

```

*****
** Program Name   : adds-s002-all1-ped6.sas                **
** Date Created  : 15Nov2021                               **
** Programmer Name : (b) (4), (b) (6)                      **
** Purpose       : Create adds-s002-all1-ped6              **
** Input data    : adsl adds                               **
** Output data   : adds-s002-all1-ped6.html               **
*****
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
title;
footnote;

**Setup the environment**
%let
bprot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_adam/saseng/cdisc3_0/;
%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_adam/saseng/cdisc3_0;
%let codename=adds-s002-all1-ped6;

libname datvprot "&bprot.data_vai" access=readonly;
%let outlog=&prot./analysis/eSUB/logs/&codename..log;
%let outtable=&prot./analysis/eSUB/output/&codename..html;

proc printto log="&outlog." new;
run;

proc datasets library=WORK kill nolist nodetails;
quit;

/* Format */
proc format;
value dsdecod 1="Adverse event" 3="Death" 5="Lost to follow-up" 7="Other"
8="Physician decision" 9="Pregnancy" 11="Protocol deviation"
13="Screen Failure" 14="Study terminated by sponsor"
16="Withdrawal by subject"
17="Medication error without associated adverse event"
18="No longer meets eligibility criteria"
25="Refused further study procedures" 26="Withdrawal by parent/guardian";
run;

/* Readin ADSL */
data g_a_dsin;
set datvprot.ADDS;
analysis_subset='Y';
run;

data g_adsl_dsin;
set datvprot.adsl;
where RANDFL eq 'Y' and AGEGR4N=1;
run;

proc sql noprint;

```

```

create table a_dsin as select * from g_a_dsin where usubjid in (select
    distinct usubjid from g_adsl_dsin);
quit;

data __trtmap;
length trtcode trtdec $100;

if 0 then
    set g_adsl_dsin(keep=TRT01PN);
trtval=1;

if vtype(TRT01PN)='C' then
    trtcode=tranwrd(compbl(quote("8")), ' ', " ");
else
    trtcode="8";
trtdec="BNT162b2 (30 (*ESC*){unicode 03BC}g)";
trtvar="TRT01PN";
trtlbl="TRT01P";
output;
trtval=2;

if vtype(TRT01PN)='C' then
    trtcode=tranwrd(compbl(quote("9")), ' ', " ");
else
    trtcode="9";
trtdec="Placebo";
trtvar="TRT01PN";
trtlbl="TRT01P";
output;
trtval=3;

if vtype(TRT01PN)='C' then
    trtcode=tranwrd(compbl(quote("8 9")), ' ', " ");
else
    trtcode="8 9";
trtdec="Total";
trtvar="TRT01PN";
trtlbl="TRT01P";
output;
stop;
run;

data g_adsl_dsin;
set g_adsl_dsin;

if TRT01PN in (8) then
    do;
        newtrtn=1;
        newtrt=coalescec("BNT162b2 (30 (*ESC*){unicode 03BC}g)", TRT01P);
        output;
    end;

if TRT01PN in (9) then
    do;

```

```

        newtrtn=2;
        newtrt=coalescec("Placebo", TRT01P);
        output;
    end;

if TRT01PN in (8 9) then
    do;
        newtrtn=3;
        newtrt=coalescec("Total", TRT01P);
        output;
    end;

run;

data g_a_dsin;
    set g_a_dsin;

    if TRT01PN in (8) then
        do;
            newtrtn=1;
            newtrt=coalescec("BNT162b2 (30 (*ESC*){unicode 03BC}g)", TRT01P);
            output;
        end;

    if TRT01PN in (9) then
        do;
            newtrtn=2;
            newtrt=coalescec("Placebo", TRT01P);
            output;
        end;

    if TRT01PN in (8 9) then
        do;
            newtrtn=3;
            newtrt=coalescec("Total", TRT01P);
            output;
        end;

run;

proc sort data=g_adsl_dsin out=_ds1;
    by usubjid newtrtn;
run;

proc sort data=g_a_dsin out=_ds2;
    by usubjid newtrtn;
run;

data final;
    merge _ds1(in=d1) _ds2(in=d2);
    by usubjid newtrtn;

    if d1;

run;

data _basetemplate(compress=no);

```

```

length _varname $8 _cvalue $35 _direct $20 _vrlabel $200 _rwlabel
    _colabel $800 _datatyp $5 _module $8 _pr_lbl $ 200;
array _c _character_;
delete;
run;

data _data1;
set final;
where (NEWTRTN is not missing);
run;

proc sort data=_data1;
by NEWTRTN USUBJID;
run;

data _data1;
retain _trt 0;
length _str $200;
_datasrt=1;
set _data1 end=eof;
by NEWTRTN USUBJID;
drop _str;
_str='';
_lastby=1;
_dummyby=0;

if first.NEWTRTN then
do;

        if not missing(NEWTRTN) then
do;
                _trt=_trt + 1;
                end;
                _str=NEWTRTN;

        if _trt > 0 then
                call symput('_trtlb'||compress(put(_trt, 4.)), trim(left(_str)));
end;
run;

proc sql noprint;
select compress(put(count(*), 5.)) into :_trt1 - :_trt3 from (select distinct
    USUBJID, _trt from _data1 where NEWTRTN is not missing) group by _trt;
select compress(put(count(*), 5.)) into :_trt4 from (select distinct USUBJID
    from _data1 where NEWTRTN is not missing);
quit;

proc sort data=_data1 out=_bydat1(keep=_datasrt _dummyby) nodupkey;
by _datasrt;
run;

data _bydat1;
set _bydat1 end=eof;
by _datasrt;

```

```

retain _preby 0;
drop _preby;
_byvar1=0;

if eof then
  do;
    call symput("_preby1", compress(put(_byvar1, 4.)));

    if 0=0 then
      output;
    end;
  run;

data _bydat1;
set _bydat1;
by _datasrt;
length _bycol _byindnt $50 _bylast $10;
_bycol=" ";
_byindnt=" ";
_bylast=" ";
run;

proc sort data=_bydat1;
by _datasrt;
run;

proc sort data=_data1 out=_data1;
by _datasrt;
run;

/* Create criteria flags */
data _data1;
set _data1;
_event1=ifN(RANDFL in ('Y'), 1, 0);
_event2=ifN(RANDFL eq 'Y' and (VAX101DT eq . and VAX102DT eq . and
  VAX10UDT=. and VAX201DT eq . and VAX202DT eq .), 1, 0);
_event3=ifN(RANDFL eq 'Y' and (VAX101DT ne . or VAX102DT ne .), 1, 0);
_event4=ifN(RANDFL eq 'Y' and VAX101DT ne ., 1, 0);
_event5=ifN(RANDFL eq 'Y' and VAX102DT ne . and (VAX102DT<UNBLNDDT or
  UNBLNDDT=.), 1, 0);
_event6=ifN(RANDFL eq 'Y' and DSPHASEN=26 and EOTDCDT ne . and dsdecodn not
  in (. 2) and (VAX101DT ne . or VAX102DT ne .) and (unblnddt=. or
  eotdcdt<unblnddt), 1, 0);
_event8=ifN(RANDFL eq 'Y' and UNBLNDDT ne . and (UNBLNDDT<=M1PD2DT or
  M1PD2DT=.), 1, 0);
_event9=ifN(RANDFL eq 'Y' and ((DSPHASEN=26 and dsdecodn=2) )
  and (unblnddt=. or astdt<unblnddt), 1, 0);
_event10=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
  in (. 2) and (VAX101DT ne . or VAX102DT ne .) and (unblnddt=. or
  eosdcdt<unblnddt) and EOSDCDT ne EOTXDCDT, 1, 0);
_event11=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
  in (. 2) and vax101dt ne . and ((vax101dt<=astdt and vax102dt eq .) or
  vax101dt<=astdt < vax102dt) and (unblnddt=. or eosdcdt<unblnddt) and EOSDCDT
  ne EOTXDCDT, 1, 0);

```

```

_event12=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax101dt ne . and vax102dt ne . and (vax102dt <=astdt
and (M1PD2DT eq . or astdt<M1PD2DT)) and (unblnddt=. or eoscdct<unblnddt) and
EOSDCDT ne EOTXDCDT, 1, 0);
_event13=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax101dt ne . and vax102dt ne . and M1PD2DT ne . and M1PD2DT le
astdt and (unblnddt=. or eoscdct<unblnddt) and EOSDCDT ne EOTXDCDT, 1, 0);
_event15=ifN(RANDFL eq 'Y' and (UNBLNDDT ne . or vax201dt ne .) and index(arm,
'BNT'), 1, 0);
_event16=ifN(RANDFL eq 'Y' and ((VAX102DT>=UNBLNDDT) or (index(VAX10u, 'BNT')
and VAX10UDT>=UNBLNDDT)) and UNBLNDDT ne . and index(arm, 'BNT'), 1, 0);
_event17=ifN(RANDFL eq 'Y' and ((DSPHASEN=26 and dsdecodn=2)) and (unblnddt
ne . and astdt>=unblnddt) and index(arm, 'BNT'), 1, 0);
_event18=ifN(RANDFL eq 'Y' and vax101dt ne . and vax102dt ne . and M6PD2DT
ne . and (UNBLNDDT ne . or vax201dt ne .) and index(arm, 'BNT'), 1, 0);
_event19=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and (VAX101DT ne . or VAX102DT ne .) and (unblnddt ne . and
eoscdct>=unblnddt) and index(arm, 'BNT'), 1, 0);
_event20=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and (VAX101DT ne . or VAX102DT ne .) and (M6PD2DT=. or
M6PD2DT> astdt) and (unblnddt ne . and eoscdct>=unblnddt) and index(arm,
'BNT'), 1, 0);
_event21=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax101dt ne . and vax102dt ne . and M6PD2DT ne . and M6PD2DT le
astdt and (unblnddt ne . and eoscdct>=unblnddt) and index(arm, 'BNT'), 1, 0);
_event23=ifN(RANDFL eq 'Y' and (UNBLNDDT ne . or vax201dt ne .) and
index(armcd, 'PLACEBO'), 1, 0);
_event24=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and (VAX201DT=. and VAX202DT=.) and (unblnddt ne . and
eoscdct>=unblnddt) and index(armcd, 'PLACEBO'), 1, 0);
_event25=ifN(RANDFL eq 'Y' and index(VAX201, 'BNT') and index(armcd,
'PLACEBO'), 1, 0);
_event26=ifN(RANDFL eq 'Y' and index(VAX202, 'BNT') and index(armcd,
'PLACEBO'), 1, 0);
_event27=ifN(RANDFL eq 'Y' and DSPHASEN=7 and EOTXDCDT ne . and dsdecodn not
in (. 2) and vax201dt ne . and index(armcd, 'PLACEBO'), 1, 0);
_event29=ifN(RANDFL eq 'Y' and ((DSPHASEN=7 and dsdecodn=2) ) and index(armcd,
'PLACEBO'), 1, 0);
_event30=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and (VAX201DT ne . or VAX202DT ne .) and ((unblnddt ne . and
eoscdct>=unblnddt) or eoscdct=eotxcdct) and index(armcd, 'PLACEBO'), 1, 0);
_event31=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax201dt ne . and ((vax201dt<=astdt and vax202dt eq .) or
vax201dt<=astdt < vax202dt) and ((unblnddt ne . and eoscdct>=unblnddt) or
eoscdct=eotxcdct) and index(armcd, 'PLACEBO'), 1, 0);
_event32=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax201dt ne . and vax202dt ne . and (vax202dt <=astdt
and (M1PX2DT eq . or astdt<M1PX2DT)) and ((unblnddt ne . and
eoscdct>=unblnddt) or eoscdct=eotxcdct) and index(armcd, 'PLACEBO'), 1, 0);
_event33=ifN(RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not
in (. 2) and vax201dt ne . and vax202dt ne . and M1PX2DT ne . and M1PX2DT le
astdt and ((unblnddt ne . and eoscdct>=unblnddt) or eoscdct=eotxcdct) and
index(armcd, 'PLACEBO'), 1, 0);

```

run;

```

/* Crit 1 */
data _anall;
  length _EVENT1 8;
  set _data1;
  where same and _EVENT1 is not missing;
  _blcksrt=1;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anall;
  by _datasrt _blcksrt _EVENT1 _trt _cat;
run;

data _temp1;
  set _anall;
  output;
run;

proc sort data=_temp1 out=_temp91 nodupkey;
  by _datasrt _blcksrt _cat _EVENT1 _trt usubjid;
  ;
run;

proc freq data=_temp91;
  format _EVENT1;
  tables _datasrt*_blcksrt*_cat * _EVENT1 * _trt / sparse norow nocol nopercnt
    out=_pct1(drop=percent);
run;

proc sort data=_anall out=_denom1(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom1;
  set _denom1;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

```

```

data _denomf1;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denomf1 out=_denomin1(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame1;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=1;
  length _EVENT1 8;
  _catLbl=" ";
  _trt=1;
  _EVENT1=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT1=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT1=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame1;
  by _datasrt _blcksrt _cat _EVENT1 _trt;
run;

proc sort data=_pct1;
  by _datasrt _blcksrt _cat _EVENT1 _trt;
run;

data _pct1;
  merge _frame1(in=_inframe) _pct1;
  by _datasrt _blcksrt _cat _EVENT1 _trt;

```



```

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct1;
    by _datasrt _blcksrt _EVENT1;
run;

data _miss1(keep=_datasrt _blcksrt _EVENT1 totcount);
    set _pct1;
    where _EVENT1=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT1;

    if first._EVENT1 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT1;
run;

data _pct1(drop=totcount);
    merge _pct1 _miss1;
    by _datasrt _blcksrt _EVENT1;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf1;
    by _datasrt _cat;
run;

proc sort data=_denomin1;
    by _datasrt _cat;
run;

data _denomin1;
    merge _denomf1(in=_inframe) _denomin1;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=1;
run;

proc sort data=_pct1;
    by _datasrt _cat;
run;

data _pct1;
    if 0 then
        set _basetemplate;

```

```

merge _denomin1(in=_a) _pct1;
by _datasrt _cat;

if _a;
  _varname="_EVENT1 ";
  _vrlabel=" ";
  _rwlabel="Randomized ";

if _EVENT1=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT1=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct1;
  by _datasrt _blcksrt _catord _EVENT1 _trt _cat;
run;

data _base1;
  length _catlabl $200;
  set _pct1 end=eof;
  by _datasrt _blcksrt _catord _EVENT1 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct=' ';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trcnt(_trt) > 0 then
      do;
        percent=count / _trcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then

```

```

                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
            else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
                _cvalue=trim(_cvalue)||_cpct;
            end;
        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT1 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=0;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 2 */
data _anal2;
    length _EVENT2 8;
    set _data1;
    where same and _EVENT2 is not missing;
    _blcksrt=1;
    _cnt=1;
    _cat=1;

if _trt <=0 then
    delete;
output;
run;

proc sort data=_anal2;
    by _datasrt _blcksrt _EVENT2 _trt _cat;

```

```

run;

data _temp2;
  set _anal2;
  output;
run;

proc sort data=_temp2 out=_temp92 nodupkey;
  by _datasrt _blcksrt _cat _EVENT2 _trt usubjid;
  ;
run;

proc freq data=_temp92;
  format _EVENT2;
  tables _datasrt*_blcksrt*_cat * _EVENT2 * _trt / sparse norow nocol nopercnt
  out=_pct2(drop=percent);
run;

proc sort data=_anal2 out=_denom2(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom2;
  set _denom2;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf2;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom2 out=_denomin2(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;

```

```

run;

data _frame2;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=1;
  length _EVENT2 8;
  _catLbl=" ";
  _trt=1;
  _EVENT2=1;
  _catord=1;
  _cat=1;
output;
  _trt=2;
  _EVENT2=1;
  _catord=1;
  _cat=1;
output;
  _trt=3;
  _EVENT2=1;
  _catord=1;
  _cat=1;
output;
run;

proc sort data=_frame2;
  by _datasrt _blcksrt _cat _EVENT2 _trt;
run;

proc sort data=_pct2;
  by _datasrt _blcksrt _cat _EVENT2 _trt;
run;

data _pct2;
  merge _frame2(in=_inframe) _pct2;
  by _datasrt _blcksrt _cat _EVENT2 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct2;
  by _datasrt _blcksrt _EVENT2;
run;

data _miss2(keep=_datasrt _blcksrt _EVENT2 totcount);
  set _pct2;
  where _EVENT2=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT2;

  if first._EVENT2 then

```

```

        totcount=0;
totcount=totcount+count;

if last._EVENT2;
run;

data _pct2(drop=totcount);
merge _pct2 _miss2;
by _datasrt _blcksrt _EVENT2;

if totcount=0 then
    delete;
run;

proc sort data=_denomf2;
by _datasrt _cat;
run;

proc sort data=_denomin2;
by _datasrt _cat;
run;

data _denomin2;
merge _denomf2(in=_inframe) _denomin2;
by _datasrt _cat;

if _inframe;
    _blcksrt=1;
run;

proc sort data=_pct2;
by _datasrt _cat;
run;

data _pct2;
if 0 then
    set _basetemplate;
merge _denomin2(in=_a) _pct2;
by _datasrt _cat;

if _a;
    _varname="_EVENT2 ";
    _vrlabel=" ";
    _rwlabel="Not vaccinated ";

if _EVENT2=9998 then
    do;
        _rwlabel="Missing ";
        _catord=9998;
    end;
else if _EVENT2=9999 then
    do;
        _rwlabel="Total ";
        _catord=9999;

```

```

        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct2;
    by _datasrt _blcksrt _catord _EVENT2 _trt _cat;
run;

data _base2;
    length _catlabl $200;
    set _pct2 end=eof;
    by _datasrt _blcksrt _catord _EVENT2 _trt _cat;
    retain _rowsrt 1 _rowmax 0;
    array _trcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

            if _trcnt(_trt) > 0 then
                do;
                    percent=count / _trcnt(_trt) * 100;

                    if percent > 0 then
                        do;

                            if round(percent, 0.1) GE 0.1 then
                                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
                            else
                                _cpct="(*ESC*){nbspspace 1}{(0.0)";
                                _cvalue=trim(_cvalue)||_cpct;
                            end;
                        end;
                    end;
                end;

            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

    if first._EVENT2 then
        do;
            _rowsrt=_rowsrt + 1;
            _rowmax=max(_rowsrt, _rowmax);

