

```

/*****
* Project       : ZRHM-REXA-07-JP
* Program name  : T1502062501_ZRHM_REXA_07_JP_V1.sas
* Author       : C. Liu
* Date created  : 06/13/2015
* Purpose      : Summary of Cough Assessments by Study Day 77 Safety Population
* Revision History
* Date         Author      Ref      Revision
* 07/02/2015   C. Liu      Per Client's comments
* 07/17/2015   C. Liu      Per Client's comments
*****/

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```
%let prgname=T1502062501_ZRHM_REXA_07_JP_V1;
```

```
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.;
```

```
options missing="";
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title;
footnote;
```

```
proc format;
  value paramf
    1 = 'Has subject experienced cough in the study period assessed'
    2 = 'VAS'
    3 = 'Intensity of cough'
    4 = 'Frequency of cough'
    5 = 'Amount of sputum produced'
  ;
  value $summf
    'N_' = 'n'
    'MEANS_' = 'Mean (SD)'
    'MEDIAN_' = 'Median'
    'MINMAX' = 'Min, Max'
  ;
  invalue summo
    'N_' = 1
    'MEANS_' = 2
    'MEDIAN_' = 3
    'MINMAX' = 4
  ;
run;
```

```
data adsl;
  set adam.adsl;
  if trt01an=3 then trt01an=6;
  if safbfl='Y' then do;
    period=1;
    output;
    trt01an=99;
    output;
  end;
  rename trt01an=trtan;
run;
```

```
data adsl;
  set adsl;
  output;
  if safaf1='Y' then do;
    period=2;
    output;
  end;
run;
```

```
proc sql noprint;
  select n(usubjid) into :n1-:n5
  from adsl
  where period=1
  group by trtan;
quit;
```

```
proc sql noprint;
  select n(usubjid) into :n6-:n9
  from adsl
  where period=2
  group by trtan;
quit;
```

```

proc freq data=adsl noprint;
  table period*trtan/out=freqn;
run;

data adqs;
  length avalc1 $200;
  set adam.adqssym(where=(safbfl='Y' and paramn not in (99)));
  avalc1=avalc;
  if trtan=3 then trtan=6;
  if avisitn in (100 101) then do;
    period=1;
  if avisitn=100 then avisit='Day -1';
  else avisit='Day 0';
  end;
  else if avisitn>101 then do;
    period=2;
  if avisitn=102 then avisit='Day 1';
  else if avisitn=103 then avisit='Day 2';
  else if avisitn=104 then avisit='Day 3';
  else if avisitn=105 then avisit='Day 4';
  else if avisitn=106 then avisit='Day 5';
  end;
  if paramn=1 then do;
    if avalc='N' then aval=1;
  else if avalc='Y' then aval=2;
  end;
  avisit=scan(avisit,1,'/');
  output;
  trtan=99;
  output;

  drop avalc;
  rename avalc1=avalc;
run;

/* Subject level: Pick the worst case per visit/subject/param */
proc sort data=adqs;
  by usubjid trtan period paramn param avisitn avisit aval;
run;

data adqs1;
  set adqs;
  by usubjid trtan period paramn param avisitn avisit aval;
  if last.avisit;
run;

/***** Subject Level *****/
data adsl_1;
  set adsl(where=(period=1));
  length avisit $40;
  avisitn=100; avisit='Day -1'; output;
  avisitn=101; avisit='Day 0'; output;
run;

data adsl_2;
  set adsl(where=(period=2));
  length avisit $40;

  avisitn=102; avisit='Day 1'; output;
  avisitn=103; avisit='Day 2'; output;
  avisitn=104; avisit='Day 3'; output;
  avisitn=105; avisit='Day 4'; output;
  avisitn=106; avisit='Day 5'; output;
  avisitn=130; avisit='Day 30'; output;
  avisitn=160; avisit='Day 60'; output;
  avisitn=190; avisit='Day 90'; output;
run;

data adsl1;
  set adsl_1 adsl_2;

  keep usubjid trtan period avisitn avisit;
run;

proc sort;
  by usubjid trtan period avisitn avisit;
run;

data adqs1_;
  merge adqs1(where=(paramn=1) in=a) adsl1(in=b);
  by usubjid trtan period avisitn avisit;
  if b and not a then do;
    paramn=1; param='Regular need to cough'; aval=3; avalc='Missing';
  end;
run;

proc freq data=adqs1_ noprint;

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```

