

```
*****
** Program Name   : adce-s010-lr-sev-ped-saf.sas                **
** Date Created  : 22Mar2021                                    **
** Programmer Name : (b) (4), (b) (6)                          **
** Purpose       : Create adce-s010-lr-sev-ped-saf             **
** Input data    : adfacevd adsl                               **
** Output file   : adce-s010-lr-sev-ped-saf.html              **
*****
```

```
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
ods escapechar="~";
proc datasets library=WORK kill nolist nodetails;
quit;
```

```
**Setup the environment**;
%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/euaext_esub_adam/saseng/cdisc3_0;
libname datvprot "&prot./data_vai" access=readonly;
```

```
%let codename=adce-s010-lr-sev-ped-saf;
%let outlog=&prot./analysis/esub/logs/&codename..log;
%let outtable=&prot./analysis/esub/output/&codename..html;
```

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

```
*****
* Specification 1                                             *.
* Create foramtms                                             *.
*****
```

```
Proc format;
value SEV
0="Any"
1="Mild"
2="Moderate"
3="Severe"
4="Grade 4"
;
value VAC
1="1"
2="2"
3="3"
99="ANY"
;
```

```
run;
```

```
*****
* Specification 2                                             *.
* Input source data adfacevd and adsl                         *.
*****
```

```
data g_adsl_dsin;
set DATVPROT.ADSL;
where SAFFL eq 'Y' and PEDREAFL="Y" and AGEGR4N ne . and hivfl ne "Y" and MULENRFL ne "Y";
```

```

run;

data g_a_dsin;
  set DATVPROT.adfacevd;
  where SAFFL eq 'Y' and CUTUNBFL ne "Y" and PEDREAFL="Y" and AGEGR4N ne . and hivfl ne "Y" and
  MULENRFL ne "Y" and knowvfl="Y";
  if TRTAN in (8) then
    do;
      newtrtn=1;
      newtrt=coalescec("BNT162b2 (30 (*ESC*){unicode 03BC}g)~{line}", TRTA);
      output;
    end;

  if TRTAN in (9) then
    do;
      newtrtn=2;
      newtrt=coalescec("Placebo~{line}", TRTA);
      output;
    end;
end;
run;

```

```

data g_a_dsin;
  set g_a_dsin;
  atptrefn=input(compress(atptref , 'A'), ??best.);
  atptref=compress(atptref , 'A');
  output;

  if atptref ne "";
  atptref="Any dose";
  atptrefn=99;
  output;
run;

```

```

*****
**Regarding medication errors, subset for Reactogenicity analysis          **;
**1.Count subjects in what they received at Dose 1 for post Dose 1 summary.  **;
**2.Remove subjects from post Dose 2 summary.                             **;
**3.Count subjects in active for after any dose summary.                   **;
*****

```

```

data g_a_dsin;
  set g_a_dsin;
  where trta ne "";
  if VAX101 ne VAX102 and cmiss(VAX101,VAX102)=0 then do;
    if atptrefn=2 then delete;
    if atptrefn=99 then do;
      TRTAN=TRT01AN;TRTA=TRT01A;
      if TRTAN=8 then do; newtrtn =1; newtrt = "BNT162b2 (30 (*ESC*){unicode 03BC}g)~{line}"; end;
      if TRTAN=9 then do; newtrtn =2; newtrt = "Placebo~{line}"; end;
    end;
  end;
run;

```

```

*****
* Specification 3
* 1) Select all necessary parameters
* 2) Create flags for Any Local Reaction and Any Dose rows
* 3) Create order variables for next statistic analyses
* 4) Merge adsl and analysis dataset
*****

```

```

proc sort data=g_a_dsin;
  by usubjid;
run;

```

```

proc sql;
  create table a1 as select distinct newtrt, usubjid, faobj , atptref from g_a_dsin where
  upcase(FATESTCD)='OCCUR';
quit;

```

```

proc sql;
  create table a2 as select distinct newtrt, usubjid, faobj , atptref from a1
  except select distinct newtrt, usubjid , faobj , atptref from g_a_dsin where FATESTCD='MAXSEV';
quit;

```

```

proc sort data=a2;
  by newtrt usubjid faobj atptref;
quit;

```

```

proc sort data=g_a_dsin out=facevd;
  by newtrt usubjid faobj atptref;
quit;

```

```

data a3;
  merge facevd(in=a) a2(in=b);
  by newtrt usubjid faobj atptref;
  if fatestd='OCCUR';
  if a and b then output;
run;

```

```

proc sort data=a3;
  by faobj newtrt usubjid atptref ady newtrtn;
quit;

```

```

data a4(drop=paramcd);
  set a3;
  by faobj newtrt usubjid atptref ady newtrtn;

```

```

  if first.atptref;
  aval=0;
  avalc='NONE';
  knowvfl='Y';
  fatestd='MAXSEV';
run;

```

```

data _param;
  set g_a_dsin;

```

```

    if fatestd='MAXSEV';
    keep faobj paramcd;
run;

proc sort nodupkey data=_param;
    by faobj paramcd;
run;

data a4;
    merge a4(in=a) _param;
    by faobj;
    if a;
run;

data g_a_dsin;
    set g_a_dsin a4;
run;

data _a_dsin;
    set g_a_dsin;
    length _faobj_ord 8;

    if missing(aval) then aval=0;

    if missing(avalc) then avalc='NONE';

    if upcase(faobj)="PAIN AT INJECTION SITE" then faobj="Pain at the injection site";
    FAOBJ=upcase(substr(FAOBJ, 1, 1))||lowcase(substr(FAOBJ, 2));

    if upcase(paramcd)="MSERE" then
        do;
            _faobj_ord=1;

            if upcase(paramcd) in ('MSERE', 'MSESW') then
                do;
                    _faobj_label=trim(FAOBJ)||"(*ESC*){super d}";
                end;
            else if upcase(paramcd) in ('MSPIS') then
                do;
                    _faobj_label=trim(FAOBJ)||"(*ESC*){super e}";
                end;
            else if upcase(paramcd) in ('MSLARM') then
                do;
                    _faobj_label=trim(FAOBJ)||"(*ESC*){super f}";
                end;
            else
                do;
                    _faobj_label=trim(FAOBJ);
                end;
            output;
        end;

    if upcase(paramcd)="MSESW" then
        do;

```

```

_faobj_ord=2;

if upcase(paramcd) in ('MSERE', 'MSESW') then
  do;
    _faobj_label=trim(FAOBJ)||"(*ESC*){super d}";
  end;
else if upcase(paramcd) in ('MSPIS') then
  do;
    _faobj_label=trim(FAOBJ)||"(*ESC*){super e}";
  end;
else if upcase(paramcd) in ('MSLARM') then
  do;
    _faobj_label=trim(FAOBJ)||"(*ESC*){super f}";
  end;
else
  do;
    _faobj_label=trim(FAOBJ);
  end;
output;
end;

if upcase(paramcd)="MSPIS" then
  do;
    _faobj_ord=3;

    if upcase(paramcd) in ('MSERE', 'MSESW') then
      do;
        _faobj_label=trim(FAOBJ)||"(*ESC*){super d}";
      end;
    else if upcase(paramcd) in ('MSPIS') then
      do;
        _faobj_label=trim(FAOBJ)||"(*ESC*){super e}";
      end;
    else if upcase(paramcd) in ('MSLARM') then
      do;
        _faobj_label=trim(FAOBJ)||"(*ESC*){super f}";
      end;
    else
      do;
        _faobj_label=trim(FAOBJ);
      end;
    output;
  end;

  if upcase(paramcd)="ANY" then
    do;
      _faobj_ord=4;

      if upcase(paramcd) in ('MSERE', 'MSESW') then
        do;
          _faobj_label=trim(FAOBJ)||"(*ESC*){super d}";
        end;
      else if upcase(paramcd) in ('MSPIS') then
        do;

```

```

        _faobj_label=trim(FAOBJ)||"(*ESC*){super e}";
    end;
else if upcase(paramcd) in ('MSLARM') then
    do;
        _faobj_label=trim(FAOBJ)||"(*ESC*){super f}";
    end;
else
    do;
        _faobj_label=trim(FAOBJ);
    end;
output;
end;
run;

proc sort data=_a_dsin;
    by newtrt faobj usubjid atptref descending aval;
run;

data _a_dsin;
    set _a_dsin;
    by newtrt faobj usubjid atptref descending aval;
    if first.atptref;
run;

data _a_any;
    set _a_dsin;
    FAOBJ='Any local reaction';
    PARAMCD='ANY';
    _faobj_ord=999;
    _faobj_label=trim(FAOBJ)||"(*ESC*){super f}";
run;

proc sort data=_a_any;
    by newtrt usubjid atptref newtrtn descending eventfl descending aval;
run;

data _a_any;
    set _a_any;
    by newtrt usubjid atptref newtrtn descending eventfl descending aval;
    if first.atptref;
run;

data _a_dsin;
    set _a_dsin _a_any;
run;

data anysev;
    set _a_dsin;

    if aval=0 then
        do;
            ex_none_flg=1;
        end;
    else

