

```

*****
* Project      : ZRHM-REXA-07-JP
*
* Program name  : t150201040301_ZRHM-REXA-07_V1.sas
*
* Author       : W. Yang
*
* Date created  : 05/22/2015
*
* Purpose      : Create Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline
Characteristics by Sex ❖ PP Set
*
* Revision History :
*
* Date      Author   Ref   Revision (Date in YYYYMMDD format)
*
*****

%let prgname=T150201040301_ZRHM_REXA_07_JP_V1;

options nomprint nosymbolgen nomlogic validvarname=upcase;

options sasautos=("W:\pmp07\macros" sasautos) notes;

%init(delivery=9);

%titlecsv(prgname=&prgname., version=3);

%put &title1;

%put &title2;

%put &APPENDIX;

```

```
%put &endpoint;
```

```
%put &outname.;
```

```
data adsl;
```

```
    set adam.adsl;
```

```
run;
```

```
%trtrtfg(pgmname=&outname., pgmid=1, new=0, style=, bookmark=%lowcase(&outname.));
```

```
%macro repeat(pop1fl=, sub=, out=);
```

```
data adsl1;
```

```
    set adsl;
```

```
    where &pop1fl.='Y';
```

```
    if   trt01an=4 and sexn=1 then do; trt=1; output; end;
```

```
    else if trt01an=4 and sexn=2 then do; trt=2; output; end;
```

```
    else if trt01an=5 and sexn=1 then do; trt=3; output; end;
```

```
    else if trt01an=5 and sexn=2 then do; trt=4; output; end;
```

```
    else if trt01an=3 and sexn=1 then do; trt=5; output; end;
```

```
    else if trt01an=3 and sexn=2 then do; trt=6; output; end;
```

```
    if &pop1fl.='Y'   and sexn=1 then do; trt=7; output; end;
```

```
    if &pop1fl.='Y'   and sexn=2 then do; trt=8; output; end;
```

```
run ;
```

```
proc freq data =adsl1 noprint;
```

```
    table trt/out=treatabt (rename =(count=total)drop=percent);
```

```
run;
```

```
Data _null_;
```

```
Set treatabt;
```

```
Call symput('n' | strip(put(trt, best.)),strip(put(total, best.)));
```

```
Run;
```

```
%put &n1 &n2 &n3 &n4 &n5 &n6 &n7 &n8;
```

```
*** Prepare data for analysis ***;
```

```
proc sort data=sdtm.vs(where=(vstestcd='WSTCIR' and vsstresn>. and visitdy<0)) out=vs; by usubjid  
vsdtc; run;
```

```
data vs(keep=usubjid wstcir);
```

```
set vs;
```

```
by usubjid;
```

```
if last.usubjid;
```

```
wstcir=vsstresn;
```

```
run;
```

```
proc transpose data=adam.adqsnd out=qs1(drop=_) prefix=qs suffix=n;
```

```
where paramn in (23) and avisit='Screening';
```

```
by usubjid;
```

```
id paramn;
```

```
var aval;
```

```
run;
```

```
proc transpose data=adam.adqsnd out=qs2(drop=_) prefix=qs suffix=c;

  where paramn in (23) and avisit='Screening';

  by usubjid;

  id paramn;

  var avalcat1;

run;
```

```
proc transpose data=adam.adqsnd out=qs3(drop=_) prefix=qs suffix=n;

  where paramn in (24 25 26 27 28 29);

  by usubjid;

  id paramn;

  var aval;

run;
```

```
proc transpose data=adam.adqsnd out=qs4(drop=_) prefix=qs suffix=c;

  where paramn in (24 25 26 27 28 29);

  by usubjid;

  id paramn;

  var avalc;

run;
```

```
data data1;

  merge adsl1(in=a) vs qs1 qs2 qs3 qs4;

  by usubjid;
```

```
if a;  
run;  
  
data demo;  
set data1;  
height=height/100;  
  
if ucpdgr1="" then do; ucpdgr1n=4; ucpdgr1='Missing'; end;  
  
if prodpref='THS 2.2 menthol' then do; prodpren=1; end;  
else if prodpref='mCC' then do; prodpren=2; end;  
else if prodpref='SA' then do; prodpren=3; end;  
else if prodpref='No preference' then do; prodpren=4; end;  
else if prodpref="" then do; prodpren=5; prodpref='Missing'; end;  
  
if qs23c='Mild' then qs23cn=1;  
else if qs23c='Moderate' then qs23cn=2;  
else if qs23c='Severe' then qs23cn=3;  
  
if qs24n=. then do; qs24n=100; qs24c='Missing'; end;  
if qs25n=1 then qs25n=3;  
else if qs25n=2 then qs25n=1;  
else if qs25n=3 then qs25n=2;  
else if qs25n=. then do; qs25n=99; qs25c='Missing'; end;  
if qs26n=. then do; qs26n=99; qs26c='Missing'; end;
```

```

if qs27n=. then do; qs27n=99; qs27c='Missing'; end;

if   qs28n=12 then qs28n=1;

else if qs28n=13 then qs28n=2;

else if qs28n>0 then qs28n=qs28n+4;

else if qs28n=. then do; qs28n=3; qs28c='Missing'; end;

if 5<=qs28n<=15 then do; qs30n=4; qs30c='Any amount reported'; end;

if qs28n in (1 2) then do;

    if   qs29n=3 then qs29n=1;

    else if qs29n=4 then qs29n=2;

    else if qs29n>0 then qs29n=qs29n+3;

    if 4<=qs29n<=5 then do; qs31n=3; qs31c='Any amount reported'; end;

end;

else do; qs29n=.; qs29c=""; end;

if qs28n in (1 2) then do; qs32n=1; qs32c='Replied "Dont Know" or "Prefer not to Say" to 5a'; end;

run;

