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Enforcing Standards in an Organization: A Practical 6 Step-Approach

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ABSTRACT

Is your organization struggling to enforce standards? Is complacency and siloed programming within functional units haunting your organization? This paper will explore a 6-step practical approach for organizations to assess standards using CDISC and FDA guidance, show the importance of standards, the possible repercussions to institute for lack standards adherence, show the importance of a gatekeeper for capturing standards adherence metrics, and finally present a generic macro adherence utility for checking the usage of standards in a study folder. A clear communication for the location and type of standards available within an organization will help eliminate excuses for not using standards. Additionally, an explicit message on the value that standardization brings in increasing efficiency; reducing the need for mundane tasks, and efficient resource utilization is explored. Further, creative methods for encouraging the use of standards are mentioned in the paper. Who is the best suited person to be the gatekeeper in your organization? We investigate the role of a gatekeeper, which is crucial in bridging the gap between the data acquisition stage and the practical implementation of standards. Consequently, several utilities whose main posit is to check the adherence of standards are available. We present a generic utility that can be adopted with a few adjustments allowable to complement your organization's platform. Furthermore, we propose that organizations assess periodically the effectiveness of the standards, tools, and utilities in use. In conclusion, we recommend that organizations utilize this 6-step approach and build on it to suit the organizational standards enforcement needs.

INTRODUCTION

This paper will focus on the questions:

1. Do Standards exist in your organization? Do your standards comply with CDISC standards and FDA Guidance?
2. What is the importance of standards (Efficiency, Automation)?
3. Are there repercussions for not adhering to standards (Public display of adherence)?
4. Is there a gatekeeper for capturing standards adherence metrics?
5. Macro adherence utility: for checking the standards macro in project folder
6. So what? We have standards, tools, and utilities. How effective are they?

STANDARDS WITHIN YOUR ORGANIZATION

Without having statistics to use, we can still estimate, based on some of the recent FDA Guidance for regulatory submissions (https://www.fda.gov/ForIndustry/FDABasicsforIndustry), that large portions of organizations supporting clinical research use CDISC for database standardization. Having standards in place and ensuring that they are used consistently is a challenge we all face.

There are tools, some available to all, like Pinnacle 21, to ensure compliance. Other tools can be created for the organization and would require having a dedicated Multi-Functional Standards Group to support the implementation of clinical data standards. The standard team can develop and maintain therapeutic area specific standards based on CDISC Implementation Guides. The organization should maintain a clear location of company standards:

- SharePoint online
- Standard Macros located in shared corporate folder
- Standard Macros located in therapeutic area standards folder in the system that the company uses

- A “Librarian” in charge of maintaining all standards documents and ensuring the most recent versions of CDISC implementation guides, Controlled Terminology and FDA Guidance are available.

With organizational standards in place, applications can then be used (Pinnacle 21 or designated company standards adherence tools) or developed to ensure compliance by running automated checks on RAW, SDTM and ADaM databases.

IMPORTANCE OF STANDARDS

The FDA gateway for submission provide yearly statistics on the number of submissions sent through electronically.

Display 1 is a screen capture of the current FDA ESG statistics (as of May 5th, 2019):

FDA ESG 2009-2019 Total Submission Statistics

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Totals
AERS	300,672	472,142	557,917	717,345	876,475	1,026,314	1,321,114	1,533,378	1,698,094	2,118,827	539,184	11,161,462
CDER	45,510	69,739	93,503	107,681	124,232	139,322	159,515	165,932	189,141	221,471	55,392	1,371,438
CBER	4,483	5,588	6,397	6,927	8,412	9,506	11,294	20,278	52,197	56,044	16,387	197,513
CDRH	21,296	119,087	280,312	462,316	666,927	812,443	1,478,524	2,032,767	1,921,871	2,247,286	662,139	10,704,968
CVM	859	2,083	20,462	37,928	40,978	44,607	52,601	64,197	70,436	70,682	16,445	421,278
OC	16,275	48,232	55,676	64,285	65,430	68,171	60,943	56,517	71,545	77,353	17,308	601,735
CTP	5	223	348	642	1,237	324	734	612	23,984	19,142	647	47,898
ACA				62	207	195	212	228	218	236	213	1,571
GDUFA				2,771	2,926	3,547	2,906	1,644	1,600	1,455	91	16,940
CFSAN				458	4,220	2,756	3,761	3,619	2,661	2,421	605	20,501
HC					324	5,835	9,366	16,497	23,595	26,927	6,687	89,231
Totals	**389,100**	**717,094**	**1,014,615**	**1,400,415**	**1,791,368**	**2,113,020**	**3,100,970**	**3,895,669**	**4,055,342**	**4,841,844**	**1,315,098**	**24,634,535**

