ABSTRACT
Adverse events (AEs) are collected in almost all clinical trials. AEs are generally summarized by severity (mild, moderate, and severe) and relationship to study drug (unrelated, possibly, probably, almost certainly). This paper shows you how to take advantage of the formats library and automate code in creating AE tables. The program was created using SAS® Version 8.2 on OpenVMS Alpha and is intended for beginner to intermediate level SAS Users.

INTRODUCTION
Adverse event severity and relationship codes change from study to study. For example, one study may have 2 relationship codes and another study may have 5. The meaning of each code also changes from study to study. In one study, ‘1’ may mean mild and in another it may mean severe. But data are always coded and formats are available in the formats library. We want to figure out the number of codes and labels for severity and relationship automatically for the table shown below.

Table 1. Adverse Event Frequency by Treatment, Severity, and Relationship to Drug

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Treatment</th>
<th>No. of Adverse Events</th>
<th>Severity</th>
<th>Relationship to Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Adverse</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Headache</td>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Neck pain</td>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Pharyngolaryngeal pain</td>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

SOLUTION
Using the CNTLOUT option in PROC FORMAT, the format values are written to a dataset and this dataset is used to create macro variables with the necessary information. These macro variables are used in the PROC REPORT.

DATA
For illustration purposes, partial data are shown below.

PTNO  TREAT  ADVERSE                  PREFERTERM                        SEVERITY  REDRUG
1     A     SORE THROAT               Pharyngolaryngeal pain  1     1
4     A     UPSET STOMACH             Dyspepsia                        1     1
8     A     PAIN IN RT POSTERIOR NECK Neck pain                 1     1
12    A     HEADACHE                  Headache                         1     2

Proc Contents:
<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Len</th>
<th>Pos</th>
<th>Format</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVERSE</td>
<td>Char</td>
<td>200</td>
<td>24</td>
<td></td>
<td>Verbatim Description of Adverse Event</td>
</tr>
<tr>
<td>PREFERTERM</td>
<td>Char</td>
<td>100</td>
<td>224</td>
<td></td>
<td>Preferred Term</td>
</tr>
<tr>
<td>PTNO</td>
<td>Num</td>
<td>8</td>
<td>16</td>
<td></td>
<td>Subject Number</td>
</tr>
<tr>
<td>REDRUG</td>
<td>Num</td>
<td>8</td>
<td>8</td>
<td>REL.</td>
<td>Relationship to Study Drug</td>
</tr>
<tr>
<td>SEVERITY</td>
<td>Num</td>
<td>8</td>
<td>0</td>
<td>SEV.</td>
<td>Severity of Event</td>
</tr>
<tr>
<td>TREAT</td>
<td>Char</td>
<td>8</td>
<td>324</td>
<td></td>
<td>Treatment</td>
</tr>
</tbody>
</table>

Format values for Severity (SEV):
1 = Mild
2 = Moderate
3 = Severe
Format values for Relationship (REL):

1 = Unrelated
2 = Unlikely
3 = Possibly
4 = Probably
5 = Almost Certainly

**CODE**

* Read formats library and create a dataset with format values for SEV and REL;
* Determine the length of each severity and relationship code;
* If the code has more then 1 word, then put ~ in between the words and set the length to maximum of the 2 words;
* This is done to split the label in the PROC REPORT;

```sas
proc format library=library cntlout=fmts(keep=start fmtname label);
    select sev rel;
run;
```

```sas
* Determine the length of each severity and relationship code;
* If the code has more then 1 word, then put ~ in between the words and set the length to maximum of the 2 words;
* This is done to split the label in the PROC REPORT;
```

```sas
data fmts;
    set fmts;
    first=scan(label,1);
    second=scan(label,2);
    lfirst=index(first,' ')-1;
    lsecond=index(second,' ')-1;
    length=max(lfirst,lsecond);
    if second ne '' then label=trim(first)||'~'||trim(second);
    drop first second lfirst lsecond;
run;
```

```sas
%let adjrel=No;
```

