Premier Research

12th Annual OCUG Conference
October 7-10, 2007

Effective Utilization of Custom Code in Validation and Derivation Procedures

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Objective

To provide tips and tricks as to how Custom Code can be used to accomplish different programming tasks

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Tip #1 – Viewing Generated Code

- Generated code is located in the RXC_PD schema. (Contact your DBA to gain access to the packages in RXC_PD)

- Procedure packages in the RXC_PD schema are named by PROCEDURE_ID (which is a column in the RXC.PROCEDURES table).
  Package name = 'RXCPD'||*_PROCEDURE_ID*||*_PROCEDURE_VER_SN*

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Tip #1 – Viewing Generated Code Cont.

Maintain Study Validation Procedure (Study: STUDY15)

Details for Procedure V_AE_101.0

Order#	Description	Expression
1	Date of Onset is missing	A.AE_ONSET_DATE is NULL

```
CREATE OR REPLACE package RXCPD_55801_0 as

/* cursor for getting AE Production */
cursor A_CUR(
I_PATIENT_POSITION_ID in RECEIVED_DCMS.PATIENT_POSITION_ID%TYPE,
I_BEGIN_VISIT_NUMBER  in RECEIVED_DCMS.VISIT_NUMBER%TYPE :=
RXCPDSTD.C_BEGIN_VISIT_NUMBER,
I_END_VISIT_NUMBER    in RECEIVED_DCMS.VISIT_NUMBER%TYPE :=
RXCPDSTD.C_END_VISIT_NUMBER) is
    select /*+ ordered use_nl(RDCM RES)
           index(RDCM RECEIVED_DCM_UK2_IDX) */
           RDCM.RECEIVED_DCM_ID,
           RDCM.RECEIVED_DCM_ENTRY_TS,
            .
            . /* Std Vars are listed here */
            .
           RDCM.VISIT_NUMBER,
           RES.REPEAT_SN,
max(decode(RES.DCM_QUESTION_ID,348401,substrb(RES.VALUE_TEXT,1,50),null
)) AE_TERM,
max(decode(RES.DCM_QUESTION_ID,348401,substrb(RES.EXCEPTION_VALUE_TEXT,
1,20),NULL)) AE_TERM$EXC_VAL,
max(decode(RES.DCM_QUESTION_ID,348401,RES.RESPONSE_ID,NULL))
AE_TERM$RESP_ID,
max(decode(RES.DCM_QUESTION_ID,348401,RES.RESPONSE_ENTRY_TS,NULL))
AE_TERM$ENT_TS
      from RECEIVED_DCMS RDCM,
```

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Tip #2 – The Cursor FOR Loop

Two Possible Uses:

- Calculating an aggregate value for a specific subset of data
  - Standard Aggregate Questions such as A.TEMP$AV are calculated while ignoring the WHERE clause.
  - To calculate the average of all the *oral* temperatures for a given subject, open a Cursor to loop through all the records where A.TEMP_METHOD equals 'Oral' and sum the temperature at each iteration (V_TEMP := V_TEMP + A_TEMP;). Then right before the detail line you could calculate the average based on the sum of the temperatures.
- Comparing one record to several other records
  - Looping through one cursor while in another cursor provides for a "search-like" functionality
  - Example: For each Adverse Event page there must be a corresponding Concomitant Medication page.

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Tip #2 – The Cursor FOR Loop Example

Question Groups:

Maintain Study Validation Procedure (Study: STUDY15)

Question Groups for V_AE_100.0

Alias	DCM	DCM Domain	DCM Question Group	Aggre-gate?	Primary Refer?
A	AE	STUDY15	AE	☐	☑
B	CONMED	STUDY15	CM_TEST	☐	☐

User Vars:

Maintain Study Validation Procedure (Study: STUDY15)

User Variables for Procedure V_AE_100.0

Variable Name	Init Alias	Data Type	Length	Decimal Places	Initial Value
V_CONMED_PRESENT		VARCHAR2	1		

Detail:

Maintain Study Validation Procedure (Study: STUDY15)

Details for Procedure V_AE_100.0

Order#	Expression
1	V_CONMED_PRESENT = 'N'

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Tip #2 – The Cursor FOR Loop Example Cont.

