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/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.1.1
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

/*Create macro variables of dataset variables to access later*/
%let vartestcd="BMI","WEIGHT","HEIGHT";
%let varlist=usubjid age sex race ethnic;
%let varlist2=usubjid vstestcd vsstresn visit;

/*Create subset of dm dataset with variables needed for table*/
data dm1;
set r.dm(keep=&varlist)
r.vs(keep=&varlist2 where=(vstestcd in (&vartestcd) and
visit="SCREENING"));
by usubjid;
run;

/*Transpose dataset*/
proc transpose data=dm1 out=dm2;
by usubjid;
id vstestcd;
var vsstresn;
where vstestcd^='';
run;

/*Merge back with Transposed dataset*/
data dm2;
merge dm1(drop=vstestcd vsstresn) dm2;
by usubjid;
drop _name_;
run;

/*Sort to keep unique records per subject*/
proc sort data=dm2 nodupkey;
by usubjid;
run;

/*Prepare data for variables age weight height and bmi */
%macro prep;

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%let var1=age;
%let var2=weight;
%let var3=height;
%let var4=bmi;

%do i=1 %to 4;
proc univariate data=dm2 noprint;
    var &&var&i;
    output out=&&var&i n=N mean=MEAN std=SD min=MIN median=MEDIAN
max=MAX;
run;
%end;

%do i=1 %to 4;
data &&var&i;
length varname $10.;
set &&var&i;
varname=upcase("&&var&i");
run;

proc transpose data=&&var&i out=&&var&i;
id varname;
var _numeric_;
run;

data &&var&i;
length order1 8.;
set &&var&i;
order1=&i;
run;

data &&var&i;
length statval $30.;
format statval $30.;
length dmvar $30.;
set &&var&i;
if order1=1 and _NAME_ ^= 'SD' then statval=put(&&var&i,14.);
if _NAME_ = 'N' then statval=put(&&var&i,14.);
if _NAME_ = 'SD' and order1=1 then statval=put(&&var&i,14.1);
if _NAME_ = 'SD' and order1^=1 then statval=put(&&var&i,14.2);
if order1^=1 and _NAME_ not in ('N','SD') then
statval=trim(put(round(&&var&i,.1),14.1));
if _NAME_ = 'N' then order2=1;
if _NAME_ = 'MEAN' then order2=2;
if _NAME_ = 'SD' then order2=3;
if _NAME_ = 'MIN' then order2=4;
if _NAME_ = 'MEDIAN' then order2=5;
if _NAME_ = 'MAX' then order2=6;

if order1=1 then dmvar="Age (years)";
if order1=2 then dmvar="Weight (kg)";
if order1=3 then dmvar="Height (cm)";

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if order1=4 then dmvar="Body Mass Index (kg/m2)";

drop &&var&i;
run;

%end;

%mend prep;

%prep;

/*Prepare data for variables sex, ethnicity, and race*/
%macro prep2;
%let var1=sex;
%let var2=ethnic;
%let var3=race;

%do i=1 %to 3;

proc freq data=dm2 noprint;
    tables &&var&i / out=&&var&i missing;
run;

data &&var&i;
length statval $30.;
length dmvar $30.;
length dmvar2 $30.;
set &&var&i;
statval=put(count,8.)||" (||trim(right(put(percent,5.1)))||"%)";
if &&var&i=" " then &&var&i="Unknown";
if &i=1 then do
dmvar="Gender:";
end;
else if &i=2 then do
dmvar="Ethnicity:";
end;
else if &i=3 then do
dmvar="Race:";
end;
dmvar2=propcase(&&var&i);
_NAME_="n (%)";
drop &&var&i percent;
run;

%end;

/*proc sql;
insert into sex set dmvar="Gender";
insert into ethnic set dmvar="Ethnicity";
insert into race set dmvar="Race";
quit;

```

```

*/
%do i=1 %to 3;
data &&var&i;
set &&var&i;
order1=&i+4;
run;
%end;

%mend prep2;

%prep2;

/*Format for Demographic variables*/
proc format;
value $dmvar  'F'='Female'
               'M'='Male'
               'Hispanic Or Latino'='Hispanic or Latino'
               'Not Hispanic Or Latino'='Not Hispanic or Latino'
               'Black Or African American'='Black or African
American'
               'Unknown'='Unknown'
               'Body Mass Index (kg/m2)'='Body Mass Index
(kg/m^{super 2})'
               'Other'='Other';
run;

/*Final Report dataset creation*/
Data fnlreport(drop=count);
Set age(in=i1) weight(in=i2) height(in=i3) bmi(in=i4) sex(in=i5)
ethnic(in=i6) race(in=i7);
If trim(upcase(dmvar2))=:trim(upcase('m')) then
order2=1;
If trim(upcase(dmvar2))=:trim(upcase('f')) then
order2=2;
If trim(upcase(dmvar2))=:upcase('hispanic or latino') then
order2=1;
If trim(upcase(dmvar2))=:upcase('not hispanic or latino') then
order2=2;
If trim(upcase(dmvar2))=:upcase('unknown') then
order2=9;
If trim(upcase(dmvar2))=:upcase('white')
then order2=1;
If trim(upcase(dmvar2))=:upcase('black or african american') then
order2=2;
If trim(upcase(dmvar2))=:upcase('other')
then order2=3;
If trim(upcase(dmvar2))=:upcase('unknown')
then order2=9;
If order1 < 5 and order2^=1 then dmvar='';

```

```

/*page counter*/
counter = _n_;
mypage = 1;
if counter > 24 then do;
counter+1;
mypage+1;
end;

Run;

options nodate nonumber;

proc sort data=fnlreport;
by order1 order2;
run;

/*Create internal labels for report variables*/
data fnlreport;
set fnlreport;
label dmvar="Demographic";
label _name_="Statistic";
label statval="Summary Result";
if order2^=1 then dmvar='';
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull12=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

proc sort data=fnlreport;
by order1 order2 mypage dmvar;
run;

/*Create blank rows after each demographic variable data*/

data fnlreport;
set fnlreport;
output;
by order1;
if last.order1;
array allnums [*] _numeric_;
array allchar [*] _character_ ;
drop i;
do i=1 to dim(allnums); allnums(i)=.; end;
do i=1 to dim(allchar); allchar{i}=' '; end;

```

```

output; /* Output blank observation */
run;

/* Proc Report section */
/* Run two proc reports simultaneously to get desired output */
/* Manual post processing done to the output by removing an empty page
and a empty row */
ods escapechar='^';
ods listing close;
ods rtf
file="\\nac103\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
1-1.rtf" bodytitle style=Styles.custom;
proc report
    data = fnlreport
    nowd
    ls=122
    ps=30
    headline
    headskip
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.152in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.152in
foreground=black bordercolor=black}
    ;

    columns (order1 dmvar _name_ statval mypage);
    where mypage=1;
    define order1 /order order = internal noprint;
    define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=20% just=l};
    define _name_ /display center "Statistic" style={cellwidth=35%
just=c};
    define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=22.5%
just=dec};
    define mypage /order group style(column)={cellwidth=22%
foreground=white background=white} " ";

    compute after _page_;
    line @1 " ";
    endcomp;

    compute before mypage;
    line @1 ' ';
    endcomp;

    title1 j=1 "OTR1021
Table 14.1-1

```

DATE:&dtnull2

```
TIME:&systemtime";
    title2 j=c "Descriptive Statistics of Screening Demographics:
Enrolled Population";
    title3 j=c "(Page 1 of 2)";
    *title3 j=c "Page ^{thispage} of ^{lastpage}";
    title4;
    title5 j=1 "Population: Enrolled
";
    footnote j=1 "Source: Listing 16.2.4-4a";

proc report
    data = fnlreport
    nowd
    ls=122
    ps=30
    headline
    headskip
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.2in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.15in
foreground=black bordercolor=black}
    ;

    columns (order1 order2 dmvar dmvar2 _name_ statval mypage );
    where mypage=2;

    define order1 /order order = internal noprint;
    define order2 /order = internal noprint;
    define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=10% just=l};
    define dmvar2 /display left " " format=$dmvar.
style={cellwidth=25% just=l};
    define _name_ /display center "Number (%) of Subjects"
style={cellwidth=32% just=c};
    define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=17.% just=dec};
    define mypage /order group style(column)={cellwidth=15%
foreground=white background=white} " ";

    compute after _page_;
    line @1 " ";
    endcomp;

    compute before mypage;
    line @1 ' ';
    endcomp;

    title1 j=1 "OTR1021
    Table 14.1-1
```

DATE:&dtnull2

```
TIME:&systime";
    title2 j=c "Descriptive Statistics of Screening Demographics:
Enrolled Population";
    title3 j=c "(Page 2 of 2)";
    *title3 j=c "Page ^{thispage} of ^{lastpage}";
    title4;
    title5 j=1 "Population: Enrolled
";
    footnote j=1 "Source: Listing 16.2.4-4a";
run;quit;
ods listing;
ods rtf close;
```



```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.1.2
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

/*Create macro variables of dataset variables to access later*/
%let vartestcd="BMI","WEIGHT","HEIGHT";
%let varlist=usubjid age sex race ethnic;
%let varlist2=usubjid vstestcd vsstresn visit;

/*Create subset of dm dataset with variables needed for table*/
data dm1;
set r.dm(keep=&varlist)
r.vs(keep=&varlist2 where=(vstestcd in (&vartestcd) and
visit="SCREENING"));
by usubjid;
run;

proc sql noprint;
delete from dm1
where usubjid not in (select distinct usubjid from r.dm where armcd ^=
"SCRNFAIL"
and usubjid in (select usubjid from r.ex where usubjid in
(select distinct usubjid from r.vs where vstptnum > 6)));
quit;

/*Transpose dataset*/
proc transpose data=dm1 out=dm2;
by usubjid;
id vstestcd;
var vsstresn;
where vstestcd^='';
run;

/*Merge back with Transposed dataset*/
data dm2;
merge dm1(drop=vstestcd vsstresn) dm2;
by usubjid;
drop _name_;
run;

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```

/*Sort to keep unique records per subject*/
proc sort data=dm2 nodupkey;
by usubjid;
run;

/*Prepare data for variables age weight height and bmi */

%macro prep;
%let var1=age;
%let var2=weight;
%let var3=height;
%let var4=bmi;

%do i=1 %to 4;
proc univariate data=dm2 noprint;
    var &&var&i;
    output out=&&var&i n=N mean=MEAN std=SD min=MIN median=MEDIAN
max=MAX;
run;
%end;

%do i=1 %to 4;
data &&var&i;
length varname $10.;
set &&var&i;
varname=upcase("&&var&i");
run;

/* Transpose numeric variables */
proc transpose data=&&var&i out=&&var&i;
id varname;
var _numeric_;
run;

data &&var&i;
length order1 8.;
set &&var&i;
order1=&i;
run;

/* Create char variable statval to store stat values with appropriate
formats */
data &&var&i;
length statval $30.;
format statval $30.;
length dmvar $30.;
set &&var&i;
if order1=1 and _NAME_ ^='SD' then statval=put(&&var&i,14.);
if _NAME_='N' then statval=put(&&var&i,14.);
if _NAME_='SD' and order1=1 then statval=put(&&var&i,14.1);
if _NAME_='SD' and order1^=1 then statval=put(&&var&i,14.2);

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if order1^=1 and _NAME_ not in ('N','SD') then
statval=trim(put(round(&&var&i,.1),14.1));
if _NAME_='N' then order2=1;
if _NAME_='MEAN' then order2=2;
if _NAME_='SD' then order2=3;
if _NAME_='MIN' then order2=4;
if _NAME_='MEDIAN' then order2=5;
if _NAME_='MAX' then order2=6;

if order1=1 then dmvar="Age (years)";
if order1=2 then dmvar="Weight (kg)";
if order1=3 then dmvar="Height (cm)";
if order1=4 then dmvar="Body Mass Index (kg/m2)";

drop &&var&i;
run;

%end;

%mend prep;

%prep;

/* Macro to prepare data for variables sex, ethnicity, and race*/
%macro prep2;
%let var1=sex;
%let var2=ethnic;
%let var3=race;

%do i=1 %to 3;

proc freq data=dm2 noprint;
    tables &&var&i / out=&&var&i missing;
run;

/* Create char variable statval to store stat values with appropriate
formats */
data &&var&i;
length statval $30.;
length dmvar $30.;
length dmvar2 $30.;
set &&var&i;
statval=put(count,8.)||" (||trim(right(put(percent,5.1)))||"%)";
if &&var&i=" " then &&var&i="Unknown";
if &i=1 then do
dmvar="Gender:";
end;
else if &i=2 then do
dmvar="Ethnicity:";
end;
else if &i=3 then do

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dmvar="Race:";
end;
dmvar2=propcase(&&var&i);
_NAME_="n (%)";
drop &&var&i percent;
run;

%end;

/*proc sql;
insert into sex set dmvar="Gender";
insert into ethnic set dmvar="Ethnicity";
insert into race set dmvar="Race";
quit;
*/
%do i=1 %to 3;
data &&var&i;
set &&var&i;
order1=&i+4;
run;
%end;

%mend prep2;

%prep2;

/*Format for Demographic variables*/
proc format;
value $dmvar  'F'='Female'
               'M'='Male'
               'Hispanic Or Latino'='Hispanic or Latino'
               'Not Hispanic Or Latino'='Not Hispanic or Latino'
               'Black Or African American'='Black or African
American'
               'Unknown'='Unknown'
               'Body Mass Index (kg/m2)'='Body Mass Index
(kg/m^{super 2})'
               'Other'='Other';
run;