```

*** Macro for both Categorical & Continuous variables statistics ***;

```
%macro mdemo(in_dsn=,var_list=,n_max=);
```

*** Macro for Continuous variables statistics ***;

```
%macro mmeans(in_dsn=, class=, var=, order1=);
```

*** Obtain decimal point of data ***;

```
data decimal (keep=&class trt deci);
```

```
    length varChar $200;
```

```
    set &in_dsn;
```

```

varChar=strip(put(&var, best32.));

if index(varChar, '.') ne 0 then deci=length(scan(varChar,2,','));

else deci=0;

if deci >= 3 then deci=1;

run;

*** Keep only the largest decimal number ***;

proc sort data=decimal;      by &class trt descending deci; run;

proc sort data=decimal nodupkey;  by &class trt;      run;

*** Statistics of Continuous Variables ***;

proc means data=&in_dsn noprint nway;

class &class trt;

var &var;

output out= stat1 n=_n mean=_mean std=_std median=_median min=_min max=_max;

run;

*** Apply decimal points and arrange statistics as required in mock ***;

data stat2 (drop=_:);

length n meansd median minmax $50 fm1-fm3 $10;

merge stat1 (in=a)

decimal;

by &class trt;

if a;

```

```

fm1=cats(12,".",strip(put(deci+1,3.)));
fm2=cats(12,".",strip(put(deci+2,3.)));
fm3=cats(12,".",strip(put(deci+0,3.)));

if   deci=0 then _std=ceil(_std*100)/100;
else if deci=1 then _std=ceil(_std*1000)/1000;
else if deci=2 then _std=ceil(_std*10000)/10000;

if   _mean ne . and _std ne . then meansd=strip(putn(_mean, fm1))||"
("||strip(putn(_std,fm2))||");

else if _mean ne . and _std eq . then meansd=strip(putn(_mean, fm1))||" (NA)";

if _min   ne . then minmax=strip(putn(_min,fm3))||", "||strip(putn(_max,fm3));

if _n     ne . then n=strip(put(_n,best12.));

if _median ne . then median=strip(putn(_median, fm1));

run;

*** Transpose data for final report ***;

proc transpose data=stat2 out=stat3 prefix=col;

  by &class;

  var n meansd median minmax;

  id trt;

run;

*** Prepare Statistic Description & sorting orders as seen in Mock ***;

data final_&order1. (drop=_name_);

  length stat1 $150;

```



```

set stat3;

if _name_='N' then do; stat1="n"; order2 =6; end;

if _name_='MEANS' then do; stat1="Mean (SD)"; order2 =7; end;

if _name_='MEDIAN' then do; stat1="Median"; order2 =8; end;

if _name_='MINMAX' then do; stat1="Min, Max"; order2 =9; end;

order1=&order1;

run;

%mend mmeans;