Custom Code:

Maintain Study Validation Procedure (Study: STUDY15)

Custom Code for Procedure V_AE_100.0

Custom Code Location

* POST-QG-A

```
V_CONMED_PRESENT := 'N';

if I_MODE = 'P' then
   FOR b_rec IN B_CUR(RXCPDSTD.PATIENTS_REC.PATIENT_POSITION_ID,
   B$BEGIN_SEQNUM, B$END_SEQNUM) LOOP
            if A.AE_MED = b_rec.CMINDICATION then
              V_CONMED_PRESENT := 'Y';
            end if;
          END LOOP;
else
       FOR b  rec IN
      B_CURT(RXCPDSTD.PATIENTS_REC.PATIENT_POSITION_ID,
      B$BEGIN_SEQNUM, B$END_SEQNUM) LOOP
            if A.AE_MED = b_rec.CMINDICATION then
              V_CONMED_PRESENT := 'Y';
            end if;
          END LOOP;
end if;
```

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Tip #2 – The Cursor FOR Loop Example

Question Groups:

Maintain Study Validation Procedure (Study: STUDY15)

Question Groups for V_AE_100.0

Alias	DCM	DCM Domain	DCM Question Group	Aggre-gate?	Primary Refer?
A	AE	STUDY15	AE	☐	☑
B	CONMED	STUDY15	CM_TEST	☐	☐

User Vars:

Maintain Study Validation Procedure (Study: STUDY15)

User Variables for Procedure V_AE_100.0

Variable Name	Init Alias	Data Type	Length	Decimal Places	Initial Value
V_CONMED_PRESENT		VARCHAR2	1		

Detail:

Maintain Study Validation Procedure (Study: STUDY15)

Details for Procedure V_AE_100.0

Order#	Expression
1	V_CONMED_PRESENT = 'N'

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Tip #3 – Flag Variables

- Flag variables are user defined variables that can be used to force events to happen at specific times

- The basic premise:

```
V_FLAG := 0;        ←  Initialized at beginning of code

if A.ONSET_DATE is NULL then
  V_FLAG := 1;      ←  Change value conditionally
end if;
```

Fire discrepancy if V_FLAG = 1

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Tip #3 – Flag Variables (A Familiar Example)

For each Adverse Event page there must be a corresponding Concomitant Medication page.

ADVERSE EVENT REPORT

Adverse Event Term: HIVES

Was this AE the result of a medication? YES

If yes, specify medication: ADVIL

Date of Onset: 26-JUL-2007

Severity: MODERATE

CONCOMITANT MEDICATIONS

Not Done: DONE

Date: 26-JUL-2007 Time: 12:00

Treatment: TYLENOL
Indication: HEADACHE
Route: ORAL Dose: 200 MG

Treatment: AMOXICILLIN
Indication: EAR INFECTION
Route: ORAL Dose: 250 MG

Treatment: CLARITIN
Indication: ALLERGIES
Route: ORAL Dose: 10 MG

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Tip #3 – Flag Variables (A Familiar Example)

```
Procedure V_AE_100.0: Debug Mode Enabled.
--------------------------------
Processing Patient: V1

A.VISIT_NUMBER = 4
A.DCM_DATE = 20070726
A.REPEAT_SN = 1
A.AE_TERM = HIVES

B.VISIT_NUMBER = 3
B.DCM_DATE = 20070726
B.REPEAT_SN = 1
B.CMINDICATION = HEADACHE
Discrepancy found for Detail 1 - Adverse Event page does not

B.VISIT_NUMBER = 3
B.DCM_DATE = 20070726
B.REPEAT_SN = 2
B.CMINDICATION = EAR INFECTION
Discrepancy found for Detail 1 - Adverse Event page does not

B.VISIT_NUMBER = 3
B.DCM_DATE = 20070726
B.REPEAT_SN = 3
B.CMINDICATION = ALLERGIES
Discrepancy found for Detail 1 - Adverse Event page does not
```

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Tip #3 – Flag Variables (A Familiar Example)

Question Groups:

Maintain Study Validation Procedure (Study: STUDY15)

Question Groups for V_AE_100.0

Alias	DCM	DCM Domain	DCM Question Group	Aggre-gate?	Primary Refer?
A	AE	STUDY15	AE	☐	☑
B	CONMED	STUDY15	CM_TEST	☐	☐

User Vars:

Maintain Study Validation Procedure (Study: STUDY15)

User Variables for Procedure V_AE_100.0

Variable Name	Init Alias	Data Type	Length	Decimal Places	Initial Value
V_CONMED_PRESENT		VARCHAR2	1		
V_DISCREP_FLAGGED		VARCHAR2	1		'N'

Detail:

Maintain Study Validation Procedure (Study: STUDY15)

Details for Procedure V_AE_100.0

Order#	Expression
1	V_CONMED_PRESENT = 'N' and V_DISCREP_FLAGGED = 'N'

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Tip #3 – Flag Variables (A Familiar Example)

Custom Code:

Maintain Study Validation Procedure (Study: STUDY15)

Custom Code for Procedure V_AE_100.0

Custom Code Location

* POST-DETAILS

```
V_DISCREP_FLAGGED := 'Y';
```

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Summary

- Tip #1 – Viewing generated code
- Tip #2 – Cursor FOR Loop
- Tip #3 – Flag variables

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Questions?

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