

An Approach to a Custom Code function for a DVG Display SN and Long Value Lookup



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Assumptions/Scope/Disclaimer

- Assumption: Audience has a basic understanding of the OLS 4.5.x architecture
- Scope: OC 4.0.x to OC 4.5.x.
- Disclaimer: The sample code and methods provided in these scripts are for demonstration purposes only. No part of the content of this presentation should construed for fitness to a particular purpose or a warranty of any kind.



Issue: VPs/DPs Do NOT Have Visibility into DVG SN/Long Values

- In Validation/Derivation Procedures, only the “Short Value” of an INTERNAL DVG can be retrieved, since this is stored in the VALUE_TEXT of Responses (the actual response itself).
- However, in the Detail Line, Messages field (which are propagated directly to RDC or to the DCF in OC) field, it would be useful to be able to show the Long Value and Display Number for a DVG.



Display SN and Long Value are not available from VP interface

- *Add Screen Capture showing Display SN and Long Value are not available from VP interface*



Approach: Create a DVG "Lookup" function

```
/* EXAMPLE CALL
```

```
dvg_lookup can be called from within an IF statement:
```

```
if (custom_dvg.dvg_lookup(p_response_id =>
<QG>.<DVG_QUESTION>$resp_id,
p_received_dcm_id => <QG>.RECEIVED_DCM_ID,
p_received_dcm_entry_ts => <QG>.RECEIVED_DCM_ENTRY_TS,
p_mode => RXCPDSTD.V_MODE,
p_debug => RXCPDSTD.V_DEBUG,
o_long_label_desc => U_DVG_LONG_VALUE,
o_display_sn => U_DVG_DISPLAY_SN)
) then <ADDITIONAL CODE>
end if;
```

where <QG> = Procedure Question Group Name

<DVG_QUESTION> = DVG Question Name

U_DVG_LONG_VALUE is a varchar2 User Variable for storing the DVG Long Value

U_DVG_DISPLAY_SN is a number User Variable for storing the DVG Number

<ADDITIONAL CODE> = the additional code required based on the DVG lookup

```
*/
```



DVG Lookup Function: Arguments

```
create or replace package custom_dvg as
```

```
function dvg_lookup
-- dvg_lookup function
-- Accepts Response_ID, Received_DCM_ID, Received_DCM_entry_ts, Mode, Debug as
  parameters
-- Returns the dvg display_sn and long_label_description
-- Function returns boolean
-- Intended to be called from validation and derivation procs
--   from an IF THEN statement and the OUT results stored in
--   USER variables
```

```
(p_response_id      IN rxc.responses.response_id%type,
  p_received_dcm_id  IN rxc.received_dcms.received_dcm_id%type,
  p_received_dcm_entry_ts IN rxc.received_dcms.received_dcm_entry_ts%type,
  p_mode             IN varchar2,
  p_debug            IN varchar2,
  o_long_label_desc   OUT rxc.discrete_values.long_label_description%type,
  o_display_sn       OUT rxc.discrete_values.display_sn%type
)
return BOOLEAN;
```



DVG Lookup Function: Error Codes

-- Error Codes:

-- o_display_sn = -1: No DVG was associated with response question

-- o_display_sn = -2: Too many DVGs were associated with response question. Internal OC data issue.

-- o_display_sn = -3: Other Error related to retrieving DVG associated with response question.

-- o_display_sn = -4: The response value was not a valid DVG value

-- o_display_sn = -5: The response value was associate with TOO MANY valid DVG values. Internal OC data issue.