Display 1. the current FDA ESG statistics (as of May 5th, 2019)

Over 3 million documents, including data, have already been submitted for this year. We strongly believe that having standards in place allows the reduction of time spent creating specifications

Programs written can be reused, hence minimizing the amount of time in the creation of an analysis database. More time can be spent on reviewing the results of the analysis.

Standardization introduces efficiency when tools are created that allow work to be consistently performed across studies within a therapeutic area. Standards can be borrowed across therapeutic areas.

With standards in place, less resources are required to performed tasks. This is a money saving venture in both short term and long run for the company.

STANDARDS “ENFORCEMENT”

The goal of “enforcement” is not to police project teams but rather to encourage and support the implementation of company-wide standards.

Put in place a creative option to encourage adherence to standards. For example:

- Provide metrics on adherence in e-brief or newsletter, or during town hall meeting
- Possibility for management to tie team and individual performance with the adherence metrics
- Provide incentives for programmers to continue complying with standards adherence

Set up clinics or training programs to show the value of using standards.

PRACTICAL OPTIONS FOR ENFORCEMENT

We talked about metrics in section 2-1. The organization can consider having a gatekeeper in charge of capturing standards adherence metrics.

- The gate keeper bridges the gap between data acquisition and practical implementation of the standards. The gate keeper does this by ensuring they are competent and up to date on the organizational standards.
- Programming managers and Project lead should serve as the standards gate keepers
- Create standards subject matter experts within a team or project that serve as gate keepers
- Add gate keeping responsibilities to the therapeutic area standards team as well as the corporate standards team. For example:
    - This team should be able to run utilities to check adherence within studies and projects
    - Monthly report should be generated and shared across the relevant therapeutic areas and project groups

PROGRAMMING OPTIONS FOR ENFORCEMENT

In-house developed tools are a great way to assess standard compliance. The advantage of using these in-house tools are numerous:

1. They are usually built to run within your programming platform
2. They can be created with the input of project teams understanding exactly what they need to improve efficiency

Some examples of such tools are:

- Creating utilities that checks within a study folder the standard macros used and generates the compliance report.
- Creating utilities that checks the usage of common variables within the standard domains

ASSESSING THE EFFECTIVENESS OF STANDARDS TOOLS AND UTILITIES

Two approaches are proposed below:

a) Internal Validity: Using Likert Scale Questionnaire Survey:

A Likert Scale is a type of rating scale used to measure attitudes or opinions. With this scale, respondents are asked to rate items on a level of agreement. For example:

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

Five to seven items are usually used in the scale. The scale doesn't have to state "agree" or "disagree"; dozens of variations are possible on themes like agreement, frequency, quality and importance. For example:

- Agreement: Strongly agree to strongly disagree.
- Frequency: Often to never.
- Quality: Very good to very bad.
- Likelihood: Definitely to never.
- Importance: Very important to unimportant.

These items are called Likert Scale Response Anchors.

Once the respondents have answered, numbers are assigned to the responses. For example:

- Strongly agree=5
- Agree=4
- Neutral=3
- Disagree=2
- Strongly disagree=1

This enables you to assign meaning to the responses. For example, a survey on a particular standard or tool can enable you to see which of your tools or utilities are providing effectiveness or good service (an average score of 4-5) and which are providing poor service (an average score of 1-2).

In summary, the following 4 factors should be considered when developing a Likert scale for your tool, utility, or standard:

1. **Define the focus**: what is it you are trying to measure? Your topic should be one-dimensional. For example “Standards Effectiveness” or “This Tool.”