```

```

    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
        _indent=0;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4)));
        _direct="TOP ";
        _p=2;
run;

```

```

/* Crit 3 */
data _anal3;
    length _EVENT3 8;
    set _data1;
    where same and _EVENT3 is not missing;
    _blcksrt=1;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

```

```

proc sort data=_anal3;
    by _datasrt _blcksrt _EVENT3 _trt _cat;
run;

```

```

data _temp3;
    set _anal3;
    output;
run;

```

```

proc sort data=_temp3 out=_temp93 nodupkey;
    by _datasrt _blcksrt _cat _EVENT3 _trt usubjid;
    ;
run;

```

```

proc freq data=_temp93;
    format _EVENT3;
    tables _datasrt*_blcksrt*_cat * _EVENT3 * _trt / sparse norow nocol nopercnt
        out=_pct3(drop=percent);
run;

```



```

proc sort data=_anal3 out=_denom3(keep=_datasrt _cat) nodupkey;
  by _datasrt _cat;
run;

data _denom3;
  set _denom3;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf3;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom3 out=_denomin3(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame3;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=1;
  length _EVENT3 8;
  _catLabl=" ";
  _trt=1;
  _EVENT3=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT3=1;
  _catord=1;
  _cat=1;
  output;

```

```

    _trt=3;
    _EVENT3=1;
    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame3;
    by _datasrt _blcksrt _cat _EVENT3 _trt;
run;

proc sort data=_pct3;
    by _datasrt _blcksrt _cat _EVENT3 _trt;
run;

data _pct3;
    merge _frame3(in=_inframe) _pct3;
    by _datasrt _blcksrt _cat _EVENT3 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct3;
    by _datasrt _blcksrt _EVENT3;
run;

data _miss3(keep=_datasrt _blcksrt _EVENT3 totcount);
    set _pct3;
    where _EVENT3=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT3;

    if first._EVENT3 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT3;
run;

data _pct3(drop=totcount);
    merge _pct3 _miss3;
    by _datasrt _blcksrt _EVENT3;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf3;
    by _datasrt _cat;
run;

```

```

proc sort data=_denomin3;
    by _datasrt _cat;
run;

data _denomin3;
    merge _denomf3(in=_inframe) _denomin3;
    by _datasrt _cat;

    if _inframe;
        _blcksrt=1;
run;

proc sort data=_pct3;
    by _datasrt _cat;
run;

data _pct3;
    if 0 then
        set _basetemplate;
    merge _denomin3(in=_a) _pct3;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT3 ";
        _vrlabel="Original blinded placebo-controlled follow-up period ";
        _rwlabel="Vaccinated ";

    if _EVENT3=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT3=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct3;
    by _datasrt _blcksrt _catord _EVENT3 _trt _cat;
run;

data _base3;
    length _catlabl $200;
    set _pct3 end=eof;
    by _datasrt _blcksrt _catord _EVENT3 _trt _cat;
    retain _rowsrt 2 _rowmax 0;
    array _trtcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;

```

```

_cpct=' ';
_module='mcatstat';

if count > . then
    _cvalue=put(count, 5.);
else
    _cvalue=put(0, 5.);

if _trt ne . then
    do;

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||)";
                        else
                            _cpct="(*ESC*){nbspspace 1}(0.0)";
                        _cvalue=trim(_cvalue)||_cpct;
                    end;
                end;
            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT3 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rwlable)='_NONE_' then
    _rwlable=' ';
_indent=2;
_dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";

```

```

    _p=2;
run;

/* Crit 4 */
data _anal4;
    length _EVENT4 8;
    set _data1;
    where same and _EVENT4 is not missing;
    _blcksrt=1;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal4;
    by _datasrt _blcksrt _EVENT4 _trt _cat;
run;

data _temp4;
    set _anal4;
    output;
run;

proc sort data=_temp4 out=_temp94 nodupkey;
    by _datasrt _blcksrt _cat _EVENT4 _trt usubjid;
run;

proc freq data=_temp94;
    format _EVENT4;
    tables _datasrt*_blcksrt*_cat * _EVENT4 * _trt / sparse norow nocol nopercnt
        out=_pct4(drop=percent);
run;

proc sort data=_anal4 out=_denom4(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom4;
    set _denom4;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;

```

```

run;

data _denomf4;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denomf4 out=_denomin4(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame4;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=1;
  length _EVENT4 8;
  _catLabl=" ";
  _trt=1;
  _EVENT4=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT4=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT4=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame4;
  by _datasrt _blcksrt _cat _EVENT4 _trt;
run;

proc sort data=_pct4;
  by _datasrt _blcksrt _cat _EVENT4 _trt;
run;

data _pct4;
  merge _frame4(in=_inframe) _pct4;
  by _datasrt _blcksrt _cat _EVENT4 _trt;

```

```

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct4;
    by _datasrt _blcksrt _EVENT4;
run;

data _miss4(keep=_datasrt _blcksrt _EVENT4 totcount);
    set _pct4;
    where _EVENT4=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT4;

    if first._EVENT4 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT4;
run;

data _pct4(drop=totcount);
    merge _pct4 _miss4;
    by _datasrt _blcksrt _EVENT4;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf4;
    by _datasrt _cat;
run;

proc sort data=_denomin4;
    by _datasrt _cat;
run;

data _denomin4;
    merge _denomf4(in=_inframe) _denomin4;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=1;
run;

proc sort data=_pct4;
    by _datasrt _cat;
run;

data _pct4;
    if 0 then

```

```

        set _basetemplate;
merge _denomin4(in=_a) _pct4;
by _datasrt _cat;

if _a;
  _varname="_EVENT4 ";
  _vrlabel=" ";
  _rwlabel="Dose 1 ";

if _EVENT4=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT4=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct4;
  by _datasrt _blcksrt _catord _EVENT4 _trt _cat;
run;

data _base4;
  length _catlabl $200;
  set _pct4 end=eof;
  by _datasrt _blcksrt _catord _EVENT4 _trt _cat;
  retain _rowsrt 3 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

```



```

        if round(percent, 0.1) GE 0.1 then
            _cpct="(*ESC*){nbspace 1}("||strip(put(percent, 5.1))||")";
        else
            _cpct="(*ESC*){nbspace 1}(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
        end;
    end;
end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT4 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=4;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 5 */
data _anal5;
    length _EVENT5 8;
    set _data1;
    where same and _EVENT5 is not missing;
    _blcksrt=1;
    _cnt=1;
    _cat=1;

if _trt <=0 then
    delete;
output;
run;

proc sort data=_anal5;

```

```

    by _datasrt _blcksrt _EVENT5 _trt _cat;
run;

data _temp5;
    set _anal5;
    output;
run;

proc sort data=_temp5 out=_temp95 nodupkey;
    by _datasrt _blcksrt _cat _EVENT5 _trt usubjid;
    ;
run;

proc freq data=_temp95;
    format _EVENT5;
    tables _datasrt*_blcksrt*_cat * _EVENT5 * _trt / sparse norow nocol nopercnt
        out=_pct5(drop=percent);
run;

proc sort data=_anal5 out=_denom5(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom5;
    set _denom5;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf5;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom5 out=_denomin5(drop=_name __label __) prefix=_trt;
    by _datasrt _cat;
    var count;

```

```

    id_trt;
run;

data _frame5;
    _datasrt=1;
    set _bydat1(keep=);
    _blcksrt=1;
    length _EVENT5 8;
    _catLbl=" ";
    _trt=1;
    _EVENT5=1;
    _catord=1;
    _cat=1;
output;
    _trt=2;
    _EVENT5=1;
    _catord=1;
    _cat=1;
output;
    _trt=3;
    _EVENT5=1;
    _catord=1;
    _cat=1;
output;
run;

proc sort data=_frame5;
    by _datasrt _blcksrt _cat _EVENT5 _trt;
run;

proc sort data=_pct5;
    by _datasrt _blcksrt _cat _EVENT5 _trt;
run;

data _pct5;
    merge _frame5(in=_inframe) _pct5;
    by _datasrt _blcksrt _cat _EVENT5 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct5;
    by _datasrt _blcksrt _EVENT5;
run;

data _miss5(keep=_datasrt _blcksrt _EVENT5 totcount);
    set _pct5;
    where _EVENT5=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT5;

```

```

if first._EVENT5 then
    totcount=0;
totcount=totcount+count;

if last._EVENT5;
run;

data _pct5(drop=totcount);
merge _pct5 _miss5;
by _datasrt _blcksrt _EVENT5;

if totcount=0 then
    delete;
run;

proc sort data=_denomf5;
by _datasrt _cat;
run;

proc sort data=_denomin5;
by _datasrt _cat;
run;

data _denomin5;
merge _denomf5(in=_inframe) _denomin5;
by _datasrt _cat;

if _inframe;
    _blcksrt=1;
run;

proc sort data=_pct5;
by _datasrt _cat;
run;

data _pct5;
if 0 then
    set _basetemplate;
merge _denomin5(in=_a) _pct5;
by _datasrt _cat;

if _a;
    _varname="_EVENT5 ";
    _vrlabel=" ";
    _rwlabel="Dose 2 ";

if _EVENT5=9998 then
    do;
        _rwlabel="Missing ";
        _catord=9998;
    end;
else if _EVENT5=9999 then
    do;
        _rwlabel="Total ";

```

```

        _catord=9999;
    end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct5;
    by _datasrt _blcksrt _catord _EVENT5 _trt _cat;
run;

data _base5;
    length _catlabl $200;
    set _pct5 end=eof;
    by _datasrt _blcksrt _catord _EVENT5 _trt _cat;
    retain _rowsrt 4 _rowmax 0;
    array _trcnt(*) _trt1- _trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct=' ';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

            if _trcnt(_trt) > 0 then
                do;
                    percent=count / _trcnt(_trt) * 100;

                    if percent > 0 then
                        do;

                            if round(percent, 0.1) GE 0.1 then
                                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
                            else
                                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;
            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

    if first._EVENT5 then
        do;
            _rowsrt=_rowsrt + 1;

```

```

        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
        _indent=4;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=2;
run;

```

/* Crit 6 */

```

data _anal6;
    length _EVENT6 8;
    set _data1;
    where same and _EVENT6 is not missing;
    _blcksrt=2;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

```

```

proc sort data=_anal6;
    by _datasrt _blcksrt _EVENT6 _trt _cat;
run;

```

```

data _temp6;
    set _anal6;
    output;
run;

```

```

proc sort data=_temp6 out=_temp96 nodupkey;
    by _datasrt _blcksrt _cat _EVENT6 _trt usubjid;
run;

```

```

proc freq data=_temp96;
    format _EVENT6;
    tables _datasrt*_blcksrt*_cat * _EVENT6 * _trt / sparse norow nocol nopercnt
        out=_pct6(drop=percent);
run;

```

```

proc sort data=_anal6 out=_denom6(keep=_datasrt _cat) nodupkey;
;
by _datasrt _cat;
run;

data _denom6;
set _denom6;
by _datasrt _cat;
label count='count';
_trt=1;
count=&_trt1.;
output;
_trt=2;
count=&_trt2.;
output;
_trt=3;
count=&_trt3.;
output;
run;

data _denomf6;
_datasrt=1;
set _bydat1(keep=);
* All treatment groups ;
_trt1=0;
_trt2=0;
_trt3=0;
* _CAT is the subgroup variable ;
_cat=1;
output;
run;

proc transpose data=_denom6 out=_denomin6(drop=_name __label_) prefix=_trt;
by _datasrt _cat;
var count;
id _trt;
run;

data _frame6;
_datasrt=1;
set _bydat1(keep=);
_bkcsrt=2;
length _EVENT6 8;
_catLabl=" ";
_trt=1;
_EVENT6=1;
_catord=1;
_cat=1;
output;
_trt=2;
_EVENT6=1;
_catord=1;
_cat=1;

```

```

output;
  _trt=3;
  _EVENT6=1;
  _catord=1;
  _cat=1;
output;
run;

proc sort data=_frame6;
  by _datasrt _blcksrt _cat _EVENT6 _trt;
run;

proc sort data=_pct6;
  by _datasrt _blcksrt _cat _EVENT6 _trt;
run;

data _pct6;
  merge _frame6(in=_inframe) _pct6;
  by _datasrt _blcksrt _cat _EVENT6 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct6;
  by _datasrt _blcksrt _EVENT6;
run;

data _miss6(keep=_datasrt _blcksrt _EVENT6 totcount);
  set _pct6;
  where _EVENT6=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT6;

  if first._EVENT6 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT6;
run;

data _pct6(drop=totcount);
  merge _pct6 _miss6;
  by _datasrt _blcksrt _EVENT6;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf6;
  by _datasrt _cat;
run;

```



```

proc sort data=_denomin6;
  by _datasrt _cat;
run;

data _denomin6;
  merge _denomf6(in=_inframe) _denomin6;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=2;
run;

proc sort data=_pct6;
  by _datasrt _cat;
run;

data _pct6;
  if 0 then
    set _basetemplate;
  merge _denomin6(in=_a) _pct6;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT6 ";
  _vrlabel=" ";
  _rwlabel="Discontinued from original blinded placebo-controlled vaccination period~{super c}";

  if _EVENT6=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT6=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct6;
  by _datasrt _blcksrt _catord _EVENT6 _trt _cat;
run;

data _base6;
  length _catlabl $200;
  set _pct6 end=eof;
  by _datasrt _blcksrt _catord _EVENT6 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;

```

```

length _cpct $100;
_cpct='';
_module='mcatstat';

if count > . then
    _cvalue=put(count, 5.);
else
    _cvalue=put(0, 5.);

if _trt ne . then
    do;

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                        else
                            _cpct="(*ESC*){nbspspace 1}(0.0)";
                        _cvalue=trim(_cvalue)||_cpct;
                    end;
                end;
            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT6 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rlabel)='_NONE_' then
    _rlabel='';
_indent=2;
_dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));

```

```

    _direct="TOP ";
    _p=2;
run;

/* Crit 7 */
data _anal7;
    length DSDECODN 8;
    set _data1;
    where same and DSDECODN is not missing;
    _blcksrt=2;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal7;
    by _datasrt _blcksrt DSDECODN _trt _cat;
run;

data _temp7;
    set _anal7;
    output;
run;

proc sort data=_temp7 out=_temp97 nodupkey;
    by _datasrt _blcksrt _cat DSDECODN _trt usubjid;
    where RANDFL eq 'Y' and DSPHASEN=26 and EOTDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblniddt=. or eotdcdt<unblniddt);
run;

proc freq data=_temp97;
    format DSDECODN;
    tables _datasrt*_blcksrt*_cat * DSDECODN * _trt / sparse norow nocol nopercnt
        out=_pct7(drop=percent);
run;

proc sort data=_anal7 out=_denom7(keep=_datasrt _cat) nodupkey;
    where RANDFL eq 'Y' and DSPHASEN=26 and EOTDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblniddt=. or eotdcdt<unblniddt);
    by _datasrt _cat;
run;

data _denom7;
    set _denom7;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;

```

```

output;
  _trt=3;
count=&_trt3.;
output;
run;

data _denomf7;
  _datasrt=1;
set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
output;
run;

proc transpose data=_denom7 out=_denomin7(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

proc sort data=_pct7 out=_expv7 (keep=_datasrt _blcksrt DSDECODN) nodupkey;
  by _datasrt _blcksrt DSDECODN;
run;

proc sort data=_expv7;
  by _datasrt _blcksrt DSDECODN;
run;

data _frame7;
  set _expv7;
  by _datasrt _blcksrt DSDECODN;

  if first._blcksrt then
    _catord=0;
  _catord + 1;
  _trt=1;
  _cat=1;
output;
  _trt=2;
  _cat=1;
output;
  _trt=3;
  _cat=1;
output;
run;

proc sort data=_frame7;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

```

```

proc sort data=_pct7;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

data _pct7;
  merge _frame7(in=_inframe) _pct7;
  by _datasrt _blcksrt _cat DSDECODN _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct7;
  by _datasrt _blcksrt DSDECODN;
run;

data _miss7(keep=_datasrt _blcksrt DSDECODN totcount);
  set _pct7;
  where DSDECODN=9998;
  retain totcount;
  by _datasrt _blcksrt DSDECODN;

  if first.DSDECODN then
    totcount=0;
  totcount=totcount+count;

  if last.DSDECODN;
run;

data _pct7(drop=totcount);
  merge _pct7 _miss7;
  by _datasrt _blcksrt DSDECODN;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf7;
  by _datasrt _cat;
run;

proc sort data=_denomin7;
  by _datasrt _cat;
run;

data _denomin7;
  merge _denomf7(in=_inframe) _denomin7;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=2;
run;

```

```

proc sort data=_pct7;
    by _datasrt _cat;
run;

data _pct7;
    if 0 then
        set _basetemplate;
    merge _denomin7(in=_a) _pct7;
    by _datasrt _cat;

    if _a;
        _varname="DSDECODN ";
        _vrlabel="Reason for discontinuation ";
        _rwlabel=put(DSDECODN, dsdecod.);

    if DSDECODN=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if DSDECODN=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct7;
    by _datasrt _blcksrt _catord DSDECODN _trt _cat;
run;

data _base7;
    length _catlabl $200;
    set _pct7 end=eof;
    by _datasrt _blcksrt _catord DSDECODN _trt _cat;
    retain _rowsrt 1 _rowmax 0;
    array _trcnt(*) _trt1- _trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

```

```

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                        else
                            _cpct="(*ESC*){nbspspace 1}(0.0)";
                        _cvalue=trim(_cvalue)||_cpct;
                    end;
                end;
            end;

end;

/* if length(_cvalue) < 13 then */
/* do; */
/* -----;
/* Put character A0x at right most character to pad text;
/* -----;
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first.DSDECODN then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=8;
    _dptindt=4;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 8 */
data _anal8;
    length _EVENT8 8;
    set _data1;
    where same and _EVENT8 is not missing;