-- o_display_sn = -6: Other Error related comparing DVG values with response value



```

Elsif (p_mode = 'P') then
    BEGIN
        SELECT discrete_val_grp_id,
               discrete_val_grp_subset_nm
           INTO v_discrete_val_grp_id,
               v_discrete_val_grp_subset_nm
        FROM   RXC.DCM_QUESTIONS
        WHERE  DCM_QUESTION_ID =
               (SELECT DCM_QUESTION_ID
                FROM   RXC.RESPONSES
                 WHERE RESPONSE_ID = p_response_id
                  AND  to_char(end_ts) = '15-AUG-3501')
        AND   (DCM_QUESTION_ID,DCM_QUE_DCM_SUBSET_SN,DCM_QUE_DCM_LAYOUT_SN) =
               (SELECT DCM_QUESTION_ID,DCM_QUE_DCM_SUBSET_SN,DCM_QUE_DCM_LAYOUT_SN
                FROM   RXC.RECEIVED_DCMS
                 WHERE RECEIVED_DCM_ID = p_received_dcm_id
                  AND  RECEIVED_DCM_ENTRY_TS = p_received_dcm_entry_ts);

        IF (v_discrete_val_grp_id is NULL) and (v_discrete_val_grp_subset_nm is NULL) THEN
            if (p_debug = 'Y') then
                dbms_output.put_line('Response ID: '||p_response_id||' is NOT associated with a DVG!');
            end if;
            o_display_sn := -1;
            o_long_label_desc := NULL;
        END IF;

    EXCEPTION
        WHEN NO_DATA_FOUND THEN
            if (p_debug = 'Y') then
                dbms_output.put_line('Response ID: '||p_response_id||' is NOT associated with a DVG!');
            end if;
            o_display_sn := -1;
            o_long_label_desc := NULL;

            WHEN TOO_MANY_ROWS THEN
                if (p_debug = 'Y') then
                    dbms_output.put_line('Response ID: '||p_response_id||' is associated with MORE than one
DVG! This is an INTERNAL OC Data corruption!');
                end if;
                o_display_sn := -2;
                o_long_label_desc := NULL;

            WHEN OTHERS THEN
                if (p_debug = 'Y') then
                    dbms_output.put_line(substr(sqlerrm,1,255));
                end if;
                o_display_sn := -3;
                o_long_label_desc := NULL;
    
```

```

IF (o_display_sn < 0) THEN
    RETURN FALSE;
END IF;

BEGIN
    SELECT display_sn,
           long_label_description
    INTO v_display_sn,
        v_long_label_description
    FROM   RXC.DISCRETE_VALUES
    WHERE  discrete_value_dvg_id = v_DISCRETE_VAL_GRP_ID
    AND    discrete_value_dvg_subset_nm = v_DISCRETE_VAL_GRP_SUBSET_NM
    AND    discrete_value_value = (select nvl(exception_value_text,value_text)
                                   from RXC.RESPONSES
                                   WHERE
                                       RESPONSE_ID = p_response_id
                                       AND to_char(end_ts) = '15-AUG-3501');

EXCEPTION
    WHEN NO_DATA_FOUND THEN
        if (p_debug = 'Y') then
            dbms_output.put_line('Response ID: '||p_response_id||' is NOT associated with a VALID DVG
value!');
        end if;
        o_display_sn := -4;
        o_long_label_desc := NULL;
        RETURN FALSE;

    WHEN TOO_MANY_ROWS THEN
        if (p_debug = 'Y') then
            dbms_output.put_line('Response ID: '||p_response_id||' is associated with MORE than one
VALID DVG value! This is an INTERNAL OC Data corruption!');
        end if;
        o_display_sn := -5;
        o_long_label_desc := NULL;
        RETURN FALSE;

    WHEN OTHERS THEN
        if (p_debug = 'Y') then
            dbms_output.put_line(substr(sqlerrm,1,255));
        end if;
        o_display_sn := -6;
        o_long_label_desc := NULL;
        RETURN FALSE;
END;

IF (o_display_sn < 0) THEN
    RETURN FALSE;
ELSE
    o_long_label_desc := v_long_label_description;
    o_display_sn := v_display_sn;
    RETURN TRUE;
END IF;

```



DVG Lookup Function: Required Grants

```
grant select on responses to <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
grant select on responsest to <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
grant select on received_dcms to
    <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
grant select on received_dcmst to
    <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
grant select on discrete_values to
    <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
grant select on discrete_value_groups to
    <CUSTOM_DVG_PACKAGE_SCHEMA_OWNER>;
```



Using DVG Lookup: DVG Definition

Maintain Discrete Value Groups

Discrete Value Groups

Name: Domain: Subset Number:

Description:

DVG Type: Thesaurus or Internal or Alpha:

Status: Subsettable? Expandable? Enter by Seq? Resequencing?

