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**********************************************************************************************
**;
**  Program Name    : adc19ef.sas                                                             **;
**  Date Created    : 17Nov2021                                                               **;
**  Programmer Name : (b) (4), (b) (6)                                                        **;
**  Purpose         : Create adc19ef dataset                                                  **;
**  Input data      : ADSYMPT and ADSL                                                        **;
**  Output data     : adc19ef.sas7bdat                                                        **;
**********************************************************************************************
**;
%let
oprot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_sdtm/saseng/cdisc3_0/data/
sdtm;
%let
protori=/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/analy
sis/eSUB;

libname dataprot "&oprot." access=readonly;
libname datvprot "&protori./data_vai" access=readonly;
libname datvout "&prot./data_vai";
libname viewpx "/Volumes/app/saseng/prod/cdisc3_0/view/" access=readonly;


%let cutoff_case_count = 500;
%let data_cutoff_date = %str(2021-09-02);

proc printto print="&prot./output/adc19ef.rpt"
      log="&prot./logs/adc19ef.log" new;
run;
*********************************************************************************************;
* Clean *;
*********************************************************************************************;

proc delete data=work._all_;
run;

proc format;
   value $stat 'UNK'='1' 'UNKNOWN'='1' 'N'='2' 'NEG'='2' 'IND'='3' 'Y'='4'
      'POS'='4';
   value stat 0=' ' 1='UNK' 2='NEG' 3='IND' 4='POS';
run;

** Create status values results. **;

data unblnd_dt;
   unblnddt=.;
   set datvprot.adsl(keep=usubjid unblnddt);
run;

proc sql;
   create table adsympt1 as select * from datvprot.adsympt left join (select
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    unblnddt from unblnd_dt as b where unblnddt ^=.) on
    strip(usubjid)=strip(b.usubjid) order by usubjid, avisitn, paramn, aval,
    avalc, adt, astdt;
  create table symp_prsnt as select distinct usubjid, visitnum, visit, avisitn,
    avisit, sum(aval) as aval, 1 as symp_prsnt_flg from adsympt1 where
    strip(paramcd) in ('CHILLS', 'DIARRHEA', 'FEVER', 'NLTSTSML', 'NCOUG',
    'NSTBRTH', 'NMUSPN', 'NSRTHROT', 'VOMIT', 'RESP', 'HR', 'OXYSAT', 'DIABP',
    'SYSBP', 'PO2FIO2', 'INTBTION', 'NIPPV', 'CPAP', 'OXYTHRP', 'MCHVENT',
    'ECMO', 'HFOXTHRP', 'VSOPRES', 'SARDFN', 'SAHDFN', 'SANDFN', 'HCUICU',
    'HCUHSP') group by usubjid, visitnum, visit, avisitn, avisit;
  create table adsympt2 as select * from adsympt1 left join (select
    symp_prsnt_flg from symp_prsnt as b) on strip(usubjid)=strip(b.usubjid) and
    visitnum=b.visitnum and strip(visit)=strip(b.visit) and avisitn=b.avisitn and
    strip(avisit)=strip(b.avisit) order by usubjid, avisitn, paramn, aval, avalc,
    adt, astdt;
quit;

** Cutoff at unblinded date. **;

data unblnd1;
  set adsympt2(keep=usubjid visitnum visit avisitn avisit paramn paramcd aval
    avalc unblnddt adt astdt aendt symp_prsnt_flg);
  by usubjid avisitn paramn aval avalc adt astdt;
  length stdt endt 8 unbl_vis_list $1000;

  if first.usubjid then
    do;
      unbl_vis_list='';
      endt=.;
    end;

  if strip(paramcd) in ('RESP', 'HR', 'OXYSAT', 'DIABP', 'SYSBP', 'PO2FIO2',
    'C19NIG', 'RTCOV2NS', 'SARSCOV2', 'PRCDTH', 'SECDTH') then
      stdt=adt;
  else
    do;
      stdt=astdt;
      endt=aendt;

      if astdt=. and endt <=aendt then
        endt=aendt;

      if astdt ^=. and aendt=. and endt < astdt then
        endt=.;
    end;

  if unblnddt=. then
    do;

      if not (indexw(strip(unbl_vis_list), strip(avisit))) then
        unbl_vis_list=strip(unbl_vis_list) || ' ' || strip(avisit);
    end;
  else
    do;
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```
        if (strip(paramcd) in ('RTCOV2NS', 'SARSCOV2') and
           (strip(avisit) in ('V1_DAY1_VAX1_L', 'V2_VAX2_L',
           'V201_SURVEIL_CONSENT') or substr(avisit, 1, 10)='SSWAB_WEEK' or
           symp_prsnt_flg=.)) or (strip(paramcd) not in ('RTCOV2NS', 'SARSCOV2')
           and (PARAMCD not in ("HCUHSP"))) then
              do;

              if not (indexw(strip(unbl_vis_list), strip(avisit))) then
                 do;

                    if (stdt=.) or (. < stdt <=unblnddt) then
                       unbl_vis_list=strip(unbl_vis_list) || ' ' || strip(avisit);
                 end;
           end;
     end;

   if last.usubjid then
      keepflg=1;
   format adt astdt aendt unblnddt stdt endt yymmdd10.;
   retain endt unbl_vis_list;
run;

data unblnd2(drop=paramn paramcd aval avalc);
   set unblnd1;
   by usubjid avisitn paramn aval avalc adt astdt;
   where unbl_vis_list ^='' and keepflg=1;
run;

data adsympt_cutoff unblnd_cutoff(keep=usubjid paramn paramcd aval avalc
      visitnum visit avisitn avisit adt astdt aendt unblnddt endt unbl_vis_list
      blnd_cutoff_flg);
   merge adsympt2(in=a) unblnd2(in=b keep=usubjid endt unbl_vis_list);
   by usubjid;

   if indexw(strip(unbl_vis_list), strip(avisit)) then
      blnd_cutoff_flg=1;

   if unblnddt=. or (paramcd in ('PRCDTH', 'SECDTH') and adt < unblnddt) then
      blnd_cutoff_flg=1;
run;

proc sort data=adsympt_cutoff out=adsympt(drop=endt unbl_vis_list
      blnd_cutoff_flg);
   by usubjid avisitn paramn aval avalc adt astdt;
   where blnd_cutoff_flg=1;
run;

** End unblind cutoff. **;

data symp_all_1 ord_data_1(keep=usubjid visitnum visit avisitn avisit srtdt)
      death(drop=ady astdy aendt aendy mbspec avisitn avisit res c19ilhfl)
      vis_colsp1(keep=usubjid visitnum visit avisitn avisit);
   recseq=put(_n_, z7.);
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```
set adsympt(keep=usubjid paramn paramcd param parcat1 aval avalc visitnum
   visit avisitn avisit adt astdt aendt ady astdy aendy vax101dt vax102dt mbspec
   c19ilhfl unblnddt);
by usubjid avisitn paramn aval avalc adt astdt;
length res $8;
** Determine result conditions. **;

if aval=. and strip(avalc)='' then
   stat=0;
else if strip(paramcd)='RESP' and aval ^=. then
   do;

      if aval < 30 then
         res='NEG';
      else
         res='POS';
   end;
else if strip(paramcd)='HR' and aval ^=. then
   do;

      if aval < 125 then
         res='NEG';
      else
         res='POS';
   end;
else if strip(paramcd)='OXYSAT' and aval ^=. then
   do;

      if aval > 93 then
         res='NEG';
      else
         res='POS';
   end;
else if strip(paramcd)='DIABP' and aval ^=. then
   do;

      if aval >=60 then
         res='NEG';
      else
         res='POS';
   end;
else if strip(paramcd)='SYSBP' and aval ^=. then
   do;

      if aval >=90 then
         res='NEG';
      else
         res='POS';
   end;
else if strip(paramcd)='PO2FIO2' and aval ^=. then
   do;

      if aval >=300 then
         res='NEG';
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        else
            res='POS';
    end;
else if strip(paramcd)='VSOPRES' then
    do;

        if avalc ^='' then
            res='POS';
        else
            res='NEG';
    end;
else
    stat=input(put(avalc, $stat.), ?? best.);

if res ^='' and stat=. then
    stat=input(put(res, $stat.), ?? best.);
srtdt=astdt;
** Group Symptoms and test results. **;

if strip(paramcd) in ('CHILLS', 'DIARRHEA', 'FEVER', 'NLTSTSML', 'NCOUG',
    'NSTBRTH', 'NMUSPN', 'NSRTHROT', 'VOMIT') then
        do;
        grp=1;
        output symp_all_1;
    end;

if strip(paramcd) in ('CHILLS', 'DIARRHEA', 'FEVER', 'NLTSTSML', 'NCOUG',
    'NSTBRTH', 'NMUSPN', 'NSRTHROT', 'VOMIT') or strip(paramcd) in ('FATIGUE',
    'HEADACHE', 'RIHNRA', 'NAUSEA', 'NNSLCONG') then
        do;
        grp=2;
        output symp_all_1;
    end;

if strip(paramcd) in ('RESP', 'HR', 'OXYSAT', 'DIABP', 'SYSBP', 'PO2FIO2') then
    do;
        grp=3;
        astdt=adt;
        srtdt=adt;
        output symp_all_1;
    end;

if strip(paramcd) in ('INTBTION', 'NIPPV', 'CPAP', 'OXYTHRP', 'MCHVENT',
    'ECMO', 'HFOXTHRP') then
        do;
        grp=4;
        output symp_all_1;
    end;

if strip(paramcd) in ('VSOPRES') then
    do;
        grp=5;
        output symp_all_1;
    end;
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if strip(paramcd) in ('SARDFN', 'SAHDFN', 'SANDFN') then
   do;
      grp=6;
      output symp_all_1;
   end;

if strip(paramcd) in ('HCUICU') then
   do;
      grp=7;
      output symp_all_1;
   end;

if strip(paramcd) in ('HCUHSP') then
   do;
      grp=11;
      output symp_all_1;
   end;

if strip(paramcd) in ('MCHVENT', 'ECMO', 'HCUICU', 'HCUHSP') then
   do;
      grp=12;
      output symp_all_1;
   end;

if strip(paramcd) in ('C19NIG') and strip(avisit)='V1_DAY1_VAX1_L' then
   do;
      grp=21;
      ** These number assignments are used below. **;
      srtdt=adt;
      output symp_all_1;
   end;

if strip(paramcd) in ('RTCOV2NS') then
   do;
      grp=22;
      srtdt=adt;
      output symp_all_1;
   end;

if strip(paramcd) in ('SARSCOV2') then
   do;
      grp=23;
      srtdt=adt;
      output symp_all_1;
   end;

if grp ^=. then
   output ord_data_1;

if strip(paramcd) in ('PRCDTH', 'SECDTH') then
   output death;

if visitnum ^=avisitn or visit ^=avisit then
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    output vis_colsp1;
  format adt astdt aendt vax101dt vax102dt srtdt yymmdd10.;
run;