```

```

*** Macro for Categorical variables statistics ***;

%macro mfreq(in_dsn=, n_max=, order1=, order2=, class=);

*** Statistics of Categorical Variables ***;

proc means data=&in_dsn noprint nway;

class &class trt;

var trt;

output out=stat1 n=count;

run;

```

```

*** Arrange count & percentage as required in mock ***;

data stat2 (drop=_type_ _freq_ percentx);

set stat1;

by &class trt;

length percentage $25;

%do i=1 %to &n_max;

```

```

        if trt=&i and count>. then percentx=count/%eval(&&n&i)*100;

        if    percentx=100 then percentage=put(count,4.)||'(100)';

        else if percentx>=0.1 then percentage=put(count,4.)||'('||strip(put(percentx,5.1))||')';

        else if percentx>.  then percentage=put(count,4.)||'(<0.1)';

    %end;

run;

```

```

*** Transpose data for final report ***;

proc transpose data=stat2 out=stat3 prefix=col;

    by &class;

    id trt;

    var percentage;

run;

```

```

*** Prepare sorting orders as seen in Mock ***;

data final_&order1 (drop=_name_);

    set stat3;

    order2=&order2;

    order1=&order1;

%do i=1 %to &n_max;

    %if col&i=" %then col&i='0';

%end;

run;

%mend mfreq;

```

```

*** Read in Macro Parameters and call Categorical & Continuous Macros respectively ***;

%local w i x _mtx;

%let w=1;

%do %while (%scan(&var_list,&w,':') ne );

    %local _mtx&w;

    %let _mtx&w=%scan(&var_list,&w,':');

    %let type=%scan(&&_mtx&w,1,' ');

    *** 'S' is short of 'Summary', stand for Continuous Variable ***;

    %if %upcase(&type)=S %then %do;

        %let sum_var=%scan(&&_mtx&w,2,' ');

        %mmeans(in_dsn=&in_dsn, order1=&w, class=, var=&sum_var);

    %end;

    /*** 'F' is short of 'Frequency', stand for Categorical Variable ***/

    %else %if %upcase(&type)=F %then %do;

        %let fr_var=%scan(&&_mtx&w,2,' ');

        %let order2=%scan(&&_mtx&w,3,' ');

        %mfreq(in_dsn=&in_dsn, n_max=&n_max, order1=&w, order2=&order2, class=&order2
&fr_var);

    data final_&w.;

        length stat stat1 $150;

        set final_&w.;

        stat="^R/RTF'\li300' " || propcase(strip(&fr_var));

```

```

        stat1='n (%)    ';

run;

%end;


%let w=%eval(&w.+1);

%end;

%let _mtx=%eval(&w-1);


data final1;

    length col1-col8 $100;

    set final_;;

    keep stat: col: order;;

run;

%mend mdemo;


options symbolgen mprint;

%mdemo(

    in_dsn=demo,

    var_list=F sexc sexn:S age:F ethnic ethnicn:S weightbl:S height:S bmi:F bmigr1 bmigr1n:S wstcir:

        F ucpdgr1 ucpdgr1n:S tarbl:F targr1 targr1n:S nicobl:F nicogr1 nicogr1n:S qs23n:F qs23c qs23cn:

        F prodpref prodpren:F qs24c qs24n:F qs25c qs25n:F qs26c qs26n:F qs27c qs27n:F qs28c qs28n:

        F qs32c qs32n:F qs30c qs30n:F qs31c qs31n:F qs29c qs29n,

    n_max=8);


data shell;

