: STOP_DATE DESC, RES. REPEAT_SN ASC

Editor: START_DATE ASC, RES. REPEAT_SN ASC

Buttons: Back, Save, Questions, Correlating Questions, Custom Code

Sorting NULL values before/after all other values in repeating QG.

- Example: Create a procedure to check if all start dates are entered.

PREVIOUS DRUG TREATMENT FOR PRIMARY DIAGNOSIS :

NONE

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

TYLENOL

Start Date 02-FEB-2009 Stop Date 10-FEB-2009 Ongoing
(dd-MMM-yyyy): (dd-MMM-yyyy):

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

TYLENOL

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

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

TYLENOL

Start Date 04-APR-2009 Stop Date 08-APR-2009 Ongoing
(dd-MMM-yyyy): (dd-MMM-yyyy):

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

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

Repeat 2 Start date is NULL
While Ongoing is checked

Repeat 4 no data entered = blank repeat

Sorting NULL values before/after other data

- To place NULL values before all other values
 - Put <question name> (ASC/DESC) **NULLS FIRST**,
RES.REPEAT_SN (ASC/DESC) in Sort Order – extension.
- To place NULL values after all other values:
 - Put <question name> (ASC/DESC) **NULLS LAST**,
RES.REPEAT_SN (ASC/DESC) in Sort Order – extension.
- Remember to **NOT** include an alias with the question
- Check “Single repeat only”
 - Only if you wish to check only the first value sorted.

Sorting NULL values before or after all the other values in repeating QG.

Sort Order

| Event | Extension | First/Last Event Only | Single Repeat Only? | Create Place Holder ? |
|---------------|-----------|-----------------------|-------------------------------------|-------------------------------------|
| RDCM.VISIT_NI | RES.REPEA | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| RDCM.VISIT_NI | START DAT | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

Only one value must be NULL for procedure to fire

NULLS FIRST - Puts NULLs before all other values

Editor

```
START_DATE ASC NULLS FIRST,  
RES.REPEAT_SN ASC
```

Details for Procedure V_EXTENSION_TEST2

| Order# | Expression |
|--------|----------------------|
| 1 | B.START_DATE is NULL |

- Significantly reduces processing time

Summary

- Sort Order simplifies the logic of a procedure
- Sorts Events, Subevents, Qualifying Values, Repeats, and Individual questions.
- Powerful tool when dealing with Log and Dosing type DCMs with large numbers of repeats.

Thank You

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Philip is an experienced Oracle Clinical database developer, specializing in Procedure Programming and User Acceptance Testing script development. He has been with Premier Research since 2010 and is happy to be attending OHSUG for the first time this year.