

Generating Color Coded Patient ID Spreadsheet (PID List) To Make It Easier for The Reviewers

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ABSTRACT

This paper is for explaining a technique for displaying changes observed in the patient information by using different colors with the help of a SAS code. This technique is useful in the discovery of the changes observed in the patient's data over a period of time. Most of the data in the illustrations involve data about adverse events, serious adverse events, lab abnormalities and reason for discontinuation. These outputs are produced in excel spreadsheets.

INTRODUCTION

In general, we generate patient id list (PID list) needed for patient profiles and narratives based on the requirements gathered from the reviewers, but these PID lists will be generated repeatedly for different analysis such as interim analysis, primary analysis, 90/120 day safety update analysis, supplemental/final analysis.

The following method to generate colored reports is intended to make it easy for all key participants involved in the review process to explore data changes over time and make key decisions in selecting patient's for writing narratives for submissions.

The method that is being used in this paper helps reviewers by identifying changes occurred to the data by color coding the text that has changed. As a result, it helps reviewers quickly identify, analyze and take decisions as needed.

METHODS

Writing patient narratives or summaries for clinical study reports (CSRs) can be a painstaking, time-consuming process with significant consequences for inaccuracies or delays.

This method is very useful to reduce the time and complexity of creating output for review. It helps data managers and data reviewers to visually monitor the status of all data and quickly identify new, modified, or duplicated data.

In this method sas-coding techniques are used to capture, identify and color data lines which have been changed or modified or altered. Several sas macros, sas functions and RTF strings and excel related technical functions have been used (sample SAS code is provided at the bottom of this paper).

With every new data transfer, we can set up this code for a regular timely run of the code to generate outputs to detect changes occurred to the data from the previous transfer. Every sort of modification to AEDECOD, SERIOUS OR NON-SERIOUS, LAB ABNORMALITIS, DEATH, CAUSE OF THE DEATH, REASON FOR DISCONTINUATION is captured and highlighted in colors.

If there are no changes observed to the data then preferred terms, serious flags, flags for death and lab abnormalities remain plain whereas if they have changed then row will bear yellow color and the changed text is red colored. For every newly added rows / patients rows are colored bright red.

RESULTS

Figure 1:

This is the first/initial data/output which will be used as base to compare for changes in Figure 2. Since this is the first output there are no colors generated as there is nothing to compare against to generate colors.

By this technique only altered, modified or edited texts will get color highlighted otherwise they remain simple plain.

Yellow=All Updated Records							
Red=Newly Added records							
PATIENT ID	PREFERRED TERM	SUBJECT HAD ANY SAE	SAE PREFERRED TERM	THE PREFERRED TERM THAT LEAD TO PERMANENT DISCONTINUATION	SUBJECT PERMANENTLY DISCONTINUED DUE TO NON-SERIOUS AE	PRIMARY REASON FOR DISCONTINUATION (DOUBLE BLIND PERIOD)	PRIMARY REASON FOR DISCONTINUATION (OPEN-LABEL PERIOD)
XXX-000001	ABDOMINAL PAIN UPPER/ ARTHRALGIA/ CYST/ DYSGEUSIA/ FALL/ FATIGUE/ IRRITABILITY/ MIDDLE EAR INFLAMMATION/ MYALGIA/ OEDEMA PERIPHERAL/ PAIN IN EXTREMITY/ PAIN IN EXTREMITY/ SKELETAL INJURY					PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)	
XXX-000002	CHEST DISCOMFORT/ DYSPEPSIA/ NAUSEA/ RESPIRATORY TRACT INFECTION/ TOOTH ABSCESS/ WEIGHT DECREASED					OTHER (OLE TRANSITION.)	

Figure 1. PID Listing for the 1st data transfer - with NO colors

Figure 2: For Figure 2 below, the data in Figure 1 is used as base for comparison.

The non-colored rows demonstrate there is no change in patient 000001 data from the previous data transfer.