/*Final Report dataset creation*/
Data fnlreport(drop=count);
Set age(in=i1) weight(in=i2) height(in=i3) bmi(in=i4) sex(in=i5)
ethnic(in=i6) race(in=i7);
If trim(upcase(dmvar2))=:trim(upcase('m')) then
order2=1;
If trim(upcase(dmvar2))=:trim(upcase('f')) then
order2=2;
If trim(upcase(dmvar2))=:upcase('hispanic or latino') then
order2=1;

```

```

If trim(uppercase(dmvar2))=:uppercase('not hispanic or latino')    then
order2=2;
If trim(uppercase(dmvar2))=:uppercase('unknown')                  then
order2=9;
If trim(uppercase(dmvar2))=:uppercase('white')
    then order2=1;
If trim(uppercase(dmvar2))=:uppercase('black or african american') then
order2=2;
If trim(uppercase(dmvar2))=:uppercase('other')
    then order2=3;
If trim(uppercase(dmvar2))=:uppercase('unknown')
    then order2=9;
If order1 < 5 and order2^=1 then dmvar='';

/*page counter*/
counter = _n_;
mypage = 1;
if counter > 24 then do;
counter+1;
mypage+1;
end;

Run;

options nodate nonumber;

proc sort data=fnlreport;
by order1 order2;
run;

/*Create internal labels for report variables*/
data fnlreport;
set fnlreport;
label dmvar="Demographic";
label _name_="Statistic";
label statval="Summary Result";
if order2^=1 then dmvar='';
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

proc sort data=fnlreport;
by order1 order2 mypage dmvar;
run;

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/*Create blank rows after each demographic variable data*/

data fnlreport;
set fnlreport;
output;
by order1;
if last.order1;
array allnums [*] _numeric_;
array allchar [*] _character_ ;
drop i;
do i=1 to dim(allnums); allnums(i)=.; end;
do i=1 to dim(allchar); allchar{i}=' '; end;
output; /* Output blank observation */
run;

/* Proc Report section */
/* Run two proc reports simultaneously to get desired output */
/* Manual post processing done to the output by removing an empty page
and a empty row */
ods escapechar='^';
options orientation=landscape;
ods listing close;
ods rtf
file="\\nac103\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
1-2.rtf" bodytitle style=Styles.custom;
proc report
    data = fnlreport
    nowd
    ls=122
    ps=30
    headline
    headskip
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.152in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.152in
foreground=black bordercolor=black}
    ;

    columns (order1 dmvar _name_ statval mypage);
    where mypage=1;
    define order1 /order order = internal noprint;
    define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=20% just=l};
    define _name_ /display center "Statistic" style={cellwidth=35%
just=c};
    define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=22.5%
just=dec};

```

```

        define mypage /order group style(column)={cellwidth=22%
foreground=white background=white} " ";

        compute after _page_;
        line @1 " ";
        endcomp;

        compute before mypage;
        line @1 ' ';
        endcomp;

        title1 j=1 "OTR1021
                    Table 14.1-2

DATE:&dtnull2
TIME:&systemtime";
        title2 j=c "Descriptive Statistics of Screening Demographics:
Randomized Safety Population";
        title3 j=c "(Page 1 of 2)";
        *title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Randomized Safety
";
        footnote j=1 "Source: Listing 16.2.4-4b";

proc report
    data = fnlreport
    nowd
    ls=122
    ps=30
    headline
    headskip
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.2in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.15in
foreground=black bordercolor=black}
    ;

    columns (order1 order2 dmvar dmvar2 _name_ statval mypage );
    where mypage=2;

    define order1 /order order = internal noprint;
    define order2 /order = internal noprint;
    define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=10% just=1};
    define dmvar2 /display left " " format=$dmvar.
style={cellwidth=25% just=1};
    define _name_ /display center "Number (%) of Subjects"
style={cellwidth=32% just=c};

```

```

        define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=17.% just=dec};
        define mypage /order group style(column)={cellwidth=15%
foreground=white background=white} " ";

        compute after _page_;
        line @1 " ";
        endcomp;

        compute before mypage;
        line @1 ' ';
        endcomp;

        title1 j=1 "OTR1021
                        Table 14.1-2
                                DATE:&dtnull2
TIME:&systime";
        title2 j=c "Descriptive Statistics of Screening Demographics:
Randomized Safety Population";
        title3 j=c "(Page 2 of 2)";
        *title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Randomized Safety
";
        footnote j=1 "Source: Listing 16.2.4-4b";

run;quit;
ods listing;
ods rtf close;

```



```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.1.3
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

/*Create macro variables of dataset variables to access later*/
%let vartestcd="BMI","WEIGHT","HEIGHT";
%let varlist=usubjid age sex race ethnic;
%let varlist2=usubjid vstestcd vsstresn visit;

/*Create subset of dm dataset with variables needed for table*/
data dm1;
set r.dm(keep=&varlist)
r.vs(keep=&varlist2 where=(vstestcd in (&vartestcd) and
visit="SCREENING"));
by usubjid;
run;

proc sql noprint;
delete from dm1
where usubjid not in (select distinct usubjid from r.dm where armcd ^=
"SCRNFAIL"
and usubjid in (select usubjid from r.ex where usubjid in
(select distinct usubjid from r.pp)));
quit;

/*Transpose dataset*/
proc transpose data=dm1 out=dm2;
by usubjid;
id vstestcd;
var vsstresn;
where vstestcd^='';
run;

/*Merge back with Transposed dataset*/
data dm2;
merge dm1(drop=vstestcd vsstresn) dm2;
by usubjid;
drop _name_;
run;

```

```

/*Sort to keep unique records per subject*/
proc sort data=dm2 nodupkey;
by usubjid;
run;

/*Prepare data for variables age weight height and bmi */

%macro prep;
%let var1=age;
%let var2=weight;
%let var3=height;
%let var4=bmi;

%do i=1 %to 4;
proc univariate data=dm2 noprint;
    var &&var&i;
    output out=&&var&i n=N mean=MEAN std=SD min=MIN median=MEDIAN
max=MAX;
run;
%end;

%do i=1 %to 4;
data &&var&i;
length varname $10.;
set &&var&i;
varname=upcase("&&var&i");
run;

proc transpose data=&&var&i out=&&var&i;
id varname;
var _numeric_;
run;

data &&var&i;
length order1 8.;
set &&var&i;
order1=&i;
run;

data &&var&i;
length statval $30.;
format statval $30.;
length dmvar $30.;
set &&var&i;
if order1=1 and _NAME_ ^= 'SD' then statval=put(&&var&i,14.);
if _NAME_ = 'N' then statval=put(&&var&i,14.);
if _NAME_ = 'SD' and order1=1 then statval=put(&&var&i,14.1);
if _NAME_ = 'SD' and order1^=1 then statval=put(&&var&i,14.2);
if order1^=1 and _NAME_ not in ('N','SD') then
statval=trim(put(round(&&var&i,.1),14.1));
if _NAME_ = 'N' then order2=1;
if _NAME_ = 'MEAN' then order2=2;

```

```

if _NAME_='SD'          then order2=3;
if _NAME_='MIN'         then order2=4;
if _NAME_='MEDIAN'      then order2=5;
if _NAME_='MAX'         then order2=6;

if order1=1 then dmvar="Age (years)";
if order1=2 then dmvar="Weight (kg)";
if order1=3 then dmvar="Height (cm)";
if order1=4 then dmvar="Body Mass Index (kg/m2)";

drop &&var&i;
run;

%end;

%mend prep;

%prep;

/*Prepare data for variables sex, ethnicity, and race*/
%macro prep2;
%let var1=sex;
%let var2=ethnic;
%let var3=race;

%do i=1 %to 3;

proc freq data=dm2 noprint;
    tables &&var&i / out=&&var&i missing;
run;

data &&var&i;
length statval $30.;
length dmvar $30.;
length dmvar2 $30.;
set &&var&i;
statval=put(count,8.)||" ("||trim(right(put(percent,5.1)))||"%)";
if &&var&i=" " then &&var&i="Unknown";
if &i=1 then do
dmvar="Gender:";
end;
else if &i=2 then do
dmvar="Ethnicity:";
end;
else if &i=3 then do
dmvar="Race:";
end;
dmvar2=propcase(&&var&i);
_NAME_="n (%)";
drop &&var&i percent;
run;

```

```

%end;

/*proc sql;
insert into sex set dmvar="Gender";
insert into ethnic set dmvar="Ethnicity";
insert into race set dmvar="Race";
quit;
*/
%do i=1 %to 3;
data &&var&i;
set &&var&i;
order1=&i+4;
run;
%end;

%mend prep2;

%prep2;

/*Format for Demographic variables*/
proc format;
value $dmvar  'F'='Female'
               'M'='Male'
               'Hispanic Or Latino'='Hispanic or Latino'
               'Not Hispanic Or Latino'='Not Hispanic or Latino'
               'Black Or African American'='Black or African
American'
               'Unknown'='Unknown'
               'Body Mass Index (kg/m2)'='Body Mass Index
(kg/m^{super 2})'
               'Other'='Other';
run;

/*Final Report dataset creation*/
Data fnlreport(drop=count);
Set age(in=i1) weight(in=i2) height(in=i3) bmi(in=i4) sex(in=i5)
ethnic(in=i6) race(in=i7);
If trim(upcase(dmvar2))=:trim(upcase('m')) then
order2=1;
If trim(upcase(dmvar2))=:trim(upcase('f')) then
order2=2;
If trim(upcase(dmvar2))=:upcase('hispanic or latino') then
order2=1;
If trim(upcase(dmvar2))=:upcase('not hispanic or latino') then
order2=2;
If trim(upcase(dmvar2))=:upcase('unknown') then
order2=9;
If trim(upcase(dmvar2))=:upcase('white')
then order2=1;

```

```

If trim(uppercase(dmvar2))=:uppercase('black or african american')      then
order2=2;
If trim(uppercase(dmvar2))=:uppercase('other')
    then order2=3;
If trim(uppercase(dmvar2))=:uppercase('unknown')
    then order2=9;
If order1 < 5 and order2^=1 then dmvar='';

/*page counter*/
counter = _n_;
mypage = 1;
if counter > 24 then do;
counter+1;
mypage+1;
end;

Run;

options nodate nonumber;

proc sort data=fnlreport;
by order1 order2;
run;

/*Create internal labels for report variables*/
data fnlreport;
set fnlreport;
label dmvar="Demographic";
label _name_="Statistic";
label statval="Summary Result";
if order2^=1 then dmvar='';
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

proc sort data=fnlreport;
by order1 order2 mypage dmvar;
run;

/*Create blank rows after each demographic variable data*/

data fnlreport;
set fnlreport;

```

```

output;
by order1;
if last.order1;
array allnums [*] _numeric_;
array allchar [*] _character_ ;
drop i;
do i=1 to dim(allnums); allnums(i)=.; end;
do i=1 to dim(allchar); allchar{i}=' '; end;
output; /* Output blank observation */
run;

/* Proc Report section */
/* Run two proc reports simultaneously to get desired output */
/* Manual post processing done to the output by removing an empty page
and a empty row */
ods escapechar='^';
options orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
1-3.rtf" bodytitle style=Styles.custom;
proc report
    data = fnlreport
    nowd
    ls=122
    ps=30
    headline
    headskip
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.152in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.152in
foreground=black bordercolor=black}
    ;

    columns (order1 dmvar _name_ statval mypage);
    where mypage=1;
    define order1 /order order = internal noprint;
    define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=20% just=l};
    define _name_ /display center "Statistic" style={cellwidth=35%
just=c};
    define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=22.5%
just=dec};
    define mypage /order group style(column)={cellwidth=22%
foreground=white background=white} " ";

    compute after _page_;
    line @1 " ";
endcomp;

```

```

compute before mypage;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
          Table 14.1-3

DATE:&dtnull2
TIME:&systime";
title2 j=c "Descriptive Statistics of Screening Demographics:
Full Analysis Population";
title3 j=c "(Page 1 of 2)";
*title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Full Analysis
";
footnote j=1 "Source: Listing 16.2.4-4c";

proc report
data = fnlreport
nowd
ls=122
ps=30
headline
headskip
style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
cellheight=.2in bordercolor=black}
style(header)={font_face=arial font_size=2.5 cellheight=.15in
foreground=black bordercolor=black}
;

columns (order1 order2 dmvar dmvar2 _name_ statval mypage );
where mypage=2;

define order1 /order order = internal noprint;
define order2 /order = internal noprint;
define dmvar /display "Demographic" format=$dmvar.
style={cellwidth=10% just=l};
define dmvar2 /display left " " format=$dmvar.
style={cellwidth=25% just=l};
define _name_ /display center "Number (%) of Subjects"
style={cellwidth=32% just=c};
define statval /display "Summary Result" center
style={protectspecialchars=off cellpadding=4 cellwidth=17.% just=dec};
define mypage /order group style(column)={cellwidth=15%
foreground=white background=white} " ";

compute after _page_;
line @1 " ";

```

```

endcomp;

compute before mypage;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
           Table 14.1-3

DATE:&dtnull2
TIME:&systime";
title2 j=c "Descriptive Statistics of Screening Demographics:
Full Analysis Population";
title3 j=c "(Page 2 of 2)";
*title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Full Analysis
";
footnote j=1 "Source: Listing 16.2.4-4c";

run;quit;
ods listing;
ods rtf close;

```



```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.1.7
    Notes:                                Re-programming sample tables as
part of QC.
*/

```