```

```

do;
    ex_none_flg=0;
end;
AVALC='ANY';
AVAL=0;
output;
run;

data _a_dsin;
    set _a_dsin anysev;
run;

proc sql;
    create table _bigN as select distinct newtrt, usubjid, paramcd, knowvfl, atptref
        from _a_dsin where fatestd='MAXSEV';
quit;

data _bigN;
    set _bigN;
    DENOMFL=0;
    output;
    DENOMFL=1;
    output;
    DENOMFL=2;
    output;
    DENOMFL=3;
    output;
    DENOMFL=4;
    output;
run;

proc sort data=_a_dsin;
    by newtrt usubjid paramcd knowvfl atptref;
quit;

proc sort data=_bigN;
    by newtrt usubjid paramcd knowvfl atptref;
quit;

data _a_dsin;
    merge _a_dsin _bigN;
    by newtrt usubjid paramcd knowvfl atptref;

    if paramcd in ('ANY') and ^missing(aval) then
        do;
            denomfl=1;
            if aval > 0 then aval=1;
        end;
run;

data _dsin_terms(keep=paramcd _faobj_ord _faobj_label);
    set _a_dsin;
run;

```

```
proc sort data=_dsin_terms out=grp(keep=paramcd _faobj_label) nodupkey;
  by _faobj_ord;
quit;
```

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

```
proc sort data=_a_dsin out=_ds2;
  by usubjid;
run;
```

```
data final;
  merge _ds1(in=d1) _ds2(in=d2);
  by usubjid;
  if d2;
run;
proc sort data=final;
  by newtrt usubjid;
run;
```

```
data final;
  set final;
  if knowvfl='Y' then _knowvfl=1;
  if avalc not in ('ANY', 'NONE') then ex_none_flg=0;
run;
```

```
*****
* Specification 4
* Create a template dataset
*****
```

```
*-----;
* Initialize structure for _BASETEMPLATE dataset. ;
*-----;
```

```
data _basetemplate(compress=no);
  length _varname $8 _cvalue $30 _direct $20 _vrlabel $200 _rwlablel
    _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;
_datastr=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;
          *-----;
          * Generate _STR as the treatment label ;
          *-----;
          _str=NEWTRT;
          *-----;
          * Update _TRTLB&n with generated treatment label ;
          *-----;

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

run;

*-----;
* Handle sub-group N=xxx/sub-group analysis request ;
*-----;

proc sql noprint;
  select count(unique AGEGR4) into :_subGrpN from _data1 where AGEGR4 is not
  missing;
  create table _subGrpData as select distinct _trt, AGEGR4, count(distinct
  USUBJID) as _subGrpCnt from _data1 where AGEGR4 is not missing group by _trt,
  AGEGR4;

quit;

proc sql noprint;
  create table _subGrpDataVH as select distinct 9999 as _trt, AGEGR4,
  count(distinct USUBJID) as _subGrpCnt from _data1 where AGEGR4 is not missing
  group by AGEGR4;

quit;

data _subGrpData;
  length _cat $100;
  set _subGrpData;
  by _trt;
  _cat=AGEGR4;

run;

data _trtframe;

```

```

    _trt=ifN(1 eq 3, 9999, 1);
output;
    _trt=ifN(2 eq 3, 9999, 2);
output;
run;

proc sql noprint;
    create table _fullSubGrp as select * from (select distinct _trt from
        _trtframe), (select distinct _cat from _subGrpData) order by _trt, _cat;
quit;

data _fullSubGrp;
    set _fullSubGrp;
    by _trt _cat;

    if first._trt then
        _subcat=0;
        _subcat + 1;

    if _subcat=2 + 1 then
        _subcat=9999;
run;

data _subGrpData _tmpsubGrpData;
    merge _fullSubGrp _subGrpData;
    by _trt _cat;
    length _colabel $200;
    _colabel=_cat;

    if _subGrpCnt=. then
        _subGrpCnt=0;
run;

*-----;
* Generate a dataset containing all by-variables ;
*-----;
proc sort data=_data1 out=_bydat1(keep=_datasrt ATPTRFNFN ATPTRFNFN
    _dummyby) nodupkey;
    by _datasrt ATPTRFNFN;
run;

data _bydat1;
    set _bydat1 end=eof;
    by _datasrt ATPTRFNFN;
    retain _preby 0;
    drop _preby ATPTRFNFN;
    length _bylab1- _bylab1 $100;
    retain _byvar1- _byvar1 0 _bylen1- _bylen1 0 _bylab1- _bylab1;

    if first.ATPTRFNFN then
        do;
            _byvar1 + 1;
            _bylab1=ATPTRFNFN;
            _bylen1=max(_bylen1, length(_bylab1));

```

```

        end;
output;

if last.ATPTREFN then
    do;

        if _byvar1 > _preby then
            _preby=_byvar1;
        call symput("_preby1", compress(put(_preby, 4.)));
    end;

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

        if 1=0 then
            output;
    end;
run;

data _bydat1;
    set _bydat1;
    by _datasrt;
    length _bycol _byindnt $50 _bylast $10;
    _bycol="1";
    _byindnt="0";
    _bylast=" ";
run;

proc sort data=_bydat1;
    by _datasrt ATPTREFN;
run;

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

*-----;
* Merge calculated by variables back into _DATAn dataset. ;
*-----;

data _data1;
    merge _bydat1(keep=_datasrt _byvar1 ATPTREFN) _data1(in=_b);
    by _datasrt ATPTREFN;

    if _b;
run;

proc sort data=_data1;
    by _datasrt _byvar1;
run;

*****
***;

```

```

* Specification 5
* 1) Count N: number of subjects with any e-diary data reported after Vaccination 1
* 2) Count n and %: number of subjects with the specified characteristic and proportion
* 3) Calculate 95% CI for %: exact 2-sided CI based on the Clopper and Pearson method
*****
***;

```

```

*****;
* Specification 5.1: Statistics for Redness category
*****;
* Specification 5.1.1: Count denominator (N)
*****;

```

```

data _anall;
  length DENOMFL 8;
  length _cat $100;
  set _data1;
  where AGEGR4 is not missing;
  where same and DENOMFL is not missing;
  _blksrt=1;
  _cnt=1;
  _cat=AGEGR4;

```

```

  if _trt <=0 then
    delete;
  output;

```

```
run;
```

```

proc sort data=_anall;
  by _datasrt _byvar1 _blksrt DENOMFL _trt _cat;
run;

```

```

proc sort data=_anall out=_catby1(keep=_byvar1) nodupkey;
  by _byvar1;
  where paramcd eq upcase("Msere");
run;

```

```

data _subgrpvar;
  set _data1 (keep=AGEGR4) ;
  where ^missing(AGEGR4);
  format AGEGR4;

```

```

run;
proc sql noprint;
  select count(distinct AGEGR4) into:subGrpN from _subgrpvar;
quit;

```

```

proc sql noprint;
  select distinct AGEGR4 into :subv1 - : subv2 from _subgrpvar where AGEGR4 is not missing;
quit;

```

```

data _templ;
  set _anall;
  output;
run;

```

```

proc sort data=_temp1 out=_temp91 nodupkey;
  by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt usubjid;
  where paramcd eq upcase("Msere");
run;

proc freq data=_temp91 noprint;
  format DENOMFL;
  tables _datasrt*_byvar1*_blcksrt*_cat * DENOMFL * _trt / sparse norow nocol
    nopercnt out=_pct1(drop=percent);
run;

proc freq data=_pct1 noprint;
  where DENOMFL ne 9999;
  weight count;
  tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom1(drop=percent);
run;

data _denomf1;
  length _cat $100 ;
  _datasrt=1;
  set _catby1(keep=_byvar1);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  * _CAT is the subgroup variable ;
  _cat = "12-15 Years ";
  output;
  _cat = "16-25 Years ";
  output;
run;

proc transpose data=_denom1 out=_denomin1(drop=_name __label_) prefix=_trt;
  by _datasrt _byvar1 _cat;
  var count;
  id _trt;
run;

data _frame1;
  _datasrt=1;
  set _catby1(keep=_byvar1);
  _blcksrt=1;
  length DENOMFL 8;
  length _cat $100;
  _catLabl=" ";
  _trt=1;
  DENOMFL=0;
  _catord=1;
  _subcat=1;
  _cat="12-15 Years ";
  output;
  _subcat=2;
  _cat="16-25 Years ";
  output;

```

```
_trt=2;
DENOMFL=0;
_catord=1;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_catLbl=" ";
_trt=1;
DENOMFL=1;
_catord=3;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
DENOMFL=1;
_catord=3;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_catLbl=" ";
_trt=1;
DENOMFL=2;
_catord=4;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
DENOMFL=2;
_catord=4;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_catLbl=" ";
_trt=1;
DENOMFL=3;
_catord=5;
_subcat=1;
_cat="12-15 Years ";
output;
```

```

    _subcat=2;
    _cat="16-25 Years ";
output;
    _trt=2;
DENOMFL=3;
    _catord=5;
    _subcat=1;
    _cat="12-15 Years ";
output;
    _subcat=2;
    _cat="16-25 Years ";
output;
    _catLabl=" ";
    _trt=1;
DENOMFL=4;
    _catord=6;
    _subcat=1;
    _cat="12-15 Years ";
output;
    _subcat=2;
    _cat="16-25 Years ";
output;
    _trt=2;
DENOMFL=4;
    _catord=6;
    _subcat=1;
    _cat="12-15 Years ";
output;
    _subcat=2;
    _cat="16-25 Years ";
output;
run;

proc sort data=_frame1;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

proc sort data=_pct1;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

data _pct1;
    merge _frame1(in=_inframe) _pct1;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
    if _inframe;
    if count=. then count=0;
run;

proc sort data=_pct1;
    by _datasrt _byvar1 _blcksrt DENOMFL;
run;

data _miss1(keep=_datasrt _byvar1 _blcksrt DENOMFL totcount);
    set _pct1;

