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*****;
* Project          : ZRHM-REXA-07-JP
*
* Program name     : t1502060101_ZRHM_REXA_07_JP_v1.sas
*
* Author          : H Shu
*
* Date created     : 06/24/2015
*
* Purpose          : Create Table 15.2.6.1.1 Summary of  Safety Population
*
* Revision History :
*
* Date      Author      Ref      Revision (Date in YYYYMMDD format)
* 07/13/2015 HS          Updated following PMP review comments
* 07/13/2015 HS          Updated following PMP review comments
*****;
%let prgname=T1502060101_ZRHM_REXA_07_JP_V1;
options sasautos=(W:\pmp07\macros" sasautos) noquotelenmax;
%init(delivery=9);
%titlecsv(prgname=&prgname,version=5);
%trtrtfg(pgmname=&outname., pgmid=1, new=0, style=, bookmark=%lowcase(&outname.));

/*order informats*/
/*order informats*/
proc format;
  inval _os 'Adverse events'=1
    'AE Serious'=2
    'AE related to IP'=3
    'AE related to study procedure'=4
    'AE severity'=5
    'Action taken with study product'=6
    'Treatment given'=7
    'Other actions taken'=8
    'No action taken'=9;
  inval _op '^S={leftmargin=6pt}Adverse events'=0.5
    '^S={leftmargin=6pt}^S={} RELATED', '^S={leftmargin=6pt}Treatment given^R"\line" Yes'=2
    '^S={leftmargin=6pt}^S={} No'=3;
  value sub1 1='AE Serious^R"\line" Yes (||SAE=)'
    2='^R" " No (||AE=)'
    3='AE related to IP^R"\line" Not Related'
    4='^R" " Related^R"\line" Expected^R"\line" Not expected'
    5='AE related to study procedure^R"\line" Not Related'
    6='^R" " Related'
    7='AE severity^R"\line" Mild'
    8='^R" " Moderate'
    9='^R" " Severe'
    10='Action taken due to AE^R"\line" Action taken with study product^R"\line" Product use inter
rupted'
    11='^R" " Product use stopped'
    12='^R" " Product use reduced'
    13='^R" " Not applicable'
    14='^R" " None'
    15='Treatment given^R"\line" Yes'
    16='^R" " No'
    17='Other actions taken^R"\line" Discontinued study'
    ;
quit;

data ADAE;
  set adam.ADAE(in=in1 where=(ASPER=1));
  by USUBJID;
  if in1;

  format sub1t $200.;

  if first.USUBJID then _ind=.;
  _flag='Y';

  /*Any AE*/
  AEBODSYS=' Adverse events';
  AEDECOD='Adverse events';
  output;

  /*AE Serious*/
  AEBODSYS='AE Serious';
  AEDECOD='AE Serious';
  if AESER='N' then do;
    sub1t='^R" " No (||AE=)';
    sub1=2;
  end;
  output;
  sub1t='';
  sub1=.;

  /*AE related to IP*/
  AEBODSYS='AE related to IP';

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AEDECOD='AE related to IP';
if AEREL='NOT RELATED' then do;
    sublt='AE related to IP^R"\line"          Not Related';
    subl=3;
end;
output;
sublt='';
subl=.;

/*AE related to study procedure*/
AEBODSYS='AE related to study procedure';
AEDECOD=AEBODSYS;
if AERELSP='NOT RELATED' then do;
    sublt='AE related to study procedure^R"\line"          Not Related';
    subl=5;
end;
else if AERELSP='RELATED' then do;
    sublt='^R" " Related';
    subl=6;
end;
output;
sublt='';
subl=.;

/*AE severity*/
AEBODSYS='AE severity';
AEDECOD=AEBODSYS;
if AESEV='MILD' then do;
    sublt='AE severity^R"\line"          Mild';
    subl=7;
end;
else if AESEV='MODERATE' then do;
    sublt='^R" " Moderate';
    subl=8;
end;
output;
sublt='';
subl=.;

/*Action taken with study product*/
AEBODSYS='Action taken with study product';
AEDECOD=AEBODSYS;
if AEACNP1='NOT APPLICABLE' then do;
    sublt='^R" " Not applicable';
    subl=13;
end;
else if AEACNP1='NONE' then do;
    sublt='^R" " None';
    subl=14;
end;
output;
sublt='';
subl=.;

