Utilizing SAS to Dynamically Generate Clinical Trial Data Transformation Programs

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ABSTRACT
We illustrate a technique, using SAS®, to convert programming specification text into a set of uniformly formatted SAS programs used to perform a clinical database transformation. The method begins by reading an Excel worksheet that contains instructions on how to modify clinical database data. Next, we demonstrate how to parse those instructions and convert the text into formal SAS syntax. This syntax is then used to build a series of SAS programs that, when finalized and executed, perform the desired database transformation.

INTRODUCTION
Standardized programming specifications are often used in clinical trial programming to guide the programmer through the data transformation process. These instructions often define the available input and the output expected from the data modification. A typical database transformation consists of modifying variable attributes, converting data types, and creating new variables. Writing the syntax to perform these basic operations is time-consuming for programmers having to manually convert the instructions into executable SAS code.

We illustrate in this paper a process for improving programming efficiency by utilizing SAS to write SAS code. We show how to use the text in a programming specification document to build a set of consistently formatted SAS programs to be used as a starting point in a database transformation. Additionally, we demonstrate how to incorporate custom code, standardized program headers, and other more complex data processing syntax into the programs being created. Figure 1 illustrates a typical data transformation process. Our paper focuses on the SAS Program Creation step in this process.

DEFINING A DATABASE TRANSFORMATION SPECIFICATION
The database transformation specification is the primary source of instructions for interpreting and modifying data in the Clinical Database. The data transformation process relies heavily on a well organized specification that contains the following three key elements:

• **Source Metadata Attributes** – source table name, column names, lengths, labels, and data types in the Clinical Database

• **Output Metadata Attributes** – output dataset name, variable names, lengths, labels, and data types in the Transformed Database

• **Derivation Calculations** – specific directions and algorithms for transforming source data to output data.

When these three elements are present, the specification document provides the required information to accomplish typical data transformations such as data type conversions, renaming columns, assigning formats, as well as more complex derivations, e.g. combining multiple character columns to create a single numeric date variable. Most importantly, if the database transformation specifications are consistently formatted across multiple projects then fewer modifications to the example outlined below are required for portability. Programming time can then shift from mundane derivations and program set-up to more complex data algorithms.
Below is a snapshot of the specification used in our paper’s data transformation process. It contains separate sets of input and output metadata listed from left to right for the DM and AE clinical database tables needing to be transformed:

CREATING SAS DATA TRANSFORMATION PROGRAMS
There are four steps to our process:
1. importing the data transformation specification
2. creating variable attribute syntax
3. creating derivation syntax
4. writing SAS syntax to .sas files

STEP 1 – IMPORTING THE DATA TRANSFORMATION SPECIFICATION
We begin by importing the specification Excel spreadsheet using the following SAS code. All header information, blank lines, and rows where there is no variable to derive will be excluded.

```
/* Step 1 - Read in the mapping specifications; */
PROC IMPORT OUT= WORK.inspec(where = (outdata ^= ''))
  DATAFILE= "C:\INSPEC.XLS"
  DBMS=EXCEL REPLACE;
RUN;
```

Below is a snapshot of the INSPEC dataset generated from this step:

<table>
<thead>
<tr>
<th>DataName</th>
<th>Label</th>
<th>Type</th>
<th>Length</th>
<th>InputFormat</th>
<th>OutputFormat</th>
<th>OutName</th>
<th>OutLabel</th>
<th>OutType</th>
<th>OutAlignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM STUDY</td>
<td>Clinical Study</td>
<td>NUM</td>
<td>5</td>
<td>DEMOG STUDY</td>
<td>Study Identifier</td>
<td>CHAR</td>
<td>20</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>DM PT</td>
<td>Patient</td>
<td>CHAR</td>
<td>8</td>
<td>DEMOG SUBJECT</td>
<td>Subject ID</td>
<td>NUM</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>DM AGE</td>
<td>Age</td>
<td>NUM</td>
<td>8</td>
<td>DEMOG AGE</td>
<td>Age</td>
<td>CHAR</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>DM BIRTHDATE</td>
<td>Birth Date</td>
<td>NUM</td>
<td>8</td>
<td>DEMOG BIRTHDATE</td>
<td>Birth Date</td>
<td>CHAR</td>
<td>9</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

STEP 2 – CREATING ATTRIBUTE SYNTAX
Next we create an ATTRIBUTES dataset that stores all of our derived variable attribute SAS code in a variable called ATTRIBUTE whose values have the following general form:

```
OUTNAME attribute1 = attribute1 definition … <attribute-n = attribute-n definition>
```

Where `OUTNAME` is the name of the variable being created and the `attributes` and `attributes definitions` are based on the OUTLABEL, OUTTYPE, and OUTFORMAT columns in the INSPEC dataset. We will use the values of the
ATTRIBUTE variable later to create a single ATTRIB statement.