```

```

    _blcksrt=3;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal8;
    by _datasrt _blcksrt _EVENT8 _trt _cat;
run;

data _temp8;
    set _anal8;
    output;
run;

proc sort data=_temp8 out=_temp98 nodupkey;
    by _datasrt _blcksrt _cat _EVENT8 _trt usubjid;
run;

proc freq data=_temp98;
    format _EVENT8;
    tables _datasrt*_blcksrt*_cat * _EVENT8 * _trt / sparse norow nocol nopercnt
        out=_pct8(drop=percent);
run;

proc sort data=_anal8 out=_denom8(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom8;
    set _denom8;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf8;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;

```



```

    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom8 out=_denomin8(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame8;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=3;
  length _EVENT8 8;
  _catLabl=" ";
  _trt=1;
  _EVENT8=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT8=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT8=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame8;
  by _datasrt _blcksrt _cat _EVENT8 _trt;
run;

proc sort data=_pct8;
  by _datasrt _blcksrt _cat _EVENT8 _trt;
run;

data _pct8;
  merge _frame8(in=_inframe) _pct8;
  by _datasrt _blcksrt _cat _EVENT8 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct8;

```

```

    by _datasrt _blcksrt _EVENT8;
run;

data _miss8(keep=_datasrt _blcksrt _EVENT8 totcount);
    set _pct8;
    where _EVENT8=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT8;

    if first._EVENT8 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT8;
run;

data _pct8(drop=totcount);
    merge _pct8 _miss8;
    by _datasrt _blcksrt _EVENT8;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf8;
    by _datasrt _cat;
run;

proc sort data=_denomin8;
    by _datasrt _cat;
run;

data _denomin8;
    merge _denomf8(in=_inframe) _denomin8;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=3;
run;

proc sort data=_pct8;
    by _datasrt _cat;
run;

data _pct8;
    if 0 then
        set _basetemplate;
    merge _denomin8(in=_a) _pct8;
    by _datasrt _cat;

    if _a;
    _varname="_EVENT8 ";
    _vrlabel=" ";
    _rwlabel="Unblinded before 1-month post(*ESC*){unicode 2013}Dose 2 visit ";

```

FDA-CBER-2022-5812-0072158

```

if _EVENT8=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT8=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct8;
  by _datasrt _blcksrt _catord _EVENT8 _trt _cat;
run;

data _base8;
  length _catlabl $200;
  set _pct8 end=eof;
  by _datasrt _blcksrt _catord _EVENT8 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trcnt(_trt) > 0 then
      do;
        percent=count / _trcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
            else
              _cpct="(*ESC*){nbspspace 1}{(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
          end;
        end;
      end;
  end;
end;

```

```

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT8 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=2;
    _dptindt=0;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;

```

```
run;
```

```

/* Crit 9 */
data _anal9;
  length _EVENT9 8;
  set _data1;
  where same and _EVENT9 is not missing;
  _blcksrt=3;
  _cnt=1;
  _cat=1;

```

```

  if _trt <=0 then
    delete;
  output;

```

```
run;
```

```

proc sort data=_anal9;
  by _datasrt _blcksrt _EVENT9 _trt _cat;
run;

```

```

data _temp9;
  set _anal9;
  output;

```

```
run;
```

```

proc sort data=_temp9 out=_temp99 nodupkey;
  by _datasrt _blcksrt _cat _EVENT9 _trt usubjid;
;
run;

proc freq data=_temp99;
  format _EVENT9;
  tables _datasrt*_blcksrt*_cat * _EVENT9 * _trt / sparse norow nocol nopercnt
  out=_pct9(drop=percent);
run;

proc sort data=_anal9 out=_denom9(keep=_datasrt _cat) nodupkey;
;
  by _datasrt _cat;
run;

data _denom9;
  set _denom9;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf9;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom9 out=_denomin9(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame9;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=3;
  length _EVENT9 8;

```

```

    _catLbl=" ";
    _trt=1;
    _EVENT9=1;
    _catord=1;
    _cat=1;
output;
    _trt=2;
    _EVENT9=1;
    _catord=1;
    _cat=1;
output;
    _trt=3;
    _EVENT9=1;
    _catord=1;
    _cat=1;
output;
run;

proc sort data=_frame9;
  by _datasrt _blcksrt _cat _EVENT9 _trt;
run;

proc sort data=_pct9;
  by _datasrt _blcksrt _cat _EVENT9 _trt;
run;

data _pct9;
  merge _frame9(in=_inframe) _pct9;
  by _datasrt _blcksrt _cat _EVENT9 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct9;
  by _datasrt _blcksrt _EVENT9;
run;

data _miss9(keep=_datasrt _blcksrt _EVENT9 totcount);
  set _pct9;
  where _EVENT9=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT9;

  if first._EVENT9 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT9;
run;

data _pct9(drop=totcount);

```

```

merge _pct9 _miss9;
by _datasrt _blcksrt _EVENT9;

if totcount=0 then
    delete;
run;

proc sort data=_denomf9;
    by _datasrt _cat;
run;

proc sort data=_denomin9;
    by _datasrt _cat;
run;

data _denomin9;
    merge _denomf9(in=_inframe) _denomin9;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=3;
run;

proc sort data=_pct9;
    by _datasrt _cat;
run;

data _pct9;
    if 0 then
        set _basetemplate;
    merge _denomin9(in=_a) _pct9;
    by _datasrt _cat;

    if _a;
    _varname="_EVENT9 ";
    _vrlabel=" ";
    _rwlabel="Completed 1-month post(*ESC*){unicode 2013}Dose 2 visit ";

    if _EVENT9=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT9=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct9;

```

```

by _datasrt _blcksrt _catord _EVENT9 _trt _cat;
run;

data _base9;
length _catlabl $200;
set _pct9 end=eof;
by _datasrt _blcksrt _catord _EVENT9 _trt _cat;
retain _rowsrt 1 _rowmax 0;
array _trtcnt(*) _trt1-_trt4;
drop _rowmax _cpct;
length _cpct $100;
_cpct=' ';
_module='mcatstat';

if count > . then
    _cvalue=put(count, 5.);
else
    _cvalue=put(0, 5.);

if _trt ne . then
    do;

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
                        else
                            _cpct="(*ESC*){nbspspace 1}{(0.0)}";
                        _cvalue=trim(_cvalue)||_cpct;
                    end;
                end;
            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT9 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

```



```

if upcase(_rwlabel)='_NONE_' then
  _rwlabel='';
  _indent=2;
  _dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
  _direct="TOP ";
  _p=2;
run;

/* Crit 10 */
data _anal10;
  length _EVENT10 8;
  set _data1;
  where same and _EVENT10 is not missing;
  _blcksrt=4;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal10;
  by _datasrt _blcksrt _EVENT10 _trt _cat;
run;

data _temp10;
  set _anal10;
  output;
run;

proc sort data=_temp10 out=_temp910 nodupkey;
  by _datasrt _blcksrt _cat _EVENT10 _trt usubjid;
run;

proc freq data=_temp910;
  format _EVENT10;
  tables _datasrt*_blcksrt*_cat * _EVENT10 * _trt / sparse norow nocol nopercnt
  out=_pct10(drop=percent);
run;

proc sort data=_anal10 out=_denom10(keep=_datasrt _cat) nodupkey;
  by _datasrt _cat;
run;

data _denom10;
  set _denom10;
  by _datasrt _cat;

```

```

label count='count';
  _trt=1;
count=&_trt1.;
output;
  _trt=2;
count=&_trt2.;
output;
  _trt=3;
count=&_trt3.;
output;
run;

data _denomf10;
  _datasrt=1;
set _bydat1(keep=);
* All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
* _CAT is the subgroup variable ;
  _cat=1;
output;
run;

proc transpose data=_denomf10 out=_denomin10(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame10;
  _datasrt=1;
set _bydat1(keep=);
  _blcksrt=4;
length _EVENT10 8;
  _catLbl=" ";
  _trt=1;
  _EVENT10=1;
  _catord=1;
  _cat=1;
output;
  _trt=2;
  _EVENT10=1;
  _catord=1;
  _cat=1;
output;
  _trt=3;
  _EVENT10=1;
  _catord=1;
  _cat=1;
output;
run;

proc sort data=_frame10;

```

```

    by _datasrt _blcksrt _cat _EVENT10 _trt;
run;

proc sort data=_pct10;
    by _datasrt _blcksrt _cat _EVENT10 _trt;
run;

data _pct10;
    merge _frame10(in=_inframe) _pct10;
    by _datasrt _blcksrt _cat _EVENT10 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct10;
    by _datasrt _blcksrt _EVENT10;
run;

data _miss10(keep=_datasrt _blcksrt _EVENT10 totcount);
    set _pct10;
    where _EVENT10=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT10;

    if first._EVENT10 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT10;
run;

data _pct10(drop=totcount);
    merge _pct10 _miss10;
    by _datasrt _blcksrt _EVENT10;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf10;
    by _datasrt _cat;
run;

proc sort data=_denomin10;
    by _datasrt _cat;
run;

data _denomin10;
    merge _denomf10(in=_inframe) _denomin10;
    by _datasrt _cat;

```

```

    if _inframe;
        _blcksrt=4;
run;

proc sort data=_pct10;
    by _datasrt _cat;
run;

data _pct10;
    if 0 then
        set _basetemplate;
    merge _denomin10(in=_a) _pct10;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT10 ";
        _vrlabel=" ";
        _rwlabel="Withdrawn from the study ";

    if _EVENT10=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT10=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct10;
    by _datasrt _blcksrt _catord _EVENT10 _trt _cat;
run;

data _base10;
    length _catlabl $200;
    set _pct10 end=eof;
    by _datasrt _blcksrt _catord _EVENT10 _trt _cat;
    retain _rowsrt 0 _rowmax 0;
    array _trtcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct=' ';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

```

```

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
              else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/*   do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/*   end; */

if first._EVENT10 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatype='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlable)='_NONE_' then
    _rwlable=' ';
  _indent=2;
  _dptindt=0;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 11 */
data _anal11;
  length _EVENT11 8;
  set _data1;
  where same and _EVENT11 is not missing;

```

```

    _blcksrt=4;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anall1;
    by _datasrt _blcksrt _EVENT11 _trt _cat;
run;

data _temp11;
    set _anall1;
    output;
run;

proc sort data=_temp11 out=_temp911 nodupkey;
    by _datasrt _blcksrt _cat _EVENT11 _trt usubjid;
    ;
run;

proc freq data=_temp911;
    format _EVENT11;
    tables _datasrt*_blcksrt*_cat * _EVENT11 * _trt / sparse norow nocol nopercnt
        out=_pct11(drop=percent);
run;

proc sort data=_anall1 out=_denom11(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom11;
    set _denom11;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf11;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;

```

```

    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom11 out=_denomin11(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame11;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=4;
  length _EVENT11 8;
  _catLabl=" ";
  _trt=1;
  _EVENT11=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT11=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT11=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame11;
  by _datasrt _blcksrt _cat _EVENT11 _trt;
run;

proc sort data=_pct11;
  by _datasrt _blcksrt _cat _EVENT11 _trt;
run;

data _pct11;
  merge _frame11(in=_inframe) _pct11;
  by _datasrt _blcksrt _cat _EVENT11 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

```

```

proc sort data=_pct11;
  by _datasrt _blcksrt _EVENT11;
run;

data _miss11(keep=_datasrt _blcksrt _EVENT11 totcount);
  set _pct11;
  where _EVENT11=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT11;

  if first._EVENT11 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT11;
run;

data _pct11(drop=totcount);
  merge _pct11 _miss11;
  by _datasrt _blcksrt _EVENT11;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf11;
  by _datasrt _cat;
run;

proc sort data=_denomin11;
  by _datasrt _cat;
run;

data _denomin11;
  merge _denomf11(in=_inframe) _denomin11;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=4;
run;

proc sort data=_pct11;
  by _datasrt _cat;
run;

data _pct11;
  if 0 then
    set _basetemplate;
  merge _denomin11(in=_a) _pct11;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT11 ";
  _vrlabel=" ";

```



```

_rwlabel="Withdrawn after Dose 1 and before Dose 2 ";

if _EVENT11=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT11=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct11;
  by _datasrt _blcksrt _catord _EVENT11 _trt _cat;
run;

data _base11;
  length _catlabl $200;
  set _pct11 end=eof;
  by _datasrt _blcksrt _catord _EVENT11 _trt _cat;
  retain _rowsrt 1 _rowmax 0;
  array _trtcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);
*-----;
* Format percent to append to display value in _CVALUE ;
*-----;

if _trt ne . then
  do;

    if _trtcnt(_trt) > 0 then
      do;
        percent=count / _trtcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
            else
              _cpct="(*ESC*){nbspspace 1}(0.0)";
          end;
        end;
      end;
  end;

```

FDA-CBER-2022-5812-0072173

```

                _cvalue=trim(_cvalue)||_cpct;
            end;
        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/* -----;
/* Put character A0x at right most character to pad text;
/* -----;
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT11 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=4;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 12 */
data _anal12;
    length _EVENT12 8;
    set _data1;
    where same and _EVENT12 is not missing;
    _blcksrt=4;
    _cnt=1;
    _cat=1;

if _trt <=0 then
    delete;
output;
run;

proc sort data=_anal12;
    by _datasrt _blcksrt _EVENT12 _trt _cat;

```

```

run;

data _temp12;
  set _anal12;
  output;
run;

proc sort data=_temp12 out=_temp912 nodupkey;
  by _datasrt _blcksrt _cat _EVENT12 _trt usubjid;
run;

proc freq data=_temp912;
  format _EVENT12;
  tables _datasrt*_blcksrt*_cat * _EVENT12 * _trt / sparse norow nocol nopercnt
  out=_pct12(drop=percent);
run;

proc sort data=_anal12 out=_denom12(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom12;
  set _denom12;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf12;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom12 out=_denomin12(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

```

```

data _frame12;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=4;
  length _EVENT12 8;
  _catLbl=" ";
  _trt=1;
  _EVENT12=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT12=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT12=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame12;
  by _datasrt _blcksrt _cat _EVENT12 _trt;
run;

proc sort data=_pct12;
  by _datasrt _blcksrt _cat _EVENT12 _trt;
run;

data _pct12;
  merge _frame12(in=_inframe) _pct12;
  by _datasrt _blcksrt _cat _EVENT12 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct12;
  by _datasrt _blcksrt _EVENT12;
run;

data _miss12(keep=_datasrt _blcksrt _EVENT12 totcount);
  set _pct12;
  where _EVENT12=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT12;

  if first._EVENT12 then
    totcount=0;

```

```

totcount=totcount+count;

if last._EVENT12;
run;

data _pct12(drop=totcount);
merge _pct12 _miss12;
by _datasrt _blcksrt _EVENT12;

if totcount=0 then
delete;
run;

proc sort data=_denomf12;
by _datasrt _cat;
run;

proc sort data=_denomin12;
by _datasrt _cat;
run;

data _denomin12;
merge _denomf12(in=_inframe) _denomin12;
by _datasrt _cat;

if _inframe;
_blcksrt=4;
run;

proc sort data=_pct12;
by _datasrt _cat;
run;

data _pct12;
if 0 then
set _basetemplate;
merge _denomin12(in=_a) _pct12;
by _datasrt _cat;

if _a;
_varname="_EVENT12 ";
_vrlabel=" ";
_rwlabel="Withdrawn after Dose 2 and before 1-month post(*ESC*){unicode 2013}Dose 2 visit ";

if _EVENT12=9998 then
do;
_rwlabel="Missing ";
_catord=9998;
end;
else if _EVENT12=9999 then
do;
_rwlabel="Total ";
_catord=9999;
end;

```

```

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct12;
    by _datasrt _blcksrt _catord _EVENT12 _trt _cat;
run;

data _base12;
    length _catlabl $200;
    set _pct12 end=eof;
    by _datasrt _blcksrt _catord _EVENT12 _trt _cat;
    retain _rowsrt 2 _rowmax 0;
    array _trcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

            if _trcnt(_trt) > 0 then
                do;
                    percent=count / _trcnt(_trt) * 100;

                    if percent > 0 then
                        do;

                            if round(percent, 0.1) GE 0.1 then
                                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                            else
                                _cpct="(*ESC*){nbspspace 1}(0.0)";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;

            end;

        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

    if first._EVENT12 then
        do;
            _rowsrt=_rowsrt + 1;
            _rowmax=max(_rowsrt, _rowmax);
        end;

```

```

    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
    _indent=4;
    _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 13 */
data _anal13;
    length _EVENT13 8;
    set _data1;
    where same and _EVENT13 is not missing;
    _blcksrt=4;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal13;
    by _datasrt _blcksrt _EVENT13 _trt _cat;
run;

data _temp13;
    set _anal13;
    output;
run;

proc sort data=_temp13 out=_temp913 nodupkey;
    by _datasrt _blcksrt _cat _EVENT13 _trt usubjid;
    ;
run;

proc freq data=_temp913;
    format _EVENT13;
    tables _datasrt*_blcksrt*_cat * _EVENT13 * _trt / sparse norow nocol nopercnt
        out=_pct13(drop=percent);
run;

```

```

proc sort data=_anal13 out=_denom13(keep=_datasrt _cat) nodupkey;
;
by _datasrt _cat;
run;

data _denom13;
set _denom13;
by _datasrt _cat;
label count='count';
_trt=1;
count=&_trt1.;
output;
_trt=2;
count=&_trt2.;
output;
_trt=3;
count=&_trt3.;
output;
run;

data _denomf13;
_datasrt=1;
set _bydat1(keep=);
* All treatment groups ;
_trt1=0;
_trt2=0;
_trt3=0;
* _CAT is the subgroup variable ;
_cat=1;
output;
run;

proc transpose data=_denom13 out=_denomin13(drop=_name __label_) prefix=_trt;
by _datasrt _cat;
var count;
id _trt;
run;

data _frame13;
_datasrt=1;
set _bydat1(keep=);
_blcksrt=4;
length _EVENT13 8;
_catLbl=" ";
_trt=1;
_EVENT13=1;
_catord=1;
_cat=1;
output;
_trt=2;
_EVENT13=1;
_catord=1;
_cat=1;
output;