```

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

```

```

data ex;
length trtc $1;
set r.ex;
if EXDOSTXT="FINELY CRUSHED 10 MG OTR" then trtc="A";
if EXDOSTXT="COARSELY CRUSHED 10 MG OTR" then trtc="B";
if EXDOSTXT="FINELY CRUSHED 10 MG OC" then trtc="C";
run;

```

```

proc sql;
create table trta as select epoch, count(trtc) as trta from ex
where trtc="A"
group by 1
order by 1,2;

```

```

create table trtb as select epoch, count(trtc) as trtb from ex
where trtc="B"
group by 1
order by 1,2;

```

```

create table trtc as select epoch, count(trtc) as trtc from ex
where trtc="C"
group by 1
order by 1,2;
quit;

```

```

data overall;
length epoch2 8;
merge trta trtb trtc;
by epoch;
epoch2=put(substr(epoch,8,1),8.);
drop epoch;
rename epoch2=epoch;
run;

```

```

proc transpose data=overall out=overall;
var _all_;
run;

```

```

data overall;
length col4 8;
set overall;
col4=sum(col1,col2,col3);
run;

proc transpose data=overall out=overall2;
id _name_;
var _numeric_;
run;

proc sort data=overall2;
by epoch;
run;

data overall3;
length overall $25;
length stat1-stat3 $30;
set overall2;
by epoch;
if epoch^=6 then do;
Overall=trim(put(sum(trta,trtb,trtc),8.))||'
'||put(trim(put(sum(trta,trtb,trtc),5.2))/trim(put(sum(trta,trtb,trtc),5.2))*100,5.2)||'%' );
end;
if epoch=6 then do;
stat1=trta||' (||put(trta/sum(trta,trtb,trtc)*100,5.1)||'%)';
stat2=trtb||' (||put(trtb/sum(trta,trtb,trtc)*100,5.1)||'%)';
stat3=trtc||' (||put(trtc/sum(trta,trtb,trtc)*100,5.1)||'%)';
end;
if epoch=6 then do;
stat1=trta||' (||put(trta/30*100,5.1)||'%)';
stat2=trtb||' (||put(trtb/30*100,5.1)||'%)';
stat3=trtc||' (||put(trtc/30*100,5.1)||'%)';
end;
run;

options nonumber;
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

proc format;
value epoch
6="Overall";
run;

```

```

ods escapechar='^';
ods listing close;
ods rtf
file="\\nac103\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
1-7.rtf" bodytitle style=Styles.custom;
proc report
    data = overall3
    nowd
    ls=122
    ps=30
    headline
    headskip
    split='*'
    style(report)={just=left font_face=arial font_size=2.5
bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.275in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 cellheight=.3in
foreground=black bordercolor=black}
    ;

    columns (epoch ('Number (%) of
Subjects*_____ ' stat1 stat2 stat3
overall));

    define epoch /order order = internal "Study Period" center
format=epoch. style={cellwidth=19% just=c};;
    define stat1 /display "Treatment A" center style={cellwidth=20%
just=c};
    define stat2 /display "Treatment B" center style={cellwidth=20%
just=c};
    define stat3 /display "Treatment C" center style={cellwidth=20%
just=c};
    define overall /display "Overall" center style={cellwidth=20%
just=c};

    compute before;
    line @1 ' ';
    endcomp;

    compute after ;
    line @1 ' ';
    endcomp;

    title1 j=1 "OTR1021
Table 14.1-7

DATE:&dtnull2
TIME:&systemtime";
    title2 j=c "Study Treatment Administration by Study Period:
Randomized Safety Population";
    title3 j=c "(Page 1 of 1)";

```

```
*title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety
";
    footnote j=1 "NOTE: TreatmentA = Finely crushed 10mg OTR;
TreatmentB = Coarsely crushed 10mg OTR; TreatmentC = Finely crushed
10mg OC.";
    footnote2 j=1 "Source: Listing 16.2.5-2c";
run;
ods listing;
ods rtf close;
```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.2.2-1
    Notes:                                Re-programming sample tables as
part of QC.                                Output table format from this
program is not completely per specs
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

/* Copy EX dataset to work folder and assign single letter treatment
codes */
data ex;
length treatc $1;
set r.ex(keep=studyid usubjid exseq exdostxt exstdtc exendtc epoch
visitnum);
if EXDOSTXT="FINELY CRUSHED 10 MG OTR" then treatc="A";
if EXDOSTXT="COARSELY CRUSHED 10 MG OTR" then treatc="B";
if EXDOSTXT="FINELY CRUSHED 10 MG OC" then treatc="C";
drop exdostxt;
run;

data pp;
set r.pp;
run;

proc transpose data=pp out=transpp;
by usubjid ppgrpid;
id pptestcd;
var ppstresn;
run;

data transpp2(drop=llambda ulambda nlamba _name_ sccat);
merge transpp(in=a) r.sc(in=b keep=usubjid scorres SCCAT
where=(sccat="RANDOMIZATION NUMBER"));
by usubjid;
if a and b;
run;

data transpp2;
length ppgrpid2 8;
set transpp2;
ppgrpid2=put(ppgrpid,8.);

```

```

drop ppgrpid;
rename ppgrpid2=ppgrpid;
run;

data ppex;
merge transpp2 ex(keep=usubjid treatc exseq rename=(exseq=ppgrpid));
by usubjid ppgrpid;
run;

proc sort data=ppex;
by treatc;
run;

proc univariate data=ppex;
by treatc;
var AUC0_T;
output n=N mean=amean std=SD min=MIN median=med max=MAX cv=cvar;
run;

proc univariate data=ppex;
by treatc;
var cmax;
output out=cmax n=N mean=amean std=SD min=MIN median=med max=MAX
cv=cvar;
run;

proc transpose data=cmax out=cmaxtrans(rename=(col1=cmax));
by treatc;
var _numeric_;
run;

option nolabel spool;

proc sql flow number;
create table final2 as select treatc,
trim(trim(scorres)||'/'||trim(substr(usubjid,15,5))) as randsubject
length=15,
ppgrpid,AUC0_T,AUC0_INF,CMAX,TMAX,LAMBDAZ,TERMHALF,TLAG from ppex
order by 1,2;
quit;

%macro prep_14221;
%let stat1=AUC0_T;
%let stat2=AUC0_INF;

```

```

%let stat3=CMAX;
%let stat4=TMAX;
%let stat5=LAMBDAZ;
%let stat6=TERMHALF;
%let stat7=TLAG;

%DO I=1 %TO 7;
proc univariate data=ppex;
by treatc;
var &&stat&i;
output out=&&stat&i n=_N mean=_MEAN std=_SD min=_MIN median=_MEDIAN
max=_MAX cv=_CV;
run;

proc transpose data=&&stat&i out=&&stat&i(rename=(coll=&&stat&i));
by treatc;
var _numeric_;
run;

proc sort data=&&stat&i;
by treatc _name_;
run;

data &&stat&i;
set &&stat&i;
*&&stat&i=round(&&stat&i,.5);
format &&stat&i best12.;
run;

%end;

data final;
merge &stat1 &stat2 &stat3 &stat4 &stat5 &stat6 &stat7;
by treatc _name_;
run;

%mend prep_14221;

%prep_14221;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

```

```

/* Proc Report Step */
dm "odsresults; clear;";
options nonumber nodate orientation=landscape;
ods listing close;
ods escapechar='^';
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
2-2-1.rtf" style=Styles.custom;
proc report
    data = final2
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.4in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns treatc randsubject ppgrpid AUC0_T AUC0_INF CMAX TMAX
LAMBDAZ TERMHALF TLAG;
    where treatc="A";
    define treatc / group "Treatment" style={cellwidth=10% just=c};
    define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
    define ppgrpid / display "Period" style={cellwidth=8% just=c};
    define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
    define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};
    define LAMBDAZ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
    define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
    define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

    compute before;
    line @1 ' ';
    endcomp;

    compute after;
    line @1 ' ';
    endcomp;

```



```

        title1 j=1 "OTR1021
                Table 14.2.2-1
DATE:&dtnull2 TIME:&systemtime";
        title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
        *title3 j=c "(Page 1 of 1)";
        title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Full Analysis
";
        footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
        footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
        footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
        footnote4;
        footnote5 j=1 "Source: Listing 16.2.6-4";
run;quit;

proc report
    data = final
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.15in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns treatc _name_ AUC0_T AUC0_INF CMAX TMAX LAMBDAZ TERMHALF
TLAG;
    where treatc="A";
    define treatc / group "Treatment" style={cellwidth=25% just=c};
    *define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
    define _name_ / display "Period" style={cellwidth=10% just=c};
    define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
    define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};

```

```

        define LAMBDAZ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
        define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
        define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

        compute before;
        line @1 ' ';
        endcomp;

        compute after;
        line @1 ' ';
        endcomp;

        title1 j=1 "OTR1021
                        Table 14.2.2-1
DATE:&dtnull2 TIME:&systeme";
        title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
        *title3 j=c "(Page 1 of 1)";
        title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Full Analysis
";
        footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
        footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
        footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
        footnote4;
        footnote5 j=1 "Source: Listing 16.2.6-4";
        run;quit;

proc report
    data = final2
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.4in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

```

```

columns treatc randsubject ppgrpid AUC0_T AUC0_INF CMAX TMAX
LAMBDAZ TERMHALF TLAG;

```

```

where treatc="B";

```

```

define treatc / group "Treatment" style={cellwidth=10% just=c};
define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
define ppgrpid / display "Period" style={cellwidth=8% just=c};
define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};
define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};
define LAMBDAZ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

```

```

compute before;
line @1 ' ';
endcomp;

```

```

compute after;
line @1 ' ';
endcomp;

```

```

title1 j=1 "OTR1021
Table 14.2.2-1
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Full Analysis
";
footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
footnote4;

```

```

        footnote5 j=1 "Source: Listing 16.2.6-4";
run;quit;

proc report
    data = final
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.15in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns treatc _name_ AUC0_T AUC0_INF CMAX TMAX LAMBDAZ TERMHALF
TLAG;

    where treatc="B";

    define treatc / group "Treatment" style={cellwidth=25% just=c};
    *define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
    define _name_ / display "Period" style={cellwidth=10% just=c};
    define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
    define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};
    define LAMBDAZ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
    define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
    define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

    compute before;
    line @1 ' ';
    endcomp;

    compute after;
    line @1 ' ';
    endcomp;

```

```

        title1 j=1 "OTR1021
                Table 14.2.2-1
DATE:&dtnull2 TIME:&systemtime";
        title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
        *title3 j=c "(Page 1 of 1)";
        title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Full Analysis
";
        footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
        footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
        footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
        footnote4;
        footnote5 j=1 "Source: Listing 16.2.6-4";
run;quit;
proc report
    data = final2
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.4in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns treatc randsubject ppgrpid AUC0_T AUC0_INF CMAX TMAX
LAMBDAZ TERMHALF TLAG;

    where treatc="C";

    define treatc / group "Treatment" style={cellwidth=10% just=c};
    define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
    define ppgrpid / display "Period" style={cellwidth=8% just=c};
    define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
    define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
    define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};

```

```

        define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};
        define LAMBDAZ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
        define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
        define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

compute before;
line @1 ' ';
endcomp;

compute after;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
           Table 14.2.2-1
DATE:&dtnull2 TIME:&systemtime";
title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Full Analysis
";
footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
footnote4;
footnote5 j=1 "Source: Listing 16.2.6-4";
run;quit;

proc report
data = final
nowd
ls=122
ps=39
headline
headskip
split='#'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
cellheight=.15in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

```

```

columns treatc _name_ AUC0_T AUC0_INF CMAX TMAX LAMBDАЗ TERMHALF
TLAG;

```

```

where treatc="C";

```

```

define treatc / group "Treatment" style={cellwidth=25% just=c};
*define randsubject / display "Randomization Number/#Subject
Number" style={cellwidth=20% just=c};
define _name_ / display "Period" style={cellwidth=10% just=c};
define AUC0_T / display "AUCt#(ng*h/mL)" format=best6.
style={cellwidth=9% just=c};
define AUC0_INF / display "AUCinf#(ng*h/mL)" format=best6.
style={cellwidth=8.5% just=c};
define CMAX / display "Cmax#(ng/mL)" format=best6.
style={cellwidth=8.5% just=c};
define TMAX / display "tmax#(h)" format=best6.
style={cellwidth=8.5% just=c};
define LAMBDАЗ / display "Lz#(1/h)" format=best6.
style={cellwidth=8.5% just=c};
define TERMHALF / display "t1/2z#(h)" format=best6.
style={cellwidth=8.5% just=c};
define TLAG / display "tlag#(h)" format=best6.
style={cellwidth=9% just=c};

```

```

compute before;
line @1 ' ';
endcomp;

```

```

compute after;
line @1 ' ';
endcomp;

```

```

title1 j=1 "OTR1021
Table 14.2.2-1
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Individual Subject and Mean Plasma Oxycodone
Pharmacokinetic Metrics";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Full Analysis
";
footnote1 j=1 "NOTE: NA = Not applicable, NC = Not calculated";
footnote2 j=1 '09'x "All Randomized Safety subjects are included
in the data listing. Only Full Analysis subjects are used in the
calculation of the summary statistics.";
footnote3 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";