/*Treatment given*/
AEBODSYS='Treatment given';
AEDECOD=AEBODSYS;
if AECONTRT='Y' then do;
    sublt='Treatment given^R"\line"          Yes';
    subl=15;
    _ind+1;
end;
else do;
    sublt='^R" " No';
    subl=16;
end;
output;
sublt='';
subl=.;

/*Other actions taken*/
AEBODSYS='Other actions taken';
AEDECOD=AEBODSYS;
if AEACNOTH='DISCONTINUED STUDY' then do;
    sublt='Other actions taken^R"\line"          Discontinued study';
    subl=17;
    _ind+1;
end;
output;
sublt='';
subl=.;

/*No action taken due to AE*/
_flag='N';
if AECONTRT='' & AEACNOTH='' then do;
    AEBODSYS='No action taken';
    AEDECOD='No action taken due to AE';

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        if last.USUBJID & _ind<=0 then _flag='Y';
        sublt=18;
        output;
    end;
run;

%global _ppg;
%let _ppg=0;
%let tit2=Safety Time Period: Pre-Randomization;
%maes(pwhere=SAFBFL='Y',awhere=SAFBFL='Y' and ASPER=1,odn=t1502060101_1,tp=15,ht1=%nrquote(^S={}Adverse events),f2=Y,f3=Y,wrap=18,
    ps=15,ptwhere=_flag='Y',
    owhere=%nrquote(&
        ((AEBODSYS=' Adverse events' & AEDECOD=AEBODSYS) | (AEBODSYS='AE Serious' & sublt in ( 1 2)) |
        (AEBODSYS='AE related to IP' & sublt in (3 4) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE related to study procedure' & sublt in (5 6) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE severity' & sublt in (7 8 9) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Action taken with study product' & sublt in (10 11 12 13 14) & AEBODSYS^=left(AEDECOD))
    |
        (AEBODSYS='Treatment given' & sublt in (15 16) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Other actions taken' & sublt in (17 18) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='No action taken' & AEDECOD='^S={leftmargin=6pt}No action taken due to AE' & sublt=.))
    )),
    sl1=sublt,sl1t=sublt,sl1r=1 to 17,sl1f=sublt.,
    exp=%str(' AE Serious^R"\line" Yes (||SAE=)'
        ' AE related to IP^R"\line" Not Related'
        ' AE related to study procedure^R"\line" Not Related'
        ' AE severity^R"\line" Mild'
        ' Action taken due to AE^R"\line" Action taken with study product^R"\line" Product use interr
upted'
        ' Treatment given^R"\line" Yes'
        ' Other actions taken^R"\line" Exdontia'
        ' Other actions taken^R"\line" Discontinued study'
    ),
    ad=adae,CM=Y,any=N,osi=_os.,opi=_op.,socdsc=%str('Treatment given'))

proc format;
    value sublt 1='AE Serious^R"\line" Yes (||SAE=)'
        2='^R" " No (||AE=)'
        3='^S={}' Expected'
        4='^S={}' Not expected'
        5='AE related to study procedure^R"\line" Not Related'
        6='^R" " Related'
        7='AE severity^R"\line" Mild'
        8='^R" " Moderate'
        9='^R" " Severe'
        10='Action taken due to AE^R"\line" Action taken with study product^R"\line" Product use inter
rupted'
        11='^R" " Product use stopped'
        12='^R" " Product use reduced'
        13='^R" " Not applicable'
        14='^R" " None'
        15='Treatment given^R"\line" Yes'
        16='^R" " No'
        17='Other actions taken^R"\line" Exdontia'
        18='^R" " Tooth extraction'
    ;

quit;

proc sort data=adam.ADAE out=ADAE0;
    where ASPER>1;
    by USUBJID descending AERELN;
quit;

data ADAE;
    set ADAE0;
    by USUBJID descending AERELN;
    retain _rel;
    format sublt $200.;

    if first.USUBJID then do;
        _ind=.;
        if AEREL='RELATED' then _rel=1;
        else _rel=0;
    end;
    _flag='Y';

    /*Any AE*/
    AEBODSYS=' Adverse events';
    AEDECOD='Adverse events';
    output;

    /*AE Serious*/
    AEBODSYS='AE Serious';
    AEDECOD='AE Serious';
    if AESER='N' then do;

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        sublt='^R" " No (||AE=)';
        sublt=2;
    end;
    output;
    sublt='';
    sublt=.;

