```
libname raw '/home/u58485303/raw';
libname output '/home/u58485303/output';
libname base '/home/u58485303/base';

options validvarname=upcase;

/* ae raw data */
/* created variables STUDYID DOMAIN   USUBJID AESPID AETERM AEDECOD
AESER AESTDTC    AEENDTC    AECONTRT AEACN AEREL
AEOUT AESEV AEHLT AELLT AEHLGT   AEBODSYS AESOC AELLTCD AEPTCD AEHLTCD
AEHLGTCD AEBDSYCD     AESOCCD */

data ae1;
set raw.ae (rename=(AETERM= AETERM1 AESER= AESER1 AEOUT= AEOUT1 AESEV=
AESEV1));
length USUBJID $40 AEREL AEOUT AESEV AEHLT AELLT AEHLGT AEBODSYS AESOC
$200;

STUDYID= 'ACP-103-020';
DOMAIN= 'AE';
SUBJID= strip(substr(SUBJECT, 4,3));
SITEID= strip(substr(SITE, 5,3));
USUBJID= compress(STUDYID || '-' || SITEID|| '-' || SUBJID);

AESPID= AESEQ;
AETERM= upcase(AETERM1);
AEDECOD= AETERM_AEDECOD;

if AESER1= 1 then AESER='Y';
if AESER1= 2 then AESER='N';
if AESER1=96 then AESER='NA';

AESTDTC= put(input(AESTDDT,??date11.),??is8601da.);
AEENDTC= put(input(AEENDDT,??date11.),??is8601da.);

if AETHER=0 then AECONTRT= 'N';
If AETHER=1 then AECONTRT= 'Y';
if AETHER=2 then AECONTRT= '';

if AEACT=0 then AEACN= 'DOSE NOT CHANGED';
if AEACT=1 then AEACN= 'DRUG INTERRUPTED';
if AEACT=4 then AEACN= 'DRUG WITHDRAWN';
```

```
if AECAUS=0 then AEREL= 'Not Related';
if AECAUS=1 then AEREL= 'Unlikely';
if AECAUS=2 then AEREL= 'Possible';
if AECAUS=3 then AEREL= 'Probable';
if AECAUS=4 then AEREL= 'Highly Probable';

if AEOUT1 in (1,6) then AEOUT= '';
if AEOUT1=2 then AEOUT= 'RECOVERED/RESOLVED';
if AEOUT1=3 then AEOUT= 'RECOVERED/RESOLVED WITH SEQUELAE';
if AEOUT1 in (4,5) then AEOUT= 'FATAL';

if AESEV1=1 then AESEV= 'Mild';
if AESEV1= 2 then AESEV= 'Moderate';
if AESEV1=3 then AESEV= 'Severe';

AEHLT= AETERM_AEHLT;
AELLT= AETERM_AELLT;
AEHLGT= AETERM_AEHLGT;
AEBODSYS= AETERM_AEBODSYS;
AESOC= AETERM_AESOC;
AELLTCD= AETERM_AELLTCD;
AEPTCD= AETERM_AEPTCD;
AEHLTCD= AETERM_AEHLTCD;
AEHLGTCD= AETERM_AEHLGTCD;
AEBDSYCD= AETERM_AEBDSYCD;
AESOCCD= AETERM_AESOCCD;

keep STUDYID DOMAIN   USUBJID AESPID AETERM AEDECOD AESER   AESTDTC
     AEENDTC    AECONTRT AEACN AEREL
     AEOUT AESEV AEHLT AELLT AEHLGT   AEBODSYS AESOC AELLTCD AEPTCD
AEHLTCD AEHLGTCD AEBDSYCD  AESOCCD AEFREQ AEDESC;
run;

/* created variables AESTDY AEENDY */

options mprint;

%macro stdy_dy (domain=, input=);

proc sort data= output.dm out= dmx (keep= usubjid rfstdtc);
by usubjid;
```

```
run;

proc sort data= &input. out= &input.x;
by usubjid;
run;

data &input._dm;
merge dmx (in= a) &input.x (in= b);
if a and b;
by usubjid;
&domain.stdt= input(&domain.stdtc,??is8601da.);
&domain.endt= input(&domain.endtc,??is8601da.);
rfstdt= input(rfstdtc,??is8601da.);

if &domain.stdt ge rfstdt then &domain.stdy= (&domain.stdt- rfstdt) +
1;
else &domain.stdy= &domain.stdt- rfstdt;

if &domain.endt ge rfstdt then &domain.endy= (&domain.endt- rfstdt) +
1;
else &domain.endy= &domain.endt- rfstdt;

run;

%mend stdy_dy;

%stdy_dy(domain=ae, input=ae1);

/* created AESEQ */

%let key= STUDYID USUBJID AEDECOD AESTDTC;

proc sort data= ae1_dm out= ae1_dm1;
by &key;
run;

data all;
set ae1_dm1;
by &key;

if first.usubjid then aeseq= 1;
else aeseq +1;
```

```
run;

/* assigned attributes and created final ae dataset */

%let keepvar= STUDYID DOMAIN USUBJID AESEQ AESPID AETERM AEDECOD AESER
AESTDTC AEENDTC AECONTRT   AEACN
     AEREL AEOUT     AESEV AEHLT     AELLT AEHLGT AEBODSYS AESOC
     AELLTCD    AEPTCD     AEHLTCD    AEHLGTCD AEBDSYCD AESOCCD
     AESTDY AEENDY;

data output.ae (label= 'Adverse Events');
retain &keepvar;
attrib STUDYID label= 'Study Identifier' length= $20
           DOMAIN label= 'Domain Abbreviation' length= $2
           USUBJID label= 'Unique Subject Identifier' length= $40
           AESEQ label= 'Sequence Number' length= 8.
           AESPID label= 'Sponsor-Defined Identifier' length= 8.
           AETERM label= 'Reported Term for the Adverse Event' length=
$200
           AEDECOD label= 'Dictionary-Derived Term' length= $200
           AESER label= 'Serious Event' length= $8
           AESTDTC label= 'Start Date/Time of Adverse Event' length=
$20
           AEENDTC label= 'End Date/Time of Adverse Event' length= $20
           AECONTRT label= 'Concomitant or Additional Trtmnt Given'
length= $8
           AEACN label= 'Action Taken with Study Treatment' length=
$200
           AEREL label= 'Causality' length= $200
           AEOUT label= 'Outcome of Adverse Event' length= $200
           AESEV label= 'Severity/Intensity' length= $200
           AEHLT label= 'High Level Term' length= $200
           AELLT label= 'Lowest Level Term' length= $200
           AEHLGT label= 'High Level Group Term' length= $200
           AEBODSYS label= 'Body System or Organ Class' length= $200
           AESOC label= 'Primary System Organ Class' length= $200
           AELLTCD label= 'Lowest Level Term Code' length= 8.
           AEPTCD label= 'Preferred Term Code' length= 8.
           AEHLTCD label= 'High Level Term Code' length= 8.
           AEHLGTCD label= 'High Level Group Term Code' length= 8.
           AEBDSYCD label= 'Body System or Organ Class Code' length= 8.
           AESOCCD label= 'Primary System Organ Class Code' length= 8.
```

```
           AESTDY label= 'Study Day of Start of Adverse Event' length=
8.
           AEENDY label= 'Study Day of End of Adverse Event' length=
8.;
set all;

keep &keepvar;
run;

/* proc compare base=base.ae comp=output.ae listall; */
/* ods listing file= '/home/u58485303/output/ae.lst'; */
/* run; */
```