    table paramn*param*period*avisitn*avisit*trtan*aval*avalc/out=freq1;
run;

proc sql;
    create table freq2 as
    select a.*, strip(put(a.count,8.0))||' ('||strip(put(100*a.count/b.count,4.1))||')' as result length=20
    from freq1 a, freqn b
    where a.period=b.period and a.trtan=b.trtan
    order by period, paramn, param, avisitn, avisit, aval, avalc;
quit;

proc transpose data=freq2 out=freq3 prefix=subj;
    by period paramn param avisitn avisit aval avalc;
    id trtan;
    var result;
run;

proc freq data=adqs1(where=(paramn=1 and avalc='Y')) noprint;
    table period*avisitn*avisit*trtan/out=freq0;
run;

proc freq data=adqs1(where=(paramn>2)) noprint;
    table period*paramn*param*avisitn*avisit*trtan*aval*avalc/out=freq4;
run;

proc sql;
    create table freq5 as
    select a.*, strip(put(a.count,8.0))||' ('||strip(put(100*a.count/b.count,4.1))||')' as result length=20
    from freq4 a, freq0 b
    where a.period=b.period and a.trtan=b.trtan and a.avisitn=b.avisitn
    order by a.period, a.paramn, a.param, a.avisitn, a.avisit, aval, avalc;
quit;

proc transpose data=freq5 out=freq6 prefix=subj;
    by period paramn param avisitn avisit aval avalc;
    id trtan;
    var result;
run;

data allsubj;
    set freq3 freq6;
    by period paramn param avisitn avisit;
run;

proc sort;
    by period paramn param avisitn avisit aval avalc;
run;

proc transpose data=freq0 out=t_freq0;
    by period avisitn avisit;
    id trtan;
    var count;
run;

data t_freq0;
    set t_freq0;

    length avalc $50;
    if period=1 then do;
        paramn=3; aval=-1; avalc="n"; output;
        paramn=4; aval=-1; avalc="n"; output;
        paramn=5; aval=-1; avalc="n"; output;
    end;
    else if period=2 then do;
        paramn=3; aval=-1; _96=.; avalc="n"; output;
        paramn=4; aval=-1; avalc="n"; output;
        paramn=5; aval=-1; avalc="n"; output;
    end;
run;

data allsubj;
    set allsubj t_freq0(in=b);

    if b then do;
        subj4=put(_4,8.0);
        subj5=put(_5,8.0);
        subj6=put(_6,8.0);
        subj96=put(_96,8.0);
        subj99=put(_99,8.0);
    end;

    if avalc='Y' then do;
        aval=1; avalc='Yes';
    end;
    else if avalc='N' then do;
        aval=2; avalc='No';
    end;
end;

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run;

proc sort;
  by period paramn param avisitn avisit aval avalc;
run;

proc summary data=adqs1(where=(paramn=2)) nway;
  class period paramn avisitn avisit trtan;
  var aval;
  output out=summ n=n mean=Mean std=std median=Median min=Min max=Max;
run;

data summ1;
  set summ;
  length n_ meansd median_ minmax $20;

  n_=left(put(n,8.0));
  meansd=strip(put(mean,6.1))||' ('||strip(put(ceil(std*100)/100,8.2))||')';
  median_=left(put(median,6.1));
  minmax=strip(put(min,6.0))||', '||left(put(max,6.0));
run;

proc transpose data=summ1 out=t_summ prefix=subj;
  by period paramn avisitn avisit;
  id trtan;
  var n_ meansd median_ minmax;
run;

proc sort data=t_summ;
  by period paramn avisitn avisit _name_;
run;

data all;
  set allsubj t_summ(in=b);

  if b then do;
    aval=input(upcase(_name_),summo.);
    avalc=put(upcase(_name_),$summf.);
  end;

run;

proc sort;
  by period paramn avisitn avisit aval avalc;
run;

/***** Event Level (Should be the same as Subject Level) *****/

%macro shell;
  paramn=1; aval=1; avalc='Yes'; output;
  aval=2; avalc='No'; output;
  paramn=3; aval=1; avalc='Very mild'; output;
  aval=2; avalc='Mild'; output;
  aval=3; avalc='Moderate'; output;
  aval=4; avalc='Severe'; output;
  aval=5; avalc='Very severe'; output;
  paramn=4; aval=1; avalc='Rarely'; output;
  aval=2; avalc='Sometimes'; output;
  aval=3; avalc='Fairly often'; output;