```



```

    _trt=3;
    _EVENT13=1;
    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame13;
    by _datasrt _blcksrt _cat _EVENT13 _trt;
run;

proc sort data=_pct13;
    by _datasrt _blcksrt _cat _EVENT13 _trt;
run;

data _pct13;
    merge _frame13(in=_inframe) _pct13;
    by _datasrt _blcksrt _cat _EVENT13 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct13;
    by _datasrt _blcksrt _EVENT13;
run;

data _miss13(keep=_datasrt _blcksrt _EVENT13 totcount);
    set _pct13;
    where _EVENT13=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT13;

    if first._EVENT13 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT13;
run;

data _pct13(drop=totcount);
    merge _pct13 _miss13;
    by _datasrt _blcksrt _EVENT13;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf13;
    by _datasrt _cat;
run;

```

```

proc sort data=_denomin13;
  by _datasrt _cat;
run;

data _denomin13;
  merge _denomf13(in=_inframe) _denomin13;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=4;
run;

proc sort data=_pct13;
  by _datasrt _cat;
run;

data _pct13;
  if 0 then
    set _basetemplate;
  merge _denomin13(in=_a) _pct13;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT13 ";
  _vrlabel=" ";
  _rwlabel="Withdrawn after 1-month post(*ESC*){unicode 2013}Dose 2 visit ";

  if _EVENT13=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT13=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct13;
  by _datasrt _blcksrt _catord _EVENT13 _trt _cat;
run;

data _base13;
  length _catlabl $200;
  set _pct13 end=eof;
  by _datasrt _blcksrt _catord _EVENT13 _trt _cat;
  retain _rowsrt 3 _rowmax 0;
  array _trtcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;

```

```

_cpct=' ';
_module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||)";
              else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT13 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rwlable)='_NONE_' then
  _rwlable=' ';
_indent=4;
_dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";

```

```

    _p=2;
run;

/* Crit 14 */
data _anal14;
    length DSDECODN 8;
    set _data1;
    where same and DSDECODN is not missing;
    _blcksrt=4;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal14;
    by _datasrt _blcksrt DSDECODN _trt _cat;
run;

data _temp14;
    set _anal14;
    output;
run;

proc sort data=_temp14 out=_temp914 nodupkey;
    by _datasrt _blcksrt _cat DSDECODN _trt usubjid;
    where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblnddt=. or eosdcdt<unblnddt) and
        EOSDCDT ne EOTXDCDT;
run;

proc freq data=_temp914;
    format DSDECODN;
    tables _datasrt*_blcksrt*_cat * DSDECODN * _trt / sparse norow nocol nopercnt
        out=_pct14(drop=percent);
run;

proc sort data=_anal14 out=_denom14(keep=_datasrt _cat) nodupkey;
    where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblnddt=. or eosdcdt<unblnddt) and
        EOSDCDT ne EOTXDCDT;
    by _datasrt _cat;
run;

data _denom14;
    set _denom14;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;

```

```

count=&_trt2.;
output;
_trt=3;
count=&_trt3.;
output;
run;

data _denomf14;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom14 out=_denomin14(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

proc sort data=_pct14 out=_expv14 (keep=_datasrt _blcksrt DSDECODN) nodupkey;
  by _datasrt _blcksrt DSDECODN;
run;

proc sort data=_expv14;
  by _datasrt _blcksrt DSDECODN;
run;

data _frame14;
  set _expv14;
  by _datasrt _blcksrt DSDECODN;

  if first._blcksrt then
    _catord=0;
  _catord + 1;
  _trt=1;
  _cat=1;
  output;
  _trt=2;
  _cat=1;
  output;
  _trt=3;
  _cat=1;
  output;
run;

proc sort data=_frame14;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

```

```

proc sort data=_pct14;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

data _pct14;
  merge _frame14(in=_inframe) _pct14;
  by _datasrt _blcksrt _cat DSDECODN _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct14;
  by _datasrt _blcksrt DSDECODN;
run;

data _miss14(keep=_datasrt _blcksrt DSDECODN totcount);
  set _pct14;
  where DSDECODN=9998;
  retain totcount;
  by _datasrt _blcksrt DSDECODN;

  if first.DSDECODN then
    totcount=0;
  totcount=totcount+count;

  if last.DSDECODN;
run;

data _pct14(drop=totcount);
  merge _pct14 _miss14;
  by _datasrt _blcksrt DSDECODN;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf14;
  by _datasrt _cat;
run;

proc sort data=_denomin14;
  by _datasrt _cat;
run;

data _denomin14;
  merge _denomf14(in=_inframe) _denomin14;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=4;

```

```

run;

proc sort data=_pct14;
  by _datasrt _cat;
run;

data _pct14;
  if 0 then
    set _basetemplate;
  merge _denomin14(in=_a) _pct14;
  by _datasrt _cat;

  if _a;
  _varname="DSDECODN ";
  _vrlabel="Reason for withdrawal from the study ";
  _rwlabel=put(DSDECODN, dsdecod.);

  if DSDECODN=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if DSDECODN=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct14;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
run;

data _base14;
  length _catlabl $200;
  set _pct14 end=eof;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
  retain _rowsrt 4 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

```

```

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspace 1}("||strip(put(percent, 5.1))||")";
                        else
                            _cpct="(*ESC*){nbspace 1}(0.0)";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;
            end;

/* if length(_cvalue) < 13 then */
/* do; */
/* -----;
/* Put character A0x at right most character to pad text;
/* -----;
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first.DSDECODN then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=8;
    _dptindt=4;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 15 */
data _anal15;
    length _EVENT15 8;
    set _data1;

```



```

where same and _EVENT15 is not missing;
  _blcksrt=5;
  _cnt=1;
  _cat=1;

if _trt <=0 then
  delete;
output;
run;

proc sort data=_anal15;
  by _datasrt _blcksrt _EVENT15 _trt _cat;
run;

data _temp15;
  set _anal15;
  output;
run;

proc sort data=_temp15 out=_temp915 nodupkey;
  by _datasrt _blcksrt _cat _EVENT15 _trt usubjid;
  ;
run;

proc freq data=_temp915;
  format _EVENT15;
  tables _datasrt*_blcksrt*_cat * _EVENT15 * _trt / sparse norow nocol nopercnt
  out=_pct15(drop=percent);
run;

proc sort data=_anal15 out=_denom15(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom15;
  set _denom15;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf15;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;

```

```

    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom15 out=_denomin15(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame15;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=5;
  length _EVENT15 8;
  _catLabl=" ";
  _trt=1;
  _EVENT15=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT15=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT15=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame15;
  by _datasrt _blcksrt _cat _EVENT15 _trt;
run;

proc sort data=_pct15;
  by _datasrt _blcksrt _cat _EVENT15 _trt;
run;

data _pct15;
  merge _frame15(in=_inframe) _pct15;
  by _datasrt _blcksrt _cat _EVENT15 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

```

```

proc sort data=_pct15;
  by _datasrt _blcksrt _EVENT15;
run;

data _miss15(keep=_datasrt _blcksrt _EVENT15 totcount);
  set _pct15;
  where _EVENT15=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT15;

  if first._EVENT15 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT15;
run;

data _pct15(drop=totcount);
  merge _pct15 _miss15;
  by _datasrt _blcksrt _EVENT15;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf15;
  by _datasrt _cat;
run;

proc sort data=_denomin15;
  by _datasrt _cat;
run;

data _denomin15;
  merge _denomf15(in=_inframe) _denomin15;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=5;
run;

proc sort data=_pct15;
  by _datasrt _cat;
run;

data _pct15;
  if 0 then
    set _basetemplate;
  merge _denomin15(in=_a) _pct15;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT15 ";

```

```

_vrlabel="Open-label follow-up period ";
_rwlabel="Originally randomized to BNT162b2 ";

if _EVENT15=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT15=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct15;
  by _datasrt _blcksrt _catord _EVENT15 _trt _cat;
run;

data _base15;
  length _catlabl $200;
  set _pct15 end=eof;
  by _datasrt _blcksrt _catord _EVENT15 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct=' ';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trcnt(_trt) > 0 then
      do;
        percent=count / _trcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
            else
              _cpct="(*ESC*){nbspspace 1}{(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
          end;
        end;
      end;
  end;

```

```

        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT15 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
        _indent=2;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4)));
        _direct="TOP ";
        _p=2;
run;

/* Crit 16 */
data _anal16;
    length _EVENT16 8;
    set _data1;
    where same and _EVENT16 is not missing;
    _blcksrt=5;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal16;
    by _datasrt _blcksrt _EVENT16 _trt _cat;
run;

data _temp16;
    set _anal16;
    output;

```

```

run;

proc sort data=_temp16 out=_temp916 nodupkey;
  by _datasrt _blcksrt _cat _EVENT16 _trt usubjid;
  ;
run;

proc freq data=_temp916;
  format _EVENT16;
  tables _datasrt*_blcksrt*_cat * _EVENT16 * _trt / sparse norow nocol nopercnt
  out=_pct16(drop=percent);
run;

proc sort data=_anal16 out=_denom16(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom16;
  set _denom16;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf16;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom16 out=_denomin16(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame16;
  _datasrt=1;
  set _bydat1(keep=);

```

```

    _blcksrt=5;
length _EVENT16 8;
    _catLbl=" ";
    _trt=1;
    _EVENT16=1;
    _catord=1;
    _cat=1;
output;
    _trt=2;
    _EVENT16=1;
    _catord=1;
    _cat=1;
output;
    _trt=3;
    _EVENT16=1;
    _catord=1;
    _cat=1;
output;
run;

proc sort data=_frame16;
    by _datasrt _blcksrt _cat _EVENT16 _trt;
run;

proc sort data=_pct16;
    by _datasrt _blcksrt _cat _EVENT16 _trt;
run;

data _pct16;
    merge _frame16(in=_inframe) _pct16;
    by _datasrt _blcksrt _cat _EVENT16 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct16;
    by _datasrt _blcksrt _EVENT16;
run;

data _miss16(keep=_datasrt _blcksrt _EVENT16 totcount);
    set _pct16;
    where _EVENT16=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT16;

    if first._EVENT16 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT16;
run;

```

```

data _pct16(drop=totcount);
  merge _pct16 _miss16;
  by _datasrt _blcksrt _EVENT16;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf16;
  by _datasrt _cat;
run;

proc sort data=_denomin16;
  by _datasrt _cat;
run;

data _denomin16;
  merge _denomf16(in=_inframe) _denomin16;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=5;
run;

proc sort data=_pct16;
  by _datasrt _cat;
run;

data _pct16;
  if 0 then
    set _basetemplate;
  merge _denomin16(in=_a) _pct16;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT16 ";
  _vrlabel=" ";
  _rwlabel="Received Dose 2/unplanned dose ";

  if _EVENT16=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT16=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

```



```

proc sort data=_pct16;
  by _datasrt _blcksrt _catord _EVENT16 _trt _cat;
run;

data _base16;
  length _catlabl $200;
  set _pct16 end=eof;
  by _datasrt _blcksrt _catord _EVENT16 _trt _cat;
  retain _rowsrt 1 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

  /* if length(_cvalue) < 13 then */
  /*   do; */
  /*     substr(_cvalue, 13, 1)='A0'x; */
  /*   end; */

  if first._EVENT16 then
    do;
      _rowsrt=_rowsrt + 1;
      _rowmax=max(_rowsrt, _rowmax);
    end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;

```

```

_rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
_indent=4;
_dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";
_p=2;
run;

/* Crit 17 */
data _anal17;
    length _EVENT17 8;
    set _data1;
    where same and _EVENT17 is not missing;
    _blcksrt=5;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal17;
    by _datasrt _blcksrt _EVENT17 _trt _cat;
run;

data _temp17;
    set _anal17;
    output;
run;

proc sort data=_temp17 out=_temp917 nodupkey;
    by _datasrt _blcksrt _cat _EVENT17 _trt usubjid;
    ;
run;

proc freq data=_temp917;
    format _EVENT17;
    tables _datasrt*_blcksrt*_cat * _EVENT17 * _trt / sparse norow nocol nopercnt
        out=_pct17(drop=percent);
run;

proc sort data=_anal17 out=_denom17(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

```

```

data _denom17;
  set _denom17;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

```

```

data _denomf17;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

```

```

proc transpose data=_denom17 out=_denomin17(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

```

```

data _frame17;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=5;
  length _EVENT17 8;
  _catLabl=" ";
  _trt=1;
  _EVENT17=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT17=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT17=1;
  _catord=1;
  _cat=1;

```

```

output;
run;

proc sort data=_frame17;
  by _datasrt _blcksrt _cat _EVENT17 _trt;
run;

proc sort data=_pct17;
  by _datasrt _blcksrt _cat _EVENT17 _trt;
run;

data _pct17;
  merge _frame17(in=_inframe) _pct17;
  by _datasrt _blcksrt _cat _EVENT17 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct17;
  by _datasrt _blcksrt _EVENT17;
run;

data _miss17(keep=_datasrt _blcksrt _EVENT17 totcount);
  set _pct17;
  where _EVENT17=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT17;

  if first._EVENT17 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT17;
run;

data _pct17(drop=totcount);
  merge _pct17 _miss17;
  by _datasrt _blcksrt _EVENT17;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf17;
  by _datasrt _cat;
run;

proc sort data=_denomin17;
  by _datasrt _cat;
run;

```

```

data _denomin17;
  merge _denomf17(in=_inframe) _denomin17;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=5;
run;

proc sort data=_pct17;
  by _datasrt _cat;
run;

data _pct17;
  if 0 then
    set _basetemplate;
  merge _denomin17(in=_a) _pct17;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT17 ";
  _vrlabel=" ";
  _rwlabel="Completed 1-month post(*ESC*){unicode 2013}Dose 2 visit ";

  if _EVENT17=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT17=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct17;
  by _datasrt _blcksrt _catord _EVENT17 _trt _cat;
run;

data _base17;
  length _catlabl $200;
  set _pct17 end=eof;
  by _datasrt _blcksrt _catord _EVENT17 _trt _cat;
  retain _rowsrt 2 _rowmax 0;
  array _trtcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then

```

```

        _cvalue=put(count, 5.);
else
    _cvalue=put(0, 5.);

if _trt ne . then
    do;

        if _trtcnt(_trt) > 0 then
            do;
                percent=count / _trtcnt(_trt) * 100;

                if percent > 0 then
                    do;

                        if round(percent, 0.1) GE 0.1 then
                            _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
                        else
                            _cpct="(*ESC*){nbspspace 1}{(0.0)";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;
            end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT17 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=4;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 18 */

```

```

data _anal18;
  length _EVENT18 8;
  set _data1;
  where same and _EVENT18 is not missing;
  _blcksrt=5;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal18;
  by _datasrt _blcksrt _EVENT18 _trt _cat;
run;

data _temp18;
  set _anal18;
  output;
run;

proc sort data=_temp18 out=_temp918 nodupkey;
  by _datasrt _blcksrt _cat _EVENT18 _trt usubjid;
  ;
run;

proc freq data=_temp918;
  format _EVENT18;
  tables _datasrt*_blcksrt*_cat * _EVENT18 * _trt / sparse norow nocol nopercnt
  out=_pct18(drop=percent);
run;

proc sort data=_anal18 out=_denom18(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom18;
  set _denom18;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf18;

```

```

    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom18 out=_denomin18(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame18;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=5;
  length _EVENT18 8;
  _catLabl=" ";
  _trt=1;
  _EVENT18=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT18=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT18=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame18;
  by _datasrt _blcksrt _cat _EVENT18 _trt;
run;

proc sort data=_pct18;
  by _datasrt _blcksrt _cat _EVENT18 _trt;
run;

data _pct18;
  merge _frame18(in=_inframe) _pct18;
  by _datasrt _blcksrt _cat _EVENT18 _trt;

  if _inframe;

```



```

        if count=. then
            count=0;
run;

proc sort data=_pct18;
    by _datasrt _blcksrt _EVENT18;
run;

data _miss18(keep=_datasrt _blcksrt _EVENT18 totcount);
    set _pct18;
    where _EVENT18=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT18;

    if first._EVENT18 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT18;
run;

data _pct18(drop=totcount);
    merge _pct18 _miss18;
    by _datasrt _blcksrt _EVENT18;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf18;
    by _datasrt _cat;
run;

proc sort data=_denomin18;
    by _datasrt _cat;
run;

data _denomin18;
    merge _denomf18(in=_inframe) _denomin18;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=5;
run;

proc sort data=_pct18;
    by _datasrt _cat;
run;

data _pct18;
    if 0 then
        set _basetemplate;
    merge _denomin18(in=_a) _pct18;
    by _datasrt _cat;

```

```

if _a;
  _varname="_EVENT18 ";
  _vrlabel=" ";
  _rwlabel="Completed 6-month post(*ESC*){unicode 2013}Dose 2 visit ";

if _EVENT18=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT18=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct18;
  by _datasrt _blcksrt _catord _EVENT18 _trt _cat;
run;

data _base18;
  length _catlabl $200;
  set _pct18 end=eof;
  by _datasrt _blcksrt _catord _EVENT18 _trt _cat;
  retain _rowsrt 3 _rowmax 0;
  array _trcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct=' ';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trcnt(_trt) > 0 then
      do;
        percent=count / _trcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||)";
            else

```

```

                _cpct="(*ESC*){nbspace 1}(0.0)";
                _cvalue=trim(_cvalue)||_cpct;
            end;
        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT18 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
        _indent=4;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=2;
run;

/* Crit 19 */
data _anal19;
    length _EVENT19 8;
    set _data1;
    where same and _EVENT19 is not missing;
    _blcksrt=5;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal19;
    by _datasrt _blcksrt _EVENT19 _trt _cat;
run;

