

How to do data validation plan automatic generation in clinical trial

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ABSTRACT

Data Validation Plan (DVP) writing, Edit Check (EC) programming and Edit Check testing are the wide spread data management procedures in clinical study build stage. However, the traditional process did not appear improvement over the past decade, data manager and database designer write and program manually one by one, a lot of errors and communication generated by the manual work. The semi-automatic DVP tool (SatDVP) was designed in light of the problems met in those processes, which could write DVP, generate test case, generate EC.

KEY WORDS

Data Validation Plan (DVP), Edit Check (EC), Test Case, Semi-automatic DVP Tool (SatDVP), Data Manager (DM), Database Designer (DBD)

INTRODUCTION

As a traditional process in clinical data management, DVP writing usually cost quite much data manager time and communication. Only a data manager with enough experience and well mutual understanding with database designer (DBD) could create a good DVP. However, for the form/form OID or field/field OID, folder/folder OID, usually need data manager cost some time on matching them and checking the spelling. The EC description and query message will be varied between different DVP writer.

EC programming used to be managed by data manager, as some data management group develop and expand, the EC programming job changed to be the responsibility of database designer. The gap occurs as the responsibility differentiates. And sometimes, same logic is applied to different fields, the repeat characteristic appears in EC programming.

Rigorous logic scenarios are usually designed by data manager as an EC testing plan to test the programmed EC. The purpose was to mimic the actual data entry to find the potential or obvious EC programming error. This design require experience in clinical study, however, also a repeat characteristic in it. The actual situation would be, an experienced data manager feels passionless to design test case, whereas fresh data manager is not competent to design a comprehensive test case.

Traditional EC programming operation is clicking in the EC edit panel of EDC system. Now some systems can upload the EC set-up by batch. However, the manual edit still necessary.

SEMI-AUTOMATIC DVP TOOL (SATDVP) OVERVIEW

To conquer the observed problems, the semi-automatic DVP tool (SatDVP) gives users an option to replace the manual works by VBA macro, which is embedded in excel document. Once required, paste the study forms, fields, and folders, data dictionary entries worksheets into this excel. The input messages will be processed by the DVP tool, generate compiled DVP document, test case document, EC quick edit codes. This semi-automatic generation could decrease the EC programming, DVP writing, test case writing time by 79%, 36% and 95% respectively.

In this article, we take Medidata RAVE system as the example to describe the tool, but in future, the tool will be designed to fit for other common used EDC system.

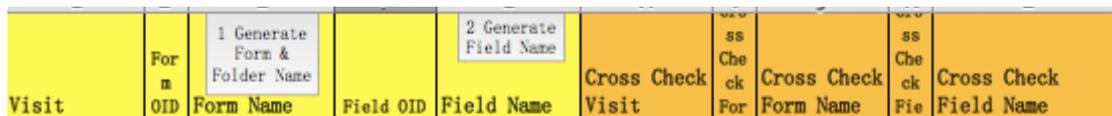
INPUT INFORMATION

In order to obtain the study structure, SatDVP require the information input. User login to iMedidata-RAVE, then go to architect, find the target study, download the Study Data Specification (SDS) from study Draft or a selected version. Make sure the information could be fully downloaded, the “Forms”, “Fields”, “Folders”, “Data Dictionaries” options must be checked before SDS downloads. Afterwards, the SDS should be opened to copy four worksheets “Forms”, “Fields”, “Folders”, “DataDictionaryEntries” to the SatDVP.

SATDVP SOLUTION

Function 1: Assisting DVP writing.

1.1 By clicking the button 1 embedded in the SatDVP, user can select the desired form, folder when designing a DVP. The buttons contain the macro, which could help to 1) create folder drop down list, 2) build linkage between folder and its corresponding forms.



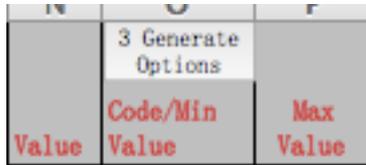
	Form OID	1 Generate Form & Folder Name	Field OID	2 Generate Field Name	Cross Check Visit	Cross Check Form Name	Cross Check Field Name
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Display 1. Button 1 and button 2 in SatDVP

1.2 By clicking the button 2, user can select the desired field name in a drop down list, which was generated by macro in button 2.

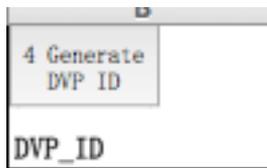
1.3 The “Cross Check Form Name” and “Cross Check Visits” are generated also by button 1, and “Cross Check Field Name” is generated by button 2.

1.4 By clicking button 3, the fields contain data dictionaries could generate a drop down list containing the data dictionary entries. The macro embedded in this button could make the linkage between field and its data dictionary entries.