Display Type: CB Layout: CB Label Source: Checked Flag Value:

Upper Case? Max Value Length: Retirement Reason:

Status Comment:

<< Discrete Values >>

Seq #	Value	Long Value	Active?
1	M	Male	<input checked="" type="checkbox"/>
2	F	Female	<input checked="" type="checkbox"/>
3	m	Lowercase male	<input checked="" type="checkbox"/>
4	AB	2 Char value will cause a discrepancy for Length=1 char DC	<input checked="" type="checkbox"/>

For Testing, mixed case DVG was used along with a length greater than the intended question length. This tests that even if the DVG value raises a discrepancy, the DVG_LOOKUP function still returns display number and long value correctly

Exit Save Thesaurus



Using DVG Lookup: DVG Questions

Maintain Study DCMs (Study: ORAQA)

DCM Questions (DEM.ORAQA.DEM.1:DEMOG)

Length for Sex question is only 1. This means the valid DVG value of "AB" will raise a discrepancy, but the DVG_LOOKUP function will still determine the correct display SN and Long Value. Weight is not a DVG question, and there is a separate call in POST DETAILS which was used to test that the function returns DISPLAY_SN = -1 in this case

Question Name	nat	Length	Decimal Places	DVG Modif?	DVG Name	DVG Domain	DVG Subset#	Alpha DVG Modif?	Alpha DVG Name
SEX		1		<input checked="" type="checkbox"/>	SEX	QA	2	<input type="checkbox"/>	
WEIGHT		3	0	<input type="checkbox"/>				<input checked="" type="checkbox"/>	NOT_DONE



Using DVG Lookup: User Variables

Maintain Study Validation Procedure (Study: ORAQA)

User Variables for Procedure TESTDVGLOOKUP

Variable Name	Init Alias	Data Type	Length	Decimal Places	Initial Value	Report?	Description
U_DVG_DISPLAY_SN	<input type="checkbox"/>	NUMBER	3	0	<input type="text"/>	<input type="checkbox"/>	DVG Display SN
U_DVG_LONG_VALUE	<input type="checkbox"/>	VARCHAR2	200	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	DVG Long Value
U_DVG_LOOKUP_SUCCE	<input type="checkbox"/>	VARCHAR2	10	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	DVG Success Status



Using DVG Lookup: Pre-Details Call

Maintain Study Validation Procedure (Study: ORAQA)

Custom Code for Procedure TESTDVGLOOKUP

Custom Code Location

* PRE-DETAILS

```
if (          dvg_lookup(p_response_id => DEM.SEX$resp_id,
p_received_dcm_id  => DEM.RECEIVED_DCM_ID,
p_received_dcm_entry_ts => DEM.RECEIVED_DCM_ENTRY_TS,
p_mode => RXCPDSTD.V_MODE,
p_debug => RXCPDSTD.V_DEBUG,
o_long_label_desc => U_DVG_LONG_VALUE,
o_display_sn => U_DVG_DISPLAY_SN)
) then
  dbms_output.put_line('Test for VALID DVG Question Successful');
  dbms_output.put_line('Value Text: '||DEM.SEX);
  dbms_output.put_line('Exception Value Text: '||DEM.SEX$exc_val);
  dbms_output.put_line('DVG Display SN: '||U_DVG_DISPLAY_SN);
  dbms_output.put_line('DVG Long Value: '||U_DVG_LONG_VALUE);
end if
```

Using DVG Lookup: Message Variables

Maintain Study Validation Procedure (Study: ORAQA)

Details for Procedure TESTDVGLOOKUP

er#	Expression	Message
	(1=1)	DVG Response Value:\DEM.SEX\ DVG DISF

Editor

DVG Response Value:\DEM.SEX\ DVG DISPLAY SN: \U_DVG_DISPLAY_SN\ DVG LONG VALUE: \U_DVG_LONG_VALUE\

OK Cancel Search

Testing DVG Lookup: Test Data

BROWSE (Study: ORAQA)

Doc# S134408 Status PASS 1 COMPLETE

Patient 1105 DCI Name DEM DEM

DCI Date 28-MAY-2009

Event BASELINE1 Visit# 1 Sub # 0

Site QA1 Investigator QA_INV DCI Book Page# 5

Comment Blank?

1 of 1 DCM DEMG Subset DEM Layout 1 Blank? N Status PASS 1 COMPLETE

Page 1 of 1, Repeat 1 of 5.