** Process Deaths. **;

data death1;
  set death;
  by usubjid;
  length cause $400;

  if first.usubjid then
    cause=strip(avalc);
  else
    cause=strip(cause) || ' , ' || strip(avalc);

  if last.usubjid then
    do;
      avalc='N';

      if indexw(cause, 'COVID') or indexw(cause, 'COVID-19') then
        avalc='Y';
      grp=10;
      stat=input(put(avalc, $stat.), ?? best.);
      astdt=adt;
      srtdt=adt;
      keepflg=1;
    end;
  retain cause;
run;

proc sql;
  create table death2 as select * from
          (select * from death1 where keepflg=1) left join
          (select adt as adt_, astdt as astdt_, grp as grp_, avisitn, avisit from
    symp_all_1 as b) on strip(usubjid)=strip(b.usubjid) and
              ((b.grp < 20 and . < b.astdt <=adt) or
               (b.grp > 20 and . < b.adt <=adt)) order by usubjid, adt_, astdt_;
quit;

data death3(drop=keepflg);
  set death2;
  by usubjid adt_ astdt_;

  if grp_ < 20 then
    finaldt=astdt_;

  if grp_ > 20 then
    finaldt=adt_;
  format finaldt yymmdd10.;
run;

proc sort data=death3;
  by usubjid finaldt;
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run;

data death4(drop=adt_ astdt_ grp_ finaldt);
   set death3;
   by usubjid finaldt;

   if last.usubjid then
      do;
         output;
         grp=20;
         output;
      end;
run;

data ord_data_1_dth;
   set ord_data_1 death4(keep=usubjid visitnum visit avisitn avisit srtdt);
run;

proc sort data=ord_data_1_dth out=ord_data_1a noduprecs;
   by usubjid srtdt avisitn avisit visitnum visit;
   where srtdt ^=. and avisit not in('V1_DAY1_VAX1_L', 'V2_VAX2_L');
run;

data ord_data_1b;
   set ord_data_1a;
   by usubjid srtdt avisitn avisit visitnum visit;
   length avislist $1000;

   if first.usubjid then
      do;
         avislist='';
         srtord=10;
      end;
   id=prxparse('/' || strip(avisit) || '/i');
   call prxsubstr(id, avislist, point, lng);

   if first.usubjid or (first.avisitn and lng=0) then
      do;
         srtord + 2;
         keepflg=1;
         avislist=strip(strip(avislist) || ' ' || strip(avisit));
      end;

   if last.usubjid then
      lastrec=1;
   retain avislist;
run;

proc sql;
   create table ord_data_1c as select * from
            (select distinct * from ord_data_1_dth) left join (select srtord from
      ord_data_1b as b where keepflg=1) on usubjid=b.usubjid and avisitn=b.avisitn
      and avisit=b.avisit order by usubjid, avisitn, srtord, srtdt;
quit;
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```
data ord_data_1d;
   set ord_data_1c;
   by usubjid avisitn srtord srtdt;

   if first.usubjid then
      srtord_b=0;

   if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
      do;

         if strip(avisit)='V1_DAY1_VAX1_L' then
            do;
               srtord_b=srtord_b + 1;
               srtord=srtord_b;
            end;

         if strip(avisit)='V2_VAX2_L' then
            do;
               srtord_b=srtord_b + 1;
               srtord=srtord_b;
            end;
      end;
   else
      do;

         if srtord=. then
            do;

               if first.usubjid then
                  srtord=10.1;
               else
                  srtord=srtord_ + .1;
            end;
         srtord_=srtord;
      end;
   retain srtord_b srtord_;
run;

proc sort data=vis_colsp1 out=vis_colsp2 nodupkey;
   by usubjid avisitn avisit;
run;

data symp_all_1_dth;
   set symp_all_1 death4;
run;

proc sql;
   ** Merge sort order. **;
   create table symp_all_2 as select * from symp_all_1_dth left join (select
      srtord from ord_data_1d as b) on usubjid=b.usubjid and visitnum=b.visitnum
      and visit=b.visit and avisitn=b.avisitn and avisit=b.avisit and srtdt=b.srtdt;
   ** Flag collapsed visits records. **;
   create table symp_all_3 as select * from symp_all_2 left join (select 1 as
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    clspflg, avisitn as avisitn_colsp, avisit as avisit_colsp from vis_colsp2 as
    b) on usubjid=b.usubjid and avisitn=b.avisitn and avisit=b.avisit;
  ** Merge Death date. **;
  create table symp_all_4 as select * from symp_all_3 left join (select adt as
    dthdt from death4 as b where grp=10) on usubjid=b.usubjid order by usubjid,
    avisitn, avisit, grp, stat, astdt, visitnum, aendt;
quit;

data symp_all_5 symp1(keep=recseq usubjid vax101dt vax102dt avisitn avisit
    parcat1 grp stat dthdt c19ilhfl srtord clspflg grpcat grp_stdt grp_endt
    visitnum_ visit_ unblnddt rename=(grp_stdt=astdt grp_endt=aendt
    visitnum_=visitnum visit_=visit)) nva_naat1(keep=recseq usubjid vax101dt
    vax102dt visitnum visit avisitn avisit paramn paramcd param parcat1 aval
    avalc mbspec grp adt srtord dthdt stat c19ilhfl clspflg unblnddt);
  set symp_all_4;
  by usubjid avisitn avisit grp stat astdt visitnum aendt;

  if avisitn_colsp ^=. then
    clspflg=1;

  if grp in (1, 2) then
    grpcat=1;

  if 3 <=grp <=10 then
    grpcat=2;

  if 11 <=grp <=20 then
    grpcat=3;

  if first.grp then
    do;
      grp_stdt=astdt;
      grp_endt=aendt;
      grp_stat=stat;
      visitnum_=visitnum;
      visit_=visit;
    end;

  if grp_stat < stat or grp in (7, 11) then
    do;
      grp_stdt=astdt;
      grp_endt=aendt;
      grp_stat=stat;
      visitnum_=visitnum;
      visit_=visit;
    end;

  if grp_stdt=. and stat=4 then
    grp_stdt=astdt;

  if (. < grp_endt < aendt) or aendt=. then
    grp_endt=aendt;

  if last.grp and grp <=20 then
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      keepflg=1;

   if grp in (7, 11) then
      keepflg=1;
   output symp_all_5;

   if keepflg=1 then
      output symp1;

   if grp in (21, 22, 23) then
      output nva_naat1;
   format grp_stdt grp_endt yymmdd10.;
   retain grp_stdt grp_endt grp_stat visitnum_ visit_;
run;

proc sort data=symp1;
   by usubjid avisitn avisit grpcat grp stat astdt aendt visitnum;
run;

data symp2(drop=vis_endtfl setflg vis_stat vis_astdt vis_aendt vis_endtfl_cdc
      vs_dth_only setflg_cdc vis_stat_cdc vis_astdt_cdc vis_aendt_cdc);
   set symp1;
   by usubjid avisitn avisit grpcat grp stat astdt aendt visitnum;

   if first.avisitn then
      do;
         vis_endtfl=0;
         vis_endtfl_cdc=0;
         vs_dth_only=1;
         setflg=0;
         setflg_cdc=0;
      end;

   if setflg=0 and 3 <=grp <=10 then
      do;
         vis_stat=stat;
         vis_astdt=astdt;
         vis_aendt=aendt;

         if stat=2 then
            vis_aendt=astdt;
         setflg=1;

         if stat=2 and astdt=. then
            setflg=0;

         if grp=3 and stat=2 then
            setflg=0;
      end;

   if setflg_cdc=0 and 11 <=grp <=20 then
      do;
         vis_stat_cdc=stat;
         vis_astdt_cdc=astdt;
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      vis_aendt_cdc=aendt;
      setflg_cdc=1;
   end;

if 3 <=grp <=10 then
   do;

      if grp not in (3, 10) then
         vs_dth_only=0;

      if aendt=. or stat ^=4 then
         vis_endtfl=1;

      if aendt=. and stat=2 then
         vis_endtfl=0;

      if vis_stat <=stat then
         do;
            vis_stat=stat;

            if vis_astdt=. or (vis_astdt ^=. and . < astdt < vis_astdt) then
               vis_astdt=astdt;
         end;

