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/*****
* Project       : ZRHM-REXA-07-JP
* Program name  : T1502061801_ZRHM_REXA_07_JP_V1.sas
* Author       : C. Liu
* Date created  : 06/18/2015
* Purpose      : Summary of Urinalysis Parameters 77 Safety Population
* Revision History
* Date         Author      Ref      Revision
* 07/02/2015   C. Liu      Per Client's comments
*****/

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```

%let prgname=T1502061801_ZRHM_REXA_07_JP_V1;
options nomprint nosymbolgen;

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options sasautos=("W:\pmp07\macros" sasautos) notes;
%init(delivery=9);

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%titlecsv(prgname=&prgname.,version=3);

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%put &title1;
%put &title2;
%put &APPENDIX;
%put &endpoint;
%put &outname.;

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options missing="";

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title;
footnote;

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proc format;
  value $summf
    'N' = 'n'
    'MEAN' = 'Mean'
    'STD' = '(SD)'
    'MEDIAN' = 'Median'
    'MIN' = 'Min,'
    'MAX' = 'Max'
  ;
  invaluel summo
    'N' = 1
    'MEAN' = 2
    'STD' = 3
    'MEDIAN' = 4
    'MIN' = 5
    'MAX' = 6
  ;
run;

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```

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;

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```

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

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```

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

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

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proc freq data=adsl noprint;
  table period*trtan/out=freqn(rename=(count=countn) drop=percent);
run;

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```

data adlb;
  set adam.adlb(where=(safbf1='Y' and 201<=paramn<=207 and anl01f1='Y'));
  length range $40;

  if trtan=3 then trtan=6;
  range=''||strip(anrlo)||'-'||strip(anrhi)||';
  avisit=scan(avisit,1,'/');
  if avisitn<=100 then period=1;
  else if safaf1='Y' then period=2;
  if period ne . then output;
  else delete;
  if ablfl='Y' then do;
    period=2; avisitn=101; avisit='Baseline';
    output;
  end;
  keep usubjid period paramn param parcat4: aval: chg shift: range lbtox: atoxgr: anr: ablfl anl01f1 bloqfl aulqfl aclsi
g avisit: trtan trta asper;
run;

proc sql;
  create table nrange as
  select unique paramn, n(unique range) as nrange
  from adlb
  group by paramn;
  create table adlb1 as
  select a.*, nrange
  from adlb a, nrange b
  where a.paramn=b.paramn;
quit;

data adlb2;
  length param $200;
  set adlb1;
  if nrange=1 then param=strip(param)||'^R/RTF"\line"'||left(range);
  else param=strip(param)||'^R/RTF"\line"[^]{super 1}';
  output;
  trtan=99;
  output;
run;

/* Summary */

%macro getsum(var=,dset=);
proc summary data=adlb2(where=(&var ne .)) nway;
  class period paramn param avisitn avisit trtan;
  var &var;
  output out=&dset n=n mean=Mean std=std median=Median min=Min max=Max;
run;

data &dset.1;
  set &dset;
  length n_ meansd median_ minmax $20;

  n_=left(put(n,8.0));
  if paramn=201 then do;
    meansd=strip(put(mean,8.2))||' ('||strip(put(ceil(std*1000)/1000,8.3))||')';
    median_=left(put(median,8.2));
    minmax=strip(put(min,8.1))||', '||left(put(max,8.1));
  end;
  else if paramn=202 then do;
    meansd=strip(put(mean,8.4))||' ('||strip(put(ceil(std*100000)/100000,8.5))||')';
    median_=left(put(median,8.4));
    minmax=strip(put(min,8.3))||', '||left(put(max,8.3));
  end;
run;

proc transpose data=&dset.1 out=t_&dset prefix=col;
  by period paramn param avisitn avisit;
  id trtan;
  var n_ meansd median_ minmax;
run;

proc sort data=t_&dset;
  by period paramn param avisitn avisit _name_;
run;
%mend getsum;

%getsum(var=aval,dset=sum)
%getsum(var=chg,dset=sumc)

/* Frequencies */

proc freq data=adlb2 noprint;
  table period*trtan*paramn*param*avisitn*avisit/out=freqvn(where=(paramn>202));
  table period*trtan*paramn*param*avisitn*avisit*avalc/out=freqv(where=(paramn>202));
  table period*trtan*paramn*param*avisitn*avisit*bloqfl/out=freqbloq(where=(bloqfl='Y'));