  aval=4; avalc='Often'; output;
  aval=5; avalc='Almost always'; output;
  paramn=5; aval=0; avalc='No sputum'; output;
  aval=1; avalc='A moderate amount of sputum'; output;
  aval=2; avalc='A larger amount of sputum'; output;
  aval=3; avalc='A very large amount of sputum'; output;
%mend shell;

data shell;
  length avalc $200 avisit $40;
  period=1; avisitn=100; avisit='Day -1'; %shell
  avisitn=101; avisit='Day 0'; %shell
  period=2; avisitn=102; avisit='Day 1'; %shell
  avisitn=103; avisit='Day 2'; %shell
  avisitn=104; avisit='Day 3'; %shell
  avisitn=105; avisit='Day 4'; %shell
  avisitn=106; avisit='Day 5'; %shell
  avisitn=130; avisit='Day 30'; %shell
  avisitn=160; avisit='Day 60'; %shell
  avisitn=190; avisit='Day 90'; %shell
run;

proc sort data=shell;
  by period paramn avisitn avisit aval avalc;
run;

data final;
  merge shell all;

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by period paramn avisitn avisit aval avalc;

array colsubj subj4 subj5 subj6 subj96 subj99;

do i=1 to dim(colsubj);
  if colsubj(i)='' then colsubj(i)='0';
  if colsubj(i)='' then colsubj(i)='0';
end;

drop i;
run;

data final1;
set final;
by period paramn avisitn avisit aval avalc;

array colsubj subj4 subj5 subj6 subj96 subj99;
length stat $40;

if paramn ne 2 then do;
  stat='n (%)';
  avalc='^R/RTF' ' '||left(avalc);
end;
else do;
  stat=avalc;
if aval=1 then avalc=avisit;
else avalc='';
end;
output;

if last.avisit and paramn ne 2 then do;
  stat='';
  do i=1 to dim(colsubj);
    colsubj(i)='';
  end;
  aval=-2; avalc=avisit;
  output;
end;

drop i param _;;
run;

proc sort data=final1;
  by period paramn avisitn aval;
run;

data final2;
set final1;
by period paramn avisitn aval;
retain _page 1;
if period=2 and first.period then do;
  _c=0; _page+1;
end;
if first.avisitn then _c+1;
if _c=3 then do;
  _page+1;
  _c=1;
end;
drop _c;
run;

proc sort data=final2;
  by _page paramn avisitn;
run;

%global totalpage;

data _null_;
set final2 end=eof;

if eof then do;
  call symput('totalpage', trim(left(put(_page,8)))));
end;
run;

%put totalpage=&totalpage;

data final3;
set final2;
by _page paramn avisitn;

array colsubj subj4 subj5 subj6 subj96 subj99;

output;
if first._page or (first.paramn and paramn ne 2) then do;
  aval=-3; avalc='^S={font_weight=bold}'||left(put(paramn,paramf.)); stat='';
  do i=1 to dim(colsubj);

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        colsubjid='';
    end;
    output;
    end;

    drop i;
run;

/*for QC purpose*/
data odata.t1502062501;
    set final3;
run;

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

%macro reppart;

    %do i = 1 %to 5;

proc report data=final3 headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
    style(header column)=[protectspecialchars=off];
    columns _page paramn avisitn aval ('^S={just=c}Variable/+Study Day' avalc) ('^S={just=l}Statistic' stat)
        ("^S={just=c}THSm2.2+(N=%cmpres(&n1))" subj4)
        ("^S={just=c}mCC+(N=%cmpres(&n2))" subj5)
        ("^S={just=c}SA+(N=%cmpres(&n3))" subj6)
        ("^S={just=c}Product Test+(N=%cmpres(&n4))" subj96)
        ("^S={just=c}Overall Safety+(N=%cmpres(&n5))" subj99)
;
    where period=1 and _page =&i.;

    define _page/group order=internal noprint;
    define paramN/group order=internal noprint;
    define avisitn/group order=internal noprint;
    define AVal/group order=internal noprint;
    define avalc/display ' ' style(column)=[cellwidth=15% just=l];
    define stat/display ' ' style(column)=[cellwidth=7% just=l];
    define subj4/display ' ' style(column)=[just=c cellwidth=7%];
    define subj5/display ' ' style(column)=[just=c cellwidth=7%];
    define subj6/display ' ' style(column)=[just=c cellwidth=7%];