```

```
        footnote4;  
        footnote5 j=1 "Source: Listing 16.2.6-4";  
run;quit;  
ods listing;  
ods rtf close;
```

```
options nolabel;
```

```
libname r "P:\Medical\SRSPProd\otr\otr1021\core\forbsp";  
run;
```

```
/* Copy EX dataset to work folder and assign single letter treatment  
codes */  
data ex;  
length treatc $1;  
set r.ex(keep=studyid usubjid exseq exdostxt exstdtc exendtc epoch  
visitnum);  
if EXDOSTXT="FINELY CRUSHED 10 MG OTR" then treatc="A";  
if EXDOSTXT="COARSELY CRUSHED 10 MG OTR" then treatc="B";  
if EXDOSTXT="FINELY CRUSHED 10 MG OC" then treatc="C";  
drop exdostxt;  
run;
```

```
data qs;  
set r.qs;  
run;
```

```
proc sort data=qs;  
by usubjid visitnum;  
run;
```

```
proc sort data=ex;  
by usubjid visitnum;  
run;
```

```
data exqs;  
merge qs ex(keep=usubjid epoch visitnum treatc);  
by usubjid visitnum;  
run;
```



```
proc sort data=exqs;
by usubjid treatc qstestcd qstptnum;
run;
```

```
data cfp;
  do until (last.usubjid);
    set exqs (where=(qsstresn^=. and visitnum=int(visitnum) and
qstestcd^="CALLMADE"));
    by usubjid treatc qstestcd qstptnum;
    if qstpt="PREDOSE" then pd=qsstresn;
    else do;
      chgpd = qsstresn - pd;
      output;
    end;
  end;
run;
```

```
proc sort data=cfp;
by treatc qstestcd qstest qstptnum qstpt;
run;
```

```
proc univariate data=cfp noprint round=0;
by treatc qstestcd qstest qstptnum qstpt;
var chgpd;
output out=cfpstat n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;
```

```
proc sort data=exqs;
by treatc qstestcd qstest qstptnum qstpt;
run;
```

```
proc univariate data=exqs noprint round=0;
where qstestcd^="CALLMADE";
by treatc qstestcd qstest qstptnum qstpt;
var qsstresn;
output out=pdstat n=a_N mean=b_mean std=c_sd min=d_min median=e_median
max=f_max;
run;
```

```
proc sort data=pdstat;
by treatc qstestcd qstest qstptnum qstpt;
run;
```

```
proc transpose data=pdstat out=pdstat;  
by treatc qstestcd qstest qstptnum qstpt;  
var a_N b_mean c_sd d_min e_median f_max;  
run;
```

```
data pdstat;  
length qstpt $50;  
set pdstat;  
qstpt=propcase(qstpt);  
run;
```

```
proc sort data=cfpstat;  
by treatc qstestcd qstest qstptnum qstpt;  
run;
```

```
proc transpose data=cfpstat out=cfpstat;  
by treatc qstestcd qstest qstptnum qstpt;  
var a_N b_mean c_sd d_min e_median f_max;  
run;
```

```
data cfpstat;  
length qstpt $50;  
set cfpstat;  
if qstpt^="PREDOSE" then qstpt=propcase(trim(qstpt)||trim(", Change  
from Predose"));  
qstpt=propcase(qstpt);  
run;
```

```
proc sort data=cfpstat;  
by treatc qstestcd qstest qstptnum qstpt;  
run;
```

```
proc sort data=pdstat;  
by treatc qstestcd qstest qstptnum qstpt;  
run;
```

```
data final;  
set pdstat cfpstat;  
by treatc qstestcd qstptnum;  
run;
```

```
proc sort data=final;  
by treatc qstestcd qstest qstptnum qstpt;  
run;
```

```
proc format;
```

```

value $statf   'a_N'='N'
               'b_mean'='MEAN'
               'c_sd'='SD'
               'd_min'='MIN'
               'e_median'='MEDIAN'
               'f_max'='MAX';

run;

data final;
length statval $30.;
format statval $30.;
set final;
if _NAME_='b_mean' then statval=put(round(coll,.5),5.0);
if _NAME_='c_sd' then statval=put(round(coll,0.01),5.1);
if _NAME_ not in ('b_mean','c_sd') then
statval=put(round(coll,1.0),5.0);
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
options nonumber nodate orientation=landscape;
ods listing close;
ods escapechar='^';
ods rtf file="\nac103\users_ab\valabojr\Documents\OTR1021\reports\14-
2-4-1.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=39
    headline
    headskip
    split='#'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
cellheight=.15in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

```

```

        columns treatc qstestcd qstest qstptnum qstpt _name_ statval;
        *where treatc="A";
        *where also qstestcd="NASAL01";
        define treatc / group order=internal "Treatment"
style={cellwidth=15% just=c};
        define qstestcd / group order=internal noprint;
        define qstest / group order=internal "Assessment"
style={cellwidth=15% just=c};
        define qstptnum / group order=internal noprint;
        define qstpt / group order=internal "Timepoint"
style={cellwidth=37% just=c};
        define _name_ / display "Statistic" format=$statf.
style={cellwidth=15% just=c};
        define statval / display "Result" style={protectspecialchars=off
cellwidth=17% just=dec};

        compute before;
        line @1 ' ';
        endcomp;

        compute after;
        line @1 ' ';
        endcomp;

        compute after qstpt;
        line @1 " ";
        endcomp;

        break after qstptnum / suppress page;

        title1 j=1 "OTR1021
                Table 14.2.4-1
DATE:&dtnull12 TIME:&sysstime";
        title2 j=c "Descriptive Statistics and Change from Predose on
Intranasal Tolerability Rating Scale Data by Treatment";
        *title3 j=c "(Page 1 of 1)";
        title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Randomized Safety
";
        footnote1 j=1 "NOTE: Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
        footnote2 j=1 "Source: Listing 16.2.8-13.";
        run;quit;
ods listing;
ods rtf close;

```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.1-1a
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

/* Copy EX dataset to work folder and assign single letter treatment
codes */
data ex;
length treatc $1;
set r.ex(keep=studyid usubjid exseq exdostxt exstdtc exendtc epoch
visitnum);
if EXDOSTXT="FINELY CRUSHED 10 MG OTR" then treatc="A";
if EXDOSTXT="COARSELY CRUSHED 10 MG OTR" then treatc="B";
if EXDOSTXT="FINELY CRUSHED 10 MG OC" then treatc="C";
drop exdostxt;
run;

/* Population counts by treatment assigned to macro variables */
proc sql noprint;
select count(distinct usubjid) into :trta from ex where treatc="A";
select count(distinct usubjid) into :trtb from ex where treatc="B";
select count(distinct usubjid) into :trtc from ex where treatc="C";
select count(distinct usubjid) into :overall from ex where treatc in
("A","B","C");
quit;

/* Re-assign Population count macro variables to remove blanks */
%let trta=&trta;
%let trtb=&trtb;
%let trtc=&trtc;
%let overall=&overall;

/* Transpose ex dataset to get start and end dates of exposure by
treatment */
proc transpose data=ex out=trex(drop=_name_);
by usubjid;
id treatc ;
var exstdtc;
run;

/* Transpose ex dataset to get start and end dates of exposure by
treatment */

```

```

proc transpose data=ex out=trex2(drop=_name_ rename=(a=paendt b=pbendt
c=pcendt));
by usubjid;
id treatc ;
var exendtc;
run;

/* Add :00 to the ae start and end dates to make use of the is8601
function later on the variables */
data ae;
set r.ae;
aestdct2=trim(trim(aestdct)||trim(":00"));
aeendtc2=trim(trim(aeendtc)||trim(":00"));
drop aestdct aeendtc;
rename aestdct2=aestdct aeendtc2=aeendtc;
run;

/* Merge ae and transposed ex datasets to get start and stop dates of
exposure for all treatments for every subject ae record */
data aeexst;
merge ae trex trex2;
by usubjid;
run;

/* Create numeric dates using is8601 function and datetime20 format
for later use */
data aeexst;
set aeexst;
array dates(8) aestdct aeendtc a b c paendt pbendt pcendt;
array numdates(8) _aestdct _aeendtc _a _b _c a _b _c _;
do i = 1 to 8;
if dates(i) ^= '' then
numdates(i) = input(dates(i),IS8601DT.);
end;
drop i;
format _aestdct _aeendtc _a _b _c a _b _c _ datetime20.;
run;

/* Create numeric dates using is8601 function and datetime20 format
for later use */
data dm;
set r.dm;
if rfstdtc ^= '' then do;
rfstdt=input(rfstdtc,IS8601DT.);
rfendtc=input(rfendtc,IS8601DT.);
end;
format rfstdt rfendtc datetime20.;
run;

/* Merge dm data with rfstdt and rfendtc variables with merged ae and
ex dataset from above */
data aed;

```

```

merge aeexst dm(keep=usubjid rfstdt rfenddt);
by usubjid;
run;

/* Delete non ae records from the merged dataset */
proc sql;
delete from aed
where usubjid not in (select usubjid from r.ae);
quit;

/* Assign treatment groups to each AE record depending on when AE
occured - used ae start dates in calculation */
proc sql;
create table aed2 as select *,
case when _aestdtc<=rfstdt then "Z"
      when (_aestdtc between _a and _a+48*60*60) or (_aestdtc between _a
and _a+48*60*60) then "A"
      when (_aestdtc between _b and _b+48*60*60) or (_aestdtc between _b
and _b+48*60*60) then "B"
      when (_aestdtc between _c and _c+48*60*60) or (_aestdtc between _c
and _c+48*60*60) then "C"
      else "" end as treatc
from aed;
quit;

options mprint mlogic symbolgen;

/* Macro to prepare final report dataset by creating horizontal and
vertical datasets and merging */
%macro aeprep;

%let trt1=%upcase(a);
%let trt2=%upcase(b);
%let trt3=%upcase(c);
%let trt4=%upcase(z);
%let trt5=overall;

%let str=%nrstr(put(count(*),3.0) ||compbl(" (N="||put(count(distinct
usubjid),3.0)||")"));
/* Vertical dataset "overall" to get overall numbers - no grouping */
proc sql ;
create table &trt5 as
(select "Any Adverse Event" as AE_GRP, %unquote(&str) as Overall,
"1" as _order from aed2)
union all
(select distinct(propcase(aesev)) as AE_GRP, %unquote(&str) as
Overall, "2" as _order from aed2
group by 1)
union all

```

```

        (select "Possible, Probably, or Definitely Related Adverse Event"
as AE_GRP,
    %unquote(&str) as Overall, "3" as _order from aed2
    where aere1 in ("POSSIBLY","PROBABLY","DEFINITELY"))
union all
    (select "Adverse Event Leading to Study Discontinuation" as
AE_GRP,
    %unquote(&str) as Overall, "4" as _order from aed2
    where aeacnoth in ("WITHDRAWN FROM STUDY","TREATMENT GIVEN AND
WITHDRAWN FROM STUDY"))
union all
    (select "Serious Adverse Event" as AE_GRP, %unquote(&str) as
Overall, "5" as _order from aed2
    where aeser="Y");
quit;

/* Vertical datasets "Pre-Study Drug", "A", "B", "C" - grouping by
treatment and pre-study */
%do i=1 %to 4;
proc sql ;
    create table &&trt&i as
    (select "Any Adverse Event" as AE_GRP, %unquote(&str) as &&trt&i,
"1" as _order from aed2
    where treatc="&&trt&i")
union all
    (select distinct(propcase(aesev)) as AE_GRP, %unquote(&str) as
&&trt&i, "2" as _order from aed2
    where treatc="&&trt&i"
    group by 1)
union all
    (select "Possible, Probably, or Definitely Related Adverse Event"
as AE_GRP,
    %unquote(&str) as &&trt&i, "3" as _order from aed2
    where treatc="&&trt&i"
    and aere1 in ("POSSIBLY","PROBABLY","DEFINITELY"))
union all
    (select "Adverse Event Leading to Study Discontinuation" as
AE_GRP,
    %unquote(&str) as &&trt&i, "4" as _order from aed2
    where treatc="&&trt&i"
    and aeacnoth in ("WITHDRAWN FROM STUDY","TREATMENT GIVEN AND
WITHDRAWN FROM STUDY"))
union all
    (select "Serious Adverse Event" as AE_GRP, %unquote(&str) as
&&trt&i, "5" as _order from aed2
    where treatc="&&trt&i"
    and aeser="Y");
quit;
%end;

/* Create row for dataset Z where proc sql did not create a row for
SEVERE ae category */

```



```

data z;
set z;
if _n_=3 then do;
output;
ae_grp="SEVERE";
_order="2";
z="---";
end;
output;
run;

/* Message data to include ae group labels and order variable values
*/
%do i=1 %to 5;
data &&trt&i;
set &&trt&i;
if _n_=6 and ae_grp='' then do;
ae_grp="Adverse Event Leading to Study Discontinuation";
_order="4";
end;
if _n_=7 and ae_grp='' then do;
ae_grp="Serious Adverse Event";
_order="5";
end;
if _order="2" then do;
ae_grp=" ||ae_grp;
end;
run;
proc sort data = &&trt&i;
by _order;
run;
%end;

/* Create final report dataset by merging all vertical datasets
created above */
data final;
merge z a b c overall;
by _order;
run;

proc datasets library=work;
save final;
run; quit;

%mend aeprep;

%aeprep; /* Macro execution step to create vertical datasets */

/* Create blank rows after each ae group category */
data final;
set final;
output;

```

```

by _order;
if _order^=1 and last._order;
array allchar [*] _character_ ;
drop i;
do i=1 to dim(allchar); allchar{i}=' '; end;
output; /* Output blank observation */
run;

/* Format values per SAP specifications */
proc format;
    value $col 30. ' 0 (N=0)'='      ---      '
                  ' 0 (N= 0)'='      ---      '
;
run;