2. **Generate the Likert Scale items.** The items should be able to be rated on some kind of scale. The image at the top of this page has some suggestions. For example, effectiveness/not effectiveness could be rated as “very effective”, “effective”, “not effective” or “very inn-effective.” Effectiveness could also be rated on a scale of 1 to 10, where 1 is not effective at all and 10 is extremely effective.

3. **Rate the Likert Scale items.** You want to be sure your focus is good, so pick a team of people to go through the items in step 2 above and rate them as favorable/neutral/unfavorable to your focus. Weed out the items that are mostly seen as unfavorable.

4. **Administer your Likert Scale test.**

b) Measuring Reliability:

The idea here is to show that if a standard is reliable, then it has a better probability of being effective.

The reliability of a standard, system, or tool is a measure of its ability to provide a failure-free operation. For many practical situations, reliability of a system/standard/tool is represented as the failure rate. For measuring the failure rate of a standard or tool, we can have a comparison of two studies under observation, one that uses the tool, and one that does not.

Most of the standards or tools we use have undergone lifecycle management. It is possible to measure the dependability by comparing a newer version with an older version.

In both cases the reliability which can be hard to measure, but it can be defined as the probability of failure-free software operation for a specified period of time in a specified environment.

CONCLUSION

The essence of checking standard adherence is to allow the organization to reach optimal efficiency and automate mundane tasks.