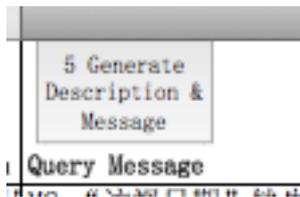
Display 2. Button 3 in SatDVP

1.5 Button 4 could generate “DVP_ID”, “Form OID”, “Field OID”, “Cross Check Form OID”, “Cross Check Field OID”, “Data Dictionary coded value” by matching the form or field name in the source worksheets.



Display 3. Button 4 in SatDVP

1.6 Button 5 clicking would lead to generate the EC description and EC query message, which were compiled by the specific programming in macro.



Display 4. Button 5 in SatDVP

Currently, the tool covers 18 types of EC logic, including check date difference and the data range, details listed in below table 1.

Edit Cehck logic Option	Detail Description
Mandatory_field	Value is mandatory required to this field.
Value_Is_Out_Of_Range	Value is out of given range.
Referece_Value_Selected_Field_Should_Not_Empty	According to the selected value of the cross check field, the target field should not be empty.
Referece_Value_Selected_Field_Should_Be_Empty	According to the selected value of the cross check field, the target field should be empty.
Date_Should_Not_Before_Reference_Date	The target date should not be before the crosscheck field date.

Date_Should_Not_After_Reference_Date	The target date should not be after the crosscheck field date.
Date_Should_Be_Equal_To_Reference_Date	The target date should be equal to the crosscheck field date.
Date-Reference_Date_Not_In_n-m_Days	The difference between target date and crosscheck field date should be between n to m days.
Date-Reference_Date_In_n-m_Days	The difference between target date and crosscheck field date should not be between n to m days.
Date-Reference_Date_Not_Equal_To_n	The difference between target date and crosscheck field date should be equal to n days.
Date-Reference_Date_Equal_To_n	The difference between target date and crosscheck field date should not be equal to n days.
Reference_Not_Empty_Field_Empty	The crosscheck field is not empty, the target field should not be empty.
Reference_Empty_Field_Not_Empty	The crosscheck field is empty, the target field should be empty.
Should_Not_Both_Empty	The crosscheck field is empty, the target field should not be empty.
Should_Not_Both_Not_Empty	The crosscheck field is not empty, the target field should be empty.
Time-Reference_Time_Not_In_n-m_min	The difference between target field time and cross check field time should be between n to m minutes.
Time-Reference_Time_Not_Equal_To_n_min	The difference between target field time and cross check field time should be equal to n minutes.
Time-Reference_Time_Not_In_n-m_H	The difference between target field time and cross check field time should be between n to m hours.
Time-Reference_Time_Not_Equal_To_n_h	The difference between target field time and cross check field time should be equal to n hours.

Table 1. Built in EC logics in SatDVP

Function 2: DVP export

When the DVP editing is done, user could go to “DVP” worksheet of the SatDVP, clicking “Run” button first to generate the desired DVP which excluded redundant information comparing with the autoDVP sheet, and then click export, an independent excel file is generated at the same folder with the SatDVP.

Function 3: Test Case export

Meanwhile, the test case corresponding to the available DVP could be generated by go to “test case” worksheet of the SatDVP, and click “Run”, “Export” button in succession to generate an independent test case excel file, saved at the same location with SatDVP. The exported test case file could be directly used to add more test cases or directly be used to enter test result or record test failure comment.

Function 4: Generate RAVE quick edit code

Another SatDVP amazing function is that it can directly generate the edit check in a quick edit format according to the available DVP. User only need to copy the quick edit code into RAVE. To obtain this, user only need to click the “Run” button in the “RAVE Quick Edit” worksheet of the SatDVP.

RESULT

By automatic generation, some traditional manual works successfully replaced. Taking 2 studies` works for example, the average study EC number is 746. In a traditional way, write DVP EC requirement details one by one, those two studies cost an average of 66 hours. And EC programming (not include Custom Function programming) cost 191 hours in average, test case writing cost 117 hours in average. However, as calculated, the DVP writing, EC programming and test case writing time could be reduce to 42 hours, 41 hours and 6 hour, respectively. Detail information is attached in below table 2.

	DVP Writing	EC Programming	Test Case Writing	Total
Before	66	191	117	374
After	42	41	6	89
Ratio	36	79	95	76

Table 2. Time cost in 2 RAVE studies before and after using SatDVP

CONCLUSION

As the EDC technology develops, implementing computer program into the DVP document, and apply in the writing DVP stage, the efficiency could be increased significantly, and the unique format of DVP and

test case also could bring convenience to the DVP and test case user, such as data manager and database designer.