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table period*trtan*paramn*param*avisitn*avisit*aulqfl/out=freqaulq(where=(aulqfl='Y'));
table period*trtan*paramn*param*avisitn*avisit*anrind/out=freqnr;
table period*trtan*paramn*param*avisitn*avisit*aclsig/out=freqsig;
table period*trtan*paramn*param*avisitn*avisit*lbtoxh*atoxgrh/out=freqtoxh;
table period*trtan*paramn*param*avisitn*avisit*lbtox1*atoxgr1/out=freqtox1;
table period*trtan*paramn*param*avisitn*avisit*shift1/out=freqshift1;
table period*trtan*paramn*param*avisitn*avisit*lbtoxh*shift2/out=freqshift2;
table period*trtan*paramn*param*avisitn*avisit*lbtox1*shift3/out=freqshift3;
run;

%macro getfrq(var=,dset=);
data freq&dset.1;
  merge freq&dset(in=a) freqn;
  by period trtan;

  if a;
  length result $20;

  %if &dset=vn %then result=left(put(count,best.));
  %else result=strip(put(count,best.))||' ('||strip(put(100*count/countn,4.1))||')';
run;

proc sort;
  by period paramn param avisitn avisit &var;
run;

proc transpose data=freq&dset.1 out=freq&dset.2(drop=_) prefix=col;
  by period paramn param avisitn avisit &var;
  id trtan;
  var result;
run;
%mend getfrq;

%getfrq(var=,dset=vn)
%getfrq(var=avalc,dset=v)
%getfrq(var=,dset=bloq)
%getfrq(var=,dset=aulq)
%getfrq(var=anrind,dset=nr)
%getfrq(var=aclsig,dset=sig)
%getfrq(var=lbtoxh atoxgrh,dset=toxh)
%getfrq(var=lbtox1 atoxgr1,dset=tox1)
%getfrq(var=shift1,dset=shift1)
%getfrq(var=lbtoxh shift2,dset=shift2)
%getfrq(var=lbtox1 shift3,dset=shift3)

data freqtoxh3;
  set freqtoxh2(where=(lbtoxh ne ''));
  by period paramn param avisitn avisit lbtoxh atoxgrh;

  output;
  if last.avisit then do;
    atoxgrh='9'; col4=''; col5=''; col6=''; col96=''; col99='';
  output;
  end;
run;

data freqtox13;
  set freqtox12(where=(lbtox1 ne ''));
  by period paramn param avisitn avisit lbtox1 atoxgr1;

  output;
  if last.avisit then do;
    atoxgr1='9'; col4=''; col5=''; col6=''; col96=''; col99='';
  output;
  end;
run;

data freqshift23;
  set freqshift22(where=(shift2 not in (' '0 to 0' '1 to 1' '2 to 2' '3 to 3')));
  by period paramn param avisitn avisit lbtoxh shift2;

  output;
  if last.avisit then do;
    shift2='9'; col4=''; col5=''; col6=''; col96=''; col99='';
  output;
  end;
run;

data freqshift33;
  set freqshift32(where=(shift3 not in (' '0 to 0' '1 to 1' '2 to 2')));
  by period paramn param avisitn avisit lbtox1 shift3;

  output;
  if last.avisit then do;
    shift3='9'; col4=''; col5=''; col6=''; col96=''; col99='';
  output;
  end;

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run;

proc format;
  value $statf
    'N_' = 'n'
    'MEANSD' = 'Mean (SD)'
    'MEDIAN_' = 'Median'
    'MINMAX' = 'Min, Max'
  ;
  invalue stato
    'N_' = 1
    'MEANSD' = 4
    'MEDIAN_' = 5
    'MINMAX' = 6
    'LOW' = 7
    'NORMAL' = 8
    'ABNORMAL' = 8.5
    'HIGH' = 9
    'NCS' = 10
    'CS' = 11
    'Normal to High' = 16
    'Normal to High, NCS' = 17
    'Normal to High, CS' = 18
    'Normal to Low' = 19
    'Normal to Low, NCS' = 20
    'Normal to Low, CS' = 21
    'High to Normal' = 22
    'High, NCS to Normal' = 23
    'High, NCS to High, CS' = 24
    'High, CS to Normal' = 25
    'High, CS to High, NCS' = 26
    'Low to Normal' = 27
    'Low, NCS to Normal' = 28
    'Low, NCS to Low, CS' = 29
    'Low, CS to Normal' = 30
    'Low, CS to Low, NCS' = 31 ;
run;