/*Create macro variable for sysdate system macro variable in format
specified in shells */
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;
%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Report procedure to export rtf file */
dm "odsresults; clear;";
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-1-1a_new.rtf" bodytitle style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=30
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black}
;

    columns (ae_grp('Incidences (Number of Distinct Subjects)*
_____
_____
z a b c overall _order));

```

```

        define ae_grp /display " " style={protectspecialchars=off
cellwidth=30% just=1 asis=on} flow;
        define z /display center "Pre-Study*Drug" format=$col.
style={protectspecialchars=off cellwidth=13% just=c};
        define a /display center "A*(N=&trta)" format=$col.
style={protectspecialchars=off cellwidth=13% just=c};
        define b /display center "B*(N=&trtb)" format=$col.
style={protectspecialchars=off cellwidth=13% just=c};
        define c /display center "C*(N=&trtc)" format=$col.
style={protectspecialchars=off cellwidth=13% just=c};
        define overall /display center "Overall*(N=&overall)"
format=$col. style={protectspecialchars=off cellwidth=17% just=c};
        define _order /order=internal noprint;

compute before;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
          Table 14.3.1-1a
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Summary of All Adverse Events";
title3 j=c "(Page 1 of 1)";
*title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Enrolled
";

footnote j=1 "NOTE: Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
footnote2 j=1 "Source: Listing 16.2.7-1a";
run;quit;
ods listing;
ods rtf close;

```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.1.1c
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

/* Copy ex dataset to get treatment information */
data ex;
length treatc $1;
set r.ex(keep=studyid usubjid exseq exdstxt exstdtc exendtc epoch
visitnum);
if EXDOSTXT="FINELY CRUSHED 10 MG OTR" then treatc="A";
if EXDOSTXT="COARSELY CRUSHED 10 MG OTR" then treatc="B";
if EXDOSTXT="FINELY CRUSHED 10 MG OC" then treatc="C";
drop exdstxt;
run;

/* Get unique subject counts by treatment groups - Not used for this
report */
proc sql noprint;
select count(distinct usubjid) into :trta from ex where treatc="A";
select count(distinct usubjid) into :trtb from ex where treatc="B";
select count(distinct usubjid) into :trtc from ex where treatc="C";
select count(distinct usubjid) into :overall from ex where treatc in
("A","B","C");
quit;
/* Not used for this report */
%let trta=&trta;
%let trtb=&trtb;
%let trtc=&trtc;
%let overall=&overall;

/* Transpose ex dose start and end dates */
proc transpose data=ex out=trex(drop=_name_);
by usubjid;
id treatc ;
var exstdtc;
run;
/* Transpose ex dose end dates */
proc transpose data=ex out=trex2(drop=_name_ rename=(a=paendt b=pbendt
c=pcendt));
by usubjid;
id treatc ;

```

```

var exendtc;
run;

/* Add :00 to the ae start and end dates to make use of the is8601
function later on the variables */
data ae;
set r.ae;
aestdct2=trim(trim(aestdct)||trim(":00"));
aeendtc2=trim(trim(aeendtc)||trim(":00"));
drop aestdct aeendtc;
rename aestdct2=aestdct aeendtc2=aeendtc;
run;

/* Merge ae and transposed ex datasets to get start and stop dates of
exposure for all treatments for every subject ae record */
data aeexst;
merge ae trex trex2;
by usubjid;
run;

/* Create numeric dates using is8601 function and datetime20 format
for later use */
data aeexst;
set aeexst;
array dates(8) aestdct aeendtc a b c paendt pbendt pcendt;
array numdates(8) _aestdct _aeendtc _a _b _c a _b _c _;
do i = 1 to 8;
if dates(i) ^= '' then
numdates(i) = input(dates(i), IS8601DT.);
end;
drop i;
format _aestdct _aeendtc _a _b _c a _b _c _ datetime20.;
run;

/* Create numeric dates using is8601 function and datetime20 format
for later use */
data dm;
set r.dm;
if rfstdtc ^= '' then do;
rfstdt=input(rfstdtc, IS8601DT.);
rfendtc=input(rfendtc, IS8601DT.);
end;
format rfstdt rfendtc datetime20.;
run;

/* Merge dm data with rfstdt and rfendtc variables with merged ae and
ex dataset from above */
data aed;
merge aeexst dm(keep=usubjid rfstdt rfendtc);
by usubjid;
run;

```

```

/* Delete non ae records from the merged dataset */
proc sql;
delete from aed
where usubjid not in (select usubjid from r.ae);
quit;

/* Assign treatment groups to each AE record depending on when AE
occured - used ae start dates in calculation */
proc sql;
create table aed2 as select *,
case when _aestdtc<=rfstdt then "Z"
      when (_aestdtc between _a and _a+48*60*60) or (_aestdtc between _a
and _a+48*60*60) then "A"
      when (_aestdtc between _b and _b+48*60*60) or (_aestdtc between _b
and _b+48*60*60) then "B"
      when (_aestdtc between _c and _c+48*60*60) or (_aestdtc between _c
and _c+48*60*60) then "C"
      else "" end as treatc
from aed;
quit;

/* Create vertical tables left to right per shell specification */

/* Step to create N subject counts by treatment group */
%let str=%nrstr(select distinct treatc, count(distinct usubjid) as
ncount from ex where treatc in);

proc sql noprint;
create table ncount as
%unquote(&str) ("A")
union all
%unquote(&str) ("B")
union all
%unquote(&str) ("C")
union all
select "Total" as treatc, count(distinct usubjid) as ncount from ex
where treatc in ("A","B","C");
quit;

/* Step to create TEAE counts by treatment groups */
proc sql;
create table nteae as select distinct treatc, count(aesev) as nteae
from aed2
where _aestdtc>rfstdt
group by 1
union all
select "Total" as treatc, count(aesev) as nteae from aed2
where _aestdtc>rfstdt;
quit;

/* Macro to prepare datasets mild, moderate, severe - ae severity
groups by treatment groups */

```

```

%macro _prep;
%let sev1=MILD;
%let sev2=MODERATE;
%let sev3=SEVERE;

%do i=1 %to 3;
proc sql;
create table &&sev&i as select distinct treatc, count(*) as &&sev&i
from aed2
where aesev="&&sev&i"
and _aestdtc>rfstdt
group by treatc
union all
select "Total" as treatc, count(*) as &&sev&i from aed2
where aesev="&&sev&i"
and _aestdtc>rfstdt;
quit;
%end;

%mend _prep;

/* Macro execution step */
%_prep;

/* Second prep macro for aerel sub categories and corresponding
vertical datasets */
%macro _prep2;
%let aerel1=NOT_RELATED;
%let aerel2=UNLIKELY;
%let aerel3=POSSIBLY;
%let aerel4=PROBABLY;
%let aerel5=DEFINITELY;

%do i=1 %to 5;
proc sql;
create table &&aerel&i as select distinct treatc, count(*) as
&&aerel&i from aed2
where aerel like ("&&aerel&i")
and _aestdtc>rfstdt
group by treatc
union all
select "Total" as treatc, count(*) as &&aerel&i from aed2
where aerel like ("&&aerel&i")
and _aestdtc>rfstdt;
quit;
%end;

%mend _prep2;
/* Macro execution */
%_prep2;

```

```

/* Create final dataset for report by merging all vertical datasets by
treatment groups and total row */
data final;
merge ncount nteae mild moderate severe not_related unlikely possibly
probably definitely;
by treatc;
run;

/* Massage final dataset - assign value 0 where value is missing */
data final;
set final;
by treatc;
array allnum [*] _numeric_ ;
do i=1 to dim(allnum);
if allnum{i}=. then allnum{i}=0;
end;
drop i;
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-1-1c.rtf" bodytitle style=Styles.custom;
proc report
data = final
nowd
ls=122
ps=30
headline
headskip
split='*'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
cellheight=.25in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

```



```

        columns treatc ncount nteae
('Severity*'_____ ' mild moderate severe)
        ('Relationship to
Drug*_____ ' not_related
unlikely possibly probably definitely);

        define treatc / display "Treatment" style={cellwidth=10% just=c};
        define ncount / display "N" style={cellwidth=8% just=c};
        define nteae / display "Total Number of*Treatment-Emergent AEs"
style={cellwidth=17% just=c};
        define mild / display "Mild" style={cellwidth=8% just=c};
        define moderate / display "Moderate" style={cellwidth=8% just=c};
        define severe / display "Severe" style={cellwidth=8% just=c};
        define not_related / display "NR" style={cellwidth=8% just=c};
        define unlikely / display "Unlikely" style={cellwidth=8% just=c};
        define possibly / display "Possibly" style={cellwidth=8% just=c};
        define probably / display "Probably" style={cellwidth=8% just=c};
        define definitely / display "Definitely" style={cellwidth=8%
just=c};

        compute before;
        line @1 ' ';
        endcomp;

        title1 j=1 "OTR1021
                Table 14.3.1-1c
DATE:&dtnull2 TIME:&systime";
        title2 j=c "Summary of Treatment-Emergent Adverse Events Based on
Severity and Relationship to Drug";
        title3 j=c "(Page 1 of 1)";
        *title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Randomized Safety
";
        footnote1 j=1 "NOTE: N=Sample Size, NR=Not Related";
        footnote2 j=1 '09'x "Treatment A = Finely crushed 10 mg OTR;
Treatment B = Coarsely crushed 10 mg OTR; Treatment C = Finely crushed
10 mg OC.";
        footnote3;
        footnote4 j=1 "Source: Listing 16.2.7-2";
run;quit;
ods listing;
ods rtf close;

```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.5-1a
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

%macro chgbase;

/* Change Information here for other lab final datasets */
%let lab1=ALBM;
%let lab2=GLUC;
%let lab3=PROTT;
/** ---- **/

%DO I=1 %TO 3;

data &&lab&i;
set r.lb (where = (lbcat="CHEMISTRY" and lbtestcd="&&lab&i"));
      by usubjid visitnum;
run;

proc univariate data=&&lab&i (where=(lbtpnum=1)) noprint round=0;
var lbstresn;
output out=scr_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=scr_&&lab&i out=scr_&&lab&i;
var _all_;
run;

data scr_&&lab&i;
set scr_&&lab&i;
lbtest="&&lab&i";
period="a_Screening";
run;

proc sort data=scr_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum=2)) noprint round=0;

```

```

var lbstresn;
output out=base_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=base_&&lab&i out=base_&&lab&i;
var _all_;
run;

data base_&&lab&i;
set base_&&lab&i;
lbtest="&&lab&i";
period="b_Baseline";
run;

proc sort data=base_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum>2 and
visitnum=int(visitnum))) noprint round=0;
var lbstresn;
output out=c_EOS_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=c_EOS_&&lab&i out=c_EOS_&&lab&i;
var _all_;
run;

data c_EOS_&&lab&i;
set c_EOS_&&lab&i;
lbtest="&&lab&i";
period="c_EOS";
run;

proc sort data=c_EOS_&&lab&i;
by _name_;
run;

data chgbl_&&lab&i;
do until (last.usubjid);
    set &&lab&i (where = (lbstresn^= . and
visitnum=int(visitnum)));
    by usubjid visitnum;
    if visitnum <= 2 then bl=lbstresn;
    else do;
        chgbl = lbstresn - bl;
        output;
    end;
end;
run;

```

```

proc univariate data=chgbl_&&lab&i noprint round=0;
var chgbl;
output out=chgbl_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=chgbl_&&lab&i out=chgbl_&&lab&i;
var _all_;
run;

data chgbl_&&lab&i;
set chgbl_&&lab&i;
lbtest="&&lab&i";
period="d_CFB";
run;

proc sort data=chgbl_&&lab&i;
by _name_;
run;

data lab_&&lab&i;
set scr_&&lab&i base_&&lab&i c_EOS_&&lab&i chgbl_&&lab&i;
run;

/* Report Decimal places that correspond to the particular lab value
and */
/* Report SD to one decimal place more than mean */
/* Labs Specific */
%if lab_&&lab&i^="lab_gluc" %then %do;
data lab_&&lab&i;
length col2 $20;
set lab_&&lab&i;
if _name_ not in ("b_mean","c_sd") then col2=put(col1,3.);
if _name_ = "b_mean" then col2=put(round(col1,1.0),3.);
if _name_ = "c_sd" then col2=put(round(col1,.1),5.1);
run;
%end;

%if lab_&&lab&i="lab_gluc" %then %do;
data lab_gluc;
length col2 $20;
set lab_gluc;
if _name_ = "N" then col2=put(col1,3.);
if _name_ = "c_sd" then col2=put(round(col1,.001),7.3);
if _name_ in ("e_median","f_max","d_min","b_mean") then
col2=put(round(col1,.001),7.2);
run;
%end;

%end;

```

```

%mend chgbase;

%chgbase;

/** Change Information here for other lab final datasets **/

data final;
set lab_albm lab_gluc lab_prott;
if lbtest="ALBM" then order1=1; /* Labs Specific */
if lbtest="GLUC" then order1=2; /* Labs Specific */
if lbtest="PROT" then order1=3; /* Labs Specific */
if period="a_Screening" then order2=1;
if period="b_Baseline" then order2=2;
if period="c_EOS" then order2=3;
if period="d_CFB" then order2=4;
run;

proc format;
value $reportf 'a_N' = 'N'
               'b_mean' = 'MEAN'
               'c_sd' = 'SD'
               'd_min' = 'MIN'
               'e_median' = 'MEDIAN'
               'f_max' = 'MAX'
               'a_Screening' = 'Screening'
               'b_Baseline' = 'Baseline, Day -1'
               'c_EOS' = 'End of Study'
               'd_CFB' = 'Change from Baseline'
               'ALBM' = 'Albumin (g/L)'
/* Labs Specific */
               'GLUC' = 'Glucose (mmol/L)' /*
Labs Specific */
               'PROT' = 'Total Protein (g/L)'; /*
Labs Specific */
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

```