      if vis_stat=stat and astdt < vis_astdt then
         vis_astdt=astdt;

      if . < vis_aendt < aendt then
         vis_aendt=aendt;
   end;

if 11 <=grp <=20 then
   do;

      if aendt=. or stat ^=4 then
         vis_endtfl_cdc=1;

      if vis_stat_cdc <=stat then
         do;
            vis_stat_cdc=stat;

            if vis_astdt_cdc=. or (vis_astdt_cdc ^=. and . < astdt < vis_astdt_cdc)
               then
                  vis_astdt_cdc=astdt;
         end;

      if vis_stat_cdc=stat and astdt < vis_astdt_cdc then
         vis_astdt_cdc=astdt;

      if . < vis_aendt_cdc < aendt then
         vis_aendt_cdc=aendt;
   end;
output;
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   if last.grpcat then
      do;

         if grpcat=2 then
            do;
               grp=20.1;
               stat=vis_stat;
               astdt=vis_astdt;

               if vis_endtfl=0 and vs_dth_only=0 then
                  aendt=vis_aendt;
               else
                  aendt=.;
               parcat1='SEVERE COVID-19 SYMPTOMS';
               output;
            end;

         if grpcat=3 then
            do;
               grp=20.2;
               stat=vis_stat_cdc;
               astdt=vis_astdt_cdc;

               if vis_endtfl_cdc=0 then
                  aendt=vis_aendt_cdc;
               else
                  aendt=.;
               parcat1='SEVERE COVID-19 SYMPTOMS';
               output;
            end;
      end;
   retain vis_endtfl vis_endtfl_cdc vs_dth_only setflg setflg_cdc vis_stat
      vis_astdt vis_aendt vis_stat_cdc vis_astdt_cdc vis_aendt_cdc;
   format vis_astdt vis_aendt vis_stat_cdc vis_aendt_cdc yymmdd10.;
run;

proc sql;
   ** Merge symptom dates based on VISITNUM. **;
   create table nva_naat1a as select * from nva_naat1 left join
         (select usubjid as usubjid_v, min(astdt) as astdt_sym_v format
      yymmdd10., max(aendt) as aendt_sym_v format yymmdd10. from symp_all_3 as b
      where grp in (1, 2) and astdt ^=. group by usubjid, visitnum, visit) on
      usubjid=b.usubjid and visitnum=b.visitnum and visit=b.visit order by usubjid,
      vax101dt, vax102dt, avisitn, avisit, visitnum, visit, grp, adt;
   ** Merge symptom dates based on AVISITN. **;
   create table nva_naat1b as select * from nva_naat1a left join
         (select usubjid as usubjid_av, min(astdt) as astdt_sym_av format
      yymmdd10., max(aendt) as aendt_sym_av format yymmdd10. from symp1 as b where
      grp in (1, 2) and astdt ^=. group by usubjid, avisitn, avisit) on
      usubjid=b.usubjid and avisitn=b.avisitn and avisit=b.avisit order by usubjid,
      vax101dt, vax102dt, avisitn, avisit, visitnum, visit, grp, stat, adt;
quit;

** Determine if NVA or NAAT result/s are valid based on dates to exclude multiple records that are out of window. **;
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```
data nva_naat2 nva_naat_flags(keep=usubjid vax101dt vax102dt dthdt c19ilhfl_
     vldrslfl vrblngfl crd1ngfl crd2ngfl pdp17fl_ pdp27fl_);
   set nva_naat1b;
   by usubjid vax101dt vax102dt avisitn avisit visitnum visit grp stat adt;
   ** Derive result flags. **;

   if first.usubjid then
      do;
         vrblngfl='U';
         crd1ngfl='U';
         crd2ngfl='U';
         pdp17fl_='N';
         pdp27fl_='N';
      end;
   vldrslfl='N';
   c19ilhfl_=c19ilhfl;

   if strip(avisit)='V1_DAY1_VAX1_L' then
      do;

         if . < adt <=vax101dt then
            vldrslfl='Y';

         if vldrslfl='Y' and strip(put(stat, stat.))='POS' then
            do;

               if grp=21 then
                  vrblngfl='N';

               if grp=22 then
                  crd1ngfl='N';
            end;

         if vldrslfl='Y' and strip(put(stat, stat.))='NEG' then
            do;

               if grp=21 then
                  vrblngfl='Y';

               if grp=22 then
                  crd1ngfl='Y';
            end;

         if last.avisitn and vrblngfl='Y' and crd1ngfl='Y' then
            pdp17fl_='Y';
      end;
   else if strip(avisit)='V2_VAX2_L' then
      do;

         if . < adt <=vax102dt then
            vldrslfl='Y';

         if vldrslfl='Y' and strip(put(stat, stat.))='POS' and grp=22 then
```

```
            crd2ngfl='N';

         if vldrslfl='Y' and strip(put(stat, stat.))='NEG' and grp=22 then
            crd2ngfl='Y';

         if last.avisitn and vrblngfl='Y' and crd1ngfl='Y' and crd2ngfl='Y' then
            pdp27fl_='Y';
      end;
   else if strip(avisit) not in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
      do;

         if usubjid_av ^='' then
            do;

               if astdt_sym_av ^=. and aendt_sym_av=. and sum(astdt_sym_av, -4) <=adt then
                  vldrslfl='Y';

               if astdt_sym_av ^=. and aendt_sym_av ^=. and sum(astdt_sym_av, -4)
                  <=adt <=sum(aendt_sym_av, 4) then
                     vldrslfl='Y';
            end;
         else if usubjid_v ^='' then
            do;

               if astdt_sym_v ^=. and aendt_sym_v=. and sum(astdt_sym_v, -4) <=adt then
                  vldrslfl='Y';
               else if astdt_sym_v ^=. and aendt_sym_v ^=. and sum(astdt_sym_v, -4)
                  <=adt <=sum(aendt_sym_v, 4) then
                     vldrslfl='Y';
            end;
         else
            cncrslfl='Y';
      end;

   if first.grp and last.grp then
      cncrslfl='Y';
   else
      do;
         ** Check if multiple results are present and valid. **;

         if vldrslfl='Y' then
            cncrslfl='Y';
      end;
   output nva_naat2;

   if last.usubjid then
      output nva_naat_flags;
   retain vrblngfl crd1ngfl crd2ngfl pdp17fl_ pdp27fl_;
run;

proc sort data=nva_naat2 out=nva_naat3(drop=usubjid_v usubjid_av);
   by usubjid vax101dt vax102dt avisitn avisit visitnum visit grp stat adt;
   where cncrslfl='Y';
run;
```

```
data nva_naat4 nva_naat4a(keep=usubjid adt stat rename=(adt=nva_dt stat=nva))
      nva_naat4b(keep=usubjid adt stat rename=(adt=cnt_1dt stat=cnt_1))
      nva_naat4c(keep=usubjid adt stat rename=(adt=cnt_2dt stat=cnt_2))
      nva_naat4d(keep=usubjid vax101dt vax102dt avisitn avisit visitnum visit adt
      stat srtord clspflg vldrslfl rename=(vldrslfl=c_vldrslfl adt=cnt_unp_dt
      stat=cnt_unp srtord=cnt_srtord)) nva_naat4e(keep=usubjid vax101dt vax102dt
      avisitn avisit visitnum visit adt stat srtord clspflg vldrslfl
      rename=(vldrslfl=l_vldrslfl adt=lcl_unp_dt stat=lcl_unp srtord=lcl_srtord));
   set nva_naat3;
   by usubjid vax101dt vax102dt avisitn avisit visitnum visit grp stat adt;

   if last.grp then
      keepflg=1;
   output nva_naat4;

   if keepflg=1 then
      do;

         if grp=21 and strip(avisit)='V1_DAY1_VAX1_L' then
            output nva_naat4a;

         if grp=22 and strip(avisit)='V1_DAY1_VAX1_L' then
            output nva_naat4b;

         if grp=22 and strip(avisit)='V2_VAX2_L' then
            output nva_naat4c;

         if grp=22 and strip(avisit) not in  ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
            output nva_naat4d;

         if grp=23 and strip(avisit) not in  ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
            output nva_naat4e;
      end;
run;

** Process central and local lab rerults. **;

data cnt_lcl1;
   merge nva_naat4d(in=a) nva_naat4e(in=b);
   by usubjid vax101dt vax102dt avisitn avisit visitnum visit;
   ** Conclude NAAT result for unplanned visits. **;

   if c_vldrslfl='Y' then
      do;
         naat_unp=cnt_unp;
         naat_unp_dt=cnt_unp_dt;
         srtord_swab=cnt_srtord;
      end;
   else if c_vldrslfl ^='Y' and l_vldrslfl='Y' then
      do;
         naat_unp=lcl_unp;
         naat_unp_dt=lcl_unp_dt;
         srtord_swab=lcl_srtord;
```

```
    end;

  if c_vldrslfl ^='Y' and l_vldrslfl ^='Y' then
    do;

      if nmiss(cnt_unp, naat_unp) < 2 then
        stat_sort=max(cnt_unp, naat_unp);

      if nmiss(cnt_unp_dt, naat_unp_dt) < 2 then
        dt_sort=max(cnt_unp_dt, naat_unp_dt);
    end;
  else
    do;
      stat_sort=naat_unp;
      dt_sort=naat_unp_dt;
    end;

  if srtord_swab=. then
    do;

      if cnt_srtord ^=. then
        srtord_swab=cnt_srtord;

      if cnt_srtord=. and lcl_srtord ^=. then
        srtord_swab=lcl_srtord;
    end;

  if c_vldrslfl='Y' or l_vldrslfl='Y' then
    vunprfl='Y';
  format naat_unp_dt yymmdd10.;
run;

proc sort data=cnt_lcl1;
  by usubjid vax101dt vax102dt avisitn avisit vunprfl naat_unp stat_sort dt_sort;
run;

data cnt_lcl2(drop=stat_sort);
  set cnt_lcl1;
  by usubjid vax101dt vax102dt avisitn avisit vunprfl naat_unp stat_sort dt_sort;

  if last.avisitn then
    keepflg=1;
  naat_rslt_flg=1;
  rename visitnum=visitnum_ visit=visit_;
run;

