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* Project : ZRHM-REXA-07-JP

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* Program name : t1502010401_ZRHM-REXA-07_V1.sas

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* Author : W. Yang

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* Date created : 06/01/2015

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* Purpose : Create Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics
◆ Safety Population

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* Revision History :

*

* Date Author Ref Revision (Date in YYYYMMDD format)

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*****,

%let prgname=T1502010401_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 adsl1;
```

```
    set adam.adsl;
```

```
    where safbfl='Y';
```

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

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

```
    else if trt01an=3 then do; trt=3; output; end;
```

```
    else if trt01an=96 then do; trt=4; output; end;
```

```
    if safbfl='Y' then do; trt=5; 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;
```

```
*** 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;

    if ucpdgr1="" then do; ucpdgr1n=4; ucpdgr1='Missing'; end;

    height=height/100;

    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 in (0 5 6) then do; qs24n=5; qs24c='Etc.'; end;*/

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_='MEANSD' 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-col5 $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=5);

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 final;
```

```
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';
```

```
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,'(');

end;

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>8 then pageno=10;

    if order1 >21 then pageno=11;

run;


%global totalpage;


data _null_;

    set final end=eof;

    if eof then do;

        call symput('totalpage', trim(left(put(pageno,8)))));

    end;

run;


%put totalpage=&totalpage;


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

options nomprint nosymbolgen;


%macro reppart;


    %do i = 1 %to &totalpage;


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

    column pageno order1 order2 stat stat1 col1-col5;

```



```

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=30% asis=on] style(header)=[just=l];

define stat1 /display "Statistic" style(column)=[cellwidth=8% asis=on] style(header)=[just=l];

define col1 /display "THSm2.2|(N=&n1)" flow style(column)=[cellwidth=11% just=c];

define col2 /display "mCC|(N=&n2)" flow style(column)=[cellwidth=11% just=c];

define col3 /display "SA|(N=&n3)" flow style(column)=[cellwidth=11% just=c];

define col4 /display "Product|Test|(N=&n4)" flow style(column)=[cellwidth=11% just=c];

define col5 /display "Overall|Safety|(N=&n5)" flow style(column)=[cellwidth=11% just=c];

```

```

compute before order1 ;

```

```

    line "";

```

```

endcomp;

```

```

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

```

```

    line @1 "&title1 &title2";

```

```

    line @1 "Safety Time Period: Pre-Randomization";

```

```

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

```

```

endcomp;

```

```

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

```

```

    line @1 "Note: ♦Product Test♦ refers to all subjects who tested the THS product but were not randomized.";

```

```

    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 "";
```

```
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;
```

```
ods listing;
```

```
ods rtf close;
```

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

```
set final(in=a);
```

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

```
run;
```