Sex	M	Weight	100
Sex	F	Weight	
Sex	m	Weight	
Sex	AB	Weight	
Sex	X	Weight	

Valid DVG values tests, including Mixed case "m" and DVG values which raise discrepancies due to short length of the question "AB". "X" is not a valid DVG value, which will return the appropriate error code where display_sn will be returned as -4

Same data used for both Test and Production mode Data entry



Testing DVG Lookup: Messages and Discrepancies Raised

```
Processing Patient: 1105]
DEM.VISIT_NUMBER = 1
DEM.DCM_DATE = 20090528
DEM.REPEAT_SN = 1
DEM.SEX = M
DEM.WEIGHT = 100
Test for VALID DVG Question Successful
Value Text: M
Exception Value Text:
DVG Display SN: 1
DVG Long Value: Male
Discrepancy found for detail 1 - Show DVG Long Value and Sequence Number in Message

DEM.VISIT_NUMBER = 1
DEM.DCM_DATE = 20090528
DEM.REPEAT_SN = 2
DEM.SEX = F
DEM.WEIGHT =
Test for VALID DVG Question Successful
Value Text: F
Exception Value Text:
DVG Display SN: 2
DVG Long Value: Female
Discrepancy found for detail 1 - Show DVG Long Value and Sequence Number in Message

DEM.VISIT_NUMBER = 1
DEM.DCM_DATE = 20090528
DEM.REPEAT_SN = 3
DEM.SEX = m
DEM.WEIGHT =
Test for VALID DVG Question successful
Value Text: m
Exception Value Text:
DVG Display SN: 3
DVG Long Value: Lowercase male
Discrepancy found for detail 1 - Show DVG Long Value and Sequence Number in Message

DEM.VISIT_NUMBER = 1
DEM.DCM_DATE = 20090528
DEM.REPEAT_SN = 4
DEM.SEX = A
DEM.WEIGHT =
Test for VALID DVG Question successful
Value Text: A
Exception Value Text: AB
DVG Display SN: 4
DVG Long Value: 2 Char value will cause a discrepancy for Length=1 char DCM question
Discrepancy found for detail 1 - show DVG Long Value and sequence Number in Message

DEM.VISIT_NUMBER = 1
DEM.DCM_DATE = 20090528
DEM.REPEAT_SN = 5
DEM.SEX = X
DEM.WEIGHT =
Response ID:1029808 is NOT associated with a VALID DVG value!
Discrepancy found for detail 1 - Show DVG Long Value and Sequence Number in Message
Discrepancies: 5 new, 0 remain current, 0 became obsolete
```



Testing DVG Lookup: Generating Comment Text in Discrepancies with Display SN/Long Value

Discrepancy Details for Study ORAQA

Investigator: QA_INV Site: QAI Patient: 1105
 Discrepancy ID: 50708 Visit: BASELINE1 Subevent #: 0 Visit Date: 28-MAY-2009
 Document #: S134408 DCM Name: DEM Subset #: 1 Qualifying Value:
 DCM Prompt Occ. #: Repeat #: Status: CURRENT Resolution Type:
 Type: MULTIVARIATE Category: 1-EVENT 1-DCM Validation Failure Type: NORMAL Review Status: UNREVIEWED
 Procedure Name: TESTDVGLOOKUP Version #: 0

Comment: DVG Response Value:F DVG DISPLAY SN: 2 DVG LONG VALUE: Female

DCM	Planned Event	Event Date/Time	Qualifying Value	Procedure Variable Name	Repeat #	Value Text
DEM	BASELINE1	28-MAY-2009 00:00		DEM.SEX	2	F
				U_DVG_DISPLAY_SN	2	
				U_DVG_LONG_VALUE		Female

Discrepancy ID: 50808 Visit: BASELINE1 Subevent #: 0 Visit Date: 28-MAY-2009
 Document #: S134408 DCM Name: DEM Subset #: 1 Qualifying Value:
 DCM Prompt Occ. #: Repeat #: Status: CURRENT Resolution Type:
 Type: MULTIVARIATE Category: 1-EVENT 1-DCM Validation Failure Type: NORMAL Review Status: UNREVIEWED
 Procedure Name: TESTDVGLOOKUP Version #: 0

Comment: DVG Response Value:m DVG DISPLAY SN: 3 DVG LONG VALUE: Lowercase male

DCM	Planned Event	Event Date/Time	Qualifying Value	Procedure Variable Name	Repeat #	Value Text
DEM	BASELINE1	28-MAY-2009 00:00		DEM.SEX	3	m
				U_DVG_DISPLAY_SN	3	
				U_DVG_LONG_VALUE		Lowercase male

