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Detecting Blank DCIs in Validation Procedures

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Topics

- What is a BLANK DCI?
- Specification for the V_BLANK Procedure
- Problems and Solutions for Procedure Development
- Testing the Procedure
- Caveats

What is a BLANK DCI?

- Created when the "Blank?" Box is set to "Y" during DCI login
- There is no data recorded for a BLANK DCI
- DCIs which are marked BLANK are given the status of RECEIVED
- Procedure Execution does not access a BLANK DCI
 - May need to query the reason for a BLANK page, but Oracle Clinical has no direct way of creating discrepancies

Requirements for the V_BLANK Procedure

- Procedure should create a discrepancy which lists all scheduled DCIs in a study which have been received as BLANK
- List of BLANK pages should be changed if
 - reason for the BLANK pages is resolved
 - page with data is received and entered
 - new BLANK pages are received
- Changes to the list of BLANK pages should not create a new discrepancy; changes should just update the current discrepancy

V_BLANK_PAGES Validation Procedure

Maintain Study Validation Procedure (Study: ASD0553_00)

Procedure Definitions

Procedure Name	Domain	Version	Status	Exec Context	Description	Category	Ver 3.1 L Style? <input type="checkbox"/>
V_BLANK_PAGES	ASD0553_00	0	P ...	OFF-LINE	Detect and report blank pages	M-EVENT M-DCM	<input checked="" type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>
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							<input type="checkbox"/>
							<input type="checkbox"/>
							<input type="checkbox"/>

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

Problem

How can you detect BLANK pages if the page has to be non-BLANK in order to be processed?

- Connect the procedure to a form which is sure to be in the study one and only one time
 - e.g., DEMOGRAPHY
- Procedure will re-run (to update list of BLANK pages) each time any new Patient Data is entered or changed

Problem

How do you get a list of DCIs which have been entered as BLANK?

- In the RECEIVED_DCIS table, BLANK DCIs have the field BLANK_FLAG as 'Y'
- Create a function to return list of blank pages
- Call the function in Pre-detail Custom Code

list_blank_pages Function Specification

```
FUNCTION list_blank_pages  
    (vMode      in varchar2  
    ,nStudy_id  in number  
    ,vPatient   in varchar2  
    )  
RETURN varchar2
```

list_blank_pages Function Body

- Declare cursor joining RECEIVED_DCIS and DCI_BOOK_PAGES
 - select START_PAGE_NUMBER from DCI_BOOK_PAGES where BLANK_FLAG in RECEIVED_DCIS is 'Y'
- Fetch from the cursor in a loop and append each START_PAGE_NUMBER to a string
- Return the string when there are no more missing pages

Pre-Detail Custom Code

Maintain Study Validation Procedure (Study: ASD0553_00)

Custom Code for Procedure V_BLANK_PAGES

Custom Code Location
* PRE-DETAILS

```
blank_list := list_blank_pages  
              (RXCPDSTD.V_MODE  
               ,RXCPDSTD.V_CLINICAL_STUDY_ID  
               ,RXCPDSTD.PATIENTS_REC.PATIENT);
```

Back Save

User Variable in Procedure

Standard Cursor Variables

Problem

How do you create a Discrepancy containing this list?

- LIST_BLANK_PAGES function is called to produce a list which is assigned to variable BLANK_LIST
- LIST_BLANK_PAGES returns null to BLANK_LIST if the list has no values
- Create discrepancy if BLANK_LIST is not null

V_BLANK_PAGES Details

Maintain Study Validation Procedure (Study: ASD0553_00)

Details for Procedure V_BLANK_PAGES

Order#	Cont if Discrep?	Cont at Detail#	Test Not Null only?	Failure Type	Description
1	<input type="checkbox"/>		<input type="checkbox"/>	NORMAL	Blank Page message

Expression	Message	Discrepancy Code
blank_list is not null	\BLANK_LIST\	UNREVIEWED

BLANK_LIST must be a reported under Variables Button

Problem

How do you “update” this discrepancy when the list changes and not create a new discrepancy?