```

```

length stat3 $150;

order1=1; order2=0; stat3='Sex'; output;

order1=2; order2=6; stat3='Age (years)'; output;

order1=3; order2=0; stat3='Ethnicity'; output;

order1=3; order2=4; stat3="^R/RTF'\li300' " | 'Non-Japanese'; output;

order1=4; order2=6; stat3='Weight (kg)'; output;

order1=5; order2=6; stat3='Height (m)'; output;

order1=6; order2=6; stat3="BMI (kg/m^{super 2})"; output;

order1=7; order2=1; stat3="^R/RTF'\li300' " | 'Underweight'; output;

/* order1=7; order2=1; stat3=""; output;*/

order1=8; order2=6; stat3='Waist circumference (cm)'; output;

order1=9; order2=0; stat3='Cigarette consumption'; output;

order1=10; order2=6; stat3='ISO tar yields'; output;

/* order1=11; order2=1; stat=""; output;*/

order1=12; order2=6; stat3='ISO nicotine yields'; output;

/* order1=13; order2=1; stat=""; output;*/

order1=14; order2=6; stat3='FTND score'; output;

/* order1=15; order2=1; stat=""; output;*/

order1=16; order2=0; stat3='Individual product preference'; output;

order1=17; order2=0; stat3="Day 4 SES Questionnaire ^R/RTF'\line' Q1: Total number living in
household (including yourself)?"'; output;

order1=18; order2=0; stat3='Q2: Highest level education attained / currently attaining?'; output;

order1=19; order2=0; stat3='Q3: How many income earners in household?'; output;

order1=20; order2=0; stat3='Q4: What is your occupation?'; output;

order1=21; order2=0; stat3='Q5a: What is approximate MONTHLY household income from all sources
before tax?'; output;

```

```
order1=22; order2=1; stat3='Replied "Don T Know" Or "Prefer not to Say" to 5a'; output;
```

```
order1=25; order2=0; stat3='Q5b: (For those who answered "Don T know" or "Prefer not to say" to  
5a) Would MONTHLY household income be over or under 800,000 yen?'; output;
```

```
run;
```

```
data final1;
```

```
set final1;
```

```
if order1=23 then order1=21;
```

```
if order1=24 then order1=25;
```

```
if order1=17 then order2=order2+1;
```

```
run;
```

```
proc sort data=final1; by order1 order2; run;
```

```
data &out.;
```

```
merge final1 shell;
```

```
by order1 order2;
```

```
if stat3^="" then stat=stat3;
```

```
if order2^=0 then do;
```

```
if col1="" then col1='0'; if col2="" then col2='0';
```

```
if col3="" then col3='0'; if col4="" then col4='0';
```

```
if col5="" then col5='0'; if col6="" then col6='0';
```

```
if col7="" then col7='0'; if col7="" then col7='0';
```

```
end;
```

```

stat=tranwrd(stat,'To ','to ');
stat=tranwrd(stat,'Ths 2.2 Menthol','THSm2.2');
stat=tranwrd(stat,'Mcc','mCC');
stat=tranwrd(stat,'" Sa','" SA");
stat=tranwrd(stat,'Don T',"Don't");
stat=tranwrd(stat,'Or ','or ');
stat=tranwrd(stat,',000 Yen ','000 Yen - ');
stat=tranwrd(stat,'Yen - or Above','Yen or Above');
stat=tranwrd(stat,'Below 100,000 Yen -','Below 100,000 Yen');
stat=tranwrd(stat,'to which ','To which ');
stat=tranwrd(stat,' Mg',' mg');

```

```

if order1=22 then do;

```

```

    col1=scan(col1,1,'('); col2=scan(col2,1,'(');
    col3=scan(col3,1,'('); col4=scan(col4,1,'(');
    col5=scan(col5,1,'('); col6=scan(col6,1,'(');
    col7=scan(col7,1,'('); col8=scan(col8,1,'(');

```

```

end;

```

```

if order1=1 then delete;

```

```

if order1=3 and order2=4 then stat1='n (%)';

```

```

if order1=7 and order2=1 then stat1='n (%)';

```

```

if order1=21 and order2>4 then stat=tranwrd(stat,"^R/RTF'\li300'", "^R/RTF'\li600'");