The yellow rows refer to modified/added texts in any one of those columns. As seen in Figure 1 above this patient 000002 was already qualified to be displayed but the patient's data has changed from previous data transfer to the recent data transfer.

The red colored texts inside yellow rows is the new addition to the already existing text. In the illustration you can see that new preferred terms were added for this subject, and also even though the text 'WEIGHT DECREASED' already exists in the previous data the same text is highlighted here because now this preferred term is repeated/duplicated.

The red colored row refers to addition of a new patient 000003 that was not seen in Figure 1 above. As this is a subject level data it refers a new patient has been added to the output who met the qualifying criteria.

Yellow=All Updated Records							
Red=Newly Added records							
PATIENT ID	PREFERRED TERM	SUBJECT HAD ANY SAE	SAE PREFERRED TERM	THE PREFERRED TERM THAT LEAD TO PERMANENT DISCONTINUATION	SUBJECT PERMANENTLY DISCONTINUED DUE TO NON-SERIOUS AE	PRIMARY REASON FOR DISCONTINUATION (DOUBLE BLIND PERIOD)	PRIMARY REASON FOR DISCONTINUATION (OPEN-LABEL PERIOD)
XXX-000001	ABDOMINAL PAIN UPPER/ ARTHRALGIA/ CYST/ DYSGEUSIA/ FALL/ FATIGUE/ IRRITABILITY/ MIDDLE EAR INFLAMMATION/ MYALGIA/ OEDEMA PERIPHERAL/ PAIN IN EXTREMITY/ PAIN IN EXTREMITY/ SKELETAL INJURY					PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)	
XXX-000002	BACK PAIN/ BACK PAIN/ BLADDER TRANSITIONAL CELL CARCINOMA/ CHEST DISCOMFORT/ DECREASED APPETITE/ DYSPEPSIA/ FATIGUE/ HAEMATURIA/ NAUSEA/ RESPIRATORY TRACT INFECTION/ TOOTH ABSCESS/ TOOTH FRACTURE/ WEIGHT DECREASED/ WEIGHT DECREASED					OTHER (OLE TRANSITION.)	PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)
XXX-000003	CARDIAC FAILURE CONGESTIVE/ COCCYDYNIA/ DECUBITUS ULCER/ DIPLOPIA/ FALL/ PROSTATE CANCER/ RASH/ UPPER RESPIRATORY TRACT INFECTION/ URINARY TRACT INFECTION	Y	CARDIAC FAILURE CONGESTIVE/ PROSTATE CANCER/ URINARY TRACT INFECTION			PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)	PROGRESSIVE DISEASE (CLINICAL PROGRESSION)

Figure 2. PID Listing for the 2nd data transfer using 1st data transfer (data in Figure 1) as base for comparison - with rows/text highlighted in different colors (Red, Yellow or none)

Figure 3: For Figure 3 below, the data in Figure 2 is used as base for comparison.

In the figure 3 you can see that the row for patient 000002 is still yellow highlighted because now this patient has new data in the last column.

Patient 000003 is not colored now because this subject was already there in Figure 2 and there is no change in data after that.

Now you can see new patient 000004 in red row as this is a new subject that met the qualifying criteria in this new data transfer compared to Figure 2.