** Merge result flags with symptom data. **;

data symp3a(drop=keepflg);
  merge symp2(in=a) cnt_lcl2(in=b where=(keepflg=1));
  by usubjid avisitn avisit;

  if a and not b then
    mflg=1;
```

```
    if a and b then
       mflg=2;

    if not a and b then
       mflg=3;

    if mflg=3 and visitnum=. then
       do;
          visitnum=visitnum_;
          visit=visit_;
          srtord=srtord_swab;
       end;
run;

data symp3b;
    merge symp3a(in=a) nva_naat_flags(in=b drop=vax101dt vax102dt vldrslfl)
       nva_naat4a(in=c) nva_naat4b(in=d) nva_naat4c(in=d);
    by usubjid;

    if a;
    call missing(stdy1, stdy2);

    if astdt ^=. then
       do;

          if vax101dt ^=. then
             do;

                if astdt >=vax101dt then
                   stdy1=(astdt - vax101dt) + 1;
                else
                   stdy1=(astdt - vax101dt);
             end;

          if vax102dt ^=. then
             do;

                if astdt >=vax102dt then
                   stdy2=(astdt - vax102dt) + 1;
                else
                   stdy2=(astdt - vax102dt);
             end;
       end;

    if vrblngfl='' then
       vrblngfl='U';

    if crd1ngfl='' then
       crd1ngfl='U';

    if crd2ngfl='' then
       crd2ngfl='U';
```

```
   if pdp17fl_='' then
      pdp17fl_='N';

   if pdp27fl_='' then
      pdp27fl_='N';
   rename pdp17fl_=pdp17fl_tmp pdp27fl_=pdp27fl_tmp;
run;

proc sort data=symp3b out=symp3c;
   by usubjid vax101dt vax102dt srtord avisitn avisit grpcat grp astdt;
run;

data symp3d;
   retain recseq usubjid parcat1 visitnum visit avisitn avisit clspflg vax101dt
      vax102dt c19ilhfl dthdt nva nva_dt vrblngfl cnt_1 cnt_1dt crd1ngfl cnt_2
      cnt_2dt crd2ngfl grpcat grp stat astdt aendt stdy1 stdy2 cnt_unp cnt_unp_dt
      c_vldrslfl lcl_unp lcl_unp_dt l_vldrslfl naat_unp naat_unp_dt vunprfl
      naat_rslt_flg pdp17fl_tmp pdp27fl_tmp;
   set symp3c;
   by usubjid vax101dt vax102dt srtord avisitn avisit grpcat grp astdt;
run;

** Determine NAAT unplanned result and derive case. **;

data symp4(drop=naat_unp_) symp_all_flags(keep=usubjid vax101dt vax102dt dthdt
      pdsymfl_ pdsdmfl_ cdcsymfl_ sevsymfl_ sevcdcfl_ pdrmufl_ pdrmupfl_ cdcrmufl_
      cdrmupfl_ pdp1fl_ pdp17fl_ pdp27fl_ pdp214fl_ cdp1fl_ cdp17fl_ cdp27fl_
      cdp214fl_);
   set symp3d end=eof;
   by usubjid vax101dt vax102dt srtord avisitn avisit grpcat grp astdt;
   ** Setting the flags. **;

   if first.usubjid then
      do;
         pdsymfl_='N';
         pdsdmfl_='N';
         cdcsymfl_='N';
         sevsymfl_='N';
         sevcdcfl_='N';
         pdrmufl_='N';
         pdrmupfl_='N';
         cdcrmufl_='N';
         cdrmupfl_='N';
         pdp1fl_=pdp17fl_tmp;
         pdp17fl_=pdp17fl_tmp;
         pdp27fl_=pdp27fl_tmp;
         pdp214fl_=pdp27fl_tmp;
         cdp1fl_=pdp1fl_;
         cdp17fl_=pdp17fl_;
         cdp27fl_=pdp27fl_;
         cdp214fl_=pdp27fl_;
         filocrfl_pd_='';
         filocrfl_cdc_='';
         filocrfl_sev_='';
```

```
      filocrfl_sev_cdc_='';
      pd_fst_pos_dt=.;
      astdt_pd_res_miss=.;
      aendt_pd_res_miss=.;
      cd_fst_pos_dt=.;
      astdt_cdc_res_miss=.;
      aendt_cdc_res_miss=.;
      last_vis_end_dt=.;
   end;
** If concluded lab result out of CDC defined symptoms date/s, reset the valid flag. **;

if grp=2 then
   do;

      if astdt=. or naat_unp_dt=. then
         vunprfl='';
      else
         do;

            if aendt=. and sum(astdt, -4) <=naat_unp_dt then
               vunprfl='Y';
            else if aendt ^=. and sum(astdt, -4) <=naat_unp_dt <=sum(aendt, 4) then
               vunprfl='Y';
            else
               vunprfl='';
         end;
   end;
** Determine illness onset for protocol defined, CDC defined and severe symptoms. **;

if first.avisitn then
   do;
      c19onst_=-1;
      cdconst_=-1;
   end;

if strip(put(stat, stat.))='POS' and vunprfl='Y' then
   do;

      if strip(put(naat_unp, stat.)) in ('') then
         naat_unp_=input(put('UNK', $stat.), ?? best.);
      else
         naat_unp_=naat_unp;

      if grp=1 then
         c19onst=naat_unp_;

      if grp=2 then
         cdconst=naat_unp_;
   end;
else if strip(put(stat, stat.))='POS' and vunprfl='' then
   do;

      if grp=1 then
         c19onst=input(put('UNK', $stat.), ?? best.);
```

```
        if grp=2 then
          cdconst=input(put('UNK', $stat.), ?? best.);
      end;
    else if strip(put(stat, stat.)) in ('', 'NEG') then
      do;

        if grp=1 then
          c19onst=input(put('NEG', $stat.), ?? best.);

        if grp=2 then
          cdconst=input(put('NEG', $stat.), ?? best.);
      end;

    if grp=1 then
      c19onst_=c19onst;

    if grp=2 then
      cdconst_=cdconst;

    if grp=20.1 then
      do;

        if c19onst_=-1 then
          c19onst_=2;

        if strip(put(stat, stat.))='POS' then
          sevconst=c19onst_;

        if strip(put(stat, stat.)) in ('', 'NEG') then
          sevconst=input(put('NEG', $stat.), ?? best.);

        /*        if strip(put(c19onst_,stat.)) = 'POS' and last.usubjid and dthdt ^= . then sevconst =
input(put('POS',$stat.),?? best.);*/
      end;

    if grp=20.2 then
      do;

        if cdconst_=-1 then
          cdconst_=2;

        if strip(put(stat, stat.))='POS' then
          cdcsonst=cdconst_;

        if strip(put(stat, stat.)) in ('', 'NEG') then
          cdcsonst=input(put('NEG', $stat.), ?? best.);

        /*        if strip(put(cdconst_,stat.)) = 'POS' and last.usubjid and dthdt ^= . then cdcsonst =
input(put('POS',$stat.),?? best.);*/
      end;

    if strip(put(c19onst, stat.))='POS' and pd_fst_pos_dt=. then
      pd_fst_pos_dt=astdt;
```

```
if strip(put(cdconst, stat.))='POS' and cd_fst_pos_dt=. then
   cd_fst_pos_dt=astdt;

if grp=1 then
   do;

      if strip(put(stat, stat.))='POS' then
         do;
            pdsymfl_='Y';

            if astdt=. then
               pdsdmfl_='Y';

            if strip(put(c19onst, stat.)) not in ('NEG', 'POS') then
               do;
                  astdt_pd_res_miss=astdt;
                  aendt_pd_res_miss=aendt;

                  if (pd_fst_pos_dt=.) or (. < astdt < pd_fst_pos_dt) then
                     do;
                        pdrmufl_='Y';
                        pdrmupfl_='Y';
                     end;
               end;

            if strip(put(c19onst, stat.))='POS' and pdrmupfl_='Y' then
               do;

                  if unblnddt=. then
                     do;

                        if  . < astdt_pd_res_miss < pd_fst_pos_dt then
                           pdrmupfl_='N';

                        if pdrmupfl_='Y' and
                           astdt_pd_res_miss=. and . < aendt_pd_res_miss < pd_fst_pos_dt then
                              pdrmupfl_='N';
                     end;
                  else
                     do;

                        if  . < astdt_pd_res_miss < pd_fst_pos_dt < unblnddt then
                           pdrmupfl_='N';

                        if pdrmupfl_='Y' and
                           astdt_pd_res_miss=. and . < aendt_pd_res_miss < pd_fst_pos_dt < unblnddt
                           then
                              pdrmupfl_='N';
                     end;
               end;
         end;
   end;
```

```
if grp=2 then
   do;

      if strip(put(stat, stat.))='POS' then
         do;
            cdcsymfl_='Y';

            if strip(put(cdconst, stat.)) not in ('NEG', 'POS') then
               do;
                  astdt_cdc_res_miss=astdt;
                  aendt_cdc_res_miss=aendt;

                  if (cd_fst_pos_dt=.) or (. < astdt < cd_fst_pos_dt) then
                     do;
                        cdcrmufl_='Y';
                        cdrmupfl_='Y';
                     end;
               end;

            if strip(put(cdconst, stat.))='POS' and cdrmupfl_='Y' then
               do;

                  if unblnddt=. then
                     do;