```

/* Proc Report Step */
/* Make changes here for additional lab reports */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14.
3.5-1a.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=35
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.15in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns order1 lbtest period _name_ col2 col1 ;

    define order1 / order order=internal noprint ;
    *define order2 / order order=internal noprint ;
    define lbtest / group "Laboratory Parameter" format=$reportf.
style={cellwidth=20% just=c};
    define period / group order=internal "Timepoint" format=$reportf.
style={cellwidth=25% just=c};
    define _name_ / display "Statistic" format=$reportf.
style={cellwidth=25% just=c};
    define col2 / display "Result" center format=$reportf.
style={cellwidth=15% just=dec};
    define col1 / center style={cellwidth=14% just=c
foreground=white};

    compute before;
    line @1 ' ';
    endcomp;

    compute after;
    line @1 ' ';
    endcomp;

    compute after order1;
    line @1 ' ';
    endcomp;

    compute after period;

```

```

line @1 ' ';
endcomp;

title1 j=1 "OTR1021
          Table 14.3.5-1a
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Descriptive Statistics and Change from b_Baseline of
Chemistry Laboratory Data: Metabolic Substrates";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: Change from b_Baseline is the change from
b_Baseline, Day -1 compared to End of Study.";
footnote2 j=1 '09'x "Lab units are presented as SI units.";
footnote3;
footnote4 j=1 "Source: Listing 16.2.8-2a";
run;quit;
ods listing;
ods rtf close;

```

```

/*
Title: OTR1021 Data Review
Reviewer/Programmer: R. Valaboju
Date: 06-18-**
Study: OTR1021
Table: 14.3.5-1b
Notes: Re-programming sample tables as
part of QC.
*/

```

```

libname r "P:\Medical\SRSPProd\otr\otr1021\core\forbsp";
run;

```

```
options nolabel;
```

```

options mprint mlogic symbolgen;
/* Make changes here for additional labs */
%let str=%nrstr("ALBM","GLUC","PROTT");
%let str2=%nrstr(ALBM, GLUC, PROTT);
%let str3=%nrstr(ALBM|GLUC|PROTT);

```

```

/*-----Generic re-usable code starts here-----
-----*/

proc sql;
create table lbsub as select usubjid, lbdtc,lbtpt, lbcat,lbtestcd,
lbstresn, lbnrind,
case when substr(lbnrind,1,1)^=' ' then
trim(put(lbstresn,best12.)||' '||trim(substr(lbnrind,1,1))||', N')
else ' ' end as lbstresn2 from r.lb
where lbtestcd in (%unquote(&str));
quit;

proc transpose data=lbsub out=lbsub;
by usubjid lbdtc lbtpt;
id lbtestcd;
var lbstresn2;
run;

data lbsub;
length sex $10;
merge lbsub(in=a)
      r.sc(in=b keep=usubjid scorres where=(scorres like ("RN%")))
      r.dm(in=c keep=usubjid age sex race);
by usubjid;
if a;
if sex='F' then sex="Female";
if sex='M' then sex="Male";
run;

data lbsub;
length rsub $25;
length asr $45;
length lbdtc2 8;
set lbsub;
rsub=trim(trim(scorres)||'/'||substr(usubjid,15,5));
asr=propcase(trim(trim(age)||'/'||trim(sex)||'/'||trim(race)));
lbdtc2=input(substr(lbdtc,1,10),yymmdd10.);
format lbdtc2 date9.;
run;

proc sql;
create table final as select rsub, asr, propcase(lbtpt) as lbtpt,
lbdtc2,substr(lbdtc,12,5) as time,%unquote(&str2)
from lbsub
where index(%unquote(&str3),',') ^=0;
quit;

/*-----End Generic code-----
-----*/

/* Make changes here for additional lab reports */

```



```

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-1b.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=35
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.4in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns rsub asr lbtpt lbdtc2 time albm gluc prott;

    define rsub / display order order=internal center
"Randomization*No/Subject No" style={cellwidth=15% just=1};
    define asr / display center "Age/Gender/*Race" flow
style={cellwidth=12.5% just=c};
    define lbtpt / display center "Timepoint" style={cellwidth=13.5%
just=c};
    define lbdtc2 / display "Date" style={cellwidth=12.5% just=c};
    define time / display "Actual*Time" center style={cellwidth=12.5%
just=c};
    define albm / display center "Albumin*(g/L)" style={cellwidth=11%
just=c};
    define gluc / display center "Glucose*(mmol/L)"
style={cellwidth=11% just=c};
    define prott / display center "Total Protein*(g/L)"
style={cellwidth=11% just=c};

    compute before;
    line @1 ' ';

```

```

endcomp;

title1 j=1 "OTR1021
          Table 14.3.5-1b
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Subjects with Abnormal Chemistry Laboratory Data
Based on the Reference Ranges: Metabolic Substrates";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: H = laboratory value above the reference
laboratory range";
footnote2 j=1 '09'x "L = laboratory value below the reference
laboratory range";
footnote3 j=1 '09'x "A = laboratory value abnormal";
footnote4 j=1 '09'x "C = laboratory value deemed clinically
significant by the investigator";
footnote5 j=1 '09'x "N = laboratory value deemed not clinically
significant by the investigator.";
footnote6 j=1 '09'x "Values out of the normal range are
flagged.";
footnote7 j=1 '09'x "Lab units are presented as SI units.";
footnote8 j=1 '09'x "Source: Listing 16.2.8-2a";
footnote9 j=1 '09'x "Reference Range Source: Listing 16.2.8-1";
run;quit;
ods listing;
ods rtf close;

```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.5-1c
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

%macro chgbase;

/* Change Information here for other lab final datasets */
%let lab1=ALP;
%let lab2=AST;
%let lab3=ALT;
%let lab4=LDH;
%let lab5=BILID;
%let lab6=BILIT;

/**  ----  **/

%do i=1 %to 6;

data &&lab&i;
set r.lb (where = (lbcat="CHEMISTRY" and lbtestcd="&&lab&i"));
      by usubjid visitnum;
run;

proc univariate data=&&lab&i (where=(lbtpnum=1)) noprint round=0;
var lbstresn;
output out=scr_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=scr_&&lab&i out=scr_&&lab&i;
var _all_;
run;

data scr_&&lab&i;
length lbtest $15;
set scr_&&lab&i;
lbtest="&&lab&i";
period="a_Screening";
run;

```

```

proc sort data=scr_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtptnum=2)) noprint round=0;
var lbstresn;
output out=base_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=base_&&lab&i out=base_&&lab&i;
var _all_;
run;

data base_&&lab&i;
set base_&&lab&i;
lbtest="&&lab&i";
period="b_Baseline";
run;

proc sort data=base_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtptnum>2 and
visitnum=int(visitnum))) noprint round=0;
var lbstresn;
output out=c_EOS_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=c_EOS_&&lab&i out=c_EOS_&&lab&i;
var _all_;
run;

data c_EOS_&&lab&i;
set c_EOS_&&lab&i;
lbtest="&&lab&i";
period="c_EOS";
run;

proc sort data=c_EOS_&&lab&i;
by _name_;
run;

data chgbl_&&lab&i;
do until (last.usubjid);
    set &&lab&i (where = (lbstresn^= . and
visitnum=int(visitnum)));
    by usubjid visitnum;
    if visitnum <= 2 then bl=lbstresn;

```

```

                else do;
                    chgbl = lbstresn - bl;
                    output;
                end;
            end;
run;

proc univariate data=chgbl_&&lab&i noprint round=0;
var chgbl;
output out=chgbl_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=chgbl_&&lab&i out=chgbl_&&lab&i;
var _all_;
run;

data chgbl_&&lab&i;
set chgbl_&&lab&i;
lbtest="&&lab&i";
period="d_CFB";
run;

proc sort data=chgbl_&&lab&i;
by _name_;
run;

data lab_&&lab&i;
length col2 $20;
set scr_&&lab&i base_&&lab&i c_EOS_&&lab&i chgbl_&&lab&i;
if lbtest^="BILID" then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="b_mean" then col2=put(round(col1,1.0),8.0);
    else if _name_="c_sd" then col2=put(round(col1,.1),8.1);
    else if _name_ not in ("a_N","b_mean","c_sd") then
col2=put(round(col1,1.0),8.);
end;
if lbtest="BILID" then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.001),8.3);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,.01),8.2);
end;
run;
%end;

data final;
set lab_alp lab_alt lab_ast lab_bilid lab_bilit lab_ldh;
run;

proc datasets lib=work nolist;

```

```

save final;
run;quit;

%mend chgbase;

%chgbase;

proc format;
    value $reportf 'a_N'          = 'N'
                  'b_mean'        = 'MEAN'
                  'c_sd'          = 'SD'
                  'd_min'         = 'MIN'
                  'e_median'      = 'MEDIAN'
                  'f_max'         = 'MAX'
                  'a_Screening'   = 'Screening'
                  'b_Baseline'   = 'Baseline, Day -1'
                  'c_EOS'         = 'End of Study'
                  'd_CFB'         = 'Change from Baseline'
                  'ALP'           = 'Alkaline Phosphatase (U/L)'
                  'AST'           = 'AST (U/L)'
                  'ALT'           = 'ALT (U/L)'
                  'LDH'           = 'LDH (U/L)'
                  'BILID'         = 'Direct Bilirubin (μmol/L)'
                  'BILIT'         = 'Total Bilirubin (μmol/L)';
run;

```

```

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

```

```

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

```

```

/* Proc Report Step */
/* Make changes here for additional lab reports */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-1c.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122

```

```

ps=35
headline
headskip
split='*'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.16in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

columns lbtest period _name_ col2 col1 ;

*define order1 / order order=internal noprint ;
*define order2 / order order=internal noprint ;
define lbtest / group "Laboratory Parameter" format=$reportf.
style={cellwidth=20% just=c};
define period / group order=internal "Timepoint" format=$reportf.
style={cellwidth=25% just=c};
define _name_ / display "Statistic" format=$reportf.
style={cellwidth=25% just=c};
define col2 / display "Result" center format=$reportf.
style={cellwidth=15% just=dec};
define col1 / center style={cellwidth=14% just=c
foreground=white};

compute before;
line @1 ' ';
endcomp;

compute after;
line @1 ' ';
endcomp;

compute after period;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
Table 14.3.5-1c
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Descriptive Statistics and Change from Baseline of
Chemistry Laboratory Data: Hepatic Status Liver Function Tests";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: Change from Baseline is the change from
Baseline, Day -1 compared to End of Study.";
footnote2 j=1 '09'x "Lab units are presented in SI units.";
footnote3;
footnote4 j=1 "Source: Listing 16.2.8-2b";

```

```

run;quit;
ods listing;
ods rtf close;

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.5-1d
    Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSPProd\otr\otr1021\core\forbsp";
run;

options nolabel;

options mprint mlogic symbolgen;
/* Make changes here for additional labs */
%let str=%nrstr("ALP","AST","ALT","LDH","BILID","BILIT");
%let str2=%nrstr(ALP,AST,ALT,LDH,BILID,BILIT);
%let str3=%nrstr(ALP||AST||ALT||LDH||BILID||BILIT);

/*-----Generic re-usable code starts here-----
-----*/

proc sql;
create table lbsub as select usubjid, lbdtc,lbtpt, lbcat,lbtestcd,
lbstresn, lbnrind,
case when substr(lbnrind,1,1)^=' ' then
trim(put(lbstresn,best12.)||' '||trim(substr(lbnrind,1,1))||', N')
else ' ' end as lbstresn2 from r.lb
where lbtestcd in (%unquote(&str));
quit;

proc transpose data=lbsub out=lbsub;
by usubjid lbdtc lbtpt;
id lbtestcd;
var lbstresn2;
run;

data lbsub;
length sex $10;

```



```

merge lbsub(in=a)
      r.sc(in=b keep=usubjid scorres where=(scorres like ("RN%")))
      r.dm(in=c keep=usubjid age sex race);
by usubjid;
if a;
if sex='F' then sex="Female";
if sex='M' then sex="Male";
run;

data lbsub;
length rsub $25;
length asr $45;
length lbdtc2 8;
set lbsub;
rsub=trim(trim(scorres)||'/'||substr(usubjid,15,5));
asr=propcase(trim(trim(age)||'/'||trim(sex)||'/'||trim(race)));
lbdtc2=input(substr(lbdtc,1,10),yymmdd10.);
format lbdtc2 date9.;
run;

proc sql;
create table final as select rsub, asr, propcase(lbtpt) as lbtpt,
lbdtc2,substr(lbdtc,12,5) as time,%unquote(&str2)
from lbsub
where index((%unquote(&str3)),',') ^=0;
quit;

/*-----End Generic code-----
-----*/

/* Make changes here for additional lab reports */

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nac103\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-1d.rtf" style=Styles.custom;
proc report
  data = final
  nowd