****************************************************************************************
* STEP 2 - Create Attribute statements;
****************************************************************************************;
data attributes(keep = outdata outname attribute);
  length attribute $200;
  set inspec;
  
  if outname ^= '' then do;
    if outlabel ^= '' then attribute = outname||' label = "'||strip(outlabel)||'"';
    if outtype = 'CHAR' then attribute = strip(attribute)||' length = $'||outlength;
    if outformat ^= '' then attribute = strip(attribute)||' format = "'||outformat||'"';
  end;
run;

Below is a snapshot of the ATTRIBUTES dataset generated from this step:

<table>
<thead>
<tr>
<th>attribute</th>
<th>OUTDATA</th>
<th>OUTNAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>DEMOG</td>
<td>STUDYID</td>
</tr>
<tr>
<td>SUBJECT</td>
<td>DEMOG</td>
<td>SUBJECT</td>
</tr>
<tr>
<td>GENDER</td>
<td>DEMOG</td>
<td>GENDER</td>
</tr>
<tr>
<td>ASEX</td>
<td>DEMOG</td>
<td>ASEX</td>
</tr>
<tr>
<td>BIRTHDTC</td>
<td>DEMOG</td>
<td>BIRTHDTC</td>
</tr>
<tr>
<td>BIRTHDTN</td>
<td>DEMOG</td>
<td>BIRTHDTN</td>
</tr>
<tr>
<td>STUDYID</td>
<td>ADEVEYE</td>
<td>STUDYID</td>
</tr>
<tr>
<td>SUBJECT</td>
<td>ADEVEYE</td>
<td>SUBJECT</td>
</tr>
<tr>
<td>ATEXT</td>
<td>ADEVEYE</td>
<td>ATEXT</td>
</tr>
<tr>
<td>SERIOUS</td>
<td>ADEVEYE</td>
<td>SERIOUS</td>
</tr>
<tr>
<td>AESTRDT</td>
<td>ADEVEYE</td>
<td>AESTRDT</td>
</tr>
<tr>
<td>AESTRTN</td>
<td>ADEVEYE</td>
<td>AESTRTN</td>
</tr>
<tr>
<td>AESTRTY</td>
<td>ADEVEYE</td>
<td>AESTRTY</td>
</tr>
<tr>
<td>AESTOTC</td>
<td>ADEVEYE</td>
<td>AESTOTC</td>
</tr>
</tbody>
</table>

STEP 3 – CREATING DERIVATION SYNTAX
The next step is to create a DERIVATIONS dataset that stores all of the information necessary to create our derived OUTNAME variables in a variable called DERIVE. Using the INSPEC data, the values of DERIVE are based on the DERIVATION variable values as well as the comparison of the INNAME variable attributes with the OUTNAME variable attributes. DERIVE values have the following general form:

```
OUTNAME = CALCULATION;
```

where OUTNAME is the name of the variable being created and CALCULATION is the derivation expression syntax.

****************************************************************************************
* STEP 3 - Create derived variable derivation code;
****************************************************************************************;
data derivations(keep = outdata outname derive where = (derive ^= ''));
  length derive $200;
  set inspec;
  