    _flag='N';
    /*AE related to IP*/
    AEBODSYS='AE related to IP';
    if AEREL='NOT RELATED' then do;
        AEDECOD='^S={}' AE related to IP^R"\line"        Not related';
        if _rel^=1 then _flag='Y';
    end;
    else if AEREL='RELATED' then do;
        _uterm=' '||left(AEDECOD);
        AEDECOD='^S={}'        Related';
        if AEEXPEC='N' then do;
            sublt='^S={}'        Not expected';
            sublt=4;
        end;
        else if AEEXPEC='Y' then do;
            sublt='^S={}'        Not expected';
            sublt=3;
        end;
        _flag='Y';
    end;
    output;
    sublt='';
    sublt=.;
    _flag='Y';

    /*AE related to study procedure*/
    AEBODSYS='AE related to study procedure';
    AEDECOD=AEBODSYS;
    if AERELSP='NOT RELATED' then do;
        sublt='AE related to study procedure^R"\line"        Not Related';
        sublt=5;
    end;
    else if AERELSP='RELATED' then do;
        sublt='^R" " Related';
        sublt=6;
    end;
    output;
    sublt='';
    sublt=.;

    /*AE severity*/
    AEBODSYS='AE severity';
    AEDECOD=AEBODSYS;
    if AESEV='MILD' then do;
        sublt='AE severity^R"\line"        Mild';
        sublt=7;
    end;
    else if AESEV='MODERATE' then do;
        sublt='^R" " Moderate';
        sublt=8;
    end;
    output;
    sublt='';
    sublt=.;

    /*Action taken with study product*/
    AEBODSYS='Action taken with study product';
    AEDECOD=AEBODSYS;
    if AEACNP1='NOT APPLICABLE' then do;
        sublt='^R" " Not applicable';
        sublt=13;
    end;
    else if AEACNP1='NONE' then do;
        sublt='^R" " None';
        sublt=14;
    end;
    output;
    sublt='';
    sublt=.;

    /*Treatment given*/
    AEBODSYS='Treatment given';
    AEDECOD=AEBODSYS;
    if AECONTRT='Y' then do;
        sublt='Treatment given^R"\line"        Yes';
        sublt=15;
        _ind+1;
    end;
    else do;
        sublt='^R" " No';

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        sub1=16;
    end;
output;
sublt='';
subl=.;

/*Other actions taken*/
AEBODSYS='Other actions taken';
AEDECOD=AEBODSYS;
if AEACNOTH='EXDONTIA' then do;
    sublt='Other actions taken^R\line'          Exdontia';
    sub1=17;
    _ind+1;
end;
else if AEACNOTH='TOOTH EXTRACTION' then do;
    sublt='^R" " Tooth extraction';
    sub1=18;
    _ind+1;
end;
output;
sublt='';
subl=.;

/*No action taken due to AE*/
_flag='N';
if AECONTRT='' & AEACNOTH='' then do;
    AEBODSYS='No action taken';
    AEDECOD='No action taken due to AE';
    if last.USUBJID & _ind<=0 then _flag='Y';
    sub1=19;
    output;
end;
run;

%let tit2=Safety Time Period: Post-Randomization;
%maes(pwhere=SAFAFL='Y',awhere=SAFAFL='Y' and ASPER>1,odn=t1502060101_2,tp=15,ht1=%nrquote(^S={})Adverse events),f2=N,f3=
Y,wrap=18,
    ps=15,ptwhere=_flag='Y',
    owhere=%nrquote(&
        ((AEBODSYS=' Adverse events' & AEDECOD=AEBODSYS) | (AEBODSYS='AE Serious' & subl in ( 1 2)) |
        (AEBODSYS='AE related to IP' & subl in (3 4) & AEBODSYS^=left(AEDECOD) & _op>=2) |
        (AEBODSYS='AE related to IP' & AEDECOD='^S={leftmargin=6pt}^S={} AE related to IP^R\line"          N
ot related' & subl=. & _text='^S={v}') |
        (AEBODSYS='AE related to IP' & AEDECOD='^S={leftmargin=6pt}^S={} Related' & subl=.) |
        (AEBODSYS='AE related to study procedure' & subl in (5 6) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE severity' & subl in (7 8 9) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Action taken with study product' & subl in (10 11 12 13 14) & AEBODSYS^=left(AEDECOD))
        |
        (AEBODSYS='Treatment given' & subl in (15 16) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Other actions taken' & subl in (17 18) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='No action taken' & AEDECOD='^S={leftmargin=6pt}No action taken due to AE' & subl=.)
    )),
    sl1=subl,sl1t=sublt,sl1r=1 to 18,sl1f=subl.,
    exp=%str(' AE Serious^R\line"          Yes (||SAE=)'
    ' AE related to IP^R\line"          Not Related'
    ' AE related to study procedure^R\line"          Not Related'
    ' AE severity^R\line"          Mild'
    ' Action taken due to AE^R\line"          Action taken with study product^R\line"          Product use interr
upted'
    ' Treatment given^R\line"          Yes'
    ' Other actions taken^R\line"          Exdontia'
    '^S={leftmargin=6pt}^S={} AE related to IP^R\line"          Not related'
    ),
    ad=adae,CM=Y,any=N,osi=_os.,opi=_op.,socdsc=%str('Treatment given'))