```

```

ls=122
ps=35
headline
headskip
split='*'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.5in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

columns rsub asr lbtpt lbdtc2 time ALP AST ALT LDH BILID BILIT;

define rsub / display group order order=internal center
"Randomization*No/Subject No" style={cellwidth=11% just=l};
define asr / display group center "Age/Gender/*Race" flow
style={cellwidth=11% just=c};
define lbtpt / display center "Timepoint"
style={cellwidth=11% just=c};
define lbdtc2 / display "Date"
style={cellwidth=8%
just=c};
define time / display "Actual*Time" center
style={cellwidth=5% just=c};
define ALP / display center "Alkaline*Phosphatase*(U/L)"
style={cellwidth=9% just=c};
define AST / display center "Aspartate*Transferase*(U/L)"
style={cellwidth=9% just=c};
define ALT / display center "Alanine*Transferase*(U/L)"
style={cellwidth=9% just=c};
define LDH / display center "Lactic Dehydrogenase*(U/L)"
style={cellwidth=11% just=c};
define BILID / display center "Bilirubin Direct*(μmol/L)"
style={cellwidth=7.5% just=c};
define BILIT / display center "Total Bilirubin*(μmol/L)"
style={cellwidth=7.5% just=c};

compute before;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
Table 14.3.5-1d
DATE:&dtnull2 TIME:&systime";
title2 j=c "Subjects with Abnormal Chemistry Laboratory Data
Based on the Reference Ranges: Hepatic Status Liver Function Tests";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";

```

```

        footnote1 j=1 "NOTE:  H = laboratory value above the reference
laboratory range";
        footnote2 j=1 '09'x "L = laboratory value below the reference
laboratory range";
        footnote3 j=1 '09'x "A = laboratory value abnormal";
        footnote4 j=1 '09'x "C = laboratory value deemed clinically
significant by the investigator";
        footnote5 j=1 '09'x "N = laboratory value deemed not clinically
significant by the investigator.";
        footnote6 j=1 '09'x "Values out of the normal range are
flagged.";
        footnote7 j=1 '09'x "Lab units are presented as SI units.";
        footnote8 j=1 '09'x "Source: Listing 16.2.8-2b";
        footnote9 j=1 '09'x "Reference Range Source: Listing 16.2.8-1";
run;quit;
ods listing;
ods rtf close;

```

```

/*
Title:                                OTR1021 Data Review
Reviewer/Programmer:  R. Valaboju
Date:                                06-18-**
Study:                                OTR1021
Table:                                14.3.5-2a
Notes:                                Re-programming sample tables as
part of QC.
*/

```

```

libname r "P:\Medical\SRSPProd\otr\otr1021\core\forbsp";
run;

```

```

options nolabel;

```

```

%macro chgbase;

```

```

/* Change Information here for other lab final datasets */

```

```

%let lab1=HCT;
%let lab2=HGB;
%let lab3=RBC;
%let lab4=PLT;
%let lab5=WBC;

```

```

/** ---- **/

```

```

%do i=1 %to 5;

data &&lab&i;
set r.lb (where = (lbcat="HEMATOLOGY" and lbtestcd="&&lab&i"));
      by usubjid visitnum;
run;

proc univariate data=&&lab&i (where=(lbtpnum=1)) noprint round=0;
var lbstresn;
output out=scr_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=scr_&&lab&i out=scr_&&lab&i;
var _all_;
run;

data scr_&&lab&i;
length lbtest $15;
set scr_&&lab&i;
lbtest="&&lab&i";
period="a_Screening";
run;

proc sort data=scr_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum=2)) noprint round=0;
var lbstresn;
output out=base_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=base_&&lab&i out=base_&&lab&i;
var _all_;
run;

data base_&&lab&i;
set base_&&lab&i;
lbtest="&&lab&i";
period="b_Baseline";
run;

proc sort data=base_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum>2 and
visitnum=int(visitnum))) noprint round=0;
var lbstresn;

```

```
output out=c_EOS_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min  
median=e_median max=f_max;  
run;
```

```
proc transpose data=c_EOS_&&lab&i out=c_EOS_&&lab&i;  
var _all_;  
run;
```

```
data c_EOS_&&lab&i;  
set c_EOS_&&lab&i;  
lbtest="&&lab&i";  
period="c_EOS";  
run;
```

```
proc sort data=c_EOS_&&lab&i;  
by _name_;  
run;
```

```
data chgbl_&&lab&i;  
  do until (last.usubjid);  
    set &&lab&i (where = (lbstresn^= . and  
visitnum=int(visitnum)));  
    by usubjid visitnum;  
    if visitnum <= 2 then bl=lbstresn;  
    else do;  
      chgbl = lbstresn - bl;  
      output;  
    end;  
  end;  
run;
```

```
proc univariate data=chgbl_&&lab&i noprint round=0;  
var chgbl;  
output out=chgbl_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min  
median=e_median max=f_max;  
run;
```

```
proc transpose data=chgbl_&&lab&i out=chgbl_&&lab&i;  
var _all_;  
run;
```

```
data chgbl_&&lab&i;  
set chgbl_&&lab&i;  
lbtest="&&lab&i";  
period="d_CFB";  
run;
```

```
proc sort data=chgbl_&&lab&i;  
by _name_;  
run;
```

```

data lab_&&lab&i;
length col2 $20;
set scr_&&lab&i base_&&lab&i c_EOS_&&lab&i chgbl_&&lab&i;
if lbtest="WBC" then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.1),8.2);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,1.0),8.1);
end;
else if lbtest in ("HCT","RBC") then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.001),8.3);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,.01),8.2);
end;
else if lbtest in ("PLT","HGB") then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.001),8.1);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,.01),8.);
end;
run;
%end;

data final;
set lab_hct lab_hgb lab_rbc lab_plt lab_wbc;
run;

proc datasets lib=work nolist;
save final;
run;quit;

%mend chgbase;

%chgbase;

proc format;
    value $reportf 'a_N'          = 'N'
                'b_mean'          = 'MEAN'
                'c_sd'            = 'SD'
                'd_min'           = 'MIN'
                'e_median'        = 'MEDIAN'
                'f_max'           = 'MAX'
                'a_Screening'      = 'Screening'
                'b_Baseline'       = 'Baseline, Day -1'
                'c_EOS'           = 'End of Study'
                'd_CFB'           = 'Change from Baseline'
                'HCT'             = 'Hematocrit (fraction)'
                'HGB'             = 'Hemoglobin (g/L)'
                'RBC'             = 'RBC (10^12/L)'
                'PLT'             = 'Platelet Count (10^9/L)'

```

```

                                'WBC'          = 'WBC (10^9/L) '
                                '0.00'         = '0';

run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
/* Make changes here for additional lab reports */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nac103\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-2a.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=35
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.16in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns lbtest period _name_ col2 col1 ;

    *define order1 / order order=internal noprint ;
    *define order2 / order order=internal noprint ;
    define lbtest / group "Laboratory Parameter" format=$reportf.
style={cellwidth=25% just=c};
    define period / group order=internal "Timepoint" format=$reportf.
style={cellwidth=27.5% just=c};
    define _name_ / display "Statistic" format=$reportf.
style={cellwidth=27.5% just=c};

```

```

        define col2 / display "Result" center format=$reportf.
style={cellwidth=11% just=dec};
        define coll / center style={cellwidth=8% just=c
foreground=white};

        compute before;
        line @1 ' ';
        endcomp;

        compute after;
        line @1 ' ';
        endcomp;

        compute after period;
        line @1 ' ';
        endcomp;

        title1 j=1 "OTR1021
                    Table 14.3.5-2a
DATE:&dtnull2 TIME:&systemtime";
        title2 j=c "Descriptive Statistics and Change from Baseline of
Hematology Laboratory Data: CBC";
        *title3 j=c "(Page 1 of 1)";
        title3 j=c "Page ^{thispage} of ^{lastpage}";
        title4;
        title5 j=1 "Population: Randomized Safety";
        footnote1 j=1 "NOTE: Change from Baseline is the change from
Baseline, Day -1 compared to End of Study.";
        footnote2 j=1 '09'x "Lab units are presented in SI units.";
        footnote3;
        footnote4 j=1 "Source: Listing 16.2.8-3a";
run;quit;
ods listing;
ods rtf close;

/*
Title:                                OTR1021 Data Review
Reviewer/Programmer:  R. Valaboju
Date:                                06-18-**
Study:                                OTR1021
Table:                                14.3.5-2b
Notes:                                Re-programming sample tables as
part of QC.
*/

```



```

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

options nolabel;

options mprint mlogic symbolgen;
/* Make changes here for additional labs */
%let str=%nrstr("HCT","HGB","RBC","PLT","WBC");
%let str2=%nrstr(HCT,HGB,RBC,PLT,WBC);
%let str3=%nrstr(HCT||HGB||RBC||PLT||WBC);

/*-----Generic re-usable code starts here-----
-----*/

proc sql;
create table lbsub as select usubjid, lbdtc,lbtpt, lbcate,lbtestcd,
lbstresn, lbnrind,
case when substr(lbnrind,1,1)^=' ' then
trim(put(lbstresn,best12.)||' '||trim(substr(lbnrind,1,1))||', N')
else ' ' end as lbstresn2 from r.lb
where lbtestcd in (%unquote(&str));
quit;

proc transpose data=lbsub out=lbsub;
by usubjid lbdtc lbtpt;
id lbtestcd;
var lbstresn2;
run;

data lbsub;
length sex $10;
merge lbsub(in=a)
      r.sc(in=b keep=usubjid scorres where=(scorres like ("RN%")))
      r.dm(in=c keep=usubjid age sex race);
by usubjid;
if a;
if sex='F' then sex="Female";
if sex='M' then sex="Male";
run;

data lbsub;
length rsub $25;
length asr $45;
length lbdtc2 8;
set lbsub;
rsub=trim(trim(scorres)||'/'||substr(usubjid,15,5));
asr=propcase(trim(trim(age)||'/'||trim(sex)||'/'||trim(race)));
lbdtc2=input(substr(lbdtc,1,10),yymmdd10.);
format lbdtc2 date9.;
run;

```

```

proc sql;
create table final as select rsub, asr, propcase(lbtpt) as lbtpt,
lbdtc2,substr(lbdtc,12,5) as time,%unquote(&str2)
from lbsub
where index((%unquote(&str3)),'') ^ =0;
quit;

/*-----End Generic code-----
-----*/

/* Make changes here for additional lab reports */

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull12=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-2b.rtf" style=Styles.custom;
proc report
data = final
nowd
ls=122
ps=35
headline
headskip
split='*'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.5in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

columns rsub asr lbtpt lbdtc2 time HCT HGB RBC PLT WBC;

define rsub / display group order order=internal center
"Randomization*No/Subject No" style={cellwidth=12% just=l};
define asr / display group center "Age/Gender/*Race" flow
style={cellwidth=12% just=c};
define lbtpt / display center "Time-point"
style={cellwidth=12% just=c};

```

```

define lbdtc2 / display "Date"
                                style={cellwidth=10%
just=c};
define time / display "Actual*Time" center
                                style={cellwidth=9% just=c};
define HCT / display center "Hematocrit*(fraction)"
                                style={cellwidth=9% just=c};
define HGB / display center "Hemoglobin*(g/L)"
                                style={cellwidth=9% just=c};
define RBC / display center "RBC*(10^12/L)"
                                style={cellwidth=9% just=c};
define PLT / display center "Platelet*Count*(10^9/L)"
                                style={cellwidth=8.5% just=c};
define WBC / display center "WBC*(10^9/L)"
                                style={cellwidth=8.5% just=c};

compute before;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
            Table 14.3.5-2b
DATE:&dtnull2 TIME:&systime";
title2 j=c "Subjects with Abnormal Hematology Laboratory Data
Based on the Reference Ranges: CBC";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: H = laboratory value above the reference
laboratory range";
footnote2 j=1 '09'x "L = laboratory value below the reference
laboratory range";
footnote3 j=1 '09'x "A = laboratory value abnormal";
footnote4 j=1 '09'x "C = laboratory value deemed clinically
significant by the investigator";
footnote5 j=1 '09'x "N = laboratory value deemed not clinically
significant by the investigator.";
footnote6 j=1 '09'x "Values out of the normal range are
flagged.";
footnote7 j=1 '09'x "Lab units are presented as SI units.";
footnote8 j=1 '09'x "Source: Listing 16.2.8-3a";
footnote9 j=1 '09'x "Reference Range Source: Listing 16.2.8-1";
run;quit;
ods listing;
ods rtf close;

```

```

/*
    Title:                                OTR1021 Data Review
    Reviewer/Programmer:  R. Valaboju
    Date:                                06-18-**
    Study:                                OTR1021
    Table:                                14.3.5-2c
    Notes:                                Re-programming sample tables as
part of QC.
*/

```

```

libname r "P:\Medical\SRSProd\otr\otr1021\core\forbsp";
run;

```

```

options nolabel;

```

```

%macro chgbase;

```

```

/* Change Information here for other lab final datasets */

```

```

%let lab1=BASOAB;
%let lab2=BASO;
%let lab3=EOSINAB;
%let lab4=EOSIN;
%let lab5=LYMPHAB;
%let lab6=LYMPH;
%let lab7=MONOAB;
%let lab8=MONO;
%let lab9=NEUTAB;
%let lab10=NEUT;

```

```

/** ---- **/

```

```

%do i=1 %to 10;

```

```

    data &&lab&i;
    set r.lb (where = (lbcat="HEMATOLOGY" and lbtestcd="&&lab&i"));
               by usubjid visitnum;
run;

```

```

proc univariate data=&&lab&i(where=(lbtpnum=1)) noprint round=0;
var lbstresn;
output out=scr_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

```

```

proc transpose data=scr_&&lab&i out=scr_&&lab&i;