  *derivations defined in the specification;
  if derivation ^= '' then derive = '/* '||strip(outname)||' = '||strip(derivation)||' */';
  else do;
    *numeric to character conversions;
    if intype = 'NUM' and outtype = 'CHAR' then do;
      if informat = '' then informat = 'BEST.';
      derive = strip(outname)||' = strip(put('||strip(inname)||','||strip(informat)||'));'
    end;
    *character to numeric conversions;
    else if intype = 'CHAR' and outtype = 'NUM' then do;
      if outformat = '' then outformat = 'BEST.';
      derive = strip(outname)||' = input('||strip(inname)||','||strip(outformat)||');'
  end;
run;
*character to character or numeric to numeric assignments;
else if intype = outtype then derive = strip(outname) || '|' || strip(inname) || ';;';
end;
*customized derivations using a macro call;
if substr(reverse(strip(outname)),1,3) = 'NTD' then derive = '
%makedate('| ||strip(outname)|| '|');
run;

Below is a snapshot of the DERIVATIONS dataset generated from this step:

<table>
<thead>
<tr>
<th>derive</th>
<th>OUTDATA</th>
<th>OUTNAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 STUDYID = strip(px(STUDY,BEST.));</td>
<td>DENOG</td>
<td>STUDYID</td>
</tr>
<tr>
<td>2 SUBJECT = input(FT 8);</td>
<td>DENOG</td>
<td>SUBJECT</td>
</tr>
<tr>
<td>3 GENDER = strip(px(SEX,MF));</td>
<td>DENOG</td>
<td>GENDER</td>
</tr>
<tr>
<td>4 AGEC = strip(px(AGE,BEST.));</td>
<td>DENOG</td>
<td>AGEC</td>
</tr>
<tr>
<td>5 BIRTHDT = BIRTHDT;</td>
<td>DENOG</td>
<td>BIRTHDT</td>
</tr>
<tr>
<td>6 %makedate(BIRTHDTN);</td>
<td>DENOG</td>
<td>BIRTHDT</td>
</tr>
<tr>
<td>7 STUDYID = strip(px(STUDY,BEST.));</td>
<td>ADEV</td>
<td>STUDYID</td>
</tr>
<tr>
<td>8 SUBJECT = input(FT 8);</td>
<td>ADEV</td>
<td>SUBJECT</td>
</tr>
<tr>
<td>9 AETEXT = AEVER;</td>
<td>ADEV</td>
<td>AETEXT</td>
</tr>
<tr>
<td>10 SERIOUS = strip(px(YESNO));</td>
<td>ADEV</td>
<td>SERIOUS</td>
</tr>
<tr>
<td>11 AESTRDT = AESTD TD;</td>
<td>ADEV</td>
<td>AESTRDT</td>
</tr>
<tr>
<td>12 AESTR TN = AESTDM;</td>
<td>ADEV</td>
<td>AESTR TN</td>
</tr>
<tr>
<td>13 AESTRTY = AESTDTY;</td>
<td>ADEV</td>
<td>AESTRTY</td>
</tr>
<tr>
<td>14 / AESTD TC = Concatenate AEAESTDTD, AE,AESTDM, and AEAESTDTY Y</td>
<td>ADEV</td>
<td>AESTD TC</td>
</tr>
<tr>
<td>15 %makedate(AESTDTN);</td>
<td>ADEV</td>
<td>AESTDTN</td>
</tr>
</tbody>
</table>

STEP 4 – WRITING SAS TRANSFORMATION PROGRAM FILES

Now that we have our attribute and derivation syntax datasets, we loop through the INSPEC dataset to generate one SAS program for each dataset being written to the transformed database. The INSPEC, ATTRIBUTES, and DERIVATIONS datasets are used to compose SAS code. We write this code to .sas files using PUT statements. All programs generated through this process will share common syntax formatting, header text, OPTIONS statements, and macro calls, as well as dataset specific ATTRIB statements, KEEP statements, comments, and derivation syntax.

****************************************************************************************;
* STEP 4 - Combine the attributes and derivations datasets and create our SAS programs;
****************************************************************************************;
proc sort data = inspec out = alldsn nodupkey;
by outdata;
run;