proc format;
value subl 1='AE Serious^R\line"          Yes (||SAE=)'
2='^R" " No (||AE=)'
3='^S={} Expected'
4='^S={} Not expected'
5='AE related to study procedure^R\line"          Not Related'
6='^R" " Related'
7='AE severity^R\line"          Mild'
8='^R" " Moderate'
9='^R" " Severe'
10='Action taken due to AE^R\line"          Action taken with study product^R\line"          Product use inter
rupted'
11='^R" " Product use stopped'
12='^R" " Product use reduced'
13='^R" " Not applicable'
14='^R" " None'
15='Treatment given^R\line"          Yes'
16='^R" " No'
17='Other actions taken - no'
18='Other actions taken'
;

quit;

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proc sort data=adam.ADAE out=ADAE0;
  where ASPER=2;
  by USUBJID descending AERELN;
quit;

data ADAE;
  set ADAE0;
  by USUBJID descending AERELN;
  retain _rel;
  format sublt $200.;

  if first.USUBJID then do;
    _ind=.;
    if AEREL='RELATED' then _rel=1;
    else _rel=0;
  end;
  _flag='Y';

  /*Any AE*/
  AEBODSYS=' Adverse events';
  AEDECOD='Adverse events';
  output;

  /*AE Serious*/
  AEBODSYS='AE Serious';
  AEDECOD='AE Serious';
  if AESER='N' then do;
    sublt='^R' " No (||AE=)';
    sublt=2;
  end;
  output;
  sublt='';
  sublt=.;

  _flag='N';
  /*AE related to IP*/
  AEBODSYS='AE related to IP';
  if AEREL='NOT RELATED' then do;
    AEDECOD='^S={}' AE related to IP^R"\line" Not related';
    if _rel=1 then _flag='Y';
  end;
  else if AEREL='RELATED' then do;
    _uterm=' '||left(AEDECOD);
    AEDECOD='^S={}' Related';
    if AEEXPEC='N' then do;
      sublt='^S={}' Not expected';
      sublt=4;
    end;
    else if AEEXPEC='Y' then do;
      sublt='^S={}' Not expected';
      sublt=3;
    end;
    _flag='Y';
  end;
  output;
  sublt='';
  sublt=.;
  _flag='Y';

  /*AE related to study procedure*/
  AEBODSYS='AE related to study procedure';
  AEDECOD=AEBODSYS;
  if AERELSP='NOT RELATED' then do;
    sublt='AE related to study procedure^R"\line" Not Related';
    sublt=5;
  end;
  else if AERELSP='RELATED' then do;
    sublt='^R' " Related';
    sublt=6;
  end;
  output;
  sublt='';
  sublt=.;

  /*AE severity*/
  AEBODSYS='AE severity';
  AEDECOD=AEBODSYS;
  if AESEV='MILD' then do;
    sublt='AE severity^R"\line" Mild';
    sublt=7;
  end;
  else if AESEV='MODERATE' then do;
    sublt='^R' " Moderate';
    sublt=8;
  end;
  output;

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sublt='';
subl=.;

/*Action taken with study product*/
AEBODSYS='Action taken with study product';
AEDECOD=AEBODSYS;
if AEACNP1='NOT APPLICABLE' then do;
    sublt='^R' " Not applicable';
    subl=13;
end;
else if AEACNP1='NONE' then do;
    sublt='^R' " None';
    subl=14;
end;
output;
sublt='';
subl=.;

/*Treatment given*/
AEBODSYS='Treatment given';
AEDECOD=AEBODSYS;
if AECONTRT='Y' then do;
    sublt='Treatment given^R"\line"          Yes';
    subl=15;
    _ind+1;
end;
else do;
    sublt='^R' " No';
    subl=16;
end;
output;
sublt='';
subl=.;