```

```

data _temp19;
  set _anal19;
  output;
run;

proc sort data=_temp19 out=_temp919 nodupkey;
  by _datasrt _blcksrt _cat _EVENT19 _trt usubjid;
  ;
run;

proc freq data=_temp919;
  format _EVENT19;
  tables _datasrt*_blcksrt*_cat * _EVENT19 * _trt / sparse norow nocol nopercnt
  out=_pct19(drop=percent);
run;

proc sort data=_anal19 out=_denom19(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom19;
  set _denom19;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf19;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom19 out=_denomin19(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

```

```

data _frame19;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=5;
  length _EVENT19 8;
  _catLbl=" ";
  _trt=1;
  _EVENT19=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT19=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT19=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame19;
  by _datasrt _blcksrt _cat _EVENT19 _trt;
run;

proc sort data=_pct19;
  by _datasrt _blcksrt _cat _EVENT19 _trt;
run;

data _pct19;
  merge _frame19(in=_inframe) _pct19;
  by _datasrt _blcksrt _cat _EVENT19 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct19;
  by _datasrt _blcksrt _EVENT19;
run;

data _miss19(keep=_datasrt _blcksrt _EVENT19 totcount);
  set _pct19;
  where _EVENT19=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT19;

  if first._EVENT19 then
    totcount=0;
  totcount=totcount+count;

```

```

    if last._EVENT19;
run;

data _pct19(drop=totcount);
    merge _pct19 _miss19;
    by _datasrt _blcksrt _EVENT19;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf19;
    by _datasrt _cat;
run;

proc sort data=_denomin19;
    by _datasrt _cat;
run;

data _denomin19;
    merge _denomf19(in=_inframe) _denomin19;
    by _datasrt _cat;

    if _inframe;
        _blcksrt=5;
run;

proc sort data=_pct19;
    by _datasrt _cat;
run;

data _pct19;
    if 0 then
        set _basetemplate;
    merge _denomin19(in=_a) _pct19;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT19 ";
        _vrlabel=" ";
        _rwlabel="Withdrawn from the study ";

    if _EVENT19=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT19=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;
end;

```

```

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct19;
    by _datasrt _blcksrt _catord _EVENT19 _trt _cat;
run;

data _base19;
    length _catlabl $200;
    set _pct19 end=eof;
    by _datasrt _blcksrt _catord _EVENT19 _trt _cat;
    retain _rowsrt 4 _rowmax 0;
    array _trcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

            if _trcnt(_trt) > 0 then
                do;
                    percent=count / _trcnt(_trt) * 100;

                    if percent > 0 then
                        do;

                            if round(percent, 0.1) GE 0.1 then
                                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                            else
                                _cpct="(*ESC*){nbspspace 1}(0.0)";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;

            end;
        end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

    if first._EVENT19 then
        do;
            _rowsrt=_rowsrt + 1;
            _rowmax=max(_rowsrt, _rowmax);
        end;
    _datatyp='data';

```

FDA-CBER-2022-5812-0072211

```

    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=4;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 20 */
data _anal20;
    length _EVENT20 8;
    set _data1;
    where same and _EVENT20 is not missing;
    _blcksrt=5;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal20;
    by _datasrt _blcksrt _EVENT20 _trt _cat;
run;

data _temp20;
    set _anal20;
    output;
run;

proc sort data=_temp20 out=_temp920 nodupkey;
    by _datasrt _blcksrt _cat _EVENT20 _trt usubjid;
    ;
run;

proc freq data=_temp920;
    format _EVENT20;
    tables _datasrt*_blcksrt*_cat * _EVENT20 * _trt / sparse norow nocol nopercnt
        out=_pct20(drop=percent);
run;

proc sort data=_anal20 out=_denom20(keep=_datasrt _cat) nodupkey;

```



```

;
by _datasrt _cat;
run;

data _denom20;
set _denom20;
by _datasrt _cat;
label count='count';
_trt=1;
count=&_trt1.;
output;
_trt=2;
count=&_trt2.;
output;
_trt=3;
count=&_trt3.;
output;
run;

data _denomf20;
_datasrt=1;
set _bydat1(keep=);
* All treatment groups ;
_trt1=0;
_trt2=0;
_trt3=0;
* _CAT is the subgroup variable ;
_cat=1;
output;
run;

proc transpose data=_denom20 out=_denomin20(drop=_name __label_) prefix=_trt;
by _datasrt _cat;
var count;
id _trt;
run;

data _frame20;
_datasrt=1;
set _bydat1(keep=);
_blcksrt=5;
length _EVENT20 8;
_catLabl=" ";
_trt=1;
_EVENT20=1;
_catord=1;
_cat=1;
output;
_trt=2;
_EVENT20=1;
_catord=1;
_cat=1;
output;
_trt=3;

```

```

    _EVENT20=1;
    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame20;
    by _datasrt _blcksrt _cat _EVENT20 _trt;
run;

proc sort data=_pct20;
    by _datasrt _blcksrt _cat _EVENT20 _trt;
run;

data _pct20;
    merge _frame20(in=_inframe) _pct20;
    by _datasrt _blcksrt _cat _EVENT20 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct20;
    by _datasrt _blcksrt _EVENT20;
run;

data _miss20(keep=_datasrt _blcksrt _EVENT20 totcount);
    set _pct20;
    where _EVENT20=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT20;

    if first._EVENT20 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT20;
run;

data _pct20(drop=totcount);
    merge _pct20 _miss20;
    by _datasrt _blcksrt _EVENT20;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf20;
    by _datasrt _cat;
run;

proc sort data=_denomin20;

```

```

    by _datasrt _cat;
run;

data _denomin20;
    merge _denomf20(in=_inframe) _denomin20;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=5;
run;

proc sort data=_pct20;
    by _datasrt _cat;
run;

data _pct20;
    if 0 then
        set _basetemplate;
    merge _denomin20(in=_a) _pct20;
    by _datasrt _cat;

    if _a;
    _varname="_EVENT20 ";
    _vrlabel=" ";
    _rwlabel="Withdrawn before 6-month post(*ESC*){unicode 2013}Dose 2 visit ";

    if _EVENT20=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT20=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct20;
    by _datasrt _blcksrt _catord _EVENT20 _trt _cat;
run;

data _base20;
    length _catlabl $200;
    set _pct20 end=eof;
    by _datasrt _blcksrt _catord _EVENT20 _trt _cat;
    retain _rowsrt 5 _rowmax 0;
    array _trtcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct=' ';

```

```

_module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT20 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
_indent=6;
_dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";
_p=2;

```

```

run;

/* Crit 21 */
data _anal21;
  length _EVENT21 8;
  set _data1;
  where same and _EVENT21 is not missing;
  _blcksrt=5;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal21;
  by _datasrt _blcksrt _EVENT21 _trt _cat;
run;

data _temp21;
  set _anal21;
  output;
run;

proc sort data=_temp21 out=_temp921 nodupkey;
  by _datasrt _blcksrt _cat _EVENT21 _trt usubjid;
  ;
run;

proc freq data=_temp921;
  format _EVENT21;
  tables _datasrt*_blcksrt*_cat * _EVENT21 * _trt / sparse norow nocol nopercnt
    out=_pct21(drop=percent);
run;

proc sort data=_anal21 out=_denom21(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom21;
  set _denom21;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;

```

```

run;

data _denomf21;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom21 out=_denomin21(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame21;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=5;
  length _EVENT21 8;
  _catLabl=" ";
  _trt=1;
  _EVENT21=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT21=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT21=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame21;
  by _datasrt _blcksrt _cat _EVENT21 _trt;
run;

proc sort data=_pct21;
  by _datasrt _blcksrt _cat _EVENT21 _trt;
run;

data _pct21;
  merge _frame21(in=_inframe) _pct21;
  by _datasrt _blcksrt _cat _EVENT21 _trt;

```

```

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct21;
    by _datasrt _blcksrt _EVENT21;
run;

data _miss21(keep=_datasrt _blcksrt _EVENT21 totcount);
    set _pct21;
    where _EVENT21=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT21;

    if first._EVENT21 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT21;
run;

data _pct21(drop=totcount);
    merge _pct21 _miss21;
    by _datasrt _blcksrt _EVENT21;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf21;
    by _datasrt _cat;
run;

proc sort data=_denomin21;
    by _datasrt _cat;
run;

data _denomin21;
    merge _denomf21(in=_inframe) _denomin21;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=5;
run;

proc sort data=_pct21;
    by _datasrt _cat;
run;

data _pct21;
    if 0 then

```

```

        set _basetemplate;
merge _denomin21(in=_a) _pct21;
by _datasrt _cat;

if _a;
  _varname="_EVENT21 ";
  _vrlabel=" ";
  _rwlabel="Withdrawn after 6-month post(*ESC*){unicode 2013}Dose 2 visit ";

if _EVENT21=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT21=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct21;
  by _datasrt _blcksrt _catord _EVENT21 _trt _cat;
run;

data _base21;
  length _catlabl $200;
  set _pct21 end=eof;
  by _datasrt _blcksrt _catord _EVENT21 _trt _cat;
  retain _rowsrt 6 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

```



```

        if round(percent, 0.1) GE 0.1 then
            _cpct="(*ESC*){nbspace 1}("||strip(put(percent, 5.1))||")";
        else
            _cpct="(*ESC*){nbspace 1}(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
        end;
    end;
end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT21 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rwlabel)='_NONE_' then
        _rwlabel=' ';
        _indent=6;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=2;
run;

/* Crit 22 */
data _anal22;
    length DSDECODN 8;
    set _data1;
    where same and DSDECODN is not missing;
    _blcksrt=5;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal22;

```

```

    by _datasrt _blcksrt DSDECODN _trt _cat;
run;

data _temp22;
    set _anal22;
    output;
run;

proc sort data=_temp22 out=_temp922 nodupkey;
    by _datasrt _blcksrt _cat DSDECODN _trt usubjid;
    where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblnddt ne . and
            eosdcdt>=unblnddt) and index(arm, 'BNT');
run;

proc freq data=_temp922;
    format DSDECODN;
    tables _datasrt*_blcksrt*_cat * DSDECODN * _trt / sparse norow nocol nopercnt
        out=_pct22(drop=percent);
run;

proc sort data=_anal22 out=_denom22(keep=_datasrt _cat) nodupkey;
    where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
        and (VAX101DT ne . or VAX102DT ne .) and (unblnddt ne . and
            eosdcdt>=unblnddt) and index(arm, 'BNT');
    by _datasrt _cat;
run;

data _denom22;
    set _denom22;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf22;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

```

```

proc transpose data=_denom22 out=_denomin22(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

proc sort data=_pct22 out=_expv22 (keep=_datasrt _blcksrt DSDECODN) nodupkey;
  by _datasrt _blcksrt DSDECODN;
run;

proc sort data=_expv22;
  by _datasrt _blcksrt DSDECODN;
run;

data _frame22;
  set _expv22;
  by _datasrt _blcksrt DSDECODN;

  if first._blcksrt then
    _catord=0;
  _catord + 1;
  _trt=1;
  _cat=1;
  output;
  _trt=2;
  _cat=1;
  output;
  _trt=3;
  _cat=1;
  output;
run;

proc sort data=_frame22;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

proc sort data=_pct22;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

data _pct22;
  merge _frame22(in=_inframe) _pct22;
  by _datasrt _blcksrt _cat DSDECODN _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct22;
  by _datasrt _blcksrt DSDECODN;
run;

```

```

data _miss22(keep=_datasrt _blcksrt DSDECODN totcount);
  set _pct22;
  where DSDECODN=9998;
  retain totcount;
  by _datasrt _blcksrt DSDECODN;

  if first.DSDECODN then
    totcount=0;
  totcount=totcount+count;

  if last.DSDECODN;
run;

data _pct22(drop=totcount);
  merge _pct22 _miss22;
  by _datasrt _blcksrt DSDECODN;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf22;
  by _datasrt _cat;
run;

proc sort data=_denomin22;
  by _datasrt _cat;
run;

data _denomin22;
  merge _denomf22(in=_inframe) _denomin22;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=5;
run;

proc sort data=_pct22;
  by _datasrt _cat;
run;

data _pct22;
  if 0 then
    set _basetemplate;
  merge _denomin22(in=_a) _pct22;
  by _datasrt _cat;

  if _a;
  _varname="DSDECODN ";
  _vrlabel="Reason for withdrawal from the study ";
  _rwlabel=put(DSDECODN, dsdecod.);

  if DSDECODN=9998 then

```

```

do;
  _rwlabel="Missing ";
  _catord=9998;
end;
else if DSDECODN=9999 then
do;
  _rwlabel="Total ";
  _catord=9999;
end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct22;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
run;

data _base22;
  length _catlabl $200;
  set _pct22 end=eof;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
  retain _rowsrt 7 _rowmax 0;
  array _trtcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;
    end;

  /* if length(_cvalue) < 13 then */

```

```

/*      do; */
          *-----;
          * Put character A0x at right most character to pad text;
          *-----;
/*      substr(_cvalue, 13, 1)='A0'x; */
/*      end; */

```

```

if first.DSDECODN then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatype='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=8;
    _dptindt=4;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;

```

```
run;
```

```

/* Crit 23 */
data _anal23;
  length _EVENT23 8;
  set _data1;
  where same and _EVENT23 is not missing;
  _blksrt=6;
  _cnt=1;
  _cat=1;

```

```

if _trt <=0 then
  delete;
output;

```

```
run;
```

```

proc sort data=_anal23;
  by _datasrt _blksrt _EVENT23 _trt _cat;
run;

```

```

data _temp23;
  set _anal23;
  output;
run;

```

```

proc sort data=_temp23 out=_temp923 nodupkey;
  by _datasrt _blcksrt _cat _EVENT23 _trt usubjid;
;
run;

proc freq data=_temp923;
  format _EVENT23;
  tables _datasrt*_blcksrt*_cat * _EVENT23 * _trt / sparse norow nocol nopercnt
  out=_pct23(drop=percent);
run;

proc sort data=_anal23 out=_denom23(keep=_datasrt _cat) nodupkey;
;
  by _datasrt _cat;
run;

data _denom23;
  set _denom23;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf23;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom23 out=_denomin23(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame23;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=6;

```

```

length _EVENT23 8;
_catLabl=" ";
_trt=1;
_EVENT23=1;
_catord=1;
_cat=1;
output;
_trt=2;
_EVENT23=1;
_catord=1;
_cat=1;
output;
_trt=3;
_EVENT23=1;
_catord=1;
_cat=1;
output;
run;

proc sort data=_frame23;
  by _datasrt _blcksrt _cat _EVENT23 _trt;
run;

proc sort data=_pct23;
  by _datasrt _blcksrt _cat _EVENT23 _trt;
run;

data _pct23;
  merge _frame23(in=_inframe) _pct23;
  by _datasrt _blcksrt _cat _EVENT23 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct23;
  by _datasrt _blcksrt _EVENT23;
run;

data _miss23(keep=_datasrt _blcksrt _EVENT23 totcount);
  set _pct23;
  where _EVENT23=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT23;

  if first._EVENT23 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT23;
run;

```



```

data _pct23(drop=totcount);
  merge _pct23 _miss23;
  by _datasrt _blcksrt _EVENT23;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf23;
  by _datasrt _cat;
run;

proc sort data=_denomin23;
  by _datasrt _cat;
run;

data _denomin23;
  merge _denomf23(in=_inframe) _denomin23;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=6;
run;

proc sort data=_pct23;
  by _datasrt _cat;
run;

data _pct23;
  if 0 then
    set _basetemplate;
  merge _denomin23(in=_a) _pct23;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT23 ";
  _vrlabel=" ";
  _rwlabel="Originally randomized to placebo ";

  if _EVENT23=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT23=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

```

```

proc sort data=_pct23;
  by _datasrt _blcksrt _catord _EVENT23 _trt _cat;
run;

data _base23;
  length _catlabl $200;
  set _pct23 end=eof;
  by _datasrt _blcksrt _catord _EVENT23 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        do;

      end;

    end;

  /* if length(_cvalue) < 13 then */
  /* do; */
  /* substr(_cvalue, 13, 1)='A0'x; */
  /* end; */

  if first._EVENT23 then
    do;
      _rowsrt=_rowsrt + 1;
      _rowmax=max(_rowsrt, _rowmax);
    end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

```

```

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
  _indent=2;
  _dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
  _direct="TOP ";
  _p=2;
run;

/* Crit 24 */
data _anal24;
  length _EVENT24 8;
  set _data1;
  where same and _EVENT24 is not missing;
  _blcksrt=6;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal24;
  by _datasrt _blcksrt _EVENT24 _trt _cat;
run;

data _temp24;
  set _anal24;
  output;
run;

proc sort data=_temp24 out=_temp924 nodupkey;
  by _datasrt _blcksrt _cat _EVENT24 _trt usubjid;
  ;
run;

proc freq data=_temp924;
  format _EVENT24;
  tables _datasrt*_blcksrt*_cat * _EVENT24 * _trt / sparse norow nocol nopercnt
  out=_pct24(drop=percent);
run;

proc sort data=_anal24 out=_denom24(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

```

```

data _denom24;
  set _denom24;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf24;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom24 out=_denomin24(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame24;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=6;
  length _EVENT24 8;
  _catLabl=" ";
  _trt=1;
  _EVENT24=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT24=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT24=1;
  _catord=1;
  _cat=1;
  output;

```

```

run;

proc sort data=_frame24;
  by _datasrt _blcksrt _cat _EVENT24 _trt;
run;

proc sort data=_pct24;
  by _datasrt _blcksrt _cat _EVENT24 _trt;
run;

data _pct24;
  merge _frame24(in=_inframe) _pct24;
  by _datasrt _blcksrt _cat _EVENT24 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct24;
  by _datasrt _blcksrt _EVENT24;
run;

data _miss24(keep=_datasrt _blcksrt _EVENT24 totcount);
  set _pct24;
  where _EVENT24=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT24;

  if first._EVENT24 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT24;
run;

data _pct24(drop=totcount);
  merge _pct24 _miss24;
  by _datasrt _blcksrt _EVENT24;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf24;
  by _datasrt _cat;
run;

proc sort data=_denomin24;
  by _datasrt _cat;
run;

data _denomin24;