```

```

where DENOMFL=9998;
retain totcount;
by _datasrt _byvar1 _blcksrt DENOMFL;

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

if last.DENOMFL;
run;

data _pct1(drop=totcount);
merge _pct1 _miss1;
by _datasrt _byvar1 _blcksrt DENOMFL;

if totcount=0 then delete;
run;

proc sort data=_denomf1;
by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin1;
by _datasrt _byvar1 _cat;
run;

data _denomin1;
merge _denomf1(in=_inframe) _denomin1;
by _datasrt _byvar1 _cat;

if _inframe;
_blcksrt=1;
run;

proc sort data=_pct1;
by _datasrt _byvar1 _cat;
run;

data _pct1;
if 0 then
    set _basetemplate;
merge _denomin1(in=_a) _pct1;
by _datasrt _byvar1 _cat;

if _a;
_varname="DENOMFL ";
_vrlabel="Redness(*ESC*){super d} ";
_rwlabel=put(DENOMFL, sev.);

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

```

```

do;
  _rwlabel="Total ";
  _catord=9999;
end;

if _catord=. then
  _catord=9997;
run;

proc sort data=_pct1;
  by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
run;

data _base1;
  length _catlabl $200;
  set _pct1 end=eof;
  by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trtcnt(*) _trt1-_trt3;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct=' ';
  _module='mcatstat';

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

  if length(_cvalue) < 5 then
    do;
      *-----;
      * Put character A0x at right most character to pad text;
      *-----;
      substr(_cvalue, 5, 1)='A0'x;
    end;

  if first.DENOMFL 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=0;

  if _trt=2 +1 then

```

```

    _trt=9999;

if eof then
    call symput('_rowsrt', compress(put(_rowmax, 4.)));
    _direct="TOP ";
    _p=0;
run;

*****
* Specification 5.1.2: Count n and percentage (%) for individual severity    *;
*****

data _anal2;
    length AVAL 8;
    length _cat $100;
    set _data1;
    where AGEGR4 is not missing;
    where same and AVAL is not missing;
    _blcksrt=1;
    _cnt=1;
    _cat = AGEGR4;

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

proc sort data=_anal2;
    by _datasrt _byvar1 _blcksrt AVAL _trt _cat;
run;

proc sort data=_anal2 out=_catby2(keep=_byvar1) nodupkey;
    by _byvar1;
    where paramcd eq upcase("Msere") and ex_none_flg=0 and knowvfl eq 'Y';
run;

data _temp2;
    set _anal2;
    output;
run;

proc sort data=_temp2 out=_temp92 nodupkey;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt usubjid;
    where paramcd eq upcase("Msere") and ex_none_flg=0 and knowvfl eq 'Y';
run;

proc freq data=_temp92 noprint;
    format AVAL;
    tables _datasrt*_byvar1*_blcksrt*_cat * AVAL * _trt / sparse norow nocol
        nopercnt out=_pct2(drop=percent);
run;

proc sort data=_temp2 out=_analcnt2 nodupkey;

```

```

by _datasrt _byvar1 _cat _trt USUBJID;
where paramcd eq upcase("Msere") and knowvfl eq 'Y';
run;

proc freq data=_analcnt2 noprint;
tables _datasrt*_byvar1*_cat *_trt / sparse noprint out=_denom2(drop=percent);
run;

data _denomf2;
length _cat $100 ;
_datasrt=1;
set _catby2(keep=_byvar1);
* All treatment groups ;
_trt1=0;
_trt2=0;
* _CAT is the subgroup variable ;
_cat = "12-15 Years ";
output;
_cat = "16-25 Years ";
output;
run;

proc transpose data=_denom2 out=_denomin2(drop=_name__label_) prefix=_trt;
by _datasrt _byvar1 _cat;
var count;
id _trt;
run;

data _frame2;
_datasrt=1;
set _catby2(keep=_byvar1);
_blcksrt=1;
length AVAL 8;
length _cat $100;
_catLbl=" ";
_trt=1;
AVAL=0;
_catord=1;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
AVAL=0;
_catord=1;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;

```

```
_catLabl=" ";
_trt=1;
AVAL=1;
_catord=3;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
AVAL=1;
_catord=3;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_catLabl=" ";
_trt=1;
AVAL=2;
_catord=4;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
AVAL=2;
_catord=4;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_catLabl=" ";
_trt=1;
AVAL=3;
_catord=5;
_subcat=1;
_cat="12-15 Years ";
output;
_subcat=2;
_cat="16-25 Years ";
output;
_trt=2;
AVAL=3;
_catord=5;
_subcat=1;
_cat="12-15 Years ";
output;
```

```

    _subcat=2;
    _cat="16-25 Years ";
    output;
    _catLbl=" ";
    _trt=1;
    AVAL=4;
    _catord=6;
    _subcat=1;
    _cat="12-15 Years ";
    output;
    _subcat=2;
    _cat="16-25 Years ";
    output;
    _trt=2;
    AVAL=4;
    _catord=6;
    _subcat=1;
    _cat="12-15 Years ";
    output;
    _subcat=2;
    _cat="16-25 Years ";
    output;
run;

proc sort data=_frame2;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

proc sort data=_pct2;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

data _pct2;
    merge _frame2(in=_inframe) _pct2;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct2;
    by _datasrt _byvar1 _blcksrt AVAL;
run;

data _miss2(keep=_datasrt _byvar1 _blcksrt AVAL totcount);
    set _pct2;
    where AVAL=9998;
    retain totcount;
    by _datasrt _byvar1 _blcksrt AVAL;

    if first.AVAL then
        totcount=0;

```

```

totcount=totcount+count;

if last.AVAL;
run;

data _pct2(drop=totcount);
merge _pct2 _miss2;
by _datasrt _byvar1 _blcksrt AVAL;

if totcount=0 then
delete;
run;

proc sort data=_denomf2;
by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin2;
by _datasrt _byvar1 _cat;
run;

data _denomin2;
merge _denomf2(in=_inframe) _denomin2;
by _datasrt _byvar1 _cat;

if _inframe;
_blcksrt=1;
run;

proc sort data=_pct2;
by _datasrt _byvar1 _cat;
run;

data _pct2;
if 0 then
set _basetemplate;
merge _denomin2(in=_a) _pct2;
by _datasrt _byvar1 _cat;

if _a;
_varname="AVAL ";
_vrlabel=" ";
_rwlabel=put(AVAL, sev.);

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

```

```

        end;

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct2;
    by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
run;

data _base2;
    length _catlabl $200;
    set _pct2 end=eof;
    by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
    retain _rowsrt 6 _rowmax 0;
    array _trtcnt(*) _trt1- _trt3;
    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._byvar1 then

```

```

    _rowsrt=6;

if first.AVAL 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=0;

if _trt=2 +1 then
    _trt=9999;

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

data _base2;
    set _base2;
    length _cvalue2 $30.;
    _cvalue2=strip(tranwrd(_cvalue, 'A0'x, ""));
    _cvalue21=strip(scan(_cvalue, 1, '('));
    _cvalue22=compress(scan(_cvalue, 2, '(', ')'));
run;

data _base1;
    set _base1;
    drop _trt1 _trt2 count;
run;

proc sort data=_base1;
    by _datasrt _byvar1 _cat _trt;
run;

data _base1;
    set _base1;

if _trt=1 then
    do;
        _trt1=input(_cvalue, ??best.);
    end;

if _trt=2 then
    do;

```

```

        _trt2=input(_cvalue, ??best.);
    end;
run;

proc sort data=_base2(keep=_datasrt _trt _cvalue2 _cvalue21 _cvalue22 _cat
    _byvar1 count);
    by _datasrt _byvar1 _cat _trt;
run;

data _base2;
    merge _base1(in=a) _base2(in=b);
    by _datasrt _byvar1 _cat _trt;

    if a;

    if a and not b then
        do;
            _cvalue2="0";
            _cvalue21="0";
        end;

    if compress(_cvalue2)="0" then
        _cvalue22=put(0, 5.1);

    if compress(_cvalue)="0" then
        do;
            _cvalue2="NA";
            _cvalue21="NA";
            _cvalue22="NA";
        end;

    if upcase(_rwlabel)="GRADE 4" then
        _rwlabel="Grade 4";
run;

data _base1;
    set _base1;
    delete;
run;

*****
* Specification 5.1.3: Calculate 95% CI for observed proportion          *;
*****

data _cnp_tmp_cnp;
    set _base2;

    if count=. then
        count=0;
    indc=1;
    output _cnp;
    indc=2;

    if _trt=1 then