                        if . < astdt_cdc_res_miss < cd_fst_pos_dt then
                           cdrmupfl_='N';

                        if cdrmupfl_='Y' and
                           astdt_cdc_res_miss=. and . < aendt_cdc_res_miss < cd_fst_pos_dt then
                              cdrmupfl_='N';
                     end;
                  else
                     do;

                        if . < astdt_cdc_res_miss < cd_fst_pos_dt < unblnddt then
                           cdrmupfl_='N';

                        if cdrmupfl_='Y' and
                           astdt_cdc_res_miss=. and . < aendt_cdc_res_miss < cd_fst_pos_dt < unblnddt
                           then
                              cdrmupfl_='N';
                     end;
               end;
         end;
   end;

if grp=20.1 and strip(put(stat, stat.))='POS' then
   sevsymfl_='Y';

if grp=20.2 and strip(put(stat, stat.))='POS' then
   sevcdcfl_='Y';

if grp=1 and c19onst=input(put('POS', $stat.), ?? best.) then
```

```
    do;

      if (vrblngfl='Y' and crd1ngfl='Y' and . < vax101dt=astdt)
         or (. < vax101dt < astdt) then
            ild1fl_pd='Y';
      else
         ild1fl_pd='N';

      if . < vax101dt < sum(vax101dt, 7) <=astdt then
         ild17fl_pd='Y';
      else
         ild17fl_pd='N';

      if (crd2ngfl='Y' and . < vax102dt=astdt) or (. < vax102dt < astdt) then
         ild2fl_pd='Y';
      else
         ild2fl_pd='N';

      if . < vax102dt < sum(vax102dt, 7) <=astdt then
         ild27fl_pd='Y';
      else
         ild27fl_pd='N';

      if . < vax102dt < sum(vax102dt, 14) <=astdt then
         ild214fl_pd='Y';
      else
         ild214fl_pd='N';

      if filocrfl_pd_='' then
         do;
            filocrfl_pd_='Y';
            filocrfl_pd='Y';
         end;
   end;

if grp=2 and cdconst=input(put('POS', $stat.), ?? best.) then
   do;

      if (vrblngfl='Y' and crd1ngfl='Y' and . < vax101dt=astdt)
         or (. < vax101dt < astdt) then
            ild1fl_cdc='Y';
      else
         ild1fl_cdc='N';

      if . < vax101dt < sum(vax101dt, 7) <=astdt then
         ild17fl_cdc='Y';
      else
         ild17fl_cdc='N';

      if (crd2ngfl='Y' and . < vax102dt=astdt) or (. < vax102dt < astdt) then
         ild2fl_cdc='Y';
      else
         ild2fl_cdc='N';
```

```
      if . < vax102dt < sum(vax102dt, 7) <=astdt then
         ild27fl_cdc='Y';
      else
         ild27fl_cdc='N';

      if . < vax102dt < sum(vax102dt, 14) <=astdt then
         ild214fl_cdc='Y';
      else
         ild214fl_cdc='N';

      if filocrfl_cdc_='' then
         do;
            filocrfl_cdc_='Y';
            filocrfl_cdc='Y';
         end;
   end;

if grp=20.1 and sevconst=input(put('POS', $stat.), ?? best.) then
   do;

      if (vrblngfl='Y' and crd1ngfl='Y' and . < vax101dt=astdt)
         or (. < vax101dt < astdt) then
            ild1fl_sev='Y';
      else
         ild1fl_sev='N';

      if . < vax101dt < sum(vax101dt, 7) <=astdt then
         ild17fl_sev='Y';
      else
         ild17fl_sev='N';

      if (crd2ngfl='Y' and . < vax102dt=astdt) or (. < vax102dt < astdt) then
         ild2fl_sev='Y';
      else
         ild2fl_sev='N';

      if . < vax102dt < sum(vax102dt, 7) <=astdt then
         ild27fl_sev='Y';
      else
         ild27fl_sev='N';

      if . < vax102dt < sum(vax102dt, 14) <=astdt then
         ild214fl_sev='Y';
      else
         ild214fl_sev='N';

      if filocrfl_sev_='' then
         do;
            filocrfl_sev_='Y';
            filocrfl_sev='Y';
         end;
   end;

if grp=20.2 and cdcsonst=input(put('POS', $stat.), ?? best.) then
```

```
   do;

      if (vrblngfl='Y' and crd1ngfl='Y' and . < vax101dt=astdt)
         or (. < vax101dt < astdt) then
            ild1fl_sev_cdc='Y';
      else
         ild1fl_sev_cdc='N';

      if . < vax101dt < sum(vax101dt, 7) <=astdt then
         ild17fl_sev_cdc='Y';
      else
         ild17fl_sev_cdc='N';

      if (crd2ngfl='Y' and . < vax102dt=astdt) or (. < vax102dt < astdt) then
         ild2fl_sev_cdc='Y';
      else
         ild2fl_sev_cdc='N';

      if . < vax102dt < sum(vax102dt, 7) <=astdt then
         ild27fl_sev_cdc='Y';
      else
         ild27fl_sev_cdc='N';

      if . < vax102dt < sum(vax102dt, 14) <=astdt then
         ild214fl_sev_cdc='Y';
      else
         ild214fl_sev_cdc='N';

      if filocrfl_sev_cdc_='' then
         do;
            filocrfl_sev_cdc_='Y';
            filocrfl_sev_cdc='Y';
         end;
   end;

if (strip(put(stat, stat.))=('POS') and strip(put(naat_unp, stat.)) ^='NEG')
   and stdy1 < 1 then
      do;

      if (vax101dt ^=. and naat_unp_dt ^=. and vax101dt <=naat_unp_dt) or
         naat_unp_dt=. or vunprfl='Y' then
            do;

            if grp=1 then
               pdp1fl_='N';

            if grp=2 then
               cdp1fl_='N';
         end;
   end;

if (strip(put(stat, stat.))=('POS') and strip(put(naat_unp, stat.)) ^='NEG')
   and stdy1 < 8 then
      do;
```

```
    if (vax101dt ^=. and naat_unp_dt ^=. and
       vax101dt <=naat_unp_dt < sum(vax101dt, 7)) or naat_unp_dt=. or vunprfl='Y'
       then
          do;

          if grp=1 then
             do;
                pdp17fl_='N';
                pdp27fl_='N';
             end;

          if grp=2 then
             do;
                cdp17fl_='N';
                cdp27fl_='N';
             end;
       end;
 end;

if (strip(put(stat, stat.))=('POS') and strip(put(naat_unp, stat.)) ^='NEG')
    and stdy2 < 8 then
       do;

    if (vax101dt ^=. and vax102dt ^=. and naat_unp_dt ^=. and
       vax101dt <=naat_unp_dt < sum(vax102dt, 7)) or naat_unp_dt=. or vunprfl='Y'
       then
          do;

          if grp=1 then
             pdp27fl_='N';

          if grp=2 then
             cdp27fl_='N';
       end;
 end;

if (strip(put(stat, stat.))=('POS') and strip(put(naat_unp, stat.)) ^='NEG')
    and stdy2 < 15 then
       do;

    if (vax101dt ^=. and vax102dt ^=. and naat_unp_dt ^=. and
       vax101dt <=naat_unp_dt < sum(vax102dt, 14)) or naat_unp_dt=. or vunprfl='Y'
       then
          do;

          if grp=1 then
             pdp214fl_='N';

          if grp=2 then
             cdp214fl_='N';
       end;
 end;
```

```
if strip(put(naat_unp, stat.))='POS' and vunprfl='Y' then
   do;

      if . < naat_unp_dt < vax101dt then
         do;
            pdp1fl_='N';
         end;

      if vax101dt ^=. and vax101dt <=naat_unp_dt < sum(vax101dt, 7) then
         do;
            pdp17fl_='N';
            pdp27fl_='N';
            cdp17fl_='N';
            cdp27fl_='N';
         end;

      if vax101dt ^=. and vax102dt ^=. and vax101dt <=naat_unp_dt < sum(vax102dt,
         7) then
            do;
            pdp27fl_='N';
            cdp27fl_='N';
         end;

      if vax101dt ^=. and vax102dt ^=. and vax101dt <=naat_unp_dt < sum(vax102dt,
         14) then
            do;
            pdp214fl_='N';
            cdp214fl_='N';
         end;
   end;

if strip(put(stat, stat.)) ^='POS' and
      ((strip(put(cnt_unp, stat.))='POS') or (strip(put(cnt_unp, stat.))='' and
   strip(put(lcl_unp, stat.))='POS')) then
      do;

      if strip(put(cnt_unp, stat.))='POS' then
         do;
            tmp_unp=cnt_unp;
            tmp_unp_dt=cnt_unp_dt;
         end;
      else if strip(put(lcl_unp, stat.))='POS' then
         do;
            tmp_unp=lcl_unp;
            tmp_unp_dt=lcl_unp_dt;
         end;

      if . < tmp_unp_dt < vax101dt then
         do;
            pdp1fl_='N';
         end;

      if vax101dt ^=. and vax101dt <=tmp_unp_dt < sum(vax101dt, 7) then
         do;
```