Yellow=All Updated Records							
Red=Newly Added records							
PATIENT ID	PREFERRED TERM	SUBJECT HAD ANY SAE	SAE PREFERRED TERM	THE PREFERRED TERM THAT LEAD TO PERMANENT DISCONTINUATION	SUBJECT PERMANENTLY DISCONTINUED DUE TO NON-SERIOUS AE	PRIMARY REASON FOR DISCONTINUATION (DOUBLE BLIND PERIOD)	PRIMARY REASON FOR DISCONTINUATION (OPEN-LABEL PERIOD)
XXX-000001	ABDOMINAL PAIN UPPER/ ARTHRALGIA/ CYST/ DYSGEUSIA/ FALL/ FATIGUE/ IRRITABILITY/ MIDDLE EAR INFLAMMATION/ MYALGIA/ OEDEMA PERIPHERAL/ PAIN IN EXTREMITY/ PAIN IN EXTREMITY/ SKELETAL INJURY					PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)	
XXX-000002	BACK PAIN/ BACK PAIN/ BLADDER TRANSITIONAL CELL CARCINOMA/ CHEST DISCOMFORT/ DECREASED APPETITE/ DYSPEPSIA/ FATIGUE/ HAEMATURIA/ NAUSEA/ RESPIRATORY TRACT INFECTION/ TOOTH ABSCESS/ TOOTH FRACTURE/ WEIGHT DECREASED/ WEIGHT DECREASED					OTHER (OLE TRANSITION.)	PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)
XXX-000003	CARDIAC FAILURE CONGESTIVE/ COCCYDYNIA/ DECUBITUS ULCER/ DIPLOPIA/ FALL/ PROSTATE CANCER/ RASH/ UPPER RESPIRATORY TRACT INFECTION/ URINARY TRACT INFECTION	Y	CARDIAC FAILURE CONGESTIVE/ PROSTATE CANCER/ URINARY TRACT INFECTION			PROGRESSIVE DISEASE (RADIOGRAPHIC PROGRESSION)	PROGRESSIVE DISEASE (CLINICAL PROGRESSION)
XXX-000004	PERIPHERAL ARTERIAL OCCLUSIVE DISEASE/ POST PROCEDURAL STROKE/ RENAL FAILURE ACUTE/ URINARY INCONTINENCE/ WEIGHT DECREASED	Y	EJECTION FRACTION DECREASED	POST PROCEDURAL STROKE	Y	OTHER (OL TRANSITION)	ADVERSE EVENT

Figure 3. PID Listing for the 3rd data transfer using 2nd data transfer (data in Figure 2) as base for comparison

CONCLUSION

With this 'traffic-lighting' appearance of the reports a reviewer can easily identify the data changes in patients from previous reports and can easily judge which patients need new narratives. This will significantly reduce the time spent on reviewing the data for new narratives.

As CDISC is standardized process of submitting data, if we use ADaM datasets as input for these reports then we can repeatedly use the same program across all studies/therapeutics areas within the organization, thus this can become a standard efficient process to generate PID lists across different therapeutics within the organization.

Further this technique can be extended to create reports of adverse events, concomitant medications, labs and vital signs, and drill down to customized patient profiles and patient narratives.

SAMPLE CODE

Below is the sample SAS code used in the process:

```
%macro update(var=decod,ar_num=, codt=, do_num=); ;
    array new_&codt(&ar_num) $2000;
    array old_&codt(&ar_num) $2000;
    array _&codt(&ar_num);
    length xd_&codt xd2_&codt $2000;
    xd_&codt="";xd2_&codt="";
    retain xd_&codt xd2_&codt;

do i = 1 to &do_num;
    if indexw(uppercase(&var.),uppercase(_&codt(i)))=0 then new_&codt(i)=strip(_&codt(i));
    if indexw(uppercase(&var.),uppercase(_&codt(i)))>0 then old_&codt(i)=strip(_&codt(i));
    if new_&codt(i) ne " then xd_&codt=catx('/ ',xd_&codt,new_&codt(i));
    if old_&codt(i) ne " then xd2_&codt=catx('/ ',xd2_&codt,old_&codt(i));
end;

if cmiss(xd_&codt, xd2_&codt)=0 then &var._=strip(xd2_&codt)||' '||strip("^{style[color=red
font_weight=bold]}||strip(xd_&codt)}");

else if xd_&codt = ' ' and xd2_&codt ne " then &var._=strip(xd2_&codt);

%mend ;
```

CONTACT INFORMATION

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