Discrepancy ID: 50908 Visit: BASELINE1 Subevent #: 0 Visit Date: 28-MAY-2009
 Document #: S134408 DCM Name: DEM Subset #: 1 Qualifying Value:
 DCM Prompt Occ. #: Repeat #: Status: CURRENT Resolution Type:
 Type: MULTIVARIATE Category: 1-EVENT 1-DCM Validation Failure Type: NORMAL Review Status: UNREVIEWED
 Procedure Name: TESTDVGLOOKUP Version #: 0

Comment: DVG Response Value:A DVG DISPLAY SN: 4 DVG LONG VALUE: 2 Char value will cause a discrepancy for Length-1 char DCM question

DCM	Planned Event	Event Date/Time	Qualifying Value	Procedure Variable Name	Repeat #	Value Text
DEM	BASELINE1	28-MAY-2009 00:00		DEM.SEX	4	A
				U_DVG_DISPLAY_SN	4	
				U_DVG_LONG_VALUE		2 Char value will cause a discrepancy for Length-1 char DCM question



Testing DVG Lookup: Generating Comment Text in Discrepancies with Display SN/Long Value

Discrepancy Details for Study ORAQA

Investigator: QA_INV Site: QA1

Patient: 1105

Discrepancy ID: 51008 Visit: BASELINE1 Subevent #: 0 Visit Date: 28-MAY-2009
 Document #: S134408 DCM Name: DEM Subset #: 1 Qualifying Value:
 DCM Prompt Occ. #: Repeat #: Status: CURRENT Resolution Type:
 Type: MULTIVARIATE Category: 1-EVENT 1-DCM Validation Failure Type: NORMAL Review Status: UNREVIEWED
 Procedure Name: TESTDVGLOOKUP Version #: 0

Comment: DVG Response Value:X DVG DISPLAY SN: -4 DVG LONG VALUE: <BLANK>

DCM	Planned Event	Event Date/Time	Qualifying Value	Procedure Variable Name	Repeat #	Value Text
DEM	BASELINE1	28-MAY-2009 00:00		DEM.SEX	5	X
				U_DVG_DISPLAY_SN		-4
				U_DVG_LONG_VALUE		

Discrepancy ID: 50608 Visit: BASELINE1 Subevent #: 0 Visit Date: 28-MAY-2009
 Document #: S134408 DCM Name: DEM Subset #: 1 Qualifying Value:
 DCM Prompt Occ. #: Repeat #: Status: CURRENT Resolution Type:
 Type: MULTIVARIATE Category: 1-EVENT 1-DCM Validation Failure Type: NORMAL Review Status: UNREVIEWED
 Procedure Name: TESTDVGLOOKUP Version #: 0

Comment: DVG Response Value:M DVG DISPLAY SN: 1 DVG LONG VALUE: Male

DCM	Planned Event	Event Date/Time	Qualifying Value	Procedure Variable Name	Repeat #	Value Text
DEM	BASELINE1	28-MAY-2009 00:00		DEM.SEX	1	M
				U_DVG_DISPLAY_SN		1
				U_DVG_LONG_VALUE		Male



DVG Lookup: Limitations and Considerations

- Limitations:
 - Will Not work for Alpha DVGs as written, but can be extended.
 - Does this really make sense?
 - Very difficult to extend to THESAURUS DVGs
 - Requires Dynamic DDL
- Considerations:
 - Retrieves DVG Display and Long Value EVEN IF there is a discrepancy associated with a valid DVG response
 - Does NOT check for existing DVG discrepancy before lookup.



Summary/Conclusions

- Possible to create a function to perform DVG Lookups for Internal DVGs, useful for Discrepancy Management Processing and RDC Messages
- Lookup for Thesaurus DVGs are more complex, and may not perform well
- Alpha DVG lookups are possible, but may not be meaningful



Question and Answers

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- Bill has worked with Oracle databases since 1987 as an application developer, database administrator, systems analyst, and project manager. He has worked in the pharmaceutical industry since 1991, primarily in the clinical trials arena. His interests and areas of expertise include information sharing, data integration, performance tuning, and getting the most out of PL/SQL. He enjoys implementing solutions which enable people to focus more of their time on business challenges, and less of their time on technology.