```
            pdp17fl_='N';
            pdp27fl_='N';
            cdp17fl_='N';
            cdp27fl_='N';
         end;

      if vax101dt ^=. and vax102dt ^=. and vax101dt <=tmp_unp_dt < sum(vax102dt,
         7) then
            do;
            pdp27fl_='N';
            cdp27fl_='N';
         end;

      if vax101dt ^=. and vax102dt ^=. and vax101dt <=tmp_unp_dt < sum(vax102dt,
         14) then
            do;
            pdp214fl_='N';
            cdp214fl_='N';
         end;
   end;

   if aendt ^=. then
      last_vis_end_dt=aendt;
   output symp4;

   if last.usubjid then
      output symp_all_flags;
   format naat_unp_dt last_vis_end_dt pd_fst_pos_dt cd_fst_pos_dt
      astdt_pd_res_miss aendt_pd_res_miss astdt_cdc_res_miss aendt_cdc_res_miss
      last_vis_end_dt yymmdd10.;
   retain c19onst_ cdconst_ pdsymfl_ pdsdmfl_ cdcsymfl_ sevsymfl_ sevcdcfl_
      pdrmufl_ pdrmupfl_ cdcrmufl_ cdrmupfl_ filocrfl_pd_ filocrfl_cdc_
      filocrfl_sev_ filocrfl_sev_cdc_ pdp1fl_ pdp17fl_ pdp27fl_ pdp214fl_ cdp1fl_
      cdp17fl_ cdp27fl_ cdp214fl_ pd_fst_pos_dt cd_fst_pos_dt astdt_pd_res_miss
      aendt_pd_res_miss astdt_cdc_res_miss aendt_cdc_res_miss last_vis_end_dt;
run;

** Join all the flags with results and symptoms data. Generate cutoff dataset. **;

data all_flags;
   merge nva_naat_flags(in=a) symp_all_flags(in=b);
   by usubjid;

   if a and not b then
      mflg=1;

   if a and b then
      mflg=2;

   if not a and b then
      mflg=3;

   if mflg=1 then
      do;
```

```
        pdsymfl_='N';
        pdsdmfl_='N';
        cdcsymfl_='N';
        sevsymfl_='N';
        sevcdcfl_='N';
        pdrmufl_='N';
        pdrmupfl_='N';
        cdcrmufl_='N';
        cdrmupfl_='N';
        pdp1fl_=pdp17fl_;
        pdp214fl_=pdp27fl_;
        cdp1fl_=pdp17fl_;
        cdp17fl_=pdp17fl_;
        cdp27fl_=pdp27fl_;
        cdp214fl_=pdp27fl_;
      end;

   if mflg=3 then
      do;
        vrblngfl='N';
        crd1ngfl='N';
        crd2ngfl='N';
      end;
   rename c19ilhfl_=c19ilhfl pdsymfl_=pdsymfl pdsdmfl_=pdsdmfl cdcsymfl_=cdcsymfl
      sevsymfl_=sevsymfl sevcdcfl_=sevcdcfl pdrmufl_=pdrmufl pdrmupfl_=pdrmupfl
      cdcrmufl_=cdcrmufl cdrmupfl_=cdrmupfl pdp1fl_=pdp1fl pdp17fl_=pdp17fl
      pdp27fl_=pdp27fl pdp214fl_=pdp214fl cdp1fl_=cdp1fl cdp17fl_=cdp17fl
      cdp27fl_=cdp27fl cdp214fl_=cdp214fl;
run;

data death_all_flags;
   merge death(in=a drop=astdt stat srtdt) all_flags(in=b drop=mflg);
   by usubjid;

   if a;
   dthdt=adt;
   avisitn=.;
   avisit='';
   grp=.;
run;

proc sort data=death_all_flags;
   by usubjid vax101dt vax102dt avisitn avisit grp;
run;

proc sql;
   ** Merge flags with NVA, NAAT results. **;
   create table nva_naat5 as select * from
         (select recseq, usubjid, vax101dt, vax102dt, visitnum, visit, avisitn,
      avisit, paramn, paramcd, param, parcat1, aval, avalc, grp, adt, stat, dthdt,
      unblnddt from nva_naat1) left join
         (select cncrslfl from nva_naat4 as b where keepflg=1) on
      strip(recseq)=strip(b.recseq);
   create table nva_naat6 as select * from nva_naat5 left join
```

```
        (select vrblngfl, crd1ngfl, crd2ngfl, c19ilhfl, pdsymfl, pdsdmfl,
      cdcsymfl, sevsymfl, sevcdcfl, pdrmufl, pdrmupfl, cdcrmufl, cdrmupfl, pdp1fl,
      pdp17fl, pdp27fl, pdp214fl, cdp1fl, cdp17fl, cdp27fl, cdp214fl from all_flags
      as b) on usubjid=b.usubjid order by usubjid, vax101dt, vax102dt, avisitn,
      avisit, grp;
   ** Merge flags with symptoms data. **;
   create table symp5(drop=pdp17fl_tmp pdp27fl_tmp c19onst_ pdsymfl_ pdsdmfl_
      cdcsymfl_ sevsymfl_ sevcdcfl_ pdrmufl_ pdrmupfl_ cdcrmufl_ cdrmupfl_ pdp1fl_
      pdp17fl_ pdp27fl_ pdp214fl_ cdp1fl_ cdp17fl_ cdp27fl_ cdp214fl_ pd_fst_pos_dt
      cd_fst_pos_dt) as select * from symp4 left join
        (select pdsymfl, pdsdmfl, cdcsymfl, sevsymfl, sevcdcfl, pdrmufl,
      pdrmupfl, cdcrmufl, cdrmupfl, pdp1fl, pdp17fl, pdp27fl, pdp214fl, cdp1fl,
      cdp17fl, cdp27fl, cdp214fl from all_flags as b) on usubjid=b.usubjid order by
      usubjid, vax101dt, vax102dt, avisitn, avisit, grp, astdt;
   create table cutoff as select usubjid, grp, stat, astdt from symp5 where grp=1
      and stat=4 and pdp27fl='Y' and c19onst=4 and ild27fl_pd='Y' and
      filocrfl_pd='Y' order by astdt, usubjid;
quit;

** Combine all data together and generate PARAMN, PARAMCD and PARAM variables. **;

data adc19ef_1;
   set nva_naat6 symp5(drop=nva nva_dt cnt_1 cnt_1dt cnt_2 cnt_2dt cnt_unp
      cnt_unp_dt c_vldrslfl lcl_unp lcl_unp_dt l_vldrslfl) death_all_flags;
   by usubjid vax101dt vax102dt avisitn avisit grp;

   if dthdt ^=. then
      dthfl='Y';

   if paramn in (95, 96) then
      output;

   if grp=1 then
      do;
         paramn=101;
         paramcd='PRPDSAD';
         param='PRESENCE OF PROTOCOL DEFINED SYMPTOMS AFTER DOSE';
      end;

   if grp=2 then
      do;
         paramn=102;
         paramcd='PRCDCSAD';
         param='PRESENCE OF CDC DEFINED SYMPTOMS AFTER DOSE';
      end;

   if grp=3 then
      do;
         paramn=103;
         paramcd='SEVCVS';
         param='SEVERE COVID-19 SYMPTOMS - VITAL SIGNS';
         parcat1='GENERAL VITAL SIGNS & OXYGENATION PARAMETERS';
         adt=astdt;
         astdt=.;
```

```
        aendt=.;
      end;

   if grp=4 then
      do;
         paramn=104;
         paramcd='SEVCRF';
         param='SEVERE COVID-19 SYMPTOMS - RESPIRATORY FAILURE';
      end;

   if grp=5 then
      do;
         paramn=105;
         paramcd='SEVCVSPR';
         param='SEVERE COVID-19 SYMPTOMS - USE OF VASOPRESSORS';
      end;

   if grp=6 then
      do;
         paramn=106;
         paramcd='SEVCRHN';
         param='SEVERE COVID-19 SYMPTOMS - SIGNIFICANT ACUTE RENAL, HEPATIC, OR NEUROLOGIC
DYSFUNCTION';
      end;

   if grp=7 then
      do;
         paramn=91;
         paramcd='HCUICU';
         param='SUBJECT IN ICU DUE TO POTENTIAL COVID-19 ILLNESS';
         parcat1='HOSPITALIZATION STATUS';
      end;

   if grp=10 then
      do;
         paramn=100;
         paramcd='DTHODC19';
         param='DEATH OCCURRED DUE TO COVID-19 ILLNESS?';
         parcat1='DEATH STATUS';
         adt=astdt;
         astdt=.;
         aendt=.;

         if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
            do;
               avisitn=.;
               avisit='';
            end;
      end;

   if grp=11 then
      do;
         paramn=92;
         paramcd='HCUHSP';
```

```
      param='HOSPITALIZED DUE TO COVID-19 ILLNESS?';
      parcat1='HOSPITALIZATION STATUS';
   end;

if grp=20.1 then
   do;
      paramn=107;
      paramcd='PRSVCSAD';
      param='PRESENCE OF PROTOCOL DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE';
      parcat1='SEVERE COVID-19 SYMPTOMS';

      if dthdt ^=. then
         aendt=dthdt;

      if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
         do;
            avisitn=.;
            avisit='';
         end;
   end;

if grp=20.2 then
   do;
      paramn=108;
      paramcd='PRSCDCAD';
      param='PRESENCE OF CDC DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE';
      parcat1='SEVERE COVID-19 SYMPTOMS';

      if dthdt ^=. then
         aendt=dthdt;

      if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
         do;
            avisitn=.;
            avisit='';
         end;
   end;

if 1 <=grp < 21 then
   do;

      if stat=0 then
         avalc='';

      if stat=2 then
         avalc='N';

      if stat=4 then
         avalc='Y';
   end;

if grp in (1, 2, 3, 4, 5, 6, 7, 10, 11, 20.1, 20.2, 21, 22, 23) then
   output;
```