```

```
if order1 in (7 11 13 15) then order2=order2+10;

if order1 in (7 11 13 15) then order1=order1-1;

if order1=19 and order2=1 then stat="^R/RTF'\li300' None - All Are Unemployed";

if order1=25 and order2>=4 then stat=tranwrd(stat,"^R/RTF'\li300'", "^R/RTF'\li600'");

if stat="^R/RTF'\li300' Professional/ Technical Worker" then stat="^R/RTF'\li300'
Professional/Technical Worker";
```

```
pageno=1;

if order1 > 4 then pageno=2;

if order1 > 7 then pageno=3;

if order1 >9 then pageno=4;

if order1 >13 then pageno=5;

if order1 >16 then pageno=6;

if order1 >17 then pageno=7;

if order1 >19 then pageno=8;

if order1 =20 and order2>12 then pageno=9;

if order1 >20 then pageno=9;

if order1 =21 and order2>6 then pageno=10;

if order1 >21 then pageno=11;

pageno=pageno+%eval((&sub-1)*11);

run;
```

```
proc sort; by pageno order1 order2; run;
```

```
%let totalpage=44;
```



```

%macro reppart(sub=,out=);

%do j = 1 %to 11;

%let i=%eval(&j+(&sub.-1)*11);

proc report data=&out.(where=(pageno=&i.)) headskip headline spacing=4 nowd split='|'
style=[outputwidth=100%] style(header column)=[protectspecialchars=off];

column pageno order1 order2 stat stat1 ("\\brdrb\\brdrs THSm2.2" col1 col2)

("\\brdrb\\brdrs mCC" col3 col4) ("\\brdrb\\brdrs SA" col5 col6);


define pageno /order order=internal noprint;

define order1 /order order=internal noprint;

define order2 /order order=internal noprint;

define stat /display "Variable" style(column)=[cellwidth=25% asis=on] style(header)=[just=l];

define stat1 /display "Statistic" style(column)=[cellwidth=10% asis=on] style(header)=[just=l];

define col1 /display "Males|(N=&n1)" flow style(column)=[cellwidth=10% just=c];

define col2 /display "Females|(N=&n2)" flow style(column)=[cellwidth=10% just=c];

define col3 /display "Males|(N=&n3)" flow style(column)=[cellwidth=10% just=c];

define col4 /display "Females|(N=&n4)" flow style(column)=[cellwidth=10% just=c];

define col5 /display "Males|(N=&n5)" flow style(column)=[cellwidth=10% just=c];

define col6 /display "Females|(N=&n6)" flow style(column)=[cellwidth=10% just=c];


compute before order1 ;

line "";

endcomp;


compute before _page_ /style=[fontweight=bold fontsize=3.75];

```

```

line @1 "&title1 &title2";

line @1 "Period &sub.";

line @1 "^R/RTF"\brdrb\brdrs\brdrw30\brsp20\b ' ' ";

endcomp;

compute after _page_/style=[fontsize=1.75];

line @1 "Note: The Overall PP Set refers to all subjects in the Per Protocol Population.";

line @1 "Note: Height at Screening and body weight and waist circumference at Admission (Day -2)
are used.";

line @1 "Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 =
Tobacco Heating System 2.2 Menthol.";

line @1 "Note: BMI = Body Mass Index; FTND = Fagerstr m Test for Nicotine Dependence, SES =
Socio-Economic Status.";

line @1 "Note: Periods defined as Period 1 ([Day 1   Day 6 confinement]), Period 2 ([Day 6
ambulatory   Day 30 Visit]), Period 3 ([Day 30 Visit   Day 60 Visit]) and Period 4 ([Day 60 Visit   Day
90 Visit]).";

line @1 "";

line @1 "&APPENDIX.";

line @1 "Study ID:ZRHM-REXA-07-JP      Program: &fprgname..sas      Status:
&repversion./&fdate.      Page: &i of &totalpage.";

endcomp;

compute after pageno ;

line "";

endcomp;

run;

%end;

%mend;

```

```
%reppart(sub=&sub.,out=&out.);
```

```
%mend;
```

```
%repeat(pop1fl=pprot1fl, sub=1, out=out1);
```

```
%repeat(pop1fl=pprot2fl, sub=2, out=out2);
```

```
%repeat(pop1fl=pprot3fl, sub=3, out=out3);
```

```
%repeat(pop1fl=pprot4fl, sub=4, out=out4);
```

```
ods listing;
```

```
ods rtf close;
```

```
data odata.%sysfunc(scan(&prgname,1,'_'));
```

```
set out1(in=a) out2(in=b) out3(in=c) out4(in=d);
```

```
if a then group="PPROT1FL";
```

```
if b then group="PPROT2FL";
```

```
if c then group="PPROT3FL";
```

```
if d then group="PPROT4FL";
```

```
drop col7 col8;
```

```
run;
```