```

```

do;
  count=_trt1 - count;
end;

if _trt=2 then
  do;
    count=_trt2 - count;
  end;
output _cnp;

if indc=2 and count=0 then
  output _tmp_cnp;
run;

proc sort data=_cnp;
  by _byvar1 _cat _rowsrt _rwlable _trt;
run;

proc sort nodupkey data=_tmp_cnp(keep=_byvar1 _cat _rowsrt _rwlable _trt);
  by _byvar1 _cat _rowsrt _rwlable _trt;
run;

*****
* Call proc freq procedure to calculate CI for observed proportion      *;
*****

proc freq data=_cnp noprint;
  by _byvar1 _cat _rowsrt _rwlable _trt;
  table indc/binomial alpha=0.05;
  output out=obsprop binomial;
  weight count;
run;

data obsprop;
  merge obsprop _tmp_cnp(in=a);
  by _byvar1 _cat _rowsrt _rwlable _trt;

  if _bin_=1 and not a then
    do;
      xl_bin_=1 - xu_bin;
      xu_bin_=1 - xl_bin;
    end;
  else
    do;
      xl_bin_=xl_bin;
      xu_bin_=xu_bin;
    end;
run;

data cnpobsprop1(keep=_byvar1 _cat _rowsrt _rwlable _trt cnp_ci);
  set obsprop;
  by _byvar1 _cat _rowsrt _rwlable _trt;
  cnp_ci=(' || compress(put(xl_bin_ * 100, 5.1))
  || ',(*ESC*){nbspace 1}' || compress(put(xu_bin_ * 100, 5.1)) || ');

```

```

label cnp_ci='95% CI';
run;

proc datasets lib=work nolist gennum=all;
delete _cnp obsprop;
run;

proc sort data=_base2;
by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

proc sort data=cnpobsprop1;
by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

data _base2;
merge _base2(in=a) cnpobsprop1;
by _byvar1 _cat _rowsrt _rwlabel _trt;

if a;

if compress(_cvalue)="0" then
do;
cnp_ci="NE";
end;
run;

*****;
* Specification 5.2: Statistics for Swelling category *;
*****;
* Specification 5.2.1: Count denominator (N) *;
*****;

data _anal3;
set _anal1;
_blcksrt=2;
run;

proc sort data=_anal3;
by _datasrt _byvar1 _blcksrt DENOMFL _trt _cat;
run;

proc sort data=_anal3 out=_catby3(keep=_byvar1) nodupkey;
by _byvar1;
where paramcd eq upcase("Msesw");
run;

data _temp3;
set _anal3;
output;
run;

proc sort data=_temp3 out=_temp93 nodupkey;
by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt usubjid;

```

```

    where paramcd eq upcase("Msesw");
run;

proc freq data=_temp93 noprint;
    format DENOMFL;
    tables _datasrt*_byvar1*_blcksrt*_cat * DENOMFL * _trt / sparse norow nocol
        nopercnt out=_pct3(drop=percent);
run;

proc freq data=_pct3 noprint;
    where DENOMFL ne 9999;
    weight count;
    tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom3(drop=percent);
run;

data _denomf3;
    length _cat $100;
    _datasrt=1;
    set _catby3(keep=_byvar1);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    * _CAT is the subgroup variable ;
    _cat="12-15 Years ";
    output;
    _cat="16-25 Years ";
    output;
run;

proc transpose data=_denom3 out=_denomin3(drop=_name__label_) prefix=_trt;
    by _datasrt _byvar1 _cat;
    var count;
    id _trt;
run;

data _frame3;
    set _frame1;
    _blcksrt=2;
run;

proc sort data=_frame3;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

proc sort data=_pct3;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

data _pct3;
    merge _frame3(in=_inframe) _pct3;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;

    if _inframe;

```

```

        if count=. then
            count=0;
run;

proc sort data=_pct3;
    by _datasrt _byvar1 _blcksrt DENOMFL;
run;

data _miss3(keep=_datasrt _byvar1 _blcksrt DENOMFL totcount);
    set _pct3;
    where DENOMFL=9998;
    retain totcount;
    by _datasrt _byvar1 _blcksrt DENOMFL;

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

    if last.DENOMFL;
run;

data _pct3(drop=totcount);
    merge _pct3 _miss3;
    by _datasrt _byvar1 _blcksrt DENOMFL;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf3;
    by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin3;
    by _datasrt _byvar1 _cat;
run;

data _denomin3;
    merge _denomf3(in=_inframe) _denomin3;
    by _datasrt _byvar1 _cat;

    if _inframe;
    _blcksrt=2;
run;

proc sort data=_pct3;
    by _datasrt _byvar1 _cat;
run;

data _pct3;
    if 0 then
        set _basemplate;
    merge _denomin3(in=_a) _pct3;
    by _datasrt _byvar1 _cat;

```

```

if _a;
  _varname="DENOMFL ";
  _vrlabel="Swelling(*ESC*){super d} ";
  _rwlabel=put(DENOMFL, sev.);

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

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct3;
  by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
run;

data _base3;
  length _catlabl $200;
  set _pct3 end=eof;
  by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1- _trt3;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct='';
  _module='mcatstat';

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

if length(_cvalue) < 5 then
  do;
    *-----;
    * Put character A0x at right most character to pad text;
    *-----;
    substr(_cvalue, 5, 1)='A0'x;
  end;

if first._byvar1 then
  _rowsrt=0;

if first.DENOMFL 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=0;

    if _trt=2 +1 then
        _trt=9999;

    if eof then
        call symput('_rowsrt', compress(put(_rowmax, 4.)));
        _direct="TOP ";
        _p=0;
run;

*****
* Specification 5.2.2: Count n and percentage (%) for individual severity    *;
*****

data _anal4;
    set _anal2;
    _blcksrt=2;
run;

proc sort data=_anal4;
    by _datasrt _byvar1 _blcksrt AVAL _trt _cat;
run;

proc sort data=_anal4 out=_catby4(keep=_byvar1) nodupkey;
    by _byvar1;
    where paramcd eq upcase("Msesw") and ex_none_flg=0 and knowvfl eq 'Y';
run;

data _temp4;
    set _anal4;
    output;
run;

proc sort data=_temp4 out=_temp94 nodupkey;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt usubjid;
    where paramcd eq upcase("Msesw") and ex_none_flg=0 and knowvfl eq 'Y';
    ;
run;

proc freq data=_temp94 noprint;
    format AVAL;

```

```

tables _datasrt*_byvar1*_blcksrt*_cat * AVAL * _trt / sparse norow nocol
  nopercnt out=_pct4(drop=percent);
run;

proc sort data=_temp4 out=_analcnt4 nodupkey;
  by _datasrt _byvar1 _cat _trt USUBJID;
  where paramcd eq upcase("Msesw") and knowvfl eq 'Y';
run;

proc freq data=_analcnt4 noprint;
  tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom4(drop=percent);
run;

data _denomf4;
  length _cat $100;
  _datasrt=1;
  set _catby4(keep=_byvar1);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  * _CAT is the subgroup variable ;
  _cat="12-15 Years ";
  output;
  _cat="16-25 Years ";
  output;
run;

proc transpose data=_denom4 out=_denomin4(drop=_name __label_) prefix=_trt;
  by _datasrt _byvar1 _cat;
  var count;
  id _trt;
run;

data _frame4;
  set _frame2;
  _blcksrt=2;
run;

proc sort data=_frame4;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

proc sort data=_pct4;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

data _pct4;
  merge _frame4(in=_inframe) _pct4;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt;

  if _inframe;

  if count=. then count=0;

```

```

run;

proc sort data=_pct4;
  by _datasrt _byvar1 _blcksrt AVAL;
run;

data _miss4(keep=_datasrt _byvar1 _blcksrt AVAL totcount);
  set _pct4;
  where AVAL=9998;
  retain totcount;
  by _datasrt _byvar1 _blcksrt AVAL;

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

  if last.AVAL;
run;

data _pct4(drop=totcount);
  merge _pct4 _miss4;
  by _datasrt _byvar1 _blcksrt AVAL;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf4;
  by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin4;
  by _datasrt _byvar1 _cat;
run;

data _denomin4;
  merge _denomf4(in=_inframe) _denomin4;
  by _datasrt _byvar1 _cat;

  if _inframe;
  _blcksrt=2;
run;

proc sort data=_pct4;
  by _datasrt _byvar1 _cat;
run;

data _pct4;
  if 0 then
    set _basetemplate;
  merge _denomin4(in=_a) _pct4;
  by _datasrt _byvar1 _cat;

  if _a;

```

```

_varname="AVAL ";
_vrlabel=" ";
_rwlable=put(AVAL, sev.);

if AVAL=9998 then
  do;
    _rwlable="Missing ";
    _catord=9998;
  end;
else if AVAL=9999 then
  do;
    _rwlable="Total ";
    _catord=9999;
  end;

if _catord=. then
  _catord=9997;

run;

proc sort data=_pct4;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
run;

data _base4;
  length _catlabl $200;
  set _pct4 end=eof;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
  retain _rowsrt 6 _rowmax 0;
  array _trcnt(*) _trt1- _trt3;
  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;

```

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```

                                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._byvar1 then
    _rowsrt=6;

if first.AVAL 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=8;
_dptindt=0;

if _trt=2 +1 then
    _trt=9999;

