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* Project : ZRHM-REXA-07-JP

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* Program name : t15020101_ZRHM-REXA-07_V1.sas

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* Author : W. Yang

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* Date created : 05/20/2015

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* Purpose : Create Table 15.2.1.1 Summary of Subject Disposition ◆ All Screened Subjects

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* Revision History :

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* Date Author Ref Revision (Date in YYYYMMDD format)

*

*****,

ods escapechar='^';

%let prgname=T15020101_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=5);

%put &title1;

%put &title2;

```
%put &APPENDIX;
```

```
%put &endpoint;
```

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

```
%put &fprgname;
```

```
data adsl;
```

```
    set adam.adsl(where=(scrffl^="));
```

```
    trt=1; output;
```

```
run ;
```

```
proc freq data =adsl 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;
```

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

```
proc sort data=sdtm.fa(where=(fatestcd='PERFORM')) out=fa1; by usubjid; run;
```

```
proc sort data=sdtm.fa(where=(fatestcd='WILLABL')) out=fa2; by usubjid; run;
```

```
data fa1(keep=usubjid ptestfl);
```

```
set fa1;  
by usubjid;  
if first.usubjid;  
if faorres='Y' then ptestfl='Y'; else ptestfl='N';  
run;
```

```
data fa2(keep=usubjid willfl);  
set fa2;  
by usubjid;  
if first.usubjid;  
if faorres='Y' then willfl='Y'; else willfl='N';  
run;
```

```
data data1;  
merge adsl(in=a) fa1 fa2;  
by usubjid;  
if a;  
run;
```

```
data data1;  
set data1;
```

```
if scrffl='Y' then do; order1=1; order2=1; output; end;  
if scrffl='Y' and ptestfl^='Y' then do; order1=1; order2=2; output; end;  
if scrffl='Y' and ptestfl='Y' then do; order1=1; order2=3; output; end;
```

```
if scrffl='Y' and willfl='N'      then do; order1=1; order2=4; output; end;
```

```
if scrffl='Y' and fupfl='Y'      then do; order1=2; order2=1; output; end;
```

```
if scrffl='Y' then do;
```

```
    if dsreas='Entry criteria not met' then do; order1=3; order2=1; output; end;
```

```
    else if dsreas='Withdrawal by subject' then do; order1=3; order2=2; output; end;
```

```
    else if dsreas='Adverse events'      then do; order1=3; order2=3; output; end;
```

```
    else if dsreas='Other'               then do; order1=3; order2=4; output; end;
```

```
end;
```

```
if enrfl='Y' then do;
```

```
    if 1 then do; order1=4; order2=1; output; end;
```

```
    if enfl='Y' then do; order1=4; order2=2; output; end;
```

```
    if enfl='Y' and fupfl='Y' then do; order1=4; order2=3; output; end;
```

```
    if randdt>. then do; order1=4; order2=4; output; end;
```

```
end;
```

```
run;
```

```
data shell;
```

```
length stat $200;
```

```
order1=1; order2=1; stat='Screen failures'; output;
```

```
order1=1; order2=2; stat=' Screening failures, without product test'; output;
```

```
order1=1; order2=3; stat=' Screening failures, with product test'; output;
```

```
order1=1; order2=4; stat=' Unwilling to use THS 2.2 Menthol'; output;
```

```

/*  order1=2; order2=1; stat=' Completed safety follow-up'; output; */

order1=3; order2=0; stat=' Reason for screen failure'; output;

order1=3; order2=1; stat=' Entry criteria not met'; output;

order1=3; order2=2; stat=' Withdrawal by subject'; output;

order1=3; order2=3; stat=' Adverse events'; output;

order1=3; order2=4; stat=' Other'; output;

order1=4; order2=1; stat='Enrolled'; output;

order1=4; order2=2; stat=' Enrolled not randomized'; output;

order1=4; order2=3; stat=' Enrolled not randomized who completed safety follow-up'; output;

order1=4; order2=4; stat=' Randomized'; output;

run;

```

```

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

proc means data=&in_dsn noprint nway;

class &class trt;

var trt;

output out=stat1 n=count;

run;

```

```

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;

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

    by &class;

    id trt;

    var percentage;

run;

data final_1 (drop=_name_);

    length col1-col&n_max. $100;

    set stat3;

    order2=&order2;

    order1=&order1;

    %do i=1 %to &n_max;

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

    %end;

run;

%mend mfreq;

%mfreq(in_dsn=data1, n_max=1, order1=order1, order2=order2, class=order1 order2);