/*Other actions taken*/
AEBODSYS='Other actions taken';
AEDECOD=AEBODSYS;
if AEACNOTH='' then do;
    sublt='Other actions taken - no';
    subl=17;
end;
output;
sublt='';
subl=.;

/*No action taken due to AE*/
_flag='N';
if AECONTRT='' & AEACNOTH='' then do;
    AEBODSYS='No action taken';
    AEDECOD='No action taken due to AE';
    if last.USUBJID & _ind<=0 then _flag='Y';
    subl=19;
    output;
end;
run;

%let tit2=Safety Time Period: Confinement;
%maes(pwhere=SAFAFL='Y',awhere=SAFAFL='Y' and ASPER=2,odn=t1502060101_3,tp=15,ht1=%nrquote(^S={}Adverse events),f2=N,f3=
Y,wrap=18,
    ps=15,ptwhere=_flag='Y',
    owhere=%nrquote(&
        ((AEBODSYS=' Adverse events' & AEDECOD=AEBODSYS) | (AEBODSYS='AE Serious' & subl in ( 1 2)) |
        (AEBODSYS='AE related to IP' & subl in (3 4) & AEBODSYS^=left(AEDECOD) & _op>=2) |
        (AEBODSYS='AE related to IP' & AEDECOD='^S={leftmargin=6pt}^S={} AE related to IP^R"\line"          N
ot related' & subl=. & _text='^S={v}') |
        (AEBODSYS='AE related to IP' & AEDECOD='^S={leftmargin=6pt}^S={} Related' & subl=.) |
        (AEBODSYS='AE related to study procedure' & subl in (5 6) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE severity' & subl in (7 8 9) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Action taken with study product' & subl in (10 11 12 13 14) & AEBODSYS^=left(AEDECOD))
        |
        (AEBODSYS='Treatment given' & subl in (15 16) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Other actions taken' & subl in (18)) |
        (AEBODSYS='No action taken' & AEDECOD='^S={leftmargin=6pt}No action taken due to AE' & subl=.)
    )),
    sl1=subl,sl1t=sublt,sl1r=1 to 18,sl1f=subl.,
    exp=%str(' AE Serious^R"\line"          Yes (||SAE=)'
    ' AE related to IP^R"\line"          Not Related'
    ' AE related to study procedure^R"\line"          Not Related'
    ' AE severity^R"\line"          Mild'
    ' Action taken due to AE^R"\line"          Action taken with study product^R"\line"          Product use interr
upted'
    ' Treatment given^R"\line"          Yes'
    '^S={leftmargin=6pt}^S={} AE related to IP^R"\line"          Not related'
    ),
    ad=adae,CM=Y,any=N,osi=_os.,opi=_op.,socdsc=%str('Treatment given'))

proc format;

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value sublt 1='AE Serious^R'\line"          Yes (||SAE=)'
              2='^R" " No (||AE=)'
              3='AE related to IP^R'\line"          Not Related'
              4='^R" " Related^R'\line"          Expected^R'\line"          Not expected'
              5='AE related to study procedure^R'\line"          Not Related'
              6='^R" " Related'
              7='AE severity^R'\line"          Mild'
              8='^R" " Moderate'
              9='^R" " Severe'
              10='Action taken due to AE^R'\line"          Action taken with study product^R'\line"          Product use inter
rupted'
              11='^R" " Product use stopped'
              12='^R" " Product use reduced'
              13='^R" " Not applicable'
              14='^R" " None'
              15='Treatment given^R'\line"          Yes'
              16='^R" " No'
              17='Other actions taken^R'\line"          Exdontia'
              18='^R" " Tooth extraction'
              ;
quit;

data ADAE;
  set adam.ADAE(in=in1 where=(ASPER=3));
  by USUBJID;

  format sublt $200.;

  if first.USUBJID then _ind=.;
  _flag='Y';

  /*Any AE*/
  AEBODSYS=' Adverse events';
  AEDECOD='Adverse events';
  output;

  /*AE Serious*/
  AEBODSYS='AE Serious';
  AEDECOD='AE Serious';
  if AESER='N' then do;
    sublt='^R" " No (||AE=)';
    sublt=2;
  end;
  output;
  sublt='';
  sublt=.;

  /*AE related to IP*/
  AEBODSYS='AE related to IP';
  AEDECOD='AE related to IP';
  if AEREL='NOT RELATED' then do;
    sublt='AE related to IP^R'\line"          Not Related';
    sublt=3;
  end;
  output;
  sublt='';
  sublt=.;

