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*****;
* Project          : ZRHM-REXA-07-JP
*
* Program name     : t1502060201_ZRHM_REXA_07_JP_v1.sas
*
* Author          : H Shu
*
* Date created     : 06/24/2015
*
* Purpose          : Create Table 15.2.6.2.1 Summary of AE by Product Use  Safety Population
*
* Revision History :
*
* Date      Author      Ref      Revision (Date in YYYYMMDD format)
* 07/13/2015 HS              Updated per PMP comments
* 07/16/2015 HS              Updated QC data set name per QC finding
*****;
%let prgname=T1502060201_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.));

data ADL;
set adam.adl;
if TRT01A='THSm2.2' then do;
    tg=1;
    TRT01A=GPUCAT1; /*no further mapping per PMP*/
    if GPUCAT1='THS 2.2' then TRT01AN=1;
    else if GPUCAT1='Not Abstinent' then TRT01AN=2;
    else if GPUCAT1='Missing' then TRT01AN=3;
end;
else if TRT01A='mCC' then do;
    tg=2;
    TRT01A=GPUCAT1;
    if GPUCAT1='CC' then TRT01AN=4;
    else if GPUCAT1='Missing' then TRT01AN=5;
end;
else if TRT01A='SA' then do;
    tg=3;
    TRT01A=GPUCAT1;
    if GPUCAT1='Abstinent' then TRT01AN=6;
    else if GPUCAT1='Predominantly Abstinent' then TRT01AN=7;
    else if GPUCAT1='Missing' then do;
        TRT01AN=8;
    end;
    TRT01A='Missing^S={}';
end;
end;

run;

/*order informat*/
proc format;
invalue _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;
invalue _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 _gtrxf 1='\brdrb\brdrs THSm2.2+(N=78)'
            2=' \brdrb\brdrs mCC+(N=42)'
            3=' \brdrb\brdrs SA+(N=40)'
            100=' ';
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" Exdontia'
            18='^R" " Tooth extraction'

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quit;

data ADAE;
merge adam.ADAE(in=in1 drop=TRTAN TRTA where=(ASPER=3)) ADSL(keep=USUBJID TRT01AN TRT01A);
by USUBJID;
if in1;

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=)';
subl=2;
end;
output;
sublt='';
subl=.;

/*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';
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';

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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;

rename TRT01AN=TRTAN TRT01A=TRTA;
run;

%global _ppg;
%let _ppg=0;
%let tit2=;
%maes(pwhere=SAFAFL='Y',awhere=SAFAFL='Y' and ASPER=3,odn=t1502060201,tp=3,ht1=%nrquote(^S={}Adverse events),f2=N,f3=Y,w
rap=18,
ps=15,tadj=N,tg=1,ptwhere=_flag='Y',
owhere=%nrquote(& TRTAN ^in (3 5 8 100) &
((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'
),
sld=adsl,ad=adae,CM=Y,any=N,osi=_os.,opi=_op.,endo=Y,socdsc=%str('Treatment given'),
f4=%nrquote("Note: No AE was observed in 3 subjects discontinued during confinement "
"(N=1 in each THSm2.2, mCC, and SA arm.) and in 1 subject (THSm2.2) with missing product use.))

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