```

```
%let t1=&n1;
```

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

```
*** Prepare the output data set per mock-up/shell ***;
```

```
data final1;
```

```
length stat $200;
```

```
merge shell final_1;
```

```
by order1 order2;
```

```
if col1="" and order2^=0 then col1='0';
```

```
if order1=1 and order2=4 then delete;
```

```
pageno=1;
```

```
run;
```

```
*** Part 2 ***;
```

```
data adsl1;
```

```
set adsl(where=(randdt>.));
```

```
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;
```

```
if randdt>. then do; trt=4; 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;
```

```
data data2;

    set adsl1;

    if index(disccat,'Period 1')=0 then do; order1=1; order2=1; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 then do; order1=1; order2=2; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 and index(disccat,'Period 3')=0 then do;
order1=1; order2=3; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 and index(disccat,'Period 3')=0
        and index(disccat,'Period 4')=0 then do; order1=1; order2=4; output; end;

    if fupfl='Y' then do; order1=1; order2=5; output; end;

    if complfl^='Y' then do;

        if 1 then do; order1=1; order2=6; output; end;

        if index(disccat,'before') then do; order1=2; order2=7; output; end;

        else if index(disccat,'Period 1') then do; order1=2; order2=8; output; end;
```



```

else if index(disccat,'Period 2') then do; order1=2; order2=9; output; end;

else if index(disccat,'Period 3') then do; order1=2; order2=10; output; end;

else if index(disccat,'Period 4') then do; order1=2; order2=11; output; end;

else
            do; order1=2; order2=12; output; end;

end;

run;

data shell;

length stat $200;

order1=1; order2=1; stat='Completed Period 1'; output;

order1=1; order2=2; stat='Completed Period 2'; output;

order1=1; order2=3; stat='Completed Period 3'; output;

order1=1; order2=4; stat='Completed Period 4'; output;

order1=1; order2=5; stat='Completed safety follow-up'; output;

order1=1; order2=6; stat='Discontinued'; output;

/* order1=2; order2=7; stat=' Discontinued, without randomized product use'; output; */

order1=2; order2=8; stat=' Discontinued Period 1'; output;

order1=2; order2=9; stat=' Discontinued Period 2'; output;

order1=2; order2=10; stat=' Discontinued Period 3'; output;

order1=2; order2=11; stat=' Discontinued Period 4'; output;

/* order1=2; order2=12; stat=' Discontinued safety follow-up'; output; */

run;

%mfreq(in_dsn=data2, n_max=4, order1=order1, order2=order2, class=order1 order2);

```

*** Prepare the output data set per mock-up/shell ***;

data final2;

length stat \$200;

merge shell final_1;

by order1 order2;

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

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

if order1=2 and order2=2 then col3='NA';

pageno=2;

run;

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

proc report data=final1 headskip headline spacing=4 nowd split='|' style=[outputwidth=100%]
style(header column)=[protectspecialchars=off];

column pageno order1 order2 stat col1;

define pageno /order order=internal noprint;

define order1 /order order=internal noprint;

define order2 /order order=internal noprint;

define stat /display "Status" style(column)=[cellwidth=35% asis=on] style(header)=[just=l];

define col1 /display "Overall Screened |(N=&t1)|n(%)" 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 "^R/RTF\brdrb\brdrs\brdrw30\brsp20\b' ";

endcomp;

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

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

    line @1 "Note: Discontinued refers to randomized subjects who discontinued from the study before the planned discharge at Day 91. ; Completed Period X Visit";

    line @1 "refers to randomized subjects who did not discontinue the study before the completion of study assessments at Period X Visit.";

    line @1 "Note: Percentages for disposition prior to randomization are based on the number of subjects screened. Percentages for 'Completed safety follow-up'";

    line @1 "under 'Screening failures, with product test' are based on the number of subjects who screen failed with the product test. Percentages for disposition";

    line @1 "after randomization are based on the number of subjects randomized indicated in the column header (N), apart from the Overall column where only percentages of completed and discontinued refer to the total number of subjects randomized.";

    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: 1 of 3";

endcomp;

compute after pageno ;

```

```

line "";

endcomp;

run;

proc report data=final2 headskip headline spacing=4 nowd split='|' style=[outputwidth=100%]
style(header column)=[protectspecialchars=off];

column pageno order1 order2 stat col1-col4;

define pageno /order order=internal noprint;

define order1 /order order=internal noprint;

define order2 /order order=internal noprint;

define stat /display "Status" style(column)=[cellwidth=35% asis=on] style(header)=[just=l];

define col1 /display "THSm2.2|(N=&n1)|n(%)" flow style(column)=[cellwidth=10% just=c];

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

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

define col4 /display "Overall|Randomized|(N=&n4)|n(%)" 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 "^R/RTF\brdrb\brdrs\brdrw30\brsp20\b' ";

endcomp;