  /*AE related to study procedure*/
  AEBODSYS='AE related to study procedure';
  AEDECOD=AEBODSYS;
  if AERELSP='NOT RELATED' then do;
    sublt='AE related to study procedure^R'\line"          Not Related';
    sublt=5;
  end;
  else if AERELSP='RELATED' then do;
    sublt='^R" " Related';
    sublt=6;
  end;
  output;
  sublt='';
  sublt=.;

  /*AE severity*/
  AEBODSYS='AE severity';
  AEDECOD=AEBODSYS;
  if AESEV='MILD' then do;
    sublt='AE severity^R'\line"          Mild';
    sublt=7;
  end;
  else if AESEV='MODERATE' then do;
    sublt='^R" " Moderate';
    sublt=8;
  end;
  output;
  sublt='';
  sublt=.;

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/*Action taken with study product*/
AEBODSYS='Action taken with study product';
AEDECOD=AEBODSYS;
if AEACNP1='NOT APPLICABLE' then do;
    sublt='^R' " Not applicable';
    subl=13;
end;
else if AEACNP1='NONE' then do;
    sublt='^R' " None';
    subl=14;
end;
output;
sublt='';
subl=.;

/*Treatment given*/
AEBODSYS='Treatment given';
AEDECOD=AEBODSYS;
if AECONTRT='Y' then do;
    sublt='Treatment given^R"\line"          Yes';
    subl=15;
    _ind+1;
end;
else do;
    sublt='^R' " No';
    subl=16;
end;
output;
sublt='';
subl=.;

/*Other actions taken*/
AEBODSYS='Other actions taken';
AEDECOD=AEBODSYS;
if AEACNOTH='EXDONTIA' then do;
    sublt='Other actions taken^R"\line"          Exdontia';
    subl=17;
    _ind+1;
end;
else if AEACNOTH='TOOTH EXTRACTION' then do;
    sublt='^R' " Tooth extraction';
    subl=18;
    _ind+1;
end;
output;
sublt='';
subl=.;

/*No action taken due to AE*/
_flag='N';
if AECONTRT='' & AEACNOTH='' then do;
    AEBODSYS='No action taken';
    AEDECOD='No action taken due to AE';
    if last.USUBJID & _ind<=0 then _flag='Y';
    subl=19;
    output;
end;

run;

%let tit2=Safety Time Period: Ambulatory;
%maes(pwhere=SAFAFL='Y',awhere=SAFAFL='Y' and ASPER=3,odn=t1502060101_4,tp=15,ht1=%nrquote(^S={}Adverse events),f2=N,f3=
Y,wrap=18,
    ps=15,ptwhere=_flag='Y',
    owhere=%nrquote(&
        ((AEBODSYS=' Adverse events' & AEDECOD=AEBODSYS) | (AEBODSYS='AE Serious' & subl in ( 1 2)) |
        (AEBODSYS='AE related to IP' & subl in (3 4) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE related to study procedure' & subl in (5 6) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='AE severity' & subl in (7 8 9) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Action taken with study product' & subl in (10 11 12 13 14) & AEBODSYS^=left(AEDECOD))
        |
        (AEBODSYS='Treatment given' & subl in (15 16) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='Other actions taken' & subl in (17 18) & AEBODSYS^=left(AEDECOD)) |
        (AEBODSYS='No action taken' & AEDECOD='^S={leftmargin=6pt}No action taken due to AE' & subl=.)
        )),
    sl1=subl,sl1t=sublt,sl1r=1 to 18,sl1f=subl.,
    exp=%str(' AE Serious^R"\line"          Yes (||SAE=)'
        ' AE related to IP^R"\line"          Not Related'
        ' AE related to study procedure^R"\line"          Not Related'
        ' AE severity^R"\line"          Mild'
        ' Action taken due to AE^R"\line"          Action taken with study product^R"\line"          Product use interr
upted'
        ' Treatment given^R"\line"          Yes'
        ' Other actions taken^R"\line"          Exdontia'
        ),
    ad=adae,CM=Y,any=N,osi=_os.,opi=_op.,socdsc=%str('Treatment given'))

```

```
%let tit2=Safety Time Period: Safety Follow-up;  
%maes(pwhere=SAFAFL='Y',awhere=SAFAFL='Y' and ASPER=4,f2=N,f3=Y,odn=t1502060101_5,tp=15,ht1=%nrquote(^S={}),  
      CM=Y,any=N,endo=Y,etext=Any adverse events)
```