```

```

var _all_;
run;

data scr_&&lab&i;
length lbtest $15;
set scr_&&lab&i;
lbtest="&&lab&i";
period="a_Screening";
run;

proc sort data=scr_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum=2)) noprint round=0;
var lbstresn;
output out=base_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=base_&&lab&i out=base_&&lab&i;
var _all_;
run;

data base_&&lab&i;
set base_&&lab&i;
lbtest="&&lab&i";
period="b_Baseline";
run;

proc sort data=base_&&lab&i;
by _name_;
run;

proc univariate data=&&lab&i (where=(lbtpnum>2 and
visitnum=int(visitnum))) noprint round=0;
var lbstresn;
output out=c_EOS_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=c_EOS_&&lab&i out=c_EOS_&&lab&i;
var _all_;
run;

data c_EOS_&&lab&i;
set c_EOS_&&lab&i;
lbtest="&&lab&i";
period="c_EOS";
run;

proc sort data=c_EOS_&&lab&i;

```

```

by _name_;
run;

data chgbl_&&lab&i;
    do until (last.usubjid);
        set &&lab&i (where = (lbstresn^= . and
visitnum=int(visitnum)));
        by usubjid visitnum;
        if visitnum = 2 then bl=lbstresn;
            else do;
                chgbl = lbstresn - bl;
                output;
            end;
        end;
    end;
run;

proc univariate data=chgbl_&&lab&i noprint round=0;
var chgbl;
output out=chgbl_&&lab&i n=a_N mean=b_mean std=c_sd min=d_min
median=e_median max=f_max;
run;

proc transpose data=chgbl_&&lab&i out=chgbl_&&lab&i;
var _all_;
run;

data chgbl_&&lab&i;
set chgbl_&&lab&i;
lbtest="&&lab&i";
period="d_CFB";
run;

proc sort data=chgbl_&&lab&i;
by _name_;
run;

data lab_&&lab&i;
length col2 $20;
set scr_&&lab&i base_&&lab&i c_EOS_&&lab&i chgbl_&&lab&i;
if lbtest not in ("BASO","EOSIN","LYMPH","MONO","NEUT") then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.1),8.1);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,1.0),8.);
end;
else if lbtest in ("BASO","EOSIN","LYMPH","MONO","NEUT") then do;
    if _name_="a_N" then col2=put(col1,8.);
    else if _name_="c_sd" then col2=put(round(col1,.001),8.3);
    else if _name_ not in ("a_N","c_sd") then
col2=put(round(col1,.01),8.2);
end;
end;

```

```

run;

%end;

data final;
set lab_baso lab_basoab lab_eosin lab_eosinab lab_lymph lab_lymphab
lab_mono lab_monoab lab_neut lab_neutab;
run;

proc datasets lib=work nolist;
save final;
run;quit;

%mend chgbase;

%chgbase;

proc format;
value $reportf 'a_N' = 'N'
               'b_mean' = 'MEAN'
               'c_sd' = 'SD'
               'd_min' = 'MIN'
               'e_median' = 'MEDIAN'
               'f_max' = 'MAX'
               'a_Screening' = 'Screening'
               'b_Baseline' = 'Baseline, Day -1'
               'c_EOS' = 'End of Study'
               'd_CFB' = 'Change from Baseline'
               'BASOAB' = 'Basophils Absolute
(10^6/L) '
               'BASO' = 'Basophils %(fraction) '
               'EOSINAB' = 'Eosinophils Absolute
(10^6/L) '
               'EOSIN' = 'Eosinophils %(fraction) '
               'LYMPHAB' = 'Lymphocytes Absolute
(10^6/L) '
               'LYMPH' = 'Lymphocytes %(fraction) '
               'MONOAB' = 'Monocytes Absolute
(10^6/L) '
               'MONO' = 'Monocytes %(fraction) '
               'NEUTAB' = 'Neutrophils Absolute
(10^6/L) '
               'NEUT' = 'Neutrophils %(fraction) '
               '0.00' = '0'
               '0.00' = '0';
run;

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);

```

```

call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
/* Make changes here for additional lab reports */
dm "odsresults; clear;";
ods escapechar='~';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-2c.rtf" style=Styles.custom;
proc report
    data = final
    nowd
    ls=122
    ps=35
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.16in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;

    columns lbtest period _name_ col2 col1 ;

    *define order1 / order order=internal noprint ;
    *define order2 / order order=internal noprint ;
    define lbtest / group "Laboratory Parameter" format=$reportf.
style={cellwidth=25% just=c};
    define period / group order=internal "Timepoint" format=$reportf.
style={cellwidth=27.5% just=c};
    define _name_ / display "Statistic" format=$reportf.
style={cellwidth=27.5% just=c};
    define col2 / display "Result" center format=$reportf.
style={cellwidth=11% just=dec};
    define col1 / center style={cellwidth=8% just=c
foreground=white};

    compute before;
    line @1 ' ';
    endcomp;

    compute after;
    line @1 ' ';

```



```

endcomp;

compute after period;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
           Table 14.3.5-2c
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Descriptive Statistics and Change from Baseline of
Hematology Laboratory Data: Differential Counts";
title3 j=c "(Page 1 of 1)";
title3 j=c "Page ~{thispage} of ~{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: Change from Baseline is the change from
Baseline, Day -1 compared to End of Study.";
footnote2 j=1 '09'x "Lab units are presented in SI units.";
footnote3;
footnote4 j=1 "Source: Listing 16.2.8-3b";
run;quit;
ods listing;
ods rtf close;

/*
Title:                                OTR1021 Data Review
Reviewer/Programmer: R. Valaboju
Date:                                06-18-**
Study:                                OTR1021
Table:                                14.3.5-2d
Notes:                                Re-programming sample tables as
part of QC.
*/

libname r "P:\Medical\SRSPProd\otr\otr1021\core\forbsp";
run;

options nolabel;

options mprint mlogic symbolgen;
/* Make changes here for additional labs */

```

```

%let
str=%nrstr("BASOAB","BASO","EOSINAB","EOSIN","LYMPHAB","LYMPH","MONOAB",
", "MONO", "NEUTAB", "NEUT");
%let
str2=%nrstr(BASOAB,BASO,EOSINAB,EOSIN,LYMPHAB,LYMPH,MONOAB,MONO,NEUTAB
,NEUT);
%let
str3=%nrstr(BASOAB||BASO||EOSINAB||EOSIN||LYMPHAB||LYMPH||MONOAB||MONO
||NEUTAB||NEUT);

/*-----Generic re-usable code starts here-----
-----*/
/* Create subset of lab standard values dataset for the required tests
*/
proc sql;
create table lbsub as select usubjid, lbdtc,lbtpt, lbcate,lbtestcd,
lbstresn, lbnrind,
case when substr(lbnrind,1,1)^=' ' then
trim(put(lbstresn,best12.)||' '||trim(substr(lbnrind,1,1))||', N')
else ' ' end as lbstresn2 from r.lb
where lbtestcd in (%unquote(&str));
quit;

/* Transpose the data subset to get standard values with corresponding
lab test column headings */
proc transpose data=lbsub out=lbsub;
by usubjid lbdtc lbtpt;
id lbtestcd;
var lbstresn2;
run;

/* Merge the lab subset with SC and DM datasets to get randomization
numbers and demographic data */
data lbsub;
length sex $10;
merge lbsub(in=a)
      r.sc(in=b keep=usubjid scorres where=(scorres like ("RN%")))
      r.dm(in=c keep=usubjid age sex race);
by usubjid;
if a;
if sex='F' then sex="Female";
if sex='M' then sex="Male";
run;

/* Create new variables required for reporting by concatenating data
*/
data lbsub;
length rsub $25;
length asr $45;
length lbdtc2 8;

```

```

set lbsub;
rsub=trim(trim(scorres)||'/'||substr(usubjid,15,5));
asr=propcase(trim(trim(age)||'/'||trim(sex)||'/'||trim(race)));
lbdtc2=input(substr(lbdtc,1,10),yymmdd10.);
format lbdtc2 date9.;
run;

/* Create final dataset with required variables for reporting */
proc sql;
create table final as select rsub, asr, propcase(lbtpt) as lbtpt,
lbdtc2,substr(lbdtc,12,5) as time,%unquote(&str2)
from lbsub
where index((%unquote(&str3))','') ^=0;
quit;

/*-----End Generic code-----
-----*/

/* Make changes here for additional lab reports */

/*Create macro variable for sysdate system macro variable*/
data _null_;
today = put(date(),date9.);
call symput('dtnull',today);
run;

%let dtnull2=%substr(&dtnull,1,2)-%substr(&dtnull,3,3)-
%substr(&dtnull,6,4);

/* Proc Report Step */
dm "odsresults; clear;";
ods escapechar='^';
options nonumber nodate orientation=landscape;
ods listing close;
ods rtf
file="\nacl03\users_ab\valabojr\Documents\OTR1021\reports\OTR1021_14-
3-5-2d.rtf" style=Styles.custom;
proc report
data = final
nowd
ls=122
ps=35
headline
headskip
split='*'
style(report)={font_face=arial font_size=2.5 bordercolor=black}
style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.5in bordercolor=black}
style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
;

```

```

where (basoab^='' or baso^='' or eosinab^='' or eosin^='' or
lymphab^='' or lymph^='');
columns rsub asr lbtpt lbdtc2 time BASOAB BASO EOSINAB EOSIN
LYMPHAB LYMPH;

define rsub / display group order order=internal center
"Randomization*No/Subject No" style={cellwidth=12% just=l};
define asr / display group center "Age/Gender/*Race" flow
style={cellwidth=12.125% just=c};
define lbtpt / display center "Time-point"
style={cellwidth=10% just=c};
define lbdtc2 / display "Date"
style={cellwidth=9%
just=c};
define time / display "Actual*Time" center
style={cellwidth=8% just=c};
define BASOAB / display center "BASO Abs*(10^6/L)"
style={cellwidth=8% just=c};
define BASO / display center "BASO %*(fraction)"
style={cellwidth=8% just=c};
define EOSINAB / display center "EOS Abs*(10^6/L)"
style={cellwidth=8% just=c};
define EOSIN / display center "EOS %*(fraction)"
style={cellwidth=8% just=c};
define LYMPHAB / display center "LYMPH Abs*(10^6/L)"
style={cellwidth=8% just=c};
define LYMPH / display center "LYMPH %*(fraction)"
style={cellwidth=8% just=c};

compute before;
line @1 ' ';
endcomp;

title1 j=1 "OTR1021
Table 14.3.5-2d
DATE:&dtnull2 TIME:&sysstime";
title2 j=c "Subjects with Abnormal Hematology Laboratory Data
Based on the Reference Ranges: Differential Counts (Part 1 of 2)";
*title3 j=c "(Page 1 of 1)";
title3 j=c "Page ^{thispage} of ^{lastpage}";
title4;
title5 j=1 "Population: Randomized Safety";
footnote1 j=1 "NOTE: H = laboratory value above the reference
laboratory range";
footnote2 j=1 '09'x "L = laboratory value below the reference
laboratory range";
footnote3 j=1 '09'x "A = laboratory value abnormal";
footnote4 j=1 '09'x "C = laboratory value deemed clinically
significant by the investigator";
footnote5 j=1 '09'x "N = laboratory value deemed not clinically
significant by the investigator.";

```

```

        footnote6 j=1 '09'x "Values out of the normal range are
flagged.";
        footnote7 j=1 '09'x "Lab units are presented as SI units.";
        footnote8 j=1 '09'x "Source: Listing 16.2.8-3b";
        footnote9 j=1 '09'x "Reference Range Source: Listing 16.2.8-1";
run;quit;
proc report
    data = final
    nowd
    ls=122
    ps=35
    headline
    headskip
    split='*'
    style(report)={font_face=arial font_size=2.5 bordercolor=black}
    style(column)={just=center font_face=arial font_size=2.5
font_size=2.5 cellheight=.5in bordercolor=black}
    style(header)={font_face=arial font_size=2.5 foreground=black
bordercolor=black flow}
    ;
where (monoab^='' or mono^='' or neutab^='' or neut^='');

    columns rsub asr lbtpt lbdtc2 time MONOAB MONO NEUTAB NEUT;

    define rsub / display group order order=internal center
"Randomization*No/Subject No" style={cellwidth=14% just=l};
    define asr / display group center "Age/Gender/*Race" flow
style={cellwidth=12.125% just=c};
    define lbtpt / display center "Time-point"
style={cellwidth=13% just=c};
    define lbdtc2 / display "Date"
style={cellwidth=10%
just=c};
    define time / display "Actual*Time" center
style={cellwidth=10% just=c};
    define MONOAB / display center "MONO Abs*(10^6/L)"
style={cellwidth=10% just=c};
    define MONO / display center "MONO %*(fraction)"
style={cellwidth=10% just=c};
    define NEUTAB / display center "NEUT Abs*(10^6/L)"
style={cellwidth=10% just=c};
    define NEUT / display center "NEUT %*(fraction)"
style={cellwidth=10% just=c};

    compute before;
    line @1 ' ';
    endcomp;

    title1 j=1 "OTR1021
Table 14.3.5-2d
DATE:&dtnull2 TIME:&systemtime";

```

```
        title2 j=c "Subjects with Abnormal Hematology Laboratory Data  
Based on the Reference Ranges: Differential Counts (Part 2 of 2)";  
        *title3 j=c "(Page 1 of 1)";  
        title3 j=c "Page ^{thispage} of ^{lastpage}";  
        title4;  
        title5 j=1 "Population: Randomized Safety";  
run;quit;  
ods listing;  
ods rtf close;
```