* Create macro variables for the number of relationship codes, for each relationship value, and for the length of each value;

```sas
data _null_;
    set fmts (where=(fmtname='REL')) end=last;
    call symput('rel'||trim(left(_n_)),trim(label));
    call symput('lrel'||trim(left(_n_)),length);
    if last then do;
        call symput('nrel',trim(left(_n_)));
        if _n_ ne start then call symput ('adjrel', 'Yes');
    end;
run;
```

```sas
%let adjsev=No;
```

* Create macro variables for the number of severity codes, for each severity value, and for the length of each value;

```sas
data _null_;
    set fmts (where=(fmtname='SEV')) end=last;
    call symput('sev'||trim(left(_n_)),trim(label));
    call symput('lsev'||trim(left(_n_)),length);
    if last then do;
        call symput('nsev',trim(left(_n_)));
        if _n_ ne start then call symput ('adjsev', 'Yes');
    end;
run;
```

```sas
%let adjsev=No;
```

* Create macro variables for the number of severity codes, for each severity value, and for the length of each value;

```sas
data _null_;
    set fmts (where=(fmtname='SEV')) end=last;
    call symput('sev'||trim(left(_n_)),trim(label));
    call symput('lsev'||trim(left(_n_)),length);
    if last then do;
        call symput('nsev',trim(left(_n_)));
        if _n_ ne start then call symput ('adjsev', 'Yes');
    end;
run;
```
** If starting value is zero then add one;
data aes;
   set <name of the SAS dataset>;
   %if &adjrel=Yes %then %do;
      redrug=redrug+1;
   %end;
   %if &adjsev=Yes %then %do;
      severity=severity+1;
   %end;
run;
Other SAS statements to count number of events under each severity and relationship

proc report data=final split="-" center headline spacing=2 missing;
   column ord prefterm treat nae
      ('Severity----' %do i=1 %to &nsev; n&i %end;)
      ('Relationship to Drug----' %do i=1 %to &nrel; nr&i %end;);
   define ord/order noprint;
   define prefterm/order format=$100. width=26 flow left 'Preferred Term';
   define treat/order format=$1. width=9 center 'Treatment';
   define nae/display format=2. width=9 center 'Adverse~Events';
   %do i=1 %to &nsev;
      define n&i/display   format=2. width=&&lsev&i. center "&&sev&i";
   %end;
   %do i=1 %to &nrel;
      define nr&i/display   format=2. width=&&lrel&i. center "&&rel&i";
   %end;
run;
Title1  'Table 1.  Adverse Event Frequency by Treatment, Severity, and Relationship to Drug';

NOTES

<table>
<thead>
<tr>
<th>Obs</th>
<th>FMTNAME</th>
<th>START</th>
<th>LABEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>REL</td>
<td>1</td>
<td>Unrelated</td>
</tr>
<tr>
<td>2</td>
<td>REL</td>
<td>2</td>
<td>Unlikely</td>
</tr>
<tr>
<td>3</td>
<td>REL</td>
<td>3</td>
<td>Possibly</td>
</tr>
<tr>
<td>4</td>
<td>REL</td>
<td>4</td>
<td>Probably</td>
</tr>
<tr>
<td>5</td>
<td>REL</td>
<td>5</td>
<td>Almost Certainly</td>
</tr>
<tr>
<td>6</td>
<td>SEV</td>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td>7</td>
<td>SEV</td>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>8</td>
<td>SEV</td>
<td>3</td>
<td>Severe</td>
</tr>
</tbody>
</table>

Notice the use of _n_ rather than START. This is because sometimes values may start with zero rather than one.

CONCLUSION
Writing a dataset from formats library is a very useful technique. This paper has shown you one application of this technique in summarizing AEs in clinical trials.

REFERENCES
Erin Christen, PROC FORMAT is Our Friend, Paper TU02, SUGI 2006.
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