REFERENCES

FDA Site for Industry: https://www.fda.gov/ForIndustry/FDABasicsforIndustry

APPENDIX

Example utility macro:

```
*************************************************************************
**
***   Macro calls:   %getpath() --> create global macro parameters with
program,
***                                  and log file paths
***                  %list_files(ext=log(default)) --> create a dataset of
all files with the defined
***                                   extension. default is log.
***                              %checklog() --> searches log for specified
text
***   in datasets: NONE
***  out datasets: NONE
***  output files: lst file with proc report showing messages searched
***
***   NOTES AND DISCLAIMER:
***   This macro is written to run in SAS windows environment.
***   It runs with SAS 9.2 or higher
***   The code is provided as an example for an utility macro.
***   It can be modified to suit your purpose
*************************************************************************
**;

dm log 'clear';

option mprint mlogic symbolgen;

%macro getpath();

%global namefile filepath filelog;

/**** Set Path for program (.sas, .log) to the folder from which the program
is being submitted. ***/
%if "%sysfunc(getoption(sysin))" ne "" %then %do;
   %let namefile = %%sysfunc(getoption(sysin));
   %let filepath = %substr(&namefile,1,%eval(%length(&namefile)-
%index(%sysfunc(reverse(&namefile)),\)));
   %let filelog =%sysfunc(tranwrd(%nrbquote(&namefile),%str(sas),%str(log)));
%end;
%else %do;
   %let namefile = %lowcase(%sysget(sas_execfilepath));
   %let filepath =
%lowcase(%nrbquote(%substr(%sysget(sas_execfilepath),1,%eval(%index(%sysget(s
as_execfilepath),%sysget(sas_execfilename))-2))));
   %let filelog =%sysfunc(tranwrd(%nrbquote(&namefile),%str(sas),%str(log)));
%end;

%put ##SAS file is: &namefile;
%put ##SAS path is: &filepath;
%put ##SAS Log is: &filelog;

%mend;

%getpath();
```

```
**------------------------------------------------------------------------;
** Create  list of all Log files
**------------------------------------------------------------------------;
%macro list_files(ext =log);

%local filrf rc did ;

%let rc =%sysfunc(filename(filrf,&filepath));
%let did =%sysfunc(dopen(&filrf));

/** _ERROR Check **/;
%if &did eq 0 %then %do;
      %put Directory &dir cannot be open or does not exist;
      %return;
%end;

/** Output a file containing all relevant files from selected directory **/
data filelist;
      length FNAME $100;
      /** Loops through entire directory **/
      %do i = 1 %to %sysfunc(dnum(&did));
            %let name =%qsysfunc(dread(&did,&i));
            /** check file extension (default is log) **/
            %if %qupcase(%qscan(&name,-1,.)) = %upcase(&ext) %then %do;
                  FNAME ="&name" ;
                  TEMP =scan(fname,1,'.');
                  VNAME ="&filepath./"||strip(fname);
                  output;
            %end;
      %end;

      run;

%let rc=%sysfunc(dclose(&did));
%let rc=%sysfunc(filename(filrf));

%mend list_files;

%list_files();


**------------------------------------------------------------------------;
** DATA CHECK STEP- NOT REQUIRED:
** CREATE SEARCHABLE LST FILE
** MANUALLY CHECK FOR A FEW MESSAGE
**------------------------------------------------------------------------;
** create macro list of all files;
**------------------------------------------------------------------------;
proc sql noprint;
      select '"'||vname||'"' into: myfile separated by ' '
      from filelist
      ;
quit;

%put &myfile;
```

```
**------------------------------------------------------------------------------;
** Read file names as one macro;
**------------------------------------------------------------------------------;
filename myfile (&myfile);

**------------------------------------------------------------------------------;
** Create bundle lst of log files;
**------------------------------------------------------------------------------;
data _null_;
  infile myfile;
  file "&filepath./LOGS.lst" ;
  input;
  put _infile_;
run;

proc printto print ="&filepath./LOGS.lst" ;
run;

**------------------------------------------------------------------------------;
** END DATA CHECK STEP- NOT REQUIRED:
**------------------------------------------------------------------------------;

*******************************************************************************;
* Select program path into macro variable
*******************************************************************************;
%macro checklog(dir=&filepath);

**------------------------------------------------------------------------------;
** Create macro list of all files;
**------------------------------------------------------------------------------;
proc sql noprint;
      select temp into: plist separated by ' '
      from filelist
      ;
      select count(*) into: vcnt
      from filelist
      ;
quit;

%put &plist;

    %let obs=%sysfunc(compress(&vcnt));
    %put ######;
    %put #---# Number of programs &obs;
    %put #####;
    %put #---#Program list &plist;
    %put **********;

    /** Check logs: one program at a time **/
    %do i=1 %to &obs;

        %let pgr =%scan(&plist,&i,' ');
        %let pgrlog&i=&pgr;

        %put >>>> &&pgrlog&i <<<< ;
        %put >>> &_exec_programpath./&pgr..sas <<< ;
```

```
    filename inlog "&dir./&pgr..log";  /** Read log **/

    data logfile;
      label sasline='Line number in SAS Log'
            errval ='Errors, Warnings and Notes' length=200;
      retain SASLINE 0;
      infile inlog;
      input;

      SASLINE =sasline + 1;
      fw= scan(_infile_,1,'20'x);
      if substr(fw,length(fw))=':' then;
          else goto bottom;

      /** Check for errors, warning and notes **/
      %macro seekstrg(string=);

          string="&string";
          i1=index(upcase(_infile_),upcase("&string"));
          if i1 then goto write;

      %mend;
      /** This section can be modified to pick specific text **/
      %seekstrg(string=warning:);
      %seekstrg(string=error:);
      %seekstrg(string=macro);
      %seekstrg(string=include);

      write:
            errval =_infile_;
      output;


      bottom:

      /** Summary of messages **/;
      proc summary data=logfile;
          class errval;
          output out=&&pgrlog&i;
      run;

     run;

 data pgrlog;
       set &pgrlog1;
   run;

        %if &i>1 %then %do;
             proc append base=pgrlog data=&&pgrlog&i force;
             run;
        %end;


%end; /** End do-loop **/


 ods pdf file="&dir./zLogCheck_View.pdf" ;
```

```
       proc report data =pgrlog(drop=_TYPE_) nowindows headline spacing=1;
         where errval ^=:'MLOGIC' and errval ^=:'MPRINT' and errval
^=:'SYMBOLGEN';
         column errval _freq_;
         define errval / "###### LOG Messages in &pgr..sas #######" flow
width=90 ;
         define _freq_ / 'Frequency' width=9;
       run;

     ods pdf close;


%mend;

%checklog;
```

CONTACT INFORMATION

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