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

data _base4;
set _base4;
length _cvalue2 $30.;
_cvalue2=strip(tranwrd(_cvalue, 'A0'x, ""));
_cvalue21=strip(scan(_cvalue, 1, '('));
_cvalue22=compress(scan(_cvalue, 2, '(', ')'));
run;

data _base3;
set _base3;
drop _trt1 _trt2 count;
run;

proc sort data=_base3;

```

```

    by _datasrt _byvar1 _cat _trt;
run;

data _base3;
    set _base3;

    if _trt=1 then
        do;
            _trt1=input(_cvalue, ??best.);
        end;

    if _trt=2 then
        do;
            _trt2=input(_cvalue, ??best.);
        end;
run;

proc sort data=_base4(keep=_datasrt _trt _cvalue2 _cvalue21 _cvalue22 _cat
    _byvar1 count);
    by _datasrt _byvar1 _cat _trt;
run;

data _base4;
    merge _base3(in=a) _base4(in=b);
    by _datasrt _byvar1 _cat _trt;

    if a;

    if a and not b then
        do;
            _cvalue2="0";
            _cvalue21="0";
        end;

    if compress(_cvalue2)="0" then
        _cvalue22=put(0, 5.1);

    if compress(_cvalue)="0" then
        do;
            _cvalue2="NA";
            _cvalue21="NA";
            _cvalue22="NA";
        end;

    if upcase(_rwlabel)="GRADE 4" then
        _rwlabel="Grade 4";
run;

data _base3;
    set _base3;
    delete;
run;

```

*****;

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```
* Specification 5.2.3: Calculate 95% CI for observed proportion          *;
*****;
```

```
data _cnp_tmp_cnp;
  set _base4;

  if count=. then
    count=0;
  indc=1;
  output _cnp;
  indc=2;

  if _trt=1 then
    do;
      count=_trt1 - count;
    end;

  if _trt=2 then
    do;
      count=_trt2 - count;
    end;
  output _cnp;

  if indc=2 and count=0 then
    output _tmp_cnp;
run;
```

```
proc sort data=_cnp;
  by _byvar1 _cat _rowsrt _rwlable _trt;
run;
```

```
proc sort nodupkey data=_tmp_cnp(keep=_byvar1 _cat _rowsrt _rwlable _trt);
  by _byvar1 _cat _rowsrt _rwlable _trt;
run;
```

```
*****;
* Call proc freq procedure to calculate CI for observed proportion      *;
*****;
```

```
proc freq data=_cnp noprint;
  by _byvar1 _cat _rowsrt _rwlable _trt;
  table indc/binomial alpha=0.05;
  output out=obsprop binomial;
  weight count;
run;
```

```
data obsprop;
  merge obsprop_tmp_cnp(in=a);
  by _byvar1 _cat _rowsrt _rwlable _trt;

  if _bin_=1 and not a then
    do;
      xl_bin_=1 - xu_bin;
      xu_bin_=1 - xl_bin;
    end;
```

```

else
  do;
    xl_bin_=xl_bin;
    xu_bin_=xu_bin;
  end;
run;

```

```

data cnpobsprop1(keep=_byvar1 _cat _rowsrt _rwlabel _trt cnp_ci);
  set obsprop;
  by _byvar1 _cat _rowsrt _rwlabel _trt;
  cnp_ci=(' || compress(put(xl_bin_ * 100, 5.1))
    || ',(*ESC*){nbspace 1}' || compress(put(xu_bin_ * 100, 5.1)) || ');
  label cnp_ci='95% CI';
run;

```

```

proc datasets lib=work nolist gennum=all;
  delete _cnp obsprop;
run;

```

```

proc sort data=_base4;
  by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

```

```

proc sort data=cnpobsprop1;
  by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

```

```

data _base4;
  merge _base4(in=a) cnpobsprop1;
  by _byvar1 _cat _rowsrt _rwlabel _trt;

  if a;

  if compress(_cvalue)="0" then
    do;
      cnp_ci="NE";
    end;
run;

```

```

*****
* Specification 5.3: Statistics for Pain at injection site category          *;
*****
* Specification 5.3.1: Count denominator (N)                               *;
*****

```

```

data _anal5;
  set _anal1;
  _blcksrt=3;
run;

proc sort data=_anal5;
  by _datasrt _byvar1 _blcksrt DENOMFL _trt _cat;
run;

```

```

proc sort data=_anal5 out=_catby5(keep=_byvar1) nodupkey;
  by _byvar1;
  where paramcd eq upcase("Mspis");
run;

data _temp5;
  set _anal5;
  output;
run;

proc sort data=_temp5 out=_temp95 nodupkey;
  by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt usubjid;
  where paramcd eq upcase("Mspis");
run;

proc freq data=_temp95 noprint;
  format DENOMFL;
  tables _datasrt*_byvar1*_blcksrt*_cat * DENOMFL * _trt / sparse norow nocol
    nopercnt out=_pct5(drop=percent);
run;

proc freq data=_pct5 noprint;
  where DENOMFL ne 9999;
  weight count;
  tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom5(drop=percent);
run;

data _denomf5;
  length _cat $100 ;
  _datasrt=1;
  set _catby5(keep=_byvar1);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  * _CAT is the subgroup variable ;
  _cat = "12-15 Years ";
output;
_cat = "16-25 Years ";
output;
run;

proc transpose data=_denom5 out=_denomin5(drop=_name__label_) prefix=_trt;
  by _datasrt _byvar1 _cat;
  var count;
  id _trt;
run;

data _frame5;
  set _frame1;
  _blcksrt=3;
run;

proc sort data=_frame5;

```

```

    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

proc sort data=_pct5;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;
run;

data _pct5;
    merge _frame5(in=_inframe) _pct5;
    by _datasrt _byvar1 _blcksrt _cat DENOMFL _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct5;
    by _datasrt _byvar1 _blcksrt DENOMFL;
run;

data _miss5(keep=_datasrt _byvar1 _blcksrt DENOMFL totcount);
    set _pct5;
    where DENOMFL=9998;
    retain totcount;
    by _datasrt _byvar1 _blcksrt DENOMFL;

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

    if last.DENOMFL;
run;

data _pct5(drop=totcount);
    merge _pct5 _miss5;
    by _datasrt _byvar1 _blcksrt DENOMFL;

    if totcount=0 then
        delete;
run;

proc sort data=_denomf5;
    by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin5;
    by _datasrt _byvar1 _cat;
run;

data _denomin5;
    merge _denomf5(in=_inframe) _denomin5;
    by _datasrt _byvar1 _cat;

```

```

    if _inframe;
        _blcksrt=3;
run;

proc sort data=_pct5;
    by _datasrt _byvar1 _cat;
run;

data _pct5;
    if 0 then
        set _basetemplate;
    merge _denomin5(in=_a) _pct5;
    by _datasrt _byvar1 _cat;

    if _a;
        _varname="DENOMFL ";
        _vrlabel="Pain at the injection site(*ESC*){super e} ";
        _rwlabel=put(DENOMFL, sev.);

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

    if _catord=. then
        _catord=9997;
run;

proc sort data=_pct5;
    by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
run;

data _base5;
    length _catlabl $200;
    set _pct5 end=eof;
    by _datasrt _byvar1 _blcksrt _catord DENOMFL _trt _cat;
    retain _rowsrt 0 _rowmax 0;
    array _trtcnt(*) _trt1- _trt3;
    drop _rowmax _cpct;
    length _cpct $100;
    _cpct='';
    _module='mcatstat';

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

```

```

if length(_cvalue) < 5 then
  do;
    *-----;
    * Put character A0x at right most character to pad text;
    *-----;
    substr(_cvalue, 5, 1)='A0'x;
  end;

if first._byvar1 then
  _rowsrt=0;

if first.DENOMFL 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=0;

if _trt=2 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
_direct="TOP ";
_p=0;
run;

*****
* Specification 5.3.2: Count n and percentage (%) for individual severity   *;
*****

data _anal6;
  set _anal2;
  _blcksrt=3;
run;

proc sort data=_anal6;
  by _datasrt _byvar1 _blcksrt AVAL _trt _cat;
run;

proc sort data=_anal6 out=_catby6(keep=_byvar1) nodupkey;
  by _byvar1;
  where paramcd eq upcase("Mspis") and ex_none_flg=0 and knowvfl eq 'Y';
run;

```

```

data _temp6;
    set _anal6;
    output;
run;

proc sort data=_temp6 out=_temp96 nodupkey;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt usubjid;
    where paramcd eq upcase("Mspis") and ex_none_flg=0 and knowvfl eq 'Y';
    ;
run;

proc freq data=_temp96 noprint;
    format AVAL;
    tables _datasrt*_byvar1*_blcksrt*_cat * AVAL * _trt / sparse norow nocol
        nopercnt out=_pct6(drop=percent);
run;

proc sort data=_temp6 out=_analcnt6 nodupkey;
    by _datasrt _byvar1 _cat _trt USUBJID;
    where paramcd eq upcase("Mspis") and knowvfl eq 'Y';
run;

proc freq data=_analcnt6 noprint;
    tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom6(drop=percent);
run;

data _denomf6;
    length _cat $100 ;
    _datasrt=1;
    set _catby6(keep=_byvar1);
    * All treatment groups ;
    _trt1=0;
    _trt2=0;
    * _CAT is the subgroup variable ;
    _cat = "12-15 Years ";
    output;
    _cat = "16-25 Years ";
    output;
run;

proc transpose data=_denom6 out=_denomin6(drop=_name __label_) prefix=_trt;
    by _datasrt _byvar1 _cat;
    var count;
    id _trt;
run;

data _frame6;
    set _frame2;
    _blcksrt=3;
run;

proc sort data=_frame6;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

