```
************************************************************************
*           CLIENT: Moderna
*         PROTOCOL: mRNA-1273-p201
*
*          PURPOSE:  Create ADAR Dataset
*
*      INPUT FILES:  TRANS.face, TRANS.vs
*     OUTPUT FILES:  ADAR.LST, ADAR.LOG, ADAR.sas7bdat
*
*      USAGE NOTES:
*      Modification History:27May2021:(b) (4), (b) (6):spec updates replace CRFTMPT with
FATPT due to SDTM change
************************************************************************
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************************************************************************;

dm'log;clear;output;clear';
options missing = ' ' validvarname=upcase compress=yes;
options mprint nomprint missing=' ';

%include "madam.sas";

proc format;
        value $pamcd (multilabel)
        'Rash' = 'RASH'
        'Rash Occurrence' = 'RASHOCC'
        'Lymphadenopathy Occurrence' = 'LYMPHOCC'
        'Underarm Gland Swelling or Tenderness' = 'LYMPH'
        'Pain' = 'PAIN'
        'Erythema Longest Diameter (mm)'  = 'ERYTHDIA'
        'Swelling Longest Diameter (mm)'  = 'SWELLDIA'
        'Headache' = 'HEADACHE'
        'Fatigue' = 'FATIGUE'
        'Myalgia' = 'MYALGIA'
        'Arthralgia' = 'ARTHRALG'
        'Nausea/Vomiting' = 'NAUSEA'
        'Chills' = 'CHILLS'
        'Receive Medical Attention?' = 'MEDATTEN'
        'Fever (C)'  = 'FEVER'
        'Prevent Pain or Fever from Occurring' = 'MEDTAKP'
        'Treat Pain or Fever already Occurred' = 'MEDTAKT'
        'Medication Taken Today for Pain or Fever' = 'MEDTAK'
        ;


run;

%revsupp(libin=TRANS, libout=WORK, ds=FACE, supp=SUPPface);
```

```
%revsupp(libin=TRANS, libout=WORK, ds=VS, supp=SUPPvs);

data fa;
        set face;
        *if index(fatptref, 'OL');
run;

data co;
        set trans.co;
run;

%REVCO(libin=work, libout=WORK, ds=fa, outds=faco,comds=CO,delco=Y,movco=Y);

proc sort data=adb.adsl out=adsl; by studyid usubjid