```
if grp=1 then
   do;
      paramn=120;
      paramcd='C19ONST';
      param='PROTOCOL DEFINED COVID-19 ILLNESS ONSET';
      parcat1='ILLNESS ONSET';
      adt=astdt;
      astdt=.;
      aendt=.;
      stat=c19onst;
      avalc=strip(put(c19onst, stat.));
      ild1fl=ild1fl_pd;
      ild17fl=ild17fl_pd;
      ild2fl=ild2fl_pd;
      ild27fl=ild27fl_pd;
      ild214fl=ild214fl_pd;
      filocrfl=filocrfl_pd;
      output;
   end;

if grp=2 then
   do;
      paramn=125;
      paramcd='CDCONST';
      param='CDC DEFINED COVID-19 ILLNESS ONSET';
      parcat1='ILLNESS ONSET';
      adt=astdt;
      astdt=.;
      aendt=.;
      stat=cdconst;
      avalc=strip(put(cdconst, stat.));
      ild1fl=ild1fl_cdc;
      ild17fl=ild17fl_cdc;
      ild2fl=ild2fl_cdc;
      ild27fl=ild27fl_cdc;
      ild214fl=ild214fl_cdc;
      filocrfl=filocrfl_cdc;
      output;
   end;

if grp=20.1 then
   do;
      paramn=130;
      paramcd='SEVCONST';
      param='PROTOCOL DEFINED SEVERE COVID-19 ILLNESS ONSET';
      parcat1='ILLNESS ONSET';
      adt=astdt;
      astdt=.;
      aendt=.;
      stat=sevconst;
      avalc=strip(put(sevconst, stat.));
      ild1fl=ild1fl_sev;
      ild17fl=ild17fl_sev;
      ild2fl=ild2fl_sev;
```

```
        ild27fl=ild27fl_sev;
        ild214fl=ild214fl_sev;
        filocrfl=filocrfl_sev;

        if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
          do;
            avisitn=.;
            avisit='';
          end;
        output;
      end;

    if grp=20.2 then
      do;
        paramn=135;
        paramcd='CDCSONST';
        param='CDC DEFINED SEVERE COVID-19 ILLNESS ONSET';
        parcat1='ILLNESS ONSET';
        adt=astdt;
        astdt=.;
        aendt=.;
        stat=cdcsonst;
        avalc=strip(put(cdcsonst, stat.));
        ild1fl=ild1fl_sev_cdc;
        ild17fl=ild17fl_sev_cdc;
        ild2fl=ild2fl_sev_cdc;
        ild27fl=ild27fl_sev_cdc;
        ild214fl=ild214fl_sev_cdc;
        filocrfl=filocrfl_sev_cdc;

        if avisit in ('V1_DAY1_VAX1_L', 'V2_VAX2_L') then
          do;
            avisitn=.;
            avisit='';
          end;
        output;
      end;

    if first.avisitn and strip(avisit) not in ('V1_DAY1_VAX1_L', 'V2_VAX2_L')
      and (grp in (1, 2) or naat_rslt_flg=1) then
        do;
        paramn=110;
        paramcd='NAATRAD';
        param='COVID-19 NAAT RESULT AFTER DOSE';
        parcat1='CENTRAL/LOCAL NAAT RESULTS';
        adt=naat_unp_dt;
        astdt=.;
        aendt=.;
        grp=.;
        avalc=strip(put(naat_unp, stat.));

        if visitnum ^=visitnum_ and visit ^=visit_ and visitnum_ ^=. and visit_ ^=''
          then
            do;
```

```
            visitnum=visitnum_;
            visit=visit_;
          end;
        output;
      end;
run;

data adc19ef_2;
   merge adc19ef_1(in=a drop=dthdt dthfl unblnddt) datvprot.adsl(in=b
      keep=studyid usubjid siteid subjid brthdt agegr1n agegr1 sex race ethnic
      armcd arm actarmcd actarm randdt trtsdt trtedt vax101dt vax102dt dvstdt dthdt
      eotdcdt eotdcrs eosdcdt eosdcrs compldt randfl evaleffl ev14effl aai1effl
      aai2effl dthfl phasen phase unblnddt);
   by usubjid;
   dcodt=input("&data_cutoff_date", yymmdd10.);

   if a and not b then
      mflg=1;

   if a and b then
      mflg=2;

   if not a and b then
      mflg=3;

   if mflg=3 then
      do;
         vrblngfl='U';
         crd1ngfl='U';
         crd2ngfl='U';
         pdsymfl='N';
         pdsdmfl='N';
         cdcsymfl='N';
         sevsymfl='N';
         sevcdcfl='N';
         pdrmufl='N';
         pdrmupfl='N';
         cdcrmufl='N';
         cdrmupfl='N';
         pdp1fl='N';
         pdp17fl='N';
         pdp27fl='N';
         pdp214fl='N';
         cdp1fl='N';
         cdp17fl='N';
         cdp27fl='N';
         cdp214fl='N';
      end;

   if vrblngfl='U' then
      vrblngfl='';

   if crd1ngfl='U' then
      crd1ngfl='';
```

```
    if crd2ngfl='U' then
       crd2ngfl='';

    if phasen=1 then
       delete;
    *dvstdt = .;
    format dcodt yymmdd10.;
run;

** Derive surveillance time. **;

%macro survltime(paramn=, paramcd=, astdt=, pnt=, aendt=, pop=, param=);
    aval=0;
    astdt=.;
    aendt=.;
    paramn=&paramn;
    paramcd="&paramcd";
    param="&param";
    *if index(param,'CROSSOVER') then srvlendt = min(srvlendt,unblnddt);
    if &astdt ^=. then do;
    astdt=sum(&astdt, &pnt);
    if "&pop"="AAI" then do;
    aendt=min(srvlendt, &aendt);
    end;
    else do;
    aendt=min(srvlendt, &aendt, dvstdt);
    end;
    if nmiss(astdt, aendt)=0 then aval=(aendt - astdt) + 1;
    output;
    end;
%mend survltime;

data adc19ef_3;
    set adc19ef_2;
    by usubjid;

    if paramcd ^='' then
       output;

    if first.usubjid then
       do;
          pd_srvlendt=.;
          cdc_srvlendt=.;
          sev_srvlendt=.;
          sev_cdc_srvlendt=.;
       end;

    if strip(paramcd)='C19ONST' and filocrfl='Y' then
       pd_srvlendt=adt;

    if strip(paramcd)='CDCONST' and filocrfl='Y' then
       cdc_srvlendt=adt;
```

```
   if strip(paramcd)='SEVCONST' and filocrfl='Y' then
      sev_srvlendt=adt;

   if strip(paramcd)='CDCSONST' and filocrfl='Y' then
      sev_cdc_srvlendt=adt;

   if eosdcdt ^=. and eosdcrs ^='' then
      withdraw_dt=eosdcdt;

   if nmiss(dcodt, withdraw_dt, dthdt, unblnddt, compldt) <=4 then
      srvlendt=min(dcodt, withdraw_dt, dthdt, unblnddt, compldt);
   else
      srvlendt=.;

   if last.usubjid then
      do;
         cncrslfl='';
         avalc='';
         visitnum=.;
         visit='';
         avisitn=.;
         avisit='';
         adt=.;
         parcat1='SURVEILLANCE TIME';
         %survltime(paramn=141, paramcd=%str(ST1PD), astdt=%str(vax101dt), pnt=0,
            aendt=%str(pd_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER DOSE
1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=142, paramcd=%str(ST17PD), astdt=%str(vax101dt), pnt=7,
            aendt=%str(pd_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=143, paramcd=%str(ST2PD), astdt=%str(vax102dt), pnt=0,
            aendt=%str(pd_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER DOSE
2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=144, paramcd=%str(ST27PD), astdt=%str(vax102dt), pnt=7,
            aendt=%str(pd_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=145, paramcd=%str(ST214PD), astdt=%str(vax102dt), pnt=14,
            aendt=%str(pd_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=151, paramcd=%str(ST1CD), astdt=%str(vax101dt), pnt=0,
            aendt=%str(cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=152, paramcd=%str(ST17CD), astdt=%str(vax101dt), pnt=7,
            aendt=%str(cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=153, paramcd=%str(ST2CD), astdt=%str(vax102dt), pnt=0,
            aendt=%str(cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=154, paramcd=%str(ST27CD), astdt=%str(vax102dt), pnt=7,
            aendt=%str(cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS));
         %survltime(paramn=155, paramcd=%str(ST214CD), astdt=%str(vax102dt), pnt=14,
            aendt=%str(cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS));
```