```

```

proc sort data=_pct6;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

data _pct6;
  merge _frame6(in=_inframe) _pct6;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt;

  if _inframe;

  if count=. then
    count=0;
run;

proc sort data=_pct6;
  by _datasrt _byvar1 _blcksrt AVAL;
run;

data _miss6(keep=_datasrt _byvar1 _blcksrt AVAL totcount);
  set _pct6;
  where AVAL=9998;
  retain totcount;
  by _datasrt _byvar1 _blcksrt AVAL;

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

  if last.AVAL;
run;

data _pct6(drop=totcount);
  merge _pct6 _miss6;
  by _datasrt _byvar1 _blcksrt AVAL;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf6;
  by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin6;
  by _datasrt _byvar1 _cat;
run;

data _denomin6;
  merge _denomf6(in=_inframe) _denomin6;
  by _datasrt _byvar1 _cat;

  if _inframe;
  _blcksrt=3;

```

```

run;

proc sort data=_pct6;
  by _datasrt _byvar1 _cat;
run;

data _pct6;
  if 0 then
    set _basetemplate;
  merge _denomin6(in=_a) _pct6;
  by _datasrt _byvar1 _cat;

  if _a;
  _varname="AVAL ";
  _vrlabel=" ";
  _rwlabel=put(AVAL, sev.);

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

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct6;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
run;

data _base6;
  length _catlabl $200;
  set _pct6 end=eof;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
  retain _rowsrt 5 _rowmax 0;
  array _trcnt(*) _trt1- _trt3;
  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)";
                _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._byvar1 then
  _rowsrt=6;

if first.AVAL 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=0;

if _trt=2 +1 then
  _trt=9999;

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

```

```

run;

data _base6;
  set _base6;
  length _cvalue2 $30.;
  _cvalue2=strip(tranwrd(_cvalue, 'A0'x, ''));
  _cvalue21=strip(scan(_cvalue, 1, '('));
  _cvalue22=compress(scan(_cvalue, 2, '(', ')'));
run;

data _base5;
  set _base5;
  drop _trt1 _trt2 count;
run;

proc sort data=_base5;
  by _datasrt _byvar1 _cat _trt;
run;

data _base5;
  set _base5;

  if _trt=1 then
    do;
      _trt1=input(_cvalue, ??best.);
    end;

  if _trt=2 then
    do;
      _trt2=input(_cvalue, ??best.);
    end;
run;

proc sort data=_base6(keep=_datasrt _trt _cvalue2 _cvalue21 _cvalue22 _cat
  _byvar1 count);
  by _datasrt _byvar1 _cat _trt;
run;

data _base6;
  merge _base5(in=a) _base6(in=b);
  by _datasrt _byvar1 _cat _trt;

  if a;

  if a and not b then
    do;
      _cvalue2="0";
      _cvalue21="0";
    end;

  if compress(_cvalue2)="0" then
    _cvalue22=put(0, 5.1);

  if compress(_cvalue)="0" then

```

```

do;
    _cvalue2="NA";
    _cvalue21="NA";
    _cvalue22="NA";
end;
run;

data _base5;
    set _base5;
    delete;
run;

*****
* Specification 5.3.3: Calculate 95% CI for observed proportion          *;
*****

data _cnp_tmp_cnp;
    set _base6;

    if count=. then
        count=0;
    indc=1;
    output _cnp;
    indc=2;

    if _trt=1 then
        do;
            count=_trt1 - count;
        end;

    if _trt=2 then
        do;
            count=_trt2 - count;
        end;
    output _cnp;

    if indc=2 and count=0 then
        output _tmp_cnp;
run;

proc sort data=_cnp;
    by _byvar1 _cat _rowsrt _rwlable _trt;
run;

proc sort nodupkey data=_tmp_cnp(keep=_byvar1 _cat _rowsrt _rwlable _trt);
    by _byvar1 _cat _rowsrt _rwlable _trt;
run;

*****
* Call proc freq procedure to calculate CI for observed proportion      *;
*****

proc freq data=_cnp noprint;
    by _byvar1 _cat _rowsrt _rwlable _trt;
    table indc/binomial alpha=0.05;

```

```

output out=obsprop binomial;
weight count;
run;

data obsprop;
merge obsprop _tmp_cnp(in=a);
by _byvar1 _cat _rowsrt _rwlable _trt;

if _bin_=1 and not a then
do;
xl_bin_=1 - xu_bin;
xu_bin_=1 - xl_bin;
end;
else
do;
xl_bin_=xl_bin;
xu_bin_=xu_bin;
end;
run;

data cnpobsprop1(keep=_byvar1 _cat _rowsrt _rwlable _trt cnp_ci);
set obsprop;
by _byvar1 _cat _rowsrt _rwlable _trt;
cnp_ci=(' || compress(put(xl_bin_ * 100, 5.1))
|| ',(*ESC*){nbspace 1}' || compress(put(xu_bin_ * 100, 5.1)) || ');
label cnp_ci='95% CI';
run;

proc datasets lib=work nolist gennum=all;
delete _cnp obsprop;
run;

proc sort data=_base6;
by _byvar1 _cat _rowsrt _rwlable _trt;
run;

proc sort data=cnpobsprop1;
by _byvar1 _cat _rowsrt _rwlable _trt;
run;

data _base6;
merge _base6(in=a) cnpobsprop1;
by _byvar1 _cat _rowsrt _rwlable _trt;

if a;

if compress(_cvalue)="0" then
do;
cnp_ci="NE";
end;
run;

```

*****,

* Specification 5.4: Statistics for Any local reaction category *;

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```
*****  
* Specification 5.4.1: Count denominator (N) *;  
*****
```

```
data _anal7;  
  length _KNOWVFL 8;  
  length _cat $100;  
  set _data1;  
  where AGEGR4 is not missing;  
  where same and _KNOWVFL is not missing;  
  _blcksrt=4;  
  _cnt=1;  
  _cat=AGEGR4;  
  
  if _trt <=0 then  
    delete;  
  output;  
run;  
  
proc sort data=_anal7;  
  by _datasrt _byvar1 _blcksrt _KNOWVFL _trt _cat;  
run;  
  
proc sort data=_anal7 out=_catby7(keep=_byvar1) nodupkey;  
  by _byvar1;  
  where paramcd eq upcase("Any");  
run;  
  
data _temp7;  
  set _anal7;  
  output;  
run;  
  
proc sort data=_temp7 out=_temp97 nodupkey;  
  by _datasrt _byvar1 _blcksrt _cat _KNOWVFL _trt usubjid;  
  where paramcd eq upcase("Any");  
run;  
  
proc freq data=_temp97 noprint;  
  format _KNOWVFL;  
  tables _datasrt*_byvar1*_blcksrt*_cat*_KNOWVFL*_trt / sparse norow nocol  
    nopercnt out=_pct7(drop=percent);  
run;  
  
proc freq data=_pct7 noprint;  
  where _KNOWVFL ne 9999;  
  weight count;  
  tables _datasrt*_byvar1*_cat*_trt / sparse noprint out=_denom7(drop=percent);  
run;  
  
data _denomf7;  
  length _cat $100;  
  _datasrt=1;  
  set _catby7(keep=_byvar1);
```

```

* All treatment groups ;
_trt1=0;
_trt2=0;
* _CAT is the subgroup variable ;
_cat="12-15 Years ";
output;
_cat="16-25 Years ";
output;
run;

proc transpose data=_denom7 out=_denomin7(drop=_name __label_) prefix=_trt;
  by _datasrt _byvar1 _cat;
  var count;
  id _trt;
run;

data _frame7;
  _datasrt=1;
  set _catby7(keep=_byvar1);
  _blcksrt=4;
  length _KNOWVFL 8;
  length _cat $100;
  _catLbl=" ";
  _trt=1;
  _KNOWVFL=1;
  _catord=1;
  _subcat=1;
  _cat="12-15 Years ";
  output;
  _subcat=2;
  _cat="16-25 Years ";
  output;
  _trt=2;
  _KNOWVFL=1;
  _catord=1;
  _subcat=1;
  _cat="12-15 Years ";
  output;
  _subcat=2;
  _cat="16-25 Years ";
  output;
run;

proc sort data=_frame7;
  by _datasrt _byvar1 _blcksrt _cat _KNOWVFL _trt;
run;

proc sort data=_pct7;
  by _datasrt _byvar1 _blcksrt _cat _KNOWVFL _trt;
run;

data _pct7;

```

```

merge _frame7(in=_inframe) _pct7;
by _datasrt _byvar1 _blcksrt _cat _KNOWVFL _trt;

if _inframe;

if count=. then
    count=0;
run;

proc sort data=_pct7;
by _datasrt _byvar1 _blcksrt _KNOWVFL;
run;

data _miss7(keep=_datasrt _byvar1 _blcksrt _KNOWVFL totcount);
set _pct7;
where _KNOWVFL=9998;
retain totcount;
by _datasrt _byvar1 _blcksrt _KNOWVFL;

