

```

/*****
* Project       : ZRHM-REXA-07-JP
* Program name  : T15020622_ZRHM_REXA_07_JP_V1.sas
* Author       : C. Liu
* Date created  : 06/10/2015
* Purpose      : Summary of Spirometry Results 卐 Safety Population
* Revision History
* Date         Author      Ref      Revision
* 07/02/2015   C. Liu      Per Client's comments
*****/

%let prgname=T15020622_ZRHM_REXA_07_JP_V1;
options nomprint nosymbolgen;

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.;

options missing="";

title;
footnote;

/*population - post-randomization safety*/
data _adsl;
  set adam.adsl;
  where SAFBFL='Y';
  if TRT01AN=3 then TRT01AN=6;
run;

proc sort data=_adsl out=_p;
  by TRT01AN;
quit;

data _trxf(keep=fmtname start label);
  set _p end=lr;
  by TRT01AN;
  if first.TR01AN then _c=.;
  _c+1;
  _t1+1;
  if trt01an ne 96 then _t+1;
  fmtname='_trxf';
  if last.TR01AN then do;
    call symput('_'||left(put(TRT01AN,8.)),trim(left(put(_c,8.))));
    start=TRT01AN;
    label='\brdrb\brdrs '||trim(left(TRT01A))||'+(N='||trim(left(put(_c,8.))||')';
    output;
  end;
  if lr then do;
    call symput('_100',trim(left(put(_t,8.))));
    start=100;
    label='\brdrb\brdrs Overall Safety+(N='||trim(left(put(_t,8.))||')';
    output;
    call symput('_101',trim(left(put(_t1,8.))));
    start=101;
    label='\brdrb\brdrs Overall Safety+(N='||trim(left(put(_t1,8.))||')';
    output;
  end;
run;

proc format cntlin=_trxf;
quit;

/*XP*/
data _xp0;
  set adam.adxp;
  *where paramcd in ('WINTP' 'INTP' 'WFEVMEAS' 'FEVMEAS' 'WFVCMEAS' 'FVCMEAS' 'WFEVFVC' 'FEVFVC' 'WFEVPCT' 'FEVPCT' 'W
WFVCPCT' 'FVCPCT')
  and ((avisitn in (1 100) and trtan=96) or (trtan ne 96 & ANL01FL='Y'));
  where paramcd in ('WINTP' 'INTP' 'WFEVMEAS' 'FEVMEAS' 'WFVCMEAS' 'FVCMEAS' 'WFEVFVC' 'FEVFVC' 'WFEVPCT' 'FEVPCT' 'W
FVCPCT' 'FVCPCT')
  and ((SAFAFL='Y' & AVISITN>100 & ANL01FL='Y') | (SAFBFL='Y' and avisitn<=100)/(& ABLFL='Y')*) ;

  if TRTAN=3 then TRTAN=6;
  if paramcd='WINTP' then do;
    paramn=1; param='Clinically Significance (with bronchodilator)';
    if index(avalc,'ABNORMAL') then avalc='Abnormal '||left(xpclsig);
  end;
  else if paramcd='INTP' then do;
    paramn=2; param='Clinically Significance';

```

```

    if index(avalc,'ABNORMAL') then avalc='Abnormal '||left(xpclsig);
end;
else do;
    if avalu ne '' then param=strip(param)||' ('||strip(avalu)||')';

    if paramcd='WFEVMEAS' then paramn=3;
    if paramcd='FEVMEAS' then paramn=4;
    if paramcd='WFVCMEAS' then paramn=5;
    if paramcd='FVCMEAS' then paramn=6;
    if paramcd='WFEVFVC' then paramn=7;
    if paramcd='FEVFVC' then paramn=8;
    if paramcd='WFEVPCT' then paramn=9;
    if paramcd='FEVPCT' then paramn=10;
    if paramcd='WFVCPCT' then paramn=11;
    if paramcd='FVCPCT' then paramn=12;
end;
avisit=propcase(avisit);
_h=1;
_res=AVAL;
output;
if ablf1='Y' then do;
    avisitn=101; avisit='Baseline';
    output;
end;
run;

data _xp0;
set _xp0;
output;
if avisitn>101 then do;
    _h=2;
    _res=CHG;
    output;
end;
if avisitn<=100 then trtan=101;
else TRTAN=100;
_h=1;
_res=AVAL;
output;
_h=2;
_res=CHG;
output;
run;

proc sort data=_xp0;
by PARAMN PARAM AVISITN AVISIT TRTAN _h;
quit;

proc freq data=_xp0(where=(index(paramcd,'INTP') and _h=1)) noprint;
table paramn*param*avisitn*avisit*trtan*_h/out=_xp1;
run;

proc freq data=_xp0(where=(index(paramcd,'INTP') and _h=1)) noprint;
table paramn*param*avisitn*avisit*trtan*_h*avalc/out=_xp2 outpct;
run;

data _xp3;
set _xp1 _xp2;