data all;
  set t_sum(in=sum)
    freqvn2(in=vn)
    freqv2(in=v)
    freqbloq2(in=bloq)
    freqaulq2(in=aulq)
    freqnr2(in=nr)
    freqsig2(in=sig where=(ac1sig ne ''))
    freqtoxh3(in=toxh)
    freqtox13(in=tox1)
    t_sumc(in=chg)
    freqshift12(in=inshift1 where=(shift1 not in (' ' 'High to High' 'High, CS to High, CS' 'High, NCS to High, NCS' 'Low to Low'
                                                    'Low, CS to Low, CS' 'Low, NCS to Low, NCS' 'Normal to Normal')))
    freqshift23(in=inshift2)
    freqshift33(in=inshift3 where=(shift3 not in ('0 to 0' '1 to 1' '2 to 2' '3 to 3')));
  by period paramn param avisitn avisit;
  length stat $40;

  if period=. then delete;

  array col col4 col5 col6 col96 col99;

  do i=1 to dim(col);
    if col(i)='' and atoxgrh ne '9' and atoxgr1 ne '9' and shift2 ne '9' and shift3 ne '9' then col(i)='0';
  end;

  if sum or chg then do;
    stat=put(upcase(_name_),$statf.);
    ord1=input(upcase(_name_),stato.);
  end;
  if vn then do;
    stat='n'; ord1=1;
  end;
  if v then do;
    stat=propcase(avalc);
  end;
  if avalc='NEGATIVE' then ord1=4;
  else if avalc='NORMAL' then ord1=5;
  else if avalc='POSITIVE' then ord1=6;
  else if avalc='1+' then ord1=6.1;
  else if avalc='2+' then ord1=6.2;
  else if avalc='3+' then ord1=6.3;
  else if avalc='TRACE' then ord1=6.4;
  end;
  if bloq then do;
    stat='BLOQ, n (%)'; ord1=2;
  end;
  if aulq then do;
    stat='ALQ, n (%)';
  end;

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ord1=3;
end;
if nr then do;
    stat=strip(propcase(anrind))||' value '||n(%)';
ord1=input(anrind,stato.);
end;
if sig then do;
    stat='Abnormal '||strip(aclsig)||' n(%)';
ord1=input(aclsig,stato.);
end;
if toxh then do;
    if atoxgrh='9' then do;
        stat=lbtohx; ord1=12;
end;
else do;
    stat="^R/RTF'  '||'Grade '||strip(atoxgrh)||' - n(%)'; ord1=13;
end;
end;
if toxl then do;
    if atoxgrl='9' then do;
        stat=lbtoxl; ord1=14;
end;
else do;
    stat="^R/RTF'  '||'Grade '||strip(atoxgrl)||' - n(%)'; ord1=15;
end;
end;
if chg then do;
    sec=2; avisit='Change from Baseline';
end;
if inshift1 then do;
    sec=3; avisit='Shift in Normality';
ord1=input(shift1,stato.);
stat=strip(shift1)||' - n(%)';
end;
if inshift2 then do;
    sec=4; avisit='Shift in Toxicity';
    if shift2='9' then do;
        stat=lbtohx; ord1=41;
end;
else do;
    stat="^R/RTF'  '||strip(shift2)||' - n(%)'; ord1=42;
end;
end;
if inshift3 then do;
    sec=4; avisit='Shift in Toxicity';
    if shift3='9' then do;
        stat=lbtoxl; ord1=43;
end;
else do;
    stat="^R/RTF'  '||strip(shift3)||' - n(%)'; ord1=44;
end;
end;

keep period paramn param avisitn avisit col: stat ord1 sec;
run;

proc sort data=all;
by period paramn param avisitn sec avisit ord1;
run;

/*for QC purpose*/
data odata.t1502061801;
set all;
run;

data final;
set all;
by period paramn param avisitn sec avisit ord1;
array col col4 col5 col6 col96 col99;

if sec=. then sec=0;
output;

if first.paramn then do;
do i=1 to dim(col);
col(i)='';
end;
stat='_A';
output;
end;

drop i;
run;

proc sql;
create table final1 as
select *, n(stat) as nline

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from final
group by period, paramn, param, avisitn, sec;
quit;

proc sort data=final1;
  by period paramn param avisitn sec avisit ord1 stat;
run;

data final2;
  set final1;
  by period paramn param avisitn sec avisit ord1 stat;

  retain _page 1 _nline 0;

  if first.sec then do;
    _nline=_nline+nline;
    if _nline>15 then do;
      _nline=nline; _page+1;
    end;
  end;

  drop _nline;
run;

data final3;
  set final2;

  if stat='_A' then stat='';
run;

proc sort data=final3;
  by period _page;
run;