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

```

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

line @1 "Note: Discontinued refers to randomized subjects who discontinued from the study before the planned discharge at Day 91. ; Completed Period X Visit";

line @1 "refers to randomized subjects who did not discontinue the study before the completion of study assessments at Period X Visit.";

line @1 "Note: Percentages for disposition prior to randomization are based on the number of subjects screened. Percentages for 'Completed safety follow-up'";

line @1 "under 'Screening failures, with product test' are based on the number of subjects who screen failed with the product test. Percentages for disposition";

line @1 "after randomization are based on the number of subjects randomized indicated in the column header (N), apart from the Overall column where only percentages of completed and discontinued refer to the total number of subjects randomized.";

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: 2 of 3";

endcomp;

compute after pageno ;

line "";

endcomp;

run;

*** Part 3 ***;

data adsl1;

```

set adsl(where=(randdt>. and siteid='TOK'));

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;

if   randdt>. then do; trt=4; 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;

```

```

data data3;

    set adsl1(where=(siteid='TOK'));

    if index(disccat,'Period 1')=0 then do; order1=1; order2=1; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 then do; order1=1; order2=2; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 and index(disccat,'Period 3')=0 then do;
order1=1; order2=3; output; end;

    if index(disccat,'Period 1')=0 and index(disccat,'Period 2')=0 and index(disccat,'Period 3')=0
        and index(disccat,'Period 4')=0 then do; order1=1; order2=4; output; end;

```

```

if fupfl='Y' then do; order1=1; order2=5; output; end;

if complfl^='Y' then do;
    if 1 then do; order1=1; order2=6; output; end;
    if index(disccat,'before') then do; order1=2; order2=7; output; end;
    else if index(disccat,'Period 1') then do; order1=2; order2=8; output; end;
    else if index(disccat,'Period 2') then do; order1=2; order2=9; output; end;
    else if index(disccat,'Period 3') then do; order1=2; order2=10; output; end;
    else if index(disccat,'Period 4') then do; order1=2; order2=11; output; end;
    else do; order1=2; order2=12; output; end;
end;

run;

data shell;

    length stat $200;

    order1=1; order2=0; stat='^S={font_weight=bold just=l}||'Subjects Randomized in Tokyo Heart
Center'; output;

    order1=1; order2=1; stat='Completed Period 1'; output;
    order1=1; order2=2; stat='Completed Period 2'; output;
    order1=1; order2=3; stat='Completed Period 3'; output;
    order1=1; order2=4; stat='Completed Period 4'; output;
    order1=1; order2=5; stat='Completed safety follow-up'; output;
    order1=1; order2=6; stat='Discontinued'; output;

/* order1=2; order2=7; stat=' Discontinued, without randomized product use'; output; */

    order1=2; order2=8; stat=' Discontinued Period 1'; output;
    order1=2; order2=9; stat=' Discontinued Period 2'; output;

```

```

order1=2; order2=10; stat=' Discontinued Period 3'; output;

order1=2; order2=11; stat=' Discontinued Period 4'; output;

/* order1=2; order2=12; stat=' Discontinued safety follow-up'; output; */

run;

%mfreq(in_dsn=data3, n_max=4, order1=order1, order2=order2, class=order1 order2);

*** Prepare the output data set per mock-up/shell ***;

data final3;

length stat $200;

merge shell final_1;

by order1 order2;

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';

end;

if order1=2 and order2=2 then col3='NA';

pageno=2;

run;

proc report data=final3 headskip headline spacing=4 nowd split='|' style=[outputwidth=100%]
style(header column)=[protectspecialchars=off];

column pageno order1 order2 stat col1-col4;

define pageno /order order=internal noprint;

define order1 /order order=internal noprint;

```



```

define order2 /order order=internal noprint;

define stat /display "Status" style(column)=[cellwidth=35% asis=on] style(header)=[just=l];

define col1 /display "THSm2.2|(N=&n1)|n(%)" flow style(column)=[cellwidth=10% just=c];

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

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

define col4 /display "Randomized|in Tokyo |Heart Center|(N=&n4)|n(%)" 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 "^R/RTF\brdrb\brdrs\brdrw30\brsp20\b ' ";

endcomp;

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

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

line @1 "Note: Discontinued refers to randomized subjects who discontinued from the study before
the planned discharge at Day 91. ; Completed Period X Visit";

line @1 "refers to randomized subjects who did not discontinue the study before the completion of
study assessments at Period X Visit.";

line @1 "Note: Percentages for disposition prior to randomization are based on the number of
subjects screened. Percentages for 'Completed safety follow-up'";

line @1 "under 'Screening failures, with product test' are based on the number of subjects who
screen failed with the product test. Percentages for disposition";

line @1 "after randomization are based on the number of subjects randomized indicated in the
column header (N), apart from the Overall column where only percentages of completed and
discontinued refer to the total number of subjects randomized.";

```

```
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: 3 of 3";
```

```
endcomp;
```

```
compute after pageno ;
```

```
line "";
```

```
endcomp;
```

```
run;
```

```
ods listing;
```

```
ods rtf close;
```

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

```
set final1(in=a) final2(in=b) final3(in=c);
```

```
if a then group="Part1";
```

```
if b then group="Part2";
```

```
if c then group="Part3";
```

```
run;
```