by PARAMN PARAM AVISITN AVISIT TRTAN _h;

length result _name_ $20;
if avalc='' then result=put(count,8.);
else result=strip(put(count,best.))||' ('||strip(put(pct_tabl,4.1))||'%)';

if avalc='' then _name_='N';
else _name_=avalc;
run;

proc univariate data=_xp0(where=(index(paramcd,'INTP')=0)) noprint;
by PARAMN PARAM AVISITN AVISIT TRTAN _h;
var _res;
output out=_xp4 n=n mean=Mean std=SD median=Median min=Min max=Max;
quit;

proc transpose data=_xp4(where=(not (_h=2 and avisitn<=101))) out=_xp5;
by PARAMN PARAM AVISITN AVISIT TRTAN _h;
var n Mean SD Median Min Max;
quit;

data _xp6;
set _xp3 _xp5;
by PARAMN PARAM AVISITN AVISIT TRTAN _h;

if avisitn<=100 then sec=1;
else sec=2;
keep param: avisit: trtan _h result _name_ _label_ col1 sec;
run;

```

```

proc sort;
  by sec PARAMN PARAM AVISITN AVISIT TRTAN _h;
run;

/*for QC purpose*/
data odata.t15020622;
  set _xp6;
run;

data _xp7;
  set _xp6;
  by sec PARAMN PARAM AVISITN AVISIT TRTAN _h;
  if sec=1 and paramn in (1 2) then _page=1;
  else if sec=2 and paramn in (1 2) then _page=9;
  else do;
    if first.AVISIT then _c+1;
    if _c=3 then do;
      _page+1;
      _c=1;
    end;
  end;
  drop _c;
run;

data _xp7;
  set _xp7;
  if paramn not in (1 2) then
    _page+1;
run;

proc sort data=_xp7;
  by _page;
run;

%global totalpage;

data _null_;
  set _xp7 end=eof;

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

%put totalpage=&totalpage;

data _rpt(keep=_page sec PARAMN PARAM AVISITN AVISIT _ord _name_ TRTAN _h start)
  _rfmt(keep=start label fmtname);
  set _xp7;
  by _page sec PARAMN PARAM AVISITN AVISIT TRTAN _h;
  format label $40.;
  start=_n_;
  *if AVISIT='Screening' then AVISIT='Baseline';
  if AVISITn=106 then AVISIT='Day 6';
  else if AVISITn=191 then AVISIT='Day 91';
  select(upcase(_name_));
  when ('N') do;
    _ord=1;
    _name_='n';
    if (_h^=2 | sec=2) and col1 ne . then label=trim(left(put(col1,8)));
  else if col1=. then label=result;
    else label='';
  end;
  when ('NORMAL') do;
    _ord=2;
    _name_='Normal';
    label=result;
  end;
  when ('ABNORMAL NCS') do;
    _ord=3;
    _name_='Abnormal NCS';
    label=result;
  end;
  when ('ABNORMAL CS') do;
    _ord=4;
    _name_='Abnormal CS';
    label=result;
  end;
  when ('MEAN') do;
    _ord=2;
    _name_='Mean';
    if _h^=2 | sec=2 then do;
      if paramn<9 then label=trim(left(put(col1,8.3)));
      else label=trim(left(put(col1,8.2)));
    end;
    else label='';
  end;

```

```

        end;
    when ('SD') do;
        _ord=3;
        _name_='SD';
        if _h^=2 | sec=2 then do;
            if paramn<9 then label=trim(left(put(ceil(col1*1000)/1000,8.3)));
            else label=trim(left(put(ceil(col1*100)/100,8.2)));
        end;
        else label='';
    end;
    when ('MEDIAN') do;
        _ord=4;
        _name_='Median';
        if _h^=2 | sec=2 then do;
            if paramn<9 then label=trim(left(put(col1,8.3)));
            else label=trim(left(put(col1,8.2)));
        end;
        else label='';
    end;
    when ('MIN') do;
        _ord=5;
        _name_='Min';
        if _h^=2 | sec=2 then do;
            if paramn<9 then label=trim(left(put(col1,8.2)));
            else label=trim(left(put(col1,8.1)));
        end;
        else label='';
    end;
    when ('MAX') do;
        _ord=6;
        _name_='Max';
        if _h^=2 | sec=2 then do;
            if paramn<9 then label=trim(left(put(col1,8.2)));
            else label=trim(left(put(col1,8.1)));