    define subj96/display ' ' style(column)=[just=c cellwidth=7%];
    define subj99/display ' ' style(column)=[just=c cellwidth=7%];

    compute after avisitN;
        line ' ';
    endcomp;
    break after _page/page;

compute before _page_ /style=[fontweight=bold fontsize=3.75];
line @1 "&title1 &title2";
line @1 " ^R/RTF'\brdrb\brdrs\brdrw30\brsp20\b ' ";
line @1 "Safety Time Period: Pre-Randomization";
endcomp;

compute before _page;
line @1 "";
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. The Overall Saf
ety refers to all subjects exposed to THSm2.2.";
line @1 "Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Ment
hol.";
line @1 "Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in th
e column header (N). Percentages for";
line @1 "intensity of cough are based on the number of subjects who have experienced a cough.";
line @1 "Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If su
bject has answered question more than once";
line @1 "then the most severe intensity is presented.";
line @1 "Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day -1 to D
ay 5, Day 30, 60, and 90, respectively.";
line @1 " ";
line @1 "&APPENDIX.";
line @1 "Study ID:ZRHM-REXA-07-JP Program: &fprgname..sas Status: &repversion./&fdate.
Page: &i. of &totalpage";
endcomp;
run;
%end;

    %do i = 6 %to &totalpage;

proc report data=final3 headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
    style(header column)=[protectspecialchars=off];
    columns _page paramn avisitn aval ('^S={just=l}Variable/+Study Day' avalc) ('^S={just=l}Statistic' stat)
        ("^S={just=c}THSm2.2+(N=%cmpres(&n6))" subj4)
        ("^S={just=c}mCC+(N=%cmpres(&n7))" subj5)
        ("^S={just=c}SA+(N=%cmpres(&n9))" subj6)
        ("^S={just=c}Overall Safety+(N=%cmpres(&n9))" subj99)

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;
  where period=2 and _page =&i.;

  define _page/group order=internal noprint;
  define paramN/group order=internal noprint;
  define avisitN/group order=internal noprint;
  define AVal/group order=internal noprint;
  define avalc/display ' ' style(column)=[cellwidth=15% just=1];
  define stat/display ' ' style(column)=[cellwidth=7% just=1];
  define subj4/display ' ' style(column)=[just=c cellwidth=7%];
  define subj5/display ' ' style(column)=[just=c cellwidth=7%];
  define subj6/display ' ' style(column)=[just=c cellwidth=7%];
  define subj99/display ' ' style(column)=[just=c cellwidth=7%];

  compute after avisitN;
    line ' ';
  endcomp;
  break after _page/page;

compute before _page;
line @1 "";
endcomp;

compute before _page_ /style=[fontweight=bold fontsize=3.75];
line @1 "&title1 &title2";
line @1 " ^R/RTF'\brdrb\brdrs\brdrw30\brsp20\b ' ";
line @1 "Safety Time Period: Randomized Period";
endcomp;

compute after _page_/style=[fontsize=1.75];
line @1 "Note: The Overall Safety refers to all subjects exposed to THSm2.2.";
line @1 "Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.";
line @1 "Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for";
line @1 "intensity of cough are based on the number of subjects who have experienced a cough.";
line @1 "Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once";
line @1 "then the most severe intensity is presented.";
line @1 "Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day -1 to Day 5, Day 30, 60, and 90, respectively.";
line @1 " ";
line @1 "&APPENDIX.";
line @1 "Study ID:ZRHM-REXA-07-JP          Program: &fprgname..sas          Status: &repversion./&fdate.
      Page: &i. of &totalpage";
endcomp;
run;
%end;
%mend;
%reppart;

ods listing;
ods rtf close;

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