%macro mydatasetLoop;
%local dsid rc nors varn i value;
%let dsid = %sysfunc(open(alldsn));
%let nors = %sysfunc(varnum(alldsn));
%let varn = %sysfunc(varnum(&dsid, indata));
%let outvar = %sysfunc(varnum(&dsid, outdata));
%do i = 1 %to &nors;
  %let rc = %sysfunc(fetchobs(&dsid, &i));
  %let indn = %sysfunc(getvarc(&dsid, &indata));
  %let outdsn = %sysfunc(getvarc(&dsid, &outdata));
  %let sasfile = "C:\&outdsn..SAS";
  **********************************************************;
  * start by writing out the program header, options,;
  * and any standard %includes;
  **********************************************************;
  proc sort data = inspec (where = (outdata = "&outdsn."))
    out = mapdsn (keep = indata outdata) nodupkey;
  by outdata;
  run;
  data _null_;
    set mapdsn;
    %end;
file &sasfile;
nowdate = symget('sysdate9');
put "*************************************************************************
        **         CLIENT: CLIENTXXX**;
        **         PROTOCOL: XXX-XXX-XXX**;
        **         PROGRAM NAME: &outdsn..SAS**;
        **         SAS VERSION: 9.1.3**;
        **         PURPOSE: This program will create the &outdsn. dataset from**
        **         the clinical trial database.**;
        **         USAGE NOTES: Batch Submit with SAS913.**;
        **                  **;
        **         INPUT FILES: &indsn..SAS7BDAT**;
        **         OUTPUT FILES: &outdsn..SAS7BDAT**;
        **         AUTHOR: AUTHORXXX**;
        ** DATE CREATED: " @;
        put nowdate;
        **                  **;
        **         MODIFICATION LOG:**
        put "**************************************************************************
        ** DATE          INITIALS        MODIFICATION DESCRIPTION**;
        put "**************************************************************************;
        put "**************************************************************************;
%include "sassetup.sas";
%include "standardmacros.sas";

run;
**********************************************************;
* now write out the data step with a keep statement;
**********************************************************;
data _null_;
    length txt $256;
    set inspec (where = (outdata = "&outdsn."));
    by outdata;
    file &sasfile mod;
    retain indent;
    if first.outdata then do;
        txt = 'data '||strip(outdata)||' (keep = '
    put txt @;
        indent = length(txt) + 1;
    end;
    if mod(_n_,8) ^= 0 then do;
        put outname @;
    end;
    else do;
        put outname;
        put +indent @;
    end;
    if last.outdata then do;
        put '});';
    put;
end;
run;
**********************************************************;
* now write out the attribute statement;
**********************************************************;
data _null_;
    length txt $256;
    set attributes (where = (outdata = "&outdsn."));
    by outdata;
    file &sasfile mod;
    if first.outdata then do;
        txt='attrib '||strip(attribute);
    put +2 txt;
    end;
    if not first.outdata then do;
        put +9 attribute;
    end;
    if last.outdata then do;
        put +2 ';';
    put;
end;
After executing the above SAS syntax, the resulting .sas program files can be used as a starting point or template for further development. The programs can now be examined, updated, and processed independent of one another to complete the database transformation.

Below is the syntax of the ADVEVE.SAS program that is generated from this step:

```sas
* ******************************************************;
* now write out the derivations for the new variables;
* ******************************************************;
data _null_;  
set derivations (where = (derive ^= '' and outdata = "$outdsn."));
by outdata;
file &sasfile mod;
if first.outdata then do;
   put +2 "set inlib.&indsn;";
   put;
   end;
   put +2 derive;
if last.outdata then do;
   put;
   put 'run;';
   put;
   end;
run;

* ******************************************************;
* now complete the program by sorting and writing out the;
* final dataset;
* ******************************************************;
data _null_;  
file &sasfile mod;
put "% write(dsn = &outdsn, sortby = <ADD &outdsn. SORT VARIABLES HERE>);";
r
run;
%end;
%let dsid = %sysfunc(close(&dsid));
%mend mydatasetLoop;
%mydatasetLoop;

After executing the above SAS syntax, the resulting .sas program files can be used as a starting point or template for further development. The programs can now be examined, updated, and processed independent of one another to complete the database transformation.

Below is the syntax of the ADVEVE.SAS program that is generated from this step:

```
CONCLUSION
The clinical database transformation process can require relatively simple yet cumbersome programming tasks. Programming specifications are used to document this transformation and to guide the programmer through this process. As an alternative to manually converting these instructions into SAS code, we illustrate in this paper a technique to utilize the specification to dynamically generate SAS programs that form the basis of a database transformation. Automating the SAS program creation saves coding time and enables the programmer to concentrate on more complex programming algorithms.

CONTACT INFORMATION
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