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* Project : ZRHM-REXA-07-JP

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* Program name : t1502010302_ZRHM-REXA-07_V1.sas

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* Date created : 05/20/2015

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* Purpose : Create Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses

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* Revision History :

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* Date Author Ref Revision (Date in YYYYMMDD format)

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*****,

%let prgname=T1502010302_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;


    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;

    else if trt01an=99 then do; trt=5; output; end;

    trt=6; output;

run;


proc freq data =adsl(where=(randfl='Y')) 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;


%let n4=1; %let n5=1;

%put &n1 &n2 &n3 &n4 &n5 &n6;

```

*** Prepare data for analysis ***;

data data1;

set adsl;

if icfdt>. then do; order1=1; order2=1; output; end;

if fsafbfl='Y' then do; order1=2; order2=1; output; end;

if fsafbfl^='Y' then do; order1=2; order2=2; output; end;

if fsafbfl^='Y' and icfdt=. then do; order1=2; order2=3; output; end;

if fsafbfl^='Y' and fsafbrea='Not exposed to THS 2.2' then do; order1=2; order2=4; output; end;

if safbfl='Y' then do; order1=3; order2=1; output; end;

if safbfl^='Y' then do; order1=3; order2=2; output; end;

if safbfl^='Y' and safbrea='Site terminated' then do; order1=3; order2=3; output; end;

if fsafbfl^='Y' and fsafbrea='Not exposed to THS 2.2' then do; order1=3; order2=4; output; end;

if randdt>. then do;

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

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

if fsafafi^='Y' then do; order1=4; order2=3; output; end;

if fsafafi^='Y' and index(fsafarea,'valid safety assessment') then do; order1=4; order2=4; output;
end;

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

if safafi^='Y' then do; order1=5; order2=2; output; end;

```

if safaf1^='Y' and safarea='Site terminated' then do; order1=5; order2=3; output; end;

if fasfl='Y' then do; order1=6; order2=1; output; end;

if fasfl^='Y' then do; order1=6; order2=2; output; end;

if fasreas='ICH/GCP non-compliance' then do; order1=6; order2=3; output; end;

if fasreas='ICH/GCP non-compliance/Was not randomized' then do; order1=6; order2=4; output;
end;

if fasreas='Was not randomized' then do; order1=6; order2=5; output; end;

if pprot1fl='Y' then do; order1=7; order2=1; output; end;

if pprot2fl='Y' then do; order1=7; order2=2; output; end;

if pprot3fl='Y' then do; order1=7; order2=3; output; end;

if pprot4fl='Y' then do; order1=7; order2=4; output; end;

if pprot1fl^='Y' then do; order1=8; order2=1; output; end;

if pprot1fl^='Y' and ppreas1='Not in FAS' then do; order1=8; order2=2; output; end;

else if pprot1fl^='Y' and ppreas1='Has major' then do; order1=8; order2=3; output; end;

else if pprot1fl^='Y' and ppreas2='Has other' then do; order1=8; order2=4; output; end;

if pprot2fl^='Y' then do; order1=9; order2=1; output; end;

if pprot2fl^='Y' and ppreas2='Discontin' then do; order1=9; order2=2; output; end;

if pprot2fl^='Y' and ppreas2='Not in FAS' then do; order1=9; order2=3; output; end;

else if pprot2fl^='Y' and ppreas2='Has major' then do; order1=9; order2=4; output; end;

else if pprot2fl^='Y' and ppreas2='Has other' then do; order1=9; order2=5; output; end;

if pprot3fl^='Y' then do; order1=10; order2=1; output; end;

```

```
if pprot3fl^='Y' and ppreas3='Discontin' then do; order1=10; order2=2; output; end;
if pprot3fl^='Y' and ppreas3='Not in FAS' then do; order1=10; order2=3; output; end;
else if pprot3fl^='Y' and ppreas3='Has major' then do; order1=10; order2=4; output; end;
else if pprot3fl^='Y' and ppreas3='Has other' then do; order1=10; order2=5; output; end;
```