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

if last._KNOWVFL;
run;

data _pct7(drop=totcount);
merge _pct7 _miss7;
by _datasrt _byvar1 _blcksrt _KNOWVFL;

if totcount=0 then
    delete;
run;

proc sort data=_denomf7;
by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin7;
by _datasrt _byvar1 _cat;
run;

data _denomin7;
merge _denomf7(in=_inframe) _denomin7;
by _datasrt _byvar1 _cat;

if _inframe;
    _blcksrt=4;
run;

proc sort data=_pct7;
by _datasrt _byvar1 _cat;
run;

```

```

data _pct7;
  if 0 then
    set _basetemplate;
  merge _denomin7(in=_a) _pct7;
  by _datasrt _byvar1 _cat;

  if _a;
  _varname="_KNOWVFL ";
  _vrlabel=" ";
  _rwlabel="Any local reaction(*ESC*){super f} ";

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

  if _catord=. then
    _catord=9997;
run;

proc sort data=_pct7;
  by _datasrt _byvar1 _blcksrt _catord _KNOWVFL _trt _cat;
run;

data _base7;
  length _catlabl $200;
  set _pct7 end=eof;
  by _datasrt _byvar1 _blcksrt _catord _KNOWVFL _trt _cat;
  retain _rowsrt 0 _rowmax 0;
  array _trcnt(*) _trt1- _trt3;
  drop _rowmax _cpct;
  length _cpct $100;
  _cpct=' ';
  _module='mcatstat';

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

  if length(_cvalue) < 5 then
    do;
      *-----;
      * Put character A0x at right most character to pad text;
      *-----;
      substr(_cvalue, 5, 1)='A0'x;
    end;

```

```

if first._byvar1 then
  _rowsrt=0;

if first._KNOWVFL 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=2 +1 then
  _trt=9999;

if eof then
  call symput('_rowsrt', compress(put(_rowmax, 4.)));
  _direct="TOP ";
  _p=0;
run;

*****
* Specification 5.4.2: Count n and percentage (%) for individual severity   *;
*****

data _anal8;
  length AVAL 8;
  length _cat $100;
  set _data1;
  where AGEGR4 is not missing;
  where same and AVAL is not missing;
  _blcksrt=4;
  _cnt=1;
  _cat=AGEGR4;

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

proc sort data=_anal8;
  by _datasrt _byvar1 _blcksrt AVAL _trt _cat;
run;

proc sort data=_anal8 out=_catby8(keep=_byvar1) nodupkey;
  by _byvar1;
  where paramcd eq upcase("Any") and ex_none_flg=0 and knowvfl eq 'Y';

```

```

run;

data _temp8;
  set _anal8;
  output;
run;

proc sort data=_temp8 out=_temp98 nodupkey;
  by _datasrt _byvar1 _blcksrt _cat AVAL _trt usubjid;
  where paramcd eq upcase("Any") and ex_none_flg=0 and knowvfl eq 'Y';
run;

proc freq data=_temp98 noprint;
  format AVAL;
  tables _datasrt*_byvar1*_blcksrt*_cat * AVAL * _trt / sparse norow nocol
    nopercnt out=_pct8(drop=percent);
run;

proc sort data=_temp8 out=_analcnt8 nodupkey;
  by _datasrt _byvar1 _cat _trt USUBJID;
  where paramcd eq upcase("Any") and knowvfl eq 'Y';
run;

proc freq data=_analcnt8 noprint;
  tables _datasrt*_byvar1*_cat * _trt / sparse noprint out=_denom8(drop=percent);
run;

data _denomf8;
  length _cat $100;
  _datasrt=1;
  set _catby8(keep=_byvar1);
  * All treatment groups ;
  _trt1=0;
  _trt2=0;
  * _CAT is the subgroup variable ;
  _cat="12-15 Years ";
  output;
  _cat="16-25 Years ";
  output;
run;

proc transpose data=_denom8 out=_denomin8(drop=_name __label_) prefix=_trt;
  by _datasrt _byvar1 _cat;
  var count;
  id _trt;
run;

data _frame8;
  _datasrt=1;
  set _catby8(keep=_byvar1);
  _blcksrt=4;
  length AVAL 8;
  length _cat $100;

```

```

    _catLbl=" ";
    _trt=1;
    AVAL=1;
    _catord=1;
    _subcat=1;
    _cat="12-15 Years ";
    output;
    _subcat=2;
    _cat="16-25 Years ";
    output;
    _trt=2;
    AVAL=1;
    _catord=1;
    _subcat=1;
    _cat="12-15 Years ";
    output;
    _subcat=2;
    _cat="16-25 Years ";
    output;
run;

proc sort data=_frame8;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

proc sort data=_pct8;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;
run;

data _pct8;
    merge _frame8(in=_inframe) _pct8;
    by _datasrt _byvar1 _blcksrt _cat AVAL _trt;

    if _inframe;

    if count=. then
        count=0;
run;

proc sort data=_pct8;
    by _datasrt _byvar1 _blcksrt AVAL;
run;

data _miss8(keep=_datasrt _byvar1 _blcksrt AVAL totcount);
    set _pct8;
    where AVAL=9998;
    retain totcount;
    by _datasrt _byvar1 _blcksrt AVAL;

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

    if last.AVAL;

```

```

run;

data _pct8(drop=totcount);
  merge _pct8 _miss8;
  by _datasrt _byvar1 _blcksrt AVAL;

  if totcount=0 then
    delete;
run;

proc sort data=_denomf8;
  by _datasrt _byvar1 _cat;
run;

proc sort data=_denomin8;
  by _datasrt _byvar1 _cat;
run;

data _denomin8;
  merge _denomf8(in=_inframe) _denomin8;
  by _datasrt _byvar1 _cat;

  if _inframe;
  _blcksrt=4;
run;

proc sort data=_pct8;
  by _datasrt _byvar1 _cat;
run;

data _pct8;
  if 0 then
    set _basetemplate;
  merge _denomin8(in=_a) _pct8;
  by _datasrt _byvar1 _cat;

  if _a;
  _varname="AVAL ";
  _vrlabel=" ";
  _rwlabel="Any local reaction(*ESC*){super f} ";

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

  if _catord=. then
    _catord=9997;

```

```

run;

proc sort data=_pct8;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
run;

data _base8;
  length _catlabl $200;
  set _pct8 end=eof;
  by _datasrt _byvar1 _blcksrt _catord AVAL _trt _cat;
  retain _rowsrt 1 _rowmax 0;
  array _trtcnt(*) _trt1- _trt3;
  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)";
              _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._byvar1 then
    _rowsrt=1;

```

```

if first.AVAL 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=2 +1 then
  _trt=9999;

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

```

```

data _base8;
set _base8;
length _cvalue2 $30.;
_cvalue2=strip(tranwrd(_cvalue, 'A0'x, ""));
_cvalue21=strip(scan(_cvalue, 1, '('));
_cvalue22=compress(scan(_cvalue, 2, '(', ')'));
run;

```

```

data _base7;
set _base7;
drop _trt1 _trt2 count;
run;

```

```

proc sort data=_base7;
by _datasrt _byvar1 _cat _trt;
run;

```

```

data _base7;
set _base7;

if _trt=1 then
  do;
    _trt1=input(_cvalue, ??best.);
  end;

if _trt=2 then
  do;
    _trt2=input(_cvalue, ??best.);
  end;

```

```

        end;
run;

proc sort data=_base8(keep=_datasrt _trt _cvalue2 _cvalue21 _cvalue22 _cat
        _byvar1 count);
    by _datasrt _byvar1 _cat _trt;
run;

```

```

data _base8;
    merge _base7(in=a) _base8(in=b);
    by _datasrt _byvar1 _cat _trt;

    if a;

    if a and not b then
        do;
            _cvalue2="0";
            _cvalue21="0";
        end;

    if compress(_cvalue2)="0" then
        _cvalue22=put(0, 5.1);

    if compress(_cvalue)="0" then
        do;
            _cvalue2="NA";
            _cvalue21="NA";
            _cvalue22="NA";
        end;
run;

```

```

data _base7;
    set _base7;
    delete;
run;

```

```

*****
* Specification 5.4.3: Calculate 95% CI for observed proportion          *;
*****

```

```

data _cnp _tmp_cnp;
    set _base8;

    if count=. then
        count=0;
    indc=1;
    output _cnp;
    indc=2;

    if _trt=1 then
        do;
            count=_trt1 - count;
        end;

```

```

if _trt=2 then
  do;
    count=_trt2 - count;
  end;
output _cnp;

if indc=2 and count=0 then
  output _tmp_cnp;
run;

proc sort data=_cnp;
  by _byvar1 _cat _rowsrt _rlabel _trt;
run;

proc sort nodupkey data=_tmp_cnp(keep=_byvar1 _cat _rowsrt _rlabel _trt);
  by _byvar1 _cat _rowsrt _rlabel _trt;
run;

*****
* Call proc freq procedure to calculate CI for observed proportion      *;
*****

proc freq data=_cnp noprint;
  by _byvar1 _cat _rowsrt _rlabel _trt;
  table indc/binomial alpha=0.05;
  output out=obsprop binomial;
  weight count;
run;

data obsprop;
  merge obsprop _tmp_cnp(in=a);
  by _byvar1 _cat _rowsrt _rlabel _trt;

  if _bin_=1 and not a then
    do;
      xl_bin_=1 - xu_bin;
      xu_bin_=1 - xl_bin;
    end;
  else
    do;
      xl_bin_=xl_bin;
      xu_bin_=xu_bin;
    end;
run;