```

```

merge_denomf24(in=_inframe) _denomin24;
by _datasrt _cat;

if _inframe;
  _blcksrt=6;
run;

proc sort data=_pct24;
  by _datasrt _cat;
run;

data _pct24;
  if 0 then
    set _basetemplate;
  merge _denomin24(in=_a) _pct24;
  by _datasrt _cat;

  if _a;
    _varname="_EVENT24 ";
    _vrlabel=" ";
    _rwlabel="Withdrawn from the study after unblinding and before Dose 3 ";

  if _EVENT24=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT24=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct24;
  by _datasrt _blcksrt _catord _EVENT24 _trt _cat;
run;

data _base24;
  length _catlabl $200;
  set _pct24 end=eof;
  by _datasrt _blcksrt _catord _EVENT24 _trt _cat;
  retain _rowsrt 1 _rowmax 0;
  array _trtcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);

```

```

else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trtcnt(_trt) > 0 then
      do;
        percent=count / _trtcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
            else
              _cpct="(*ESC*){nbspspace 1}(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
          end;
        end;
      end;
  end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT24 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatype='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rlabel)='_NONE_' then
    _rlabel=' ';
  _indent=4;
  _dptindt=0;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 25 */
data _anal25;

```

```

length _EVENT25 8;
set _data1;
where same and _EVENT25 is not missing;
_blcksrt=6;
_cnt=1;
_cat=1;

if _trt <=0 then
  delete;
output;
run;

proc sort data=_anal25;
  by _datasrt _blcksrt _EVENT25 _trt _cat;
run;

data _temp25;
  set _anal25;
  output;
run;

proc sort data=_temp25 out=_temp925 nodupkey;
  by _datasrt _blcksrt _cat _EVENT25 _trt usubjid;
  ;
run;

proc freq data=_temp925;
  format _EVENT25;
  tables _datasrt*_blcksrt*_cat * _EVENT25 * _trt / sparse norow nocol nopercnt
  out=_pct25(drop=percent);
run;

proc sort data=_anal25 out=_denom25(keep=_datasrt _cat) nodupkey;
  ;
  by _datasrt _cat;
run;

data _denom25;
  set _denom25;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf25;
  _datasrt=1;

```



```

set _bydat1(keep=);
* All treatment groups ;
_trt1=0;
_trt2=0;
_trt3=0;
* _CAT is the subgroup variable ;
_cat=1;
output;
run;

proc transpose data=_denom25 out=_denomin25(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame25;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=6;
  length _EVENT25 8;
  _catLabl=" ";
  _trt=1;
  _EVENT25=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT25=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT25=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame25;
  by _datasrt _blcksrt _cat _EVENT25 _trt;
run;

proc sort data=_pct25;
  by _datasrt _blcksrt _cat _EVENT25 _trt;
run;

data _pct25;
  merge _frame25(in=_inframe) _pct25;
  by _datasrt _blcksrt _cat _EVENT25 _trt;

  if _inframe;

  if count=. then

```

```

        count=0;
run;

proc sort data=_pct25;
    by _datasrt _blcksrt _EVENT25;
run;

data _miss25(keep=_datasrt _blcksrt _EVENT25 totcount);
    set _pct25;
    where _EVENT25=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT25;

    if first._EVENT25 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT25;
run;

data _pct25(drop=totcount);
    merge _pct25 _miss25;
    by _datasrt _blcksrt _EVENT25;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf25;
    by _datasrt _cat;
run;

proc sort data=_denomin25;
    by _datasrt _cat;
run;

data _denomin25;
    merge _denomf25(in=_inframe) _denomin25;
    by _datasrt _cat;

    if _inframe;
    _blcksrt=6;
run;

proc sort data=_pct25;
    by _datasrt _cat;
run;

data _pct25;
    if 0 then
        set _basetemplate;
    merge _denomin25(in=_a) _pct25;
    by _datasrt _cat;

```

```

if _a;
  _varname="_EVENT25 ";
  _vrlabel=" ";
  _rwlabel="Received Dose 3 (first dose of BNT162b2 [30 (*ESC*){unicode 03BC}g]) ";

if _EVENT25=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT25=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct25;
  by _datasrt _blcksrt _catord _EVENT25 _trt _cat;
run;

data _base25;
  length _catlabl $200;
  set _pct25 end=eof;
  by _datasrt _blcksrt _catord _EVENT25 _trt _cat;
  retain _rowsrt 2 _rowmax 0;
  array _trcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trcnt(_trt) > 0 then
      do;
        percent=count / _trcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
            else
              _cpct="(*ESC*){nbspspace 1}{(0.0)";
          end;
        end;
      end;
  end;

```

FDA-CBER-2022-5812-0072239

```

                _cvalue=trim(_cvalue)||_cpct;
            end;
        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT25 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatyp='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

    if upcase(_rlabel)='_NONE_' then
        _rlabel=' ';
        _indent=4;
        _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=2;
run;

/* Crit 26 */
data _anal26;
    length _EVENT26 8;
    set _data1;
    where same and _EVENT26 is not missing;
    _blcksrt=6;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal26;
    by _datasrt _blcksrt _EVENT26 _trt _cat;
run;

data _temp26;

```

```

    set _anal26;
    output;
run;

proc sort data=_temp26 out=_temp926 nodupkey;
    by _datasrt _blcksrt _cat _EVENT26 _trt usubjid;
    ;
run;

proc freq data=_temp926;
    format _EVENT26;
    tables _datasrt*_blcksrt*_cat * _EVENT26 * _trt / sparse norow nocol nopercnt
        out=_pct26(drop=percent);
run;

proc sort data=_anal26 out=_denom26(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom26;
    set _denom26;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf26;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom26 out=_denomin26(drop=_name __label_) prefix=_trt;
    by _datasrt _cat;
    var count;
    id _trt;
run;

data _frame26;

```

```

    _datasrt=1;
    set _bydat1(keep=);
    _blcksrt=6;
    length _EVENT26 8;
    _catLbl=" ";
    _trt=1;
    _EVENT26=1;
    _catord=1;
    _cat=1;
    output;
    _trt=2;
    _EVENT26=1;
    _catord=1;
    _cat=1;
    output;
    _trt=3;
    _EVENT26=1;
    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame26;
    by _datasrt _blcksrt _cat _EVENT26 _trt;
run;

proc sort data=_pct26;
    by _datasrt _blcksrt _cat _EVENT26 _trt;
run;

data _pct26;
    merge _frame26(in=_inframe) _pct26;
    by _datasrt _blcksrt _cat _EVENT26 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct26;
    by _datasrt _blcksrt _EVENT26;
run;

data _miss26(keep=_datasrt _blcksrt _EVENT26 totcount);
    set _pct26;
    where _EVENT26=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT26;

    if first._EVENT26 then
        totcount=0;
    totcount=totcount+count;

```

```

    if last._EVENT26;
run;

data _pct26(drop=totcount);
    merge _pct26 _miss26;
    by _datasrt _blcksrt _EVENT26;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf26;
    by _datasrt _cat;
run;

proc sort data=_denomin26;
    by _datasrt _cat;
run;

data _denomin26;
    merge _denomf26(in=_inframe) _denomin26;
    by _datasrt _cat;

    if _inframe;
        _blcksrt=6;
run;

proc sort data=_pct26;
    by _datasrt _cat;
run;

data _pct26;
    if 0 then
        set _basetemplate;
    merge _denomin26(in=_a) _pct26;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT26 ";
        _vrlabel=" ";
        _rwlabel="Received Dose 4 (second dose of BNT162b2 [30 (*ESC*){unicode 03BC}g]) ";

    if _EVENT26=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT26=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then

```

```

        _catord=9997;
run;

proc sort data=_pct26;
    by _datasrt _blcksrt _catord _EVENT26 _trt _cat;
run;

data _base26;
    length _catlabl $200;
    set _pct26 end=eof;
    by _datasrt _blcksrt _catord _EVENT26 _trt _cat;
    retain _rowsrt 3 _rowmax 0;
    array _trtcnt(*) _trt1- _trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct=' ';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

    if _trt ne . then
        do;

            if _trtcnt(_trt) > 0 then
                do;
                    percent=count / _trtcnt(_trt) * 100;

                    if percent > 0 then
                        do;

                            if round(percent, 0.1) GE 0.1 then
                                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                            else
                                _cpct="(*ESC*){nbspspace 1}{(0.0)";
                            _cvalue=trim(_cvalue)||_cpct;
                        end;
                    end;
                end;
            end;

        end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

    if first._EVENT26 then
        do;
            _rowsrt=_rowsrt + 1;
            _rowmax=max(_rowsrt, _rowmax);
        end;
    _datatype='data';
    _indent=0;

```



```

_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
_indent=4;
_dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";
_p=2;
run;

/* Crit 27 */
data _anal27;
  length _EVENT27 8;
  set _data1;
  where same and _EVENT27 is not missing;
  _blcksrt=7;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal27;
  by _datasrt _blcksrt _EVENT27 _trt _cat;
run;

data _temp27;
  set _anal27;
  output;
run;

proc sort data=_temp27 out=_temp927 nodupkey;
  by _datasrt _blcksrt _cat _EVENT27 _trt usubjid;
  ;
run;

proc freq data=_temp927;
  format _EVENT27;
  tables _datasrt*_blcksrt*_cat * _EVENT27 * _trt / sparse norow nocol nopercnt
  out=_pct27(drop=percent);
run;

proc sort data=_anal27 out=_denom27(keep=_datasrt _cat) nodupkey;
  ;

```

```

    by _datasrt _cat;
run;

data _denom27;
    set _denom27;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf27;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom27 out=_denomin27(drop=_name __label_) prefix=_trt;
    by _datasrt _cat;
    var count;
    id _trt;
run;

data _frame27;
    _datasrt=1;
    set _bydat1(keep=);
    _blcksrt=7;
    length _EVENT27 8;
    _catLabl=" ";
    _trt=1;
    _EVENT27=1;
    _catord=1;
    _cat=1;
    output;
    _trt=2;
    _EVENT27=1;
    _catord=1;
    _cat=1;
    output;
    _trt=3;
    _EVENT27=1;

```

```

    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame27;
    by _datasrt _blcksrt _cat _EVENT27 _trt;
run;

proc sort data=_pct27;
    by _datasrt _blcksrt _cat _EVENT27 _trt;
run;

data _pct27;
    merge _frame27(in=_inframe) _pct27;
    by _datasrt _blcksrt _cat _EVENT27 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct27;
    by _datasrt _blcksrt _EVENT27;
run;

data _miss27(keep=_datasrt _blcksrt _EVENT27 totcount);
    set _pct27;
    where _EVENT27=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT27;

    if first._EVENT27 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT27;
run;

data _pct27(drop=totcount);
    merge _pct27 _miss27;
    by _datasrt _blcksrt _EVENT27;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf27;
    by _datasrt _cat;
run;

proc sort data=_denomin27;
    by _datasrt _cat;

```

```

run;

data _denomin27;
  merge _denomf27(in=_inframe) _denomin27;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=7;
run;

proc sort data=_pct27;
  by _datasrt _cat;
run;

data _pct27;
  if 0 then
    set _basetemplate;
  merge _denomin27(in=_a) _pct27;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT27 ";
  _vrlabel=" ";
  _rwlabel="Discontinued from open-label vaccination period~{super d} ";

  if _EVENT27=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT27=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct27;
  by _datasrt _blcksrt _catord _EVENT27 _trt _cat;
run;

data _base27;
  length _catlabl $200;
  set _pct27 end=eof;
  by _datasrt _blcksrt _catord _EVENT27 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

```

```

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
              else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT27 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
  _indent=4;
  _dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
  _direct="TOP ";
  _p=2;
run;

```

```

/* Crit 28 */
data _anal28;
  length DSDECODN 8;
  set _data1;
  where same and DSDECODN is not missing;
  _blcksrt=7;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal28;
  by _datasrt _blcksrt DSDECODN _trt _cat;
run;

data _temp28;
  set _anal28;
  output;
run;

proc sort data=_temp28 out=_temp928 nodupkey;
  by _datasrt _blcksrt _cat DSDECODN _trt usubjid;
  where RANDFL eq 'Y' and DSPHASEN=7 and EOTXDCDT ne . and dsdecodn not in (. 2)
    and vax201dt ne . and index(armcd, 'PLACEBO');
run;

proc freq data=_temp928;
  format DSDECODN;
  tables _datasrt*_blcksrt*_cat * DSDECODN * _trt / sparse norow nocol nopercnt
    out=_pct28(drop=percent);
run;

proc sort data=_anal28 out=_denom28(keep=_datasrt _cat) nodupkey;
  where RANDFL eq 'Y' and DSPHASEN=7 and EOTXDCDT ne . and dsdecodn not in (. 2)
    and vax201dt ne . and index(armcd, 'PLACEBO');
  by _datasrt _cat;
run;

data _denom28;
  set _denom28;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;

```

```

output;
run;

data _denomf28;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom28 out=_denomin28(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

proc sort data=_pct28 out=_expv28 (keep=_datasrt _blcksrt DSDECODN) nodupkey;
  by _datasrt _blcksrt DSDECODN;
run;

proc sort data=_expv28;
  by _datasrt _blcksrt DSDECODN;
run;

data _frame28;
  set _expv28;
  by _datasrt _blcksrt DSDECODN;

  if first._blcksrt then
    _catord=0;
  _catord + 1;
  _trt=1;
  _cat=1;
  output;
  _trt=2;
  _cat=1;
  output;
  _trt=3;
  _cat=1;
  output;
run;

proc sort data=_frame28;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

proc sort data=_pct28;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

```

```

data _pct28;
  merge _frame28(in=_inframe) _pct28;
  by _datasrt _blcksrt _cat DSDECODN _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct28;
  by _datasrt _blcksrt DSDECODN;
run;

data _miss28(keep=_datasrt _blcksrt DSDECODN totcount);
  set _pct28;
  where DSDECODN=9998;
  retain totcount;
  by _datasrt _blcksrt DSDECODN;

  if first.DSDECODN then
    totcount=0;
  totcount=totcount+count;

  if last.DSDECODN;
run;

data _pct28(drop=totcount);
  merge _pct28 _miss28;
  by _datasrt _blcksrt DSDECODN;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf28;
  by _datasrt _cat;
run;

proc sort data=_denomin28;
  by _datasrt _cat;
run;

data _denomin28;
  merge _denomf28(in=_inframe) _denomin28;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=7;
run;

proc sort data=_pct28;
  by _datasrt _cat;

```



```

run;

data _pct28;
  if 0 then
    set _basetemplate;
  merge _denomin28(in=_a) _pct28;
  by _datasrt _cat;

  if _a;
  _varname="DSDECODN ";
  _vrlabel="Reason for discontinuation from open-label vaccination period ";
  _rwlabel=put(DSDECODN, dsdecod.);

  if DSDECODN=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if DSDECODN=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;

```

```

run;

proc sort data=_pct28;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
run;

```

```

data _base28;
  length _catlabl $200;
  set _pct28 end=eof;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
  retain _rowsrt 1 _rowmax 0;
  array _trcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

```

```

        if percent > 0 then
            do;

                if round(percent, 0.1) GE 0.1 then
                    _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
                else
                    _cpct="(*ESC*){nbspspace 1}(0.0)";
                _cvalue=trim(_cvalue)||_cpct;
            end;
        end;
    end;

/* if length(_cvalue) < 13 then */
/* do; */
/* -----;
/* Put character A0x at right most character to pad text;
/* -----;
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first.DSDECODN then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=8;
    _dptindt=4;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 29 */
data _anal29;
    length _EVENT29 8;
    set _data1;
    where same and _EVENT29 is not missing;
    _blcksrt=8;
    _cnt=1;
    _cat=1;

```

```

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal29;
    by _datasrt _blcksrt _EVENT29 _trt _cat;
run;

data _temp29;
    set _anal29;
    output;
run;

proc sort data=_temp29 out=_temp929 nodupkey;
    by _datasrt _blcksrt _cat _EVENT29 _trt usubjid;
    ;
run;

proc freq data=_temp929;
    format _EVENT29;
    tables _datasrt*_blcksrt*_cat * _EVENT29 * _trt / sparse norow nocol nopercnt
        out=_pct29(drop=percent);
run;

proc sort data=_anal29 out=_denom29(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom29;
    set _denom29;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf29;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;

```

```

    _cat=1;
    output;
run;

proc transpose data=_denom29 out=_denomin29(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame29;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=8;
  length _EVENT29 8;
  _catLbl=" ";
  _trt=1;
  _EVENT29=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT29=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT29=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame29;
  by _datasrt _blcksrt _cat _EVENT29 _trt;
run;

proc sort data=_pct29;
  by _datasrt _blcksrt _cat _EVENT29 _trt;
run;

data _pct29;
  merge _frame29(in=_inframe) _pct29;
  by _datasrt _blcksrt _cat _EVENT29 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct29;
  by _datasrt _blcksrt _EVENT29;
run;

```

```

data _miss29(keep=_datasrt _blcksrt _EVENT29 totcount);
  set _pct29;
  where _EVENT29=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT29;

  if first._EVENT29 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT29;
run;

data _pct29(drop=totcount);
  merge _pct29 _miss29;
  by _datasrt _blcksrt _EVENT29;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf29;
  by _datasrt _cat;
run;

proc sort data=_denomin29;
  by _datasrt _cat;
run;

data _denomin29;
  merge _denomf29(in=_inframe) _denomin29;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=8;
run;

proc sort data=_pct29;
  by _datasrt _cat;
run;

data _pct29;
  if 0 then
    set _basetemplate;
  merge _denomin29(in=_a) _pct29;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT29 ";
  _vrlabel=" ";
  _rwlabel="Completed 1-month post(*ESC*){unicode 2013}Dose 4 visit ";

  if _EVENT29=9998 then

```

```

do;
  _rwlabel="Missing ";
  _catord=9998;
end;
else if _EVENT29=9999 then
do;
  _rwlabel="Total ";
  _catord=9999;
end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct29;
  by _datasrt _blcksrt _catord _EVENT29 _trt _cat;
run;

data _base29;
  length _catlabl $200;
  set _pct29 end=eof;
  by _datasrt _blcksrt _catord _EVENT29 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;
    end;

  /* if length(_cvalue) < 13 then */