```
if pprot4fl^='Y' then do; order1=11; order2=1; output; end;
if pprot4fl^='Y' and ppreas4='Discontin' then do; order1=11; order2=2; output; end;
if pprot4fl^='Y' and ppreas4='Not in FAS' then do; order1=11; order2=3; output; end;
else if pprot4fl^='Y' and ppreas4='Has major' then do; order1=11; order2=4; output; end;
else if pprot4fl^='Y' and ppreas4='Has other' then do; order1=11; order2=5; output; end;
```

```
if comp1fl='Y' then do; order1=12; order2=1; output; end;
if comp2fl='Y' then do; order1=12; order2=2; output; end;
if comp3fl='Y' then do; order1=12; order2=3; output; end;
if comp4fl='Y' then do; order1=12; order2=4; output; end;
```

```
end;
```

```
run;
```

```
data shell;
```

```
length stat $200;
```

```
order1=1; order2=1; stat='Subjects screened'; output;
```

```
order1=2; order2=1; stat='Subjects included in Full Safety Population'; output;
```

```
order1=2; order2=2; stat='Subjects excluded from Full Safety Population'; output;
```

```
order1=2; order2=3; stat="^R/RTF'\li300' " || 'Did not give informed consent'; output;
```

order1=2; order2=4; stat="^R/RTF'\li300' " || 'Not exposed to THS m2.2'; output;

order1=3; order2=1; stat='Subjects included in Safety Population'; output;

order1=3; order2=2; stat='Subjects excluded from Safety Population'; output;

order1=3; order2=3; stat="^R/RTF'\li300' " || 'Exposed at site terminated due to ICH/GCP non-compliance'; output;

order1=3; order2=4; stat="^R/RTF'\li300' " || 'Not exposed to THS m2.2'; output;

order1=4; order2=1; stat='Total Subjects Randomized¹'; output;

order1=4; order2=2; stat='Randomized Subjects included in Full Safety Population'; output;

order1=4; order2=3; stat='Subjects excluded from Full Safety Population'; output;

order1=4; order2=4; stat="^R/RTF'\li300' " || 'Subjects did not have valid safety assessment post-randomization'; output;

order1=5; order2=1; stat='Randomized Subjects included in Safety Population'; output;

order1=5; order2=2; stat='Subjects excluded from Safety Population'; output;

order1=5; order2=3; stat="^R/RTF'\li300' " || 'Exposed at site terminated due to ICH/GCP non-compliance'; output;

order1=6; order2=1; stat='Subjects included in FAS'; output;

order1=6; order2=2; stat='Subjects excluded from FAS'; output;

order1=6; order2=3; stat="^R/RTF'\li300' " || 'ICH/GCP non-compliance'; output;

order1=6; order2=4; stat="^R/RTF'\li300' " || 'ICH/GCP non-compliance/Was not randomized'; output;

order1=6; order2=5; stat="^R/RTF'\li300' " || 'Was not randomized'; output;

order1=7; order2=0; stat='Subjects included in PP Set'; output;

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

order1=7; order2=2; stat="^R/RTF'\li300' " || 'Period 2'; output;

order1=7; order2=3; stat="^R/RTF'\li300' " || 'Period 3'; output;

order1=7; order2=4; stat="^R/RTF'\li300' " || 'Period 4'; output;

order1=8; order2=1; stat='Subjects excluded from PP Set for Period 1'; output;

order1=8; order2=2; stat="^R/RTF'\li300' " || 'Not in FAS'; output;

order1=8; order2=3; stat="^R/RTF'\li300' " || 'Has major protocol deviations not compliant'; output;

order1=8; order2=4; stat="^R/RTF'\li300' " || 'Has other major protocol deviations impacting evaluability'; output;

order1=9; order2=1; stat='Subjects excluded from PP Set for Period 2'; output;

order1=9; order2=2; stat="^R/RTF'\li300' " || 'Discontinued in previous period'; output;

order1=9; order2=3; stat="^R/RTF'\li300' " || 'Not in FAS'; output;

order1=9; order2=4; stat="^R/RTF'\li300' " || 'Has major protocol deviations not compliant'; output;

order1=9; order2=5; stat="^R/RTF'\li300' " || 'Has other major protocol deviations impacting evaluability'; output;

order1=10; order2=1; stat='Subjects excluded from PP Set for Period 3'; output;

order1=10; order2=2; stat="^R/RTF'\li300' " || 'Discontinued in previous period'; output;

order1=10; order2=3; stat="^R/RTF'\li300' " || 'Not in FAS'; output;

order1=10; order2=4; stat="^R/RTF'\li300' " || 'Has major protocol deviations not compliant'; output;

order1=10; order2=5; stat="^R/RTF'\li300' " || 'Has other major protocol deviations impacting evaluability'; output;

order1=11; order2=1; stat='Subjects excluded from PP Set for Period 4'; output;

order1=11; order2=2; stat="^R/RTF'\li300' " || 'Discontinued in previous period'; output;

order1=11; order2=3; stat="^R/RTF'\li300' " || 'Not in FAS'; output;