        end;
        else label='';
    end;
    otherwise;
end;
fmtname='_xprpt';
run;

proc format cntlin=_rfmt;
quit;

proc format;
value _sh 1='Raw+value'
          2='+Change';
quit;

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

%macro reppart;

    %do i = 1 %to 8;*&totalpage;

proc report data=_rpt headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
            style(header column)=[protectspecialchars=off];
    columns _page PARAMN ('^S={just=1}Parameter+(units)' PARAM) AVISITN ('^S={just=1}Study+Day' AVISIT) _ord ('^S={just
=1}Statistic' _name_) (TRTAN,(_h,start));
    where _page =&i.;

    define _page/group order=internal noprint;
    define PARAMN/group order=internal noprint;
    define PARAM/group ' ' order=internal style(column)=[cellwidth=20% just=1 font_weight=bold vjust=b];
    define AVISITN/group order=internal noprint;
    define AVISIT/group ' ' order=internal style(column)=[cellwidth=8% just=1 vjust=b];
    define _ord/group order=internal noprint;
    define _name_/group ' ' order=internal style(column)=[cellwidth=8% just=1 vjust=b];
    define TRTAN/across ' ' order=internal f=_trxf. style(column)=[just=c];
    define _h/across ' ' order=internal f=_sh. style(column)=[just=c];
    define start/analysis ' ' f=_xprpt. style(column)=[just=c cellwidth=7% vjust=b];

    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 Period";
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 on Day -2 but were not randomized.";
line @1 "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 Ment
hol; NCS=Not Clinically Significant.";
line @1 "Note: Change is change from baseline, where baseline is defined defined as the last assessment prior to first r
andomized product use in mCC / THS 2.2";
line @1 "Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.";
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 = 9 %to &totalpage;

proc report data=_rpt headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
      style(header column)=[protectspecialchars=off];
      columns _page PARAMN ('^S={just=1}Parameter+(units)' PARAM) AVISITN ('^S={just=1}Study+Day' AVISIT) _ord ('^S={just
=1}Statistic' _name_) (TRTAN,(_h,start));
      where _page =&i.;

      define _page/group order=internal noprint;
      define PARAMN/group order=internal noprint;
      define PARAM/group ' ' order=internal style(column)=[cellwidth=20% just=1 font_weight=bold vjust=b];
      define AVISITN/group order=internal noprint;
      define AVISIT/group ' ' order=internal style(column)=[cellwidth=8% just=1 vjust=b];
      define _ord/group order=internal noprint;
      define _name_/group ' ' order=internal style(column)=[cellwidth=8% just=1 vjust=b];
      define TRTAN/across ' ' order=internal f=_trxf. style(column)=[just=c];
      define _h/across ' ' order=internal f=_sh. style(column)=[just=c];
      define start/analysis ' ' f=_xprpt. style(column)=[just=c cellwidth=7% vjust=b];

      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: Randomized Period";
endcomp;

compute before _page;
line @1 "";
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 Ment
hol; NCS=Not Clinically Significant.";
line @1 "Note: Change is change from baseline, where baseline is defined defined as the last assessment prior to first r
andomized product use in mCC / THS 2.2";
line @1 "Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.";
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;

```