- On the Variable Details screen, report but do not test for the **BLANK_LIST** variable

V_BLANK_PAGES

Variable Details

Maintain Study Validation Procedure (Study: ASD0553_00)

Variables for Detail 1

<----- Perform Detail Only If -----> <-----> <----->

Variable	Not Null?	No Univariate Error(s)	Unresolved?	Discrep Test?	Report?	Report Order
BLANK_LIST	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1
A.GENDER	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2
	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Back Save

Changes in this variable will not be tested to obsolete a current discrepancy and/or create a new one

Problem

- If the variable change is not tested to create a new discrepancy, it doesn't update the reported value (or message) either - ☹️

How can the message be updated?

- Write a procedure and use "undocumented" variables controlling Discrepancy Creation

Discrepancy Control

- When detail line evaluates to indicate a discrepancy, an internal routine determines discrepancy is new or duplicate
 - Discrepancy is duplicate if none of the reported variables which are marked to test for discrepancy have changed

Discrepancy Control

- If discrepancy is a duplicate, then **v_duplicate_discrepancy** is set to TRUE
- If discrepancy is duplicate, call a procedure in post-detail custom code which updates message with current “blank list”

Post-Detail Custom Code

Maintain Study Validation Procedure (Study: ASD0553_00)

Custom Code for Procedure V_BLANK_PAGES

Custom Code Location

* POST-DETAILS

```
IF V_duplicate_discrepancy then
  update_vrv_comment (RXCPDSTD.v_Mode
                    ,RXCPDSTD.disc_ent_rec.DISCREPANCY_ENTRY_ID
                    ,BLANK_LIST
                    ,BLANK_LIST);
end IF;
```

Undocumented Variables

Note: The variables `v_duplicate_discrepancy` and `rxcpdstd.disc_ent_rec.discrepancy_entry_id` apply to the discrepancy created on the last detail line

update_VRV_comment Procedure Specification

```
PROCEDURE update_VRV_comments  
    (vMode          in varchar2  
    ,nDisc_id      in number  
    ,vVRV_name     in varchar2  
    ,vValue        in varchar2  
    )
```

update VRV comment Procedure Body

- **DISCREPANCY_ENTRY_ID** is key to table of **DISCREPANCY_ENTRIES**
 - Procedure updates the **COMMENT_TEXT**
 - Change captured in audit trail by database trigger
- **DISCREPANCY_ENTRY_ID** along with **PROC_VARIABLE_NAME** are the key fields in the **VALIDATION_REPORTED_VALUES** table
 - Procedure updates the **VALUE_TEXT**

Problem

How can a data manager accept (resolve) a BLANK Page without data to enter?

- By convention, if the BLANK page is "OK", set the comment of the BLANK DCI to a special code, e.g. BRSV for "blank resolved"
- If this code is present in the comment_text field of a BLANK received_DCI, then it is not fetched by the list_blank_pages function

Test the Procedure: Enter Data

INITIAL LOG-IN AND FIRST-PASS ENTRY (Study: ASD0553_00)

Doc# Status NOT COMPLETE

Patient 201 DCI Name DEMOG DEMOGRAPHY

DCI Date 01-MAR-2003

Event SCREENING Visit Number 0 SubEvent Number 0

Site 1290 Investigator 876 Book Page# 1

Comment Blank?

Data Entry DCI Book

Book WHOLE PROTOCOL Start Page 1 End Page 18

Pg #	Vis#	Visit Name	DCI Short N.	DCI Name
1	0	SCREENING	DEMOG	DEMOGRAPHY
2	0	SCREENING	VITALS	VITALS
3	0	SCREENING	PE	PE
4	0	SCREENING	AE	AE
5	0	SCREENING	LABCON	LABCON
6	1	VISIT 1	VITALS	VITALS
7	1	VISIT 1	EKG	EKG
8	1	VISIT 1	CONMED	CONMED
9	1	VISIT 1	AE	AE
10	2	VISIT 2	VITALS	VITALS
11	2	VISIT 2	EKG	EKG
12	2	VISIT 2	AE	AE