```
%survltime(paramn=161, paramcd=%str(ST1SE), astdt=%str(vax101dt), pnt=0,
  aendt=%str(sev_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=162, paramcd=%str(ST17SE), astdt=%str(vax101dt), pnt=7,
  aendt=%str(sev_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=163, paramcd=%str(ST2SE), astdt=%str(vax102dt), pnt=0,
  aendt=%str(sev_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=164, paramcd=%str(ST27SE), astdt=%str(vax102dt), pnt=7,
  aendt=%str(sev_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=165, paramcd=%str(ST214SE), astdt=%str(vax102dt), pnt=14,
  aendt=%str(sev_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=171, paramcd=%str(STC1SE), astdt=%str(vax101dt), pnt=0,
  aendt=%str(sev_cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=172, paramcd=%str(STC17SE), astdt=%str(vax101dt), pnt=7,
  aendt=%str(sev_cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=173, paramcd=%str(STC2SE), astdt=%str(vax102dt), pnt=0,
  aendt=%str(sev_cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=174, paramcd=%str(STC27SE), astdt=%str(vax102dt), pnt=7,
  aendt=%str(sev_cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=175, paramcd=%str(STC214SE), astdt=%str(vax102dt), pnt=14,
  aendt=%str(sev_cdc_srvlendt), pop=%str(), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14
DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS));
%survltime(paramn=201, paramcd=%str(ST1PDA), astdt=%str(vax101dt), pnt=0,
  aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=202, paramcd=%str(ST17PDA), astdt=%str(vax101dt), pnt=7,
  aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=203, paramcd=%str(ST2PDA), astdt=%str(vax102dt), pnt=0,
  aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=204, paramcd=%str(ST27PDA), astdt=%str(vax102dt), pnt=7,
  aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=205, paramcd=%str(ST214PDA), astdt=%str(vax102dt), pnt=14,
  aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=211, paramcd=%str(ST1CDA), astdt=%str(vax101dt), pnt=0,
  aendt=%str(cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=212, paramcd=%str(ST17CDA), astdt=%str(vax101dt), pnt=7,
  aendt=%str(cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
%survltime(paramn=213, paramcd=%str(ST2CDA), astdt=%str(vax102dt), pnt=0,
  aendt=%str(cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
```

```
        %survltime(paramn=214, paramcd=%str(ST27CDA), astdt=%str(vax102dt), pnt=7,
          aendt=%str(cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=215, paramcd=%str(ST214CDA), astdt=%str(vax102dt), pnt=14,
          aendt=%str(cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=221, paramcd=%str(ST1SEA), astdt=%str(vax101dt), pnt=0,
          aendt=%str(sev_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=222, paramcd=%str(ST17SEA), astdt=%str(vax101dt), pnt=7,
          aendt=%str(sev_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=223, paramcd=%str(ST2SEA), astdt=%str(vax102dt), pnt=0,
          aendt=%str(sev_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=224, paramcd=%str(ST27SEA), astdt=%str(vax102dt), pnt=7,
          aendt=%str(sev_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=225, paramcd=%str(ST214SEA), astdt=%str(vax102dt), pnt=14,
          aendt=%str(sev_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14 DAYS
AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=231, paramcd=%str(STC1SA), astdt=%str(vax101dt), pnt=0,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME
AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=232, paramcd=%str(STC17SA), astdt=%str(vax101dt), pnt=7,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7
DAYS AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=233, paramcd=%str(STC2SA), astdt=%str(vax102dt), pnt=0,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME
AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=234, paramcd=%str(STC27SA), astdt=%str(vax102dt), pnt=7,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 7
DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=235, paramcd=%str(STC214SA), astdt=%str(vax102dt), pnt=14,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME 14
DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE));
        %survltime(paramn=301, paramcd=%str(ST1PDX), astdt=%str(vax101dt), pnt=0,
          aendt=%str(pd_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME AFTER
DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - CROSSOVER));
        %survltime(paramn=331, paramcd=%str(STC1SX), astdt=%str(vax101dt), pnt=0,
          aendt=%str(sev_cdc_srvlendt), pop=%str(AAI), param=%bquote(SUBJECT'S SURVEILLANCE TIME
AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - CROSSOVER));
      end;
    format dcodt date9. srvlendt pd_srvlendt cdc_srvlendt sev_srvlendt
      sev_cdc_srvlendt yymmdd10.;
    retain pd_srvlendt cdc_srvlendt sev_srvlendt sev_cdc_srvlendt;
run;

data adc19ef_4;
    set adc19ef_3;
    by usubjid;

    if paramn > 140 and aval <=-1 then
      aval=0;
```

```
    if strip(avalc)='.' then
       avalc='';
    nmpdocfl='';

    if strip(paramcd) in ('C19ONST', 'CDCONST', 'SEVCONST', 'CDCSONST') then
       do;

          if dvstdt=. then
             nmpdocfl='Y';

          if . < adt < dvstdt then
             nmpdocfl='Y';
       end;
    else
       call missing(ild1fl, ild17fl, ild2fl, ild27fl, ild214fl, filocrfl);
    call missing(ady, astdy, aendy);

    if trtsdt ^=. then
       do;

          if adt ^=. then
             do;
                ady=adt - trtsdt;

                if adt >=trtsdt then
                   ady=ady + 1;
             end;

          if astdt ^=. then
             do;
                astdy=astdt - trtsdt;

                if astdt >=trtsdt then
                   astdy=astdy + 1;
             end;

          if aendt ^=. then
             do;
                aendy=aendt - trtsdt;

                if aendt >=trtsdt then
                   aendy=aendy + 1;
             end;
       end;
 run;

 /***Update to keep only subject 12-15 years old ***/
 proc sql;
    create table adc19ef_4_ped as select a.* from adc19ef_4 as a inner join
       datvprot.adsl as b on a.usubjid=b.usubjid and 12 <=b.agetr01 <=15 order by
       usubjid;
 quit;
```

```
data adc19ef;
   retain studyid usubjid siteid subjid brthdt agegr1n agegr1 sex race ethnic
      armcd arm actarmcd actarm paramn paramcd param parcat1 aval avalc visitnum
      visit avisitn avisit adt ady astdt astdy aendt aendy dcodt randdt trtsdt
      trtedt vax101dt vax102dt dvstdt unblnddt dthdt eotdcdt eosdcdt randfl
      evaleffl ev14effl aai1effl aai2effl dthfl c19ilhfl cncrslfl vrblngfl crd1ngfl
      crd2ngfl pdsymfl pdsdmfl cdcsymfl sevsymfl sevcdcfl ild1fl ild17fl ild2fl
      ild27fl ild214fl filocrfl pdrmufl pdrmupfl cdcrmufl cdrmupfl pdp1fl pdp17fl
      pdp27fl pdp214fl cdp1fl cdp17fl cdp27fl cdp214fl nmpdocfl;
   set adc19ef_4_ped;
   by usubjid;
   keep studyid usubjid siteid subjid brthdt agegr1n agegr1 sex race ethnic armcd
      arm actarmcd actarm paramn paramcd param parcat1 aval avalc visitnum visit
      avisitn avisit adt ady astdt astdy aendt aendy dcodt randdt trtsdt trtedt
      vax101dt vax102dt dvstdt unblnddt dthdt eotdcdt eosdcdt randfl evaleffl
      ev14effl aai1effl aai2effl dthfl c19ilhfl cncrslfl vrblngfl crd1ngfl crd2ngfl
      pdsymfl pdsdmfl cdcsymfl sevsymfl sevcdcfl ild1fl ild17fl ild2fl ild27fl
      ild214fl filocrfl pdrmufl pdrmupfl cdcrmufl cdrmupfl pdp1fl pdp17fl pdp27fl
      pdp214fl cdp1fl cdp17fl cdp27fl cdp214fl nmpdocfl;
   label dcodt='Data Cutoff Date' dthdt='Date of Death' aval='Analysis Value'
      avalc='Analysis Value (C)' adt='Analysis Date' ady='Analysis Relative Day'
      astdt='Analysis Start Date' astdy='Analysis Start Relative Day'
      aendt='Analysis End Date' aendy='Analysis End Relative Day'
      cncrslfl='Consider Result for Analysis Flag'
      vrblngfl='NVA Baseline Result Negative Flag'
      crd1ngfl='NAAT Result At Dose 1 Negative Flag'
      crd2ngfl='NAAT Result At Dose 2 Negative Flag'
      pdsymfl='Protocol Defined SYMP Present Flag'
      pdsdmfl='Protocol Defined SYMP Date Missing Flag'
      cdcsymfl='CDC Defined SYMP Present Flag'
      sevsymfl='Severe Covid PD SYMP Present Flag'
      sevcdcfl='Severe Covid CDC SYMP Present Flag'
      ild1fl='Illness Occur After Dose 1 Flag'
      ild17fl='Illness Occur 7 Days After Dose 1 Flag'
      ild2fl='Illness Occur After Dose 2 Flag'
      ild27fl='Illness Occur 7 Days After Dose 2 Flag'
      ild214fl='Illness Occur 14 Days After Dose 2 Flag'
      filocrfl='First Illness Occurrence Flag'
      pdrmufl='PD SYMP Result Missing or Unknown Flag'
      pdrmupfl='PD SYMP Rslt Miss/UNK With POS Rslt Flag'
      cdcrmufl='CDC SYMP Result Missing or Unknown Flag'
      cdrmupfl='CD SYMP Rslt Miss/UNK With POS Rslt Flag'
      pdp1fl='VE Prot Def Pop Incl Post D1 Flag'
      pdp17fl='VE Prot Def Pop Incl 7D Post D1 Flag'
      pdp27fl='VE Prot Def Pop Incl 7D Post D2 Flag'
      pdp214fl='VE Prot Def Pop Incl 14D Post D2 Flag'
      cdP1fl='VE CDC Def Pop Incl Post Dose 1 Flag'
      cdP17fl='VE CDC Def Pop Incl 7D Post Dose 1 Flag'
      cdp27fl='VE CDC Def Pop Incl 7D Post Dose 2 Flag'
      cdp214fl='VE CDC Def Pop Incl 14D Post Dose 2 Flag'
      nmpdocfl='No Major Protocol Deviation Occur Flag';
   format adt astdt aendt dcodt dthdt vax101dt vax102dt date9.;
run;
```

```
proc sort data=adc19ef out=datvout.adc19ef(label="Covid-19 Efficacy Analysis Dataset");
   by studyid usubjid descending avisitn paramn adt astdt;
run;

proc printto;
run;
```