*****
* SPECIFICATION 5 *;
* - Store the CI value in variable requested by user. *;
* - output the dataset with CI value. *;
*****

data cnpobsprop1(keep=_byvar1 _cat _rowsrt _rlabel _trt cnp_ci);
  set obsprop;
  by _byvar1 _cat _rowsrt _rlabel _trt;

```

```

cnp_ci=(' || compress(put(xl_bin_ * 100, 5.1))
      || ',(*ESC*){nbspace 1}' || compress(put(xu_bin_ * 100, 5.1)) || ');
label cnp_ci='95% CI';
run;

proc datasets lib=work nolist gennum=all;
  delete _cnp obsprop;
run;

proc sort data=_base8;
  by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

proc sort data=cnpobsprop1;
  by _byvar1 _cat _rowsrt _rwlabel _trt;
run;

data _base8;
  merge _base8(in=a) cnpobsprop1;
  by _byvar1 _cat _rowsrt _rwlabel _trt;

  if a;

  if compress(_cvalue)="0" then
    do;
      cnp_ci="NE";
    end;
run;

*****
* Specification 6
* 1) Generate final report dataset
* 2) Titles and footnotes
* 3) Display: output html file
*****

data _final;
  set _base1 _base2 _base3 _base4 _base5 _base6 _base7 _base8;
run;

proc sort data=_final;
  by _datasrt _byvar1 _blcksrt _rowsrt;
run;

data _bydata;
  set _bydat1;

  if _byvar1=0 then
    delete;
run;

proc sort data=_bydata;
  by _datasrt _byvar1;
run;

```

```

data _final;
  merge _bydata _final(in=_b);
  by _datasrt _byvar1;

  if _b;
run;

*-----;
* Generate treatment header labels and make further modifications ;
*-----;

proc sort data=_final;
  by _trt _subcat;
run;

data _final;
  merge _subGrpData _final(in=_b drop=_colabel);
  by _trt _subcat;

  if _b;
run;

proc sort data=_final;
  by _datasrt _byvar1 _blcksrt _rowsrt;
run;

data _final;
  set _final;
  drop __trt;

  if _trt=9999 then
    __trt=2 + 1;
  else
    __trt=_trt;

  if __trt=. then
    __trt=1;

  if _subcat in (., 9990, 9999) then
    _subcat=2;

  if _subcat < 9990 then
    _column=_subcat + (__trt - 1) * 2;
  else
    _column=_subcat;
  _colabel=translate(trim(_colabel), '^', ' ');

  if _column=9999 then
    _column=2 + 1;
run;

proc sort data=_final out=_final;
  by _datasrt _byvar1 _blcksrt _rowsrt _column;

```

```

run;

proc sql noprint;
  create table rson as select distinct _trt, _column , _subcat, _colabel ,
    _byvar1, _bylab1 , _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 , _subcat , _byvar1 ,
    _datasrt, _blcksrt, _vrlabel;
quit;

data ADCE_S010_LR_sev_ped_SAF;
  length _rvalue $200;
  set _final rson end=eof;
  _rwindt=sum(_indent, _dptindt);

  if _rwindt <=0 then
    _rvalue=_rwlabel;
  else
    _rvalue=repeat(byte(160), _rwindt-1)||_rwlabel;
  _dummy=1;

  if _trt=. then
    _trt=1;
run;

proc sort data=ADCE_S010_LR_sev_ped_SAF;
  by _datasrt _byvar1 _bylab1 _trt _blcksrt _rowsrt;
run;

data ADCE_S010_LR_sev_ped_SAF;
  set ADCE_S010_LR_sev_ped_SAF;
  _cvalue=left(compress(_cvalue, 'A0'x));
run;

data treat;
  length FMTNAME $8 start 8 label $200;
  fmtname='TREAT';

  do start=1 to 2 + ("N"="Y");
    label=symget('_TRTLB'|| compress(put(start, 4.)));
    label=trim(label);
    output;
  end;
run;

proc sql;
  create table subcat as select distinct 'SUBCAT' as FMTNAME length=8 , _subcat
    as start, tranwrd(_colabel, '^', ' ') as label from
    ADCE_S010_LR_SEV_PED_SAF order by fmtname, start;
quit;
proc format cntlin=subcat;

proc sql noprint;
  select distinct start, label, count(distinct start) into :start1,

```

```

: _trlbl1 - : _trlbl199, :maxtrt from treat where start ne 9999 order by start;
quit;

*-----;
* titles and footnotes ;
*-----;

options orientation=LANDSCAPE papersize="LETTER";
ods escapechar="~";
title1 "Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (*ESC*){Unicode 2013}";
title2 "Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) (*ESC*){Unicode 2013}
Safety Population";
footnote1 "Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.";
footnote2 "Note: Grade 4 reactions were classified by the investigator or medically qualified person.";
footnote3 "a.(*ESC*){nbspspace 5}N = number of subjects reporting at least 1 yes or no response for the specified
reaction after the specified dose. ";
footnote4 "b.(*ESC*){nbspspace 5}n = Number of subjects with the specified characteristic.";
footnote5 "c.(*ESC*){nbspspace 5}Exact 2-sided CI based on the Clopper and Pearson method. ";
footnote6 "d.(*ESC*){nbspspace 5}Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis
(redness and swelling categories) or exfoliative dermatitis (redness category only). ";
footnote7 "e.(*ESC*){nbspspace 5}Mild: does not interfere with activity; moderate: interferes with activity; severe:
prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site. ";
footnote8 "f.(*ESC*){nbspspace 5}Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the
injection site. ";

*-----;
* Output html file;
*-----;

ods html file="&outtable.";

data report;
  set ADCE_S010_LR_SEV_PED_SAF;

  if _trt=9999 then
    _trt=2 +1;
  _bylab1=tranwrd(_bylab1, "|", '036e'x);
  _rvalue=tranwrd(_rvalue, "|", '036e'x);
run;

proc sort data=report;
  by _datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat _trt;
run;

data data_1 (keep=_datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat
  COL:);
  set report;
  where _trt=1;
  rename _cvalue=COL11 _cvalue2=COL12 cnp_ci=COL13;
run;

data data_2 (keep=_datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat
  COL:);
  set report;

```

```

where _trt=2;
rename _cvalue=COL21 _cvalue2=COL22 cnp_ci=COL23;
run;

proc sort data=report out=extradata (keep=_datasrt _byvar1 _bylab1 _blcksrt
      _rowsrt _rvalue _subcat) nodupkey;
by _datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat;
run;

data report;
merge data_1 data_2 extradata;
by _datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat;
run;

data report;
set report;
_fixvar=1;
_fix2var=1;
_dummy=1;
run;

proc sort data=report out=outdata1;
by _datasrt _byvar1 _bylab1 _blcksrt _rowsrt _rvalue _subcat;
run;

*-----;
* proc report statements ;
*-----;

proc report data=outdata1 nowd list missing contents="" split="" spanrows style(report)={} style(header)={}
style(column)={};
column _fixvar _fix2var _datasrt _byvar1 _bylab1 _blcksrt _rowsrt (" " " " " " _rvalue) ("Vaccine Group (as
Administered)~{line}"
("&_trlbl1." _subcat, (COL11 COL12 COL13)) ("&_trlbl2." _subcat, (COL21 COL22 COL23))) ) _dummy;
define _fixvar / group noprint;
define _fix2var / group noprint;
define _subcat / across order=internal ' ' format=subcat. style(header)={just=center} center;
define _byvar1 / group order=internal noprint;
define _bylab1 / group "Dose" style(column)={just=left} style(header)={just=left} left;
define _datasrt / group order=internal noprint;
define _blcksrt / group order=internal noprint;
define _rowsrt / group order=internal noprint;
define _rvalue / group "Local Reaction" order=data style(column)={just=left} style(header)={just=left} left;
define COL11 / group nozero "N(*ESC*){super a}" style(column)={leftmargin=12px} style(header)=
{just=center} center;
define COL12 / group nozero "n(*ESC*){super b}{*ESC*}{nbspace 1}{%}" style(column)={leftmargin=12px}
style(header)={just=center} center;
define COL13 / group nozero "(95%(*ESC*){nbspace 1}CI(*ESC*){super c})" style(column)={leftmargin=12px}
style(header)={just=center} center;
define COL21 / group nozero "N(*ESC*){super a}" style(column)={leftmargin=12px} style(header)=
{just=center} center;
define COL22 / group nozero "n(*ESC*){super b}{*ESC*}{nbspace 1}{%}" style(column)={leftmargin=12px}
style(header)={just=center} center;

```

```
define COL23 / group nozero "(95%(*ESC*){nbspspace 1}CI(*ESC*){super c})" style(column)={leftmargin=12px}
style(header)={just=center} center;
define _dummy / sum noprint;

break before _fixvar / contents="" page;
compute before _fix2var;
  line @1 " ~n ";
endcomp;
compute after _blcksrt;
  line " ~n ";
endcomp;
run;

ods html close;
proc printto;
run;
```