Enter Demography Data

Mark these pages as blank

Test the Procedure: Discrepancy

Maintain Discrepancy Database (Study: ASD0553_00) "DM Master Profile"

Discrepancy

Patient 201 | Visit SCREENING | Subevent 0 | DCM Name DEMOGRAPHY DATA

System CURRENT | Comment The following pages have been returned BLANK: 3, 6, 10 | Aa

Review UNREVIEWED | Inter Com |

Resolution | Res Com |

Characteristics

Discrepancy Type MULTIVARIATE | Category M-EVENT M-DCM | Failure Type NORMAL

Questions

Related

Study Site 6001 | Site 1290 | Visit Date 01-MAR-2003

Investigator 876 | Name Remsen, Kenneth | Initials |

Document # S655001 | Subset DEMOGDAT | Discrep ID 376701

CRF pages | Qualif Value | Assoc ID |

After Batch Validation, there is a discrepancy with Comment indicating BLANK Pages

Note!

Test the Procedure: Change Data

INITIAL LOG-IN AND FIRST-PASS ENTRY (Study: ASD0553_00)

Doc# Status: NOT COMPLETE

Patient: 201 DCI Name: DEMOG DEMOGRAPHY

DCI Date: 01-MAR-2003

Event: SCREENING Visit Number: 0 SubEvent Number: 0

Site: 1290 Investigator: 876 Book Page#: 1

Comment: Blank?: N

DCI Book

Book: WHOLE PROTOCOL Start Page: 1 End Page: 18

Pg #	Vis#	Visit Name	DCI Short N.	DCI Name
1	0	SCREENING	DEMOG	DEMOGRAPHY
2	0	SCREENING	VITALS	VITALS
3	0	SCREENING	PE	PE
4	0	SCREENING	AE	AE
5	0	SCREENING	LABCON	LABCON
6	1	VISIT 1	VITALS	VITALS
7	1	VISIT 1	EKG	EKG
8	1	VISIT 1	CONMED	CONMED
9	1	VISIT 1	AE	AE
10	2	VISIT 2	VITALS	VITALS
11	2	VISIT 2	EKG	EKG
12	2	VISIT 2	AE	AE

Annotations:

- Enter data on BLANK DCI (points to row 3)
- Resolved in comment (points to row 6)
- Still BLANK (points to row 10)
- New BLANK (points to row 12)

Test the Procedure: Discrepancy

Maintain Discrepancy Database (Study: ASD0553_00) "DM Master Profile"

Discrepancy

Patient Visit Subevent DCM Name

System Comment

Review Inter Com

Resolution Res Com

Related Information

Procedure Version Detail

Study Site Site Visit Date

Investigator Name Initials

Document # Subset Discrep ID

CRF pages Qualif Value Assoc ID

After Batch Validation, Comment is updated with current BLANK Pages

Original Discrepancy ID

Initials

Discrep ID

Assoc ID

Same Discrepancy

Caveats

- Un-documented features may not work on future releases
 - May need minor “tune-up” or a complete re-write
 - Problem is minimized by using Custom code to call to functions
 - Functions can be changed independent of the procedure and/or
 - Custom code can be changed in a new Procedure Version

Summary

- Blank DCIs can be detected
- Reporting changed BLANK status can be accomplished using a PL/SQL Package called from custom code
 - PL/SQL package uses “un-documented” features
 - so use cautiously

Package Procedure Code

PL/SQL code for the `list_blank_pages` function and the `update_VRV_comments` procedure is available

Request via e-mail to srifkin@biopharm.com or stop at the BioPharm Booth in the exhibit hall and leave a card

Steve Rifkin has almost 14 years of experience working with the OLS Product Suite. As an Functional Consultant, and then as a Practice Manager with Oracle Consulting in the Oracle Clinical Group, Steve has assisted over 60 companies with implementation of Oracle Clinical, RDC and TMS. He has led the implementation process and has provided training and performed custom coding. Since joining Biopharm Systems in 2000, Steve has been responsible for developing Oracle Clinical training courses, and providing training and implementation services for Biopharm clients.