```
order1=11; order2=4; stat="^R/RTF'\li300' " || 'Has major protocol deviations not compliant'; output;  
order1=11; order2=5; stat="^R/RTF'\li300' " || 'Has other major protocol deviations impacting  
evaluability'; output;
```

```
order1=12; order2=0; stat='Subjects included in Compliant Population'; output;  
order1=12; order2=1; stat="^R/RTF'\li300' " || 'Period 1'; output;  
order1=12; order2=2; stat="^R/RTF'\li300' " || 'Period 2'; output;  
order1=12; order2=3; stat="^R/RTF'\li300' " || 'Period 3'; output;  
order1=12; order2=4; stat="^R/RTF'\li300' " || 'Period 4'; output;  
run;
```

```
%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_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=6, order1=order1, order2=order2, class=order1 order2);
```

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

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

```
data final;
```

```
length stat $200;
```

```
merge shell final_1;
```

```
by order1 order2;
```

```
if (order1=2 and order2=3 or order1=6 and order2>1 or order1>8 and order2>1)
```

```
and cmiss(col1,col2,col3,col4,col5,col6)=6 then delete;
```

```
if order1<4 or order1=4 and order2=1 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,'(');
```

```
end;
```

```
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';
```

```
end;
```

```
if order1=4 and order2=1 then do; col4='NA'; col5='NA'; end;
```

```
if order1>4 or order1=4 and order2>1 then do; col4=""; col5=""; end;
```

```
%macro mtemp;
```

```

if order1<=6 and order2=1 or order1=4 and order2=2 or order1 in (7 12) and order2=0 then do;

    stat='^S={font_weight=bold}' || strip(stat);

/*    if order1=4 and order2=1 then do;*/

        %do i=1 %to 6; col&i.='^S={font_weight=bold just=c}' || strip(col&i.); %end;

/*    end;*/

end;

%mend;

%mtmp;

/*    if order1=1 and order2=1 then call missing (col1,col2,col3,col4,col5,col6);*/

pageno=1;

if order1>4 then pageno=2;

if order1>7 then pageno=3;

if order1>9 then pageno=4;

run;

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

    set final;

run;

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

%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;

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 col1-col6;


    define pageno /order order=internal noprint;

    define order1 /order order=internal noprint;

    define order2 /order order=internal noprint;

    define stat /display "Population Sets" style(column)=[cellwidth=30% asis=on] style(header)=[just=l];

    define col1 /display "THSm2.2|n(%)" flow style(column)=[cellwidth=8% just=c];

    define col2 /display "mCC|n(%)" flow style(column)=[cellwidth=8% just=c];

    define col3 /display "SA|n(%)" flow style(column)=[cellwidth=8% just=c];

    define col4 /display "Product|Test|n(%)" flow style(column)=[cellwidth=8% just=c];

```

```

define col5 /display "Screen|Failure|n(%)" flow style(column)=[cellwidth=8% just=c];

define col6 /display "Overall| |n(%)" flow style(column)=[cellwidth=8% 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: NA = Not applicable; Note: mCC = Menthol conventional cigarettes; SA = Smoking
abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.";

    line @1 "Note: Percentages appearing after randomization are based on the number of randomized
subjects in each column.";

    line @1 '[1]: "Total Subjects Randomized" refers to randomized subjects and not excluded because
of due to ICH/GCP non-compliance.';

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

endcomp;

```

```
compute after pageno ;  
    line "";  
endcomp;  
run;  
%end;  
%mend;  
%reppart;
```

```
ods listing;  
ods rtf close;
```