%global page1 totalpage;

data _null_;
  set final3(where=(period=1)) end=eof;

  if eof then do;
    call symput('page1', trim(left(put(_page,8)))));
  end;
run;

data _null_;
  set final3 end=eof;

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

%put page1=&page1 totalpage=&totalpage;

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

%macro reppart;

  %do i = 1 %to &page1;

proc report data=final3 headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
  style(header column)=[protectspecialchars=off];
  columns _page paramn ('^S={just=l}Parameter (units)+[Reference range]' param) avisitn sec
  ('^S={just=l}Study Day' avisit) ord1 ('^S={just=l}Statistic' stat)
  ('^S={just=c}THSm2.2+(N=%cmpres(&n1))" col4)
  ('^S={just=c}mCC+(N=%cmpres(&n2))" col5)
  ('^S={just=c}SA+(N=%cmpres(&n3))" col6)
  ('^S={just=c}Product Test+(N=%cmpres(&n4))" col96)
  ('^S={just=c}Overall Safety+(N=%cmpres(&n5))" col99)
;
  where period=1 and _page =&i.;

  define _page/group order=internal noprint;
  define paramN/group order=internal noprint;
  define param/group ' ' order=internal style(column)=[cellwidth=12% just=l font_weight=bold vjust=b];
  define avisitn/group order=internal noprint;
  define sec/group order=internal noprint;
  define avisit/group ' ' order=internal style(column)=[cellwidth=7% just=l vjust=b];
  define ord1/group order=internal noprint;
  define stat/group ' ' order=internal style(column)=[cellwidth=13% just=l vjust=b];
  define col4/display ' ' style(column)=[just=c cellwidth=9% vjust=b];
  define col5/display ' ' style(column)=[just=c cellwidth=9% vjust=b];
  define col6/display ' ' style(column)=[just=c cellwidth=9% vjust=b];
  define col96/display ' ' style(column)=[just=c cellwidth=9% vjust=b];
  define col99/display ' ' style(column)=[just=c cellwidth=9% vjust=b];

  compute after sec;

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        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 are based on the number of subjects indicated in the column header (N).";
line @1 "Note: 1: Normality ranges are provided in Appendix 15.3.6.6";
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 = %eval(&page1+1) %to &totalpage;

proc report data=final3 headskip headline spacing=4 nowd split='+' style=[outputwidth=100%]
    style(header column)=[protectspecialchars=off];
    columns _page paramn ('^S={just=1}Parameter (units)+[Reference range]' param) avisitn sec
    ('^S={just=1}Study Day' avisit) ord1 ('^S={just=1}Statistic' stat)
    ('^S={just=c}THSm2.2+(N=%cmpres(&n6))" col4)
    ('^S={just=c}mCC+(N=%cmpres(&n7))" col5)
    ('^S={just=c}SA+(N=%cmpres(&n8))" col6)
    ('^S={just=c}Overall Safety+(N=%cmpres(&n9))" col99)
;
    where period=2 and _page =&i.;

    define _page/order order=internal noprint;
    define paramN/order order=internal noprint;
    define param/group ' ' order=internal style(column)=[cellwidth=12% just=1 font_weight=bold vjust=b];
    define avisitn/group order=internal noprint;
    define sec/group order=internal noprint;
    define avisit/group ' ' order=internal style(column)=[cellwidth=7% just=1 vjust=b];
    define ord1/group order=internal noprint;
    define stat/group ' ' order=internal style(column)=[cellwidth=13% just=1 vjust=b];
    define col4/display ' ' style(column)=[just=c cellwidth=8% vjust=b];
    define col5/display ' ' style(column)=[just=c cellwidth=8% vjust=b];
    define col6/display ' ' style(column)=[just=c cellwidth=8% vjust=b];
    define col99/display ' ' style(column)=[just=c cellwidth=8% vjust=b];

    compute after sec;
        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 Ment
hol.";
line @1 "Note: Percentages are based on the number of subjects indicated in the column header (N).";
line @1 "Note: 1: Normality ranges are provided in Appendix 15.3.6.6";
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;

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ods rtf close;
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