```

```

/*      do; */
/*      substr(_cvalue, 13, 1)='A0'x; */
/*      end; */

if first._EVENT29 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=4;
    _dptindt=0;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 30 */
data _anal30;
  length _EVENT30 8;
  set _data1;
  where same and _EVENT30 is not missing;
  _blcksrt=9;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal30;
  by _datasrt _blcksrt _EVENT30 _trt _cat;
run;

data _temp30;
  set _anal30;
  output;
run;

proc sort data=_temp30 out=_temp930 nodupkey;
  by _datasrt _blcksrt _cat _EVENT30 _trt usubjid;

```

```

;
run;

proc freq data=_temp930;
  format _EVENT30;
  tables _datasrt*_blcksrt*_cat * _EVENT30 * _trt / sparse norow nocol nopercnt
  out=_pct30(drop=percent);
run;

proc sort data=_anal30 out=_denom30(keep=_datasrt _cat) nodupkey;
;
by _datasrt _cat;
run;

data _denom30;
  set _denom30;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf30;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom30 out=_denomin30(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame30;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=9;
  length _EVENT30 8;
  _catLabl=" ";
  _trt=1;

```



```

    _EVENT30=1;
    _catord=1;
    _cat=1;
    output;
    _trt=2;
    _EVENT30=1;
    _catord=1;
    _cat=1;
    output;
    _trt=3;
    _EVENT30=1;
    _catord=1;
    _cat=1;
    output;
run;

proc sort data=_frame30;
    by _datasrt _blcksrt _cat _EVENT30 _trt;
run;

proc sort data=_pct30;
    by _datasrt _blcksrt _cat _EVENT30 _trt;
run;

data _pct30;
    merge _frame30(in=_inframe) _pct30;
    by _datasrt _blcksrt _cat _EVENT30 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct30;
    by _datasrt _blcksrt _EVENT30;
run;

data _miss30(keep=_datasrt _blcksrt _EVENT30 totcount);
    set _pct30;
    where _EVENT30=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT30;

    if first._EVENT30 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT30;
run;

data _pct30(drop=totcount);
    merge _pct30 _miss30;
    by _datasrt _blcksrt _EVENT30;

```

```

        if totcount=0 then
            delete;
run;

proc sort data=_denomf30;
    by _datasrt _cat;
run;

proc sort data=_denomin30;
    by _datasrt _cat;
run;

data _denomin30;
    merge _denomf30(in=_inframe) _denomin30;
    by _datasrt _cat;

    if _inframe;
        _blcksrt=9;
run;

proc sort data=_pct30;
    by _datasrt _cat;
run;

data _pct30;
    if 0 then
        set _basetemplate;
    merge _denomin30(in=_a) _pct30;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT30 ";
        _vrlabel=" ";
        _rwlabel="Withdrawn from the study ";

    if _EVENT30=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT30=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct30;
    by _datasrt _blcksrt _catord _EVENT30 _trt _cat;
run;

```

```

data _base30;
  length _catlabl $200;
  set _pct30 end=eof;
  by _datasrt _blcksrt _catord _EVENT30 _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trtcnt(*) _trt1- _trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

  /* if length(_cvalue) < 13 then */
  /* do; */
  /* substr(_cvalue, 13, 1)='A0'x; */
  /* end; */

  if first._EVENT30 then
    do;
      _rowsrt=_rowsrt + 1;
      _rowmax=max(_rowsrt, _rowmax);
    end;
  _datatype='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlabel)='_NONE_' then
    _rwlabel='';

```

```

    _indent=4;
    _dptindt=0;

    if _trt=3 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=2;
run;

/* Crit 31 */
data _anal31;
    length _EVENT31 8;
    set _data1;
    where same and _EVENT31 is not missing;
    _blcksrt=9;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal31;
    by _datasrt _blcksrt _EVENT31 _trt _cat;
run;

data _temp31;
    set _anal31;
    output;
run;

proc sort data=_temp31 out=_temp931 nodupkey;
    by _datasrt _blcksrt _cat _EVENT31 _trt usubjid;
    ;
run;

proc freq data=_temp931;
    format _EVENT31;
    tables _datasrt*_blcksrt*_cat * _EVENT31 * _trt / sparse norow nocol nopercnt
        out=_pct31(drop=percent);
run;

proc sort data=_anal31 out=_denom31(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom31;
    set _denom31;
    by _datasrt _cat;

```

```

label count='count';
  _trt=1;
count=&_trt1.;
output;
  _trt=2;
count=&_trt2.;
output;
  _trt=3;
count=&_trt3.;
output;
run;

data _denomf31;
  _datasrt=1;
set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
output;
run;

proc transpose data=_denom31 out=_denomin31(drop=_name__label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame31;
  _datasrt=1;
set _bydat1(keep=);
  _blcksrt=9;
length _EVENT31 8;
  _catLbl=" ";
  _trt=1;
  _EVENT31=1;
  _catord=1;
  _cat=1;
output;
  _trt=2;
  _EVENT31=1;
  _catord=1;
  _cat=1;
output;
  _trt=3;
  _EVENT31=1;
  _catord=1;
  _cat=1;
output;
run;

proc sort data=_frame31;

```

```

    by _datasrt _blcksrt _cat _EVENT31 _trt;
run;

proc sort data=_pct31;
    by _datasrt _blcksrt _cat _EVENT31 _trt;
run;

data _pct31;
    merge _frame31(in=_inframe) _pct31;
    by _datasrt _blcksrt _cat _EVENT31 _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct31;
    by _datasrt _blcksrt _EVENT31;
run;

data _miss31(keep=_datasrt _blcksrt _EVENT31 totcount);
    set _pct31;
    where _EVENT31=9998;
    retain totcount;
    by _datasrt _blcksrt _EVENT31;

    if first._EVENT31 then
        totcount=0;
    totcount=totcount+count;

    if last._EVENT31;
run;

data _pct31(drop=totcount);
    merge _pct31 _miss31;
    by _datasrt _blcksrt _EVENT31;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf31;
    by _datasrt _cat;
run;

proc sort data=_denomin31;
    by _datasrt _cat;
run;

data _denomin31;
    merge _denomf31(in=_inframe) _denomin31;
    by _datasrt _cat;

```

```

    if _inframe;
        _blcksrt=9;
run;

proc sort data=_pct31;
    by _datasrt _cat;
run;

data _pct31;
    if 0 then
        set _basetemplate;
    merge _denomin31(in=_a) _pct31;
    by _datasrt _cat;

    if _a;
        _varname="_EVENT31 ";
        _vrlabel=" ";
        _rwlabel="Withdrawn after Dose 3 and before Dose 4 ";

    if _EVENT31=9998 then
        do;
            _rwlabel="Missing ";
            _catord=9998;
        end;
    else if _EVENT31=9999 then
        do;
            _rwlabel="Total ";
            _catord=9999;
        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct31;
    by _datasrt _blcksrt _catord _EVENT31 _trt _cat;
run;

data _base31;
    length _catlabl $200;
    set _pct31 end=eof;
    by _datasrt _blcksrt _catord _EVENT31 _trt _cat;
    retain _rowsrt 1 _rowmax 0;
    array _trtcnt(*) _trt1-_trt4;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

    if count > . then
        _cvalue=put(count, 5.);
    else
        _cvalue=put(0, 5.);

```

```

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
              else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/* do; */
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT31 then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

  if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
  _indent=6;
  _dptindt=0;

  if _trt=3 +1 then
    _trt=9999;

  if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Crit 32 */
data _anal32;
  length _EVENT32 8;
  set _data1;
  where same and _EVENT32 is not missing;

```



```

    _blcksrt=9;
    _cnt=1;
    _cat=1;

    if _trt <=0 then
        delete;
    output;
run;

proc sort data=_anal32;
    by _datasrt _blcksrt _EVENT32 _trt _cat;
run;

data _temp32;
    set _anal32;
    output;
run;

proc sort data=_temp32 out=_temp932 nodupkey;
    by _datasrt _blcksrt _cat _EVENT32 _trt usubjid;
    ;
run;

proc freq data=_temp932;
    format _EVENT32;
    tables _datasrt*_blcksrt*_cat * _EVENT32 * _trt / sparse norow nocol nopercnt
        out=_pct32(drop=percent);
run;

proc sort data=_anal32 out=_denom32(keep=_datasrt _cat) nodupkey;
    ;
    by _datasrt _cat;
run;

data _denom32;
    set _denom32;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf32;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;

```

```

    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom32 out=_denomin32(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame32;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=9;
  length _EVENT32 8;
  _catLabl=" ";
  _trt=1;
  _EVENT32=1;
  _catord=1;
  _cat=1;
  output;
  _trt=2;
  _EVENT32=1;
  _catord=1;
  _cat=1;
  output;
  _trt=3;
  _EVENT32=1;
  _catord=1;
  _cat=1;
  output;
run;

proc sort data=_frame32;
  by _datasrt _blcksrt _cat _EVENT32 _trt;
run;

proc sort data=_pct32;
  by _datasrt _blcksrt _cat _EVENT32 _trt;
run;

data _pct32;
  merge _frame32(in=_inframe) _pct32;
  by _datasrt _blcksrt _cat _EVENT32 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

```

```

proc sort data=_pct32;
  by _datasrt _blcksrt _EVENT32;
run;

data _miss32(keep=_datasrt _blcksrt _EVENT32 totcount);
  set _pct32;
  where _EVENT32=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT32;

  if first._EVENT32 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT32;
run;

data _pct32(drop=totcount);
  merge _pct32 _miss32;
  by _datasrt _blcksrt _EVENT32;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf32;
  by _datasrt _cat;
run;

proc sort data=_denomin32;
  by _datasrt _cat;
run;

data _denomin32;
  merge _denomf32(in=_inframe) _denomin32;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=9;
run;

proc sort data=_pct32;
  by _datasrt _cat;
run;

data _pct32;
  if 0 then
    set _basetemplate;
  merge _denomin32(in=_a) _pct32;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT32 ";
  _vrlabel=" ";

```

```

_rwlabel="Withdrawn after Dose 4 and before 1-month post(*ESC*){unicode 2013}Dose 4 visit ";

if _EVENT32=9998 then
  do;
    _rwlabel="Missing ";
    _catord=9998;
  end;
else if _EVENT32=9999 then
  do;
    _rwlabel="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct32;
  by _datasrt _blcksrt _catord _EVENT32 _trt _cat;
run;

data _base32;
  length _catlabl $200;
  set _pct32 end=eof;
  by _datasrt _blcksrt _catord _EVENT32 _trt _cat;
  retain _rowsrt 2 _rowmax 0;
  array _trtcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

    if _trtcnt(_trt) > 0 then
      do;
        percent=count / _trtcnt(_trt) * 100;

        if percent > 0 then
          do;

            if round(percent, 0.1) GE 0.1 then
              _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
            else
              _cpct="(*ESC*){nbspspace 1}(0.0)";
            _cvalue=trim(_cvalue)||_cpct;
          end;
        end;
      end;
  end;
end;

```

```

        end;

/* if length(_cvalue) < 13 then */
/* do; */
/*     substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first._EVENT32 then
    do;
        _rowsrt=_rowsrt + 1;
        _rowmax=max(_rowsrt, _rowmax);
    end;
    _datatype='data';
    _indent=0;
    _dptindt=0;
    _vorder=1;
    _rowjump=1;

if upcase(_rwlabel)='_NONE_' then
    _rwlabel=' ';
    _indent=6;
    _dptindt=0;

if _trt=3 +1 then
    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4)));
    _direct="TOP ";
    _p=2;

```

```
run;
```

```

/* Crit 33 */
data _anal33;
    length _EVENT33 8;
    set _data1;
    where same and _EVENT33 is not missing;
    _blksrt=9;
    _cnt=1;
    _cat=1;

```

```

if _trt <=0 then
    delete;
output;

```

```
run;
```

```

proc sort data=_anal33;
    by _datasrt _blksrt _EVENT33 _trt _cat;
run;

```

```

data _temp33;
    set _anal33;
    output;
run;

```

```

proc sort data=_temp33 out=_temp933 nodupkey;
  by _datasrt _blcksrt _cat _EVENT33 _trt usubjid;
;
run;

proc freq data=_temp933;
  format _EVENT33;
  tables _datasrt*_blcksrt*_cat * _EVENT33 * _trt / sparse norow nocol nopercnt
  out=_pct33(drop=percent);
run;

proc sort data=_anal33 out=_denom33(keep=_datasrt _cat) nodupkey;
;
  by _datasrt _cat;
run;

data _denom33;
  set _denom33;
  by _datasrt _cat;
  label count='count';
  _trt=1;
  count=&_trt1.;
  output;
  _trt=2;
  count=&_trt2.;
  output;
  _trt=3;
  count=&_trt3.;
  output;
run;

data _denomf33;
  _datasrt=1;
  set _bydat1(keep=);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  _trt3=0;
  * _CAT is the subgroup variable ;
  _cat=1;
  output;
run;

proc transpose data=_denom33 out=_denomin33(drop=_name __label_) prefix=_trt;
  by _datasrt _cat;
  var count;
  id _trt;
run;

data _frame33;
  _datasrt=1;
  set _bydat1(keep=);
  _blcksrt=9;

```

```

length _EVENT33 8;
_catLabl=" ";
_trt=1;
_EVENT33=1;
_catord=1;
_cat=1;
output;
_trt=2;
_EVENT33=1;
_catord=1;
_cat=1;
output;
_trt=3;
_EVENT33=1;
_catord=1;
_cat=1;
output;
run;

proc sort data=_frame33;
  by _datasrt _blcksrt _cat _EVENT33 _trt;
run;

proc sort data=_pct33;
  by _datasrt _blcksrt _cat _EVENT33 _trt;
run;

data _pct33;
  merge _frame33(in=_inframe) _pct33;
  by _datasrt _blcksrt _cat _EVENT33 _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct33;
  by _datasrt _blcksrt _EVENT33;
run;

data _miss33(keep=_datasrt _blcksrt _EVENT33 totcount);
  set _pct33;
  where _EVENT33=9998;
  retain totcount;
  by _datasrt _blcksrt _EVENT33;

  if first._EVENT33 then
    totcount=0;
  totcount=totcount+count;

  if last._EVENT33;
run;

```

```

data _pct33(drop=totcount);
  merge _pct33 _miss33;
  by _datasrt _blcksrt _EVENT33;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf33;
  by _datasrt _cat;
run;

proc sort data=_denomin33;
  by _datasrt _cat;
run;

data _denomin33;
  merge _denomf33(in=_inframe) _denomin33;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=9;
run;

proc sort data=_pct33;
  by _datasrt _cat;
run;

data _pct33;
  if 0 then
    set _basetemplate;
  merge _denomin33(in=_a) _pct33;
  by _datasrt _cat;

  if _a;
  _varname="_EVENT33 ";
  _vrlabel=" ";
  _rwlabel="Withdrawn after 1-month post(*ESC*){unicode 2013}Dose 4 visit ";

  if _EVENT33=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if _EVENT33=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

```



```

proc sort data=_pct33;
  by _datasrt _blcksrt _catord _EVENT33 _trt _cat;
run;

data _base33;
  length _catlabl $200;
  set _pct33 end=eof;
  by _datasrt _blcksrt _catord _EVENT33 _trt _cat;
  retain _rowsrt 3 _rowmax 0;
  array _trcnt(*) _trt1-_trt4;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

  if count > . then
    _cvalue=put(count, 5.);
  else
    _cvalue=put(0, 5.);

  if _trt ne . then
    do;

      if _trcnt(_trt) > 0 then
        do;
          percent=count / _trcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}{||strip(put(percent, 5.1))||}";
              else
                _cpct="(*ESC*){nbspspace 1}{(0.0)}";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        do;

      end;

    end;

  /* if length(_cvalue) < 13 then */
  /* do; */
  /* substr(_cvalue, 13, 1)='A0'x; */
  /* end; */

  if first._EVENT33 then
    do;
      _rowsrt=_rowsrt + 1;
      _rowmax=max(_rowsrt, _rowmax);
    end;
  _datatyp='data';
  _indent=0;
  _dptindt=0;
  _vorder=1;
  _rowjump=1;

```

FDA-CBER-2022-5812-0072277

```

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
  _indent=6;
  _dptindt=0;

if _trt=3 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
  _direct="TOP ";
  _p=2;
run;

/* Crit 34 */
data _anal34;
  length DSDECODN 8;
  set _data1;
  where same and DSDECODN is not missing;
  _blcksrt=9;
  _cnt=1;
  _cat=1;

  if _trt <=0 then
    delete;
  output;
run;

proc sort data=_anal34;
  by _datasrt _blcksrt DSDECODN _trt _cat;
run;

data _temp34;
  set _anal34;
  output;
run;

proc sort data=_temp34 out=_temp934 nodupkey;
  by _datasrt _blcksrt _cat DSDECODN _trt usubjid;
  where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
    and (VAX201DT ne . or VAX202DT ne .) and ((unblnddt ne . and
    eosdcdt>=unblnddt) or eosdcdt=eotxcdct) and index(armcd, 'PLACEBO');
run;

proc freq data=_temp934;
  format DSDECODN;
  tables _datasrt*_blcksrt*_cat * DSDECODN * _trt / sparse norow nocol nopercnt
    out=_pct34(drop=percent);
run;

proc sort data=_anal34 out=_denom34(keep=_datasrt _cat) nodupkey;
  where RANDFL eq 'Y' and DSPHASEN=31 and EOSDCDT ne . and dsdecodn not in (. 2)
    and (VAX201DT ne . or VAX202DT ne .) and ((unblnddt ne . and

```

FDA-CBER-2022-5812-0072278

```

        eosdcdt>=unblnddt) or eosdcdt=eotxdcddt) and index(armed, 'PLACEBO');
    by _datasrt _cat;
run;

data _denom34;
    set _denom34;
    by _datasrt _cat;
    label count='count';
    _trt=1;
    count=&_trt1.;
    output;
    _trt=2;
    count=&_trt2.;
    output;
    _trt=3;
    count=&_trt3.;
    output;
run;

data _denomf34;
    _datasrt=1;
    set _bydat1(keep=);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    _trt3=0;
    * _CAT is the subgroup variable ;
    _cat=1;
    output;
run;

proc transpose data=_denom34 out=_denomin34(drop=_name __label_) prefix=_trt;
    by _datasrt _cat;
    var count;
    id _trt;
run;

proc sort data=_pct34 out=_expv34 (keep=_datasrt _blcksrt DSDECODN) nodupkey;
    by _datasrt _blcksrt DSDECODN;
run;

proc sort data=_expv34;
    by _datasrt _blcksrt DSDECODN;
run;

data _frame34;
    set _expv34;
    by _datasrt _blcksrt DSDECODN;

    if first._blcksrt then
        _catord=0;
    _catord + 1;
    _trt=1;
    _cat=1;

```

```

output;
  _trt=2;
  _cat=1;
output;
  _trt=3;
  _cat=1;
output;
run;

proc sort data=_frame34;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

proc sort data=_pct34;
  by _datasrt _blcksrt _cat DSDECODN _trt;
run;

data _pct34;
  merge _frame34(in=_inframe) _pct34;
  by _datasrt _blcksrt _cat DSDECODN _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct34;
  by _datasrt _blcksrt DSDECODN;
run;

data _miss34(keep=_datasrt _blcksrt DSDECODN totcount);
  set _pct34;
  where DSDECODN=9998;
  retain totcount;
  by _datasrt _blcksrt DSDECODN;

  if first.DSDECODN then
    totcount=0;
  totcount=totcount+count;

  if last.DSDECODN;
run;

data _pct34(drop=totcount);
  merge _pct34 _miss34;
  by _datasrt _blcksrt DSDECODN;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf34;
  by _datasrt _cat;

```

```

run;

proc sort data=_denomin34;
  by _datasrt _cat;
run;

data _denomin34;
  merge _denomf34(in=_inframe) _denomin34;
  by _datasrt _cat;

  if _inframe;
  _blcksrt=9;
run;

proc sort data=_pct34;
  by _datasrt _cat;
run;

data _pct34;
  if 0 then
    set _basetemplate;
  merge _denomin34(in=_a) _pct34;
  by _datasrt _cat;

  if _a;
  _varname="DSDECODN ";
  _vrlabel="Reason for withdrawal from the study ";
  _rwlabel=put(DSDECODN, dsdecod.);

  if DSDECODN=9998 then
    do;
      _rwlabel="Missing ";
      _catord=9998;
    end;
  else if DSDECODN=9999 then
    do;
      _rwlabel="Total ";
      _catord=9999;
    end;

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct34;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
run;

data _base34;
  length _catlabl $200;
  set _pct34 end=eof;
  by _datasrt _blcksrt _catord DSDECODN _trt _cat;
  retain _rowsrt 4 _rowmax 0;
  array _trcnt(*) _trt1- _trt4;

```

```

drop _rowmax _cpct;
length _cpct $100;
_cpct='';
_module='mcatstat';

if count > . then
  _cvalue=put(count, 5.);
else
  _cvalue=put(0, 5.);

if _trt ne . then
  do;

      if _trtcnt(_trt) > 0 then
        do;
          percent=count / _trtcnt(_trt) * 100;

          if percent > 0 then
            do;

              if round(percent, 0.1) GE 0.1 then
                _cpct="(*ESC*){nbspspace 1}("||strip(put(percent, 5.1))||")";
              else
                _cpct="(*ESC*){nbspspace 1}(0.0)";
              _cvalue=trim(_cvalue)||_cpct;
            end;
          end;
        end;
      end;

/* if length(_cvalue) < 13 then */
/* do; */
/* -----;
/* Put character A0x at right most character to pad text;
/* -----;
/* substr(_cvalue, 13, 1)='A0'x; */
/* end; */

if first.DSDECODN then
  do;
    _rowsrt=_rowsrt + 1;
    _rowmax=max(_rowsrt, _rowmax);
  end;
_datatyp='data';
_indent=0;
_dptindt=0;
_vorder=1;
_rowjump=1;

if upcase(_rwlabel)='_NONE_' then
  _rwlabel=' ';
_indent=8;
_dptindt=4;

if _trt=3 +1 then

```

```

    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=2;
run;

/* Set together */
data _final;
    set _base1 _base2 _base3 _base4 _base5 _base6 _base7 _base8 _base9 _base10
        _base11 _base12 _base13 _base14 _base15 _base16 _base17 _base18 _base19
        _base20 _base21 _base22 _base23 _base24 _base25 _base26 _base27 _base28
        _base29 _base30 _base31 _base32 _base33 _base34;
run;

proc sort data=_final;
    by _datasrt _blcksrt _rowsrt;
run;

data _final;
    set _final;
    drop __trt;

    if _trt=9999 then
        __trt=3 + 1;
    else
        __trt=_trt;

    if __trt=. then
        __trt=1;
        _column=_trt;

    if _column=9999 then
        _column=3 + 1;
run;

proc sort data=_final out=_final;
    by _datasrt _blcksrt _rowsrt _column;
run;

data _linecnt;
    set _final end=eof;
    by _datasrt _blcksrt _rowsrt _column;
    retain _totline _maxval _maxrow _rwlbttag _vrlbttag 0 _maxline _linecnt;
    keep _datasrt _blcksrt _totline _linecnt _maxrow;

    if _rowjump=. then
        _rowjump=1;

    if first._blcksrt then
        do;
            _token=repeat(' ', 99);
            _count=1;

```

```

    _token=scan(_vrlabel, _count, "|");

if _token=: '_' then
    _tag=1;
else
    _tag=0;

do while(_token ^=' ');
    _count=_count + 1;
    _token=scan(_vrlabel, _count, "|");
end;
_linecnt=_count - 1 + _tag;
;
_totline=_linecnt;

if _vrlabel ne '' and _vrlabel ne '^' & _datatyp='data' then
    _vrlbtag=1;
end;

if first._rowsrt then
do;
    _token=repeat(' ', 99);
    _count=1;
    _token=scan(_rwlabel, _count, "|");

if _token=: '_' then
    _tag=1;
else
    _tag=0;

do while(_token ^=' ');
    _maxrow=max(_maxrow, length(_token) + _indent);
    _count=_count + 1;
    _token=scan(_rwlabel, _count, "|");
end;
_maxline=_count - 1 + _tag;
;

if _rwlabel ne '' then
    _rwlbttag=1;
    _totline + _rowjump - 1;
end;
_token=repeat(' ', 99);
_count=1;
_token=scan(_cvalue, _count, "|");

if _token=: '_' then
    _tag=1;
else
    _tag=0;

do while(_token ^=' ');
    _maxval=max(_maxval, length(_token));
    _count=_count + 1;

```



```

        _token=scan(_cvalue, _count, "|");
end;
_ccnt=_count - 1 + _tag;
_maxline=max(_maxline, _ccnt);

if last._rowsrt then
    _totline=_maxline + _totline;

if last._blcksrt then
    do;
        _totline=_totline - _rowjump + 1;
        output;
    end;

if eof then
    do;
        call symput('_valwid', compress(put(_maxval, 3.)));
        call symput('_rwlbttag', put(_rwlbttag, 1.));
        call symput('_vrlbttag', put(_vrlbttag, 1.));
    end;
run;

data _final;
length _direct $20;
_direct=' ';
merge _final_linecnt;
by _datasrt _blcksrt;
run;

data _sph (keep=name _s_col _e_col _splabl);
length _splabl $ 200 _s_col $ 40 _e_col $ 40 name $ 40;
_s_col=' ';
_e_col=' ';
_splabl=' ';
name=' ';
_s_col="TRT1";
_e_col="TRT2";
name=_s_col;
_splabl="Vaccine Group (as Randomized)~{line}";
output _sph;
name=_e_col;
output _sph;
_s_col="TRT4";
_e_col="TRT5";
name=_s_col;
_splabl="Vaccine Group (as Randomized)~{line}";
output _sph;
name=_e_col;
output _sph;
run;

data _sph;
set _sph;
_s_col_num=input(translate(_s_col, " ", "TRT"), best.);

```

```

    _e_col_num=input(translate(_e_col, " ", "TRT"), best.);
run;

proc sort data=_sph (where=( _s_col=name)) out=_span_start;
    by _s_col_num descending _e_col_num;
run;

data _span_start;
    retain _span_hdr_order 1;
    set _span_start;
    by _s_col_num descending _e_col_num;

    if (first._s_col_num) then
        _span_hdr_order=1;
    else
        _span_hdr_order=_span_hdr_order + 1;
run;

proc sort data=_sph (where=( _e_col=name)) out=_span_end;
    by _e_col_num descending _s_col_num;
run;

data _span_end;
    retain _span_hdr_order 1;
    set _span_end;
    by _e_col_num descending _s_col_num;

    if (first._e_col_num) then
        _span_hdr_order=1;
    else
        _span_hdr_order=_span_hdr_order + 1;
run;

data _sph;
    set _span_start _span_end;
run;

proc sort data=_sph out=_sph nodupkey;
    by _s_col_num descending _e_col_num _s_col _e_col _splabl name;
run;

proc sql noprint;
    create table rspan as select distinct _trt, _column , _vrlabel as _rwlabel ,
        _datasrt, _blcksrt, (min(_rowsrt)-0.5) as _rowsrt , _dptindt as _indent , 0
        as _dptindt from _final(where=( _vrlabel^=' ')) group by _trt, _column ,
        _datasrt, _blcksrt, _vrlabel;
quit;

data outdata1;
    length _rvalue $800;
    set _final rspan end=eof;
    _rwindt=sum(_indent, _dptindt);

    if _rwindt <=0 then

```

```

        _rvalue=_rwlabel;
    else
/*      _rvalue=repeat(byte(160), _rwindt-1)||_rwlabel; */
        _rvalue=repeat('~{nbspace 1}', _rwindt-1)||_rwlabel;
        _dummy=1;

        if _trt=. then
            _trt=1;
run;

proc sort data=outdata1;
    by _datasrt _trt _blcksrt _rowsrt;
run;

data treat;
    length FMTNAME $8 start 8 label $200;
    fmtname='TREAT';

    do start=1 to 3 + ("N"="Y");
        label=symget('_TRTLB' || compress(put(start, 4.)));
        label=trim(label)
            || " (N~{super a}=" || compress(symget("_TRT" || compress(put(start,
            4.)))) || ")" || "n~{super b} (%)";
        output;
    end;
run;

data outdata1;
    set outdata1(rename=( _cvalue=_cvalue11));
    _fixvar=1;
    _fix2var=1;

    if index(_cvalue11, "(") then
        do;

            if substr(_cvalue11, length(_cvalue11), 1) ne ")" then
                _cvalue=_cvalue11||"";
            else
                _cvalue=_cvalue11;
            end;
        else if not missing(_cvalue11) then
            _cvalue=_cvalue11;
run;

proc sort data=outdata1;
    by _datasrt _trt _blcksrt _rowsrt;
run;

proc sort data=outdata1 out=_pre_transposed;
    by _fixvar _fix2var _datasrt _blcksrt _rowsrt _rvalue _trt;
run;

data _pre_transposed;
    set _pre_transposed;

```

```

    if _trt=9999 then
        _trt=3 +1;
run;

proc sql noprint;
    select min(_blcksrt) into: openord1 from _pre_transposed where
        index(uppercase(_rwlabel), 'RANDOMIZED TO BNT162B2');
    select min(_blcksrt) into: openord2 from _pre_transposed where
        index(uppercase(_rwlabel), 'RANDOMIZED TO PLACEBO');
    select max(_blcksrt) into: openord3 from _pre_transposed;
    select max(_column) into: totnx from _pre_transposed;
    select max(_trt) into: maxtrtx from _pre_transposed;
quit;

data _pre_transposed;
    set _pre_transposed;

    if &openord1.<=_blcksrt<&openord2. and (_trt=&maxtrtx. or (_trt=2 and
        count=0)) then
        _cvalue=";

    if &openord2.<=_blcksrt<=&openord3. and (_trt=&maxtrtx. or (_trt=1 and
        count=0)) then
        _cvalue=";
run;

proc transpose data=_pre_transposed out=_column_transposed (drop=_name_)
    prefix=TRT;
    by _fixvar _fix2var _datasrt _blcksrt _rowsrt _rvalue;
    var _cvalue;
    id _trt;
run;

data maxtrtv;
    set _pre_transposed;

    if _trt=3;
run;

proc transpose data=maxtrtv out=_cntsort (drop=_name_) prefix=cntsort;
    by _fixvar _fix2var _datasrt _blcksrt _rowsrt _rvalue;
    var count;
run;

data _column_transposed;
    merge _column_transposed(in=a) _cntsort;
    by _fixvar _fix2var _datasrt _blcksrt _rowsrt _rvalue;

    if a;
    cntsort=input(cntsort1, best.);
    drop cntsort1;
run;

```

```

proc sort;
  by _fixvar _fix2var _datasrt _blcksrt descending cntsort _rowsrt _rvalue;
run;

data _column_transposed;
  set _column_transposed;
  by _fixvar _fix2var _datasrt _blcksrt descending cntsort _rowsrt _rvalue;

  if _blcksrt=2 then
    do;

      if _rowsrt>1.5 then
        do;

          if first._blcksrt then
            srt=1;
          else
            srt+1;
          _rowsrt=1.5+srt;

          if index(upcase(_rvalue), 'OTHER')>0 then
            _rowsrt=999;

          if cntsort=0 then
            delete;
        end;
      end;

  if _blcksrt=4 then
    do;

      if _rowsrt>4.5 then
        do;

          if first._blcksrt then
            srt=1;
          else
            srt+1;
          _rowsrt=4.5+srt;

          if index(upcase(_rvalue), 'OTHER')>0 then
            _rowsrt=999;

          if cntsort=0 then
            delete;
        end;
      end;

  if _blcksrt=5 then
    do;

      if _rowsrt>7.5 then
        do;

```

```

        if first._blcksrt then
            srt=1;
        else
            srt+1;
        _rowsrt=7.5+srt;

        if index(upcase(_rvalue), 'OTHER')>0 then
            _rowsrt=999;

            if cntsort=0 then
                delete;
            end;
        end;
    end;

if _blcksrt=7 then
    do;

        if _rowsrt>1.5 then
            do;

                if first._blcksrt then
                    srt=1;
                else
                    srt+1;
                _rowsrt=1.5+srt;

                if index(upcase(_rvalue), 'OTHER')>0 then
                    _rowsrt=999;

                    if cntsort=0 then
                        delete;
                    end;
                end;
            end;
        end;

if _blcksrt=9 then
    do;

        if _rowsrt>4.5 then
            do;

                if first._blcksrt then
                    srt=1;
                else
                    srt+1;
                _rowsrt=4.5+srt;

                if index(upcase(_rvalue), 'OTHER')>0 then
                    _rowsrt=999;

                    if cntsort=0 then
                        delete;
                    end;
                end;
            end;
        end;
    drop srt cntsort;

```

```

run;

proc sort;
  by _fixvar _fix2var _datasrt _blcksrt _rowsrt _rvalue;
run;

proc contents data=_column_transposed
  out=_col_labels (where=(upcase(name)= "TRT") keep=name) noprint;
run;

data _col_labels;
  length name $ 40;
  set _col_labels end=eof;
  _sort_order=_n_;
  name=upcase(name);

  if eof then
    call symput("_max_trt", left(put(_sort_order, best.)));
run;

proc sort data=_col_labels out=_col_labels;
  by name;
run;

proc sort data=_sph out=_sph;
  by name;
run;

data _final_sph;
  merge _col_labels (in=a) _sph;
  by name;

  if a;
run;

proc sort data=_final_sph out=_final_sph nodup;
  by _sort_order _span_hdr_order;
run;

data REPORT;
  set _column_transposed;
  _dummy=1;
run;

proc sort data=report;
  by _datasrt _blcksrt _rowsrt _dummy;
run;

/* Output report */
ods escapechar="~";
ods html file="&outtable.";
title1 "Disposition of All Randomized Subjects (*ESC*){unicode 2013} Phase 2/3 Subjects 12 Through 15 Years of Age";
footnote1 "a.(*ESC*){nbsp 5}N = number of randomized subjects in the specified group, or the total sample. This

```

FDA-CBER-2022-5812-0072291

value is the denominator for the percentage calculations.";

footnote2

"b.(**ESC**) {n = Number of subjects with the specified characteristic.";

footnote3 "c.(**ESC**) {Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1-month postâ€Dose 2 visit.";

footnote4 "d.(**ESC**) {Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 (**ESC**) {Unicode 00B5}g]) to 1-month postâ€Dose 4 (second dose of BNT162b2 [30 (**ESC**) {Unicode 00B5}g]) visit.";

```
proc report data=report nowd list missing contents="" split=""
  style(report)={} style(header)={} style(column)={};
  column _fixvar _fix2var _datasrt _blcksrt _rowsrt (" _rvalue)
  (("Vaccine Group (as Randomized)~{line}" TRT1 TRT2) TRT3 _dummy);
  define _fixvar / group noprint;
  define _fix2var / group noprint;
  define _datasrt / group order=internal noprint;
  define _blcksrt / group order=internal noprint;
  define _rowsrt / group order=internal noprint;
  define _rvalue / group id " " order=data style(column)={just=left width=25mm
    rightmargin=18px} style(header)={just=left asis=on} left;
  define _dummy / sum noprint;
  define TRT1 / group nozero "BNT162b2 (30 (ESC) {unicode 03BC}g)| (N~{super a}=&_trt1.)|n~{super b}
  (%)"
    spacing=2 style(header)={just=center} center;
  define TRT2 / group nozero
    "Placebo| (N~{super a}=&_trt2.)|n~{super b} (%)" spacing=2
    style(header)={just=center} center;
  define TRT3 / group nozero
    "Total| (N~{super a}=&_trt3.)|n~{super b} (%)" spacing=2
    style(header)={just=center} center;
  break before _fixvar / contents="" page;
  compute before _fix2var;
    line @1 " ~n ";
  endcomp;
  compute after _blcksrt;
    line " ~n ";
  endcomp;
run;

ods markup close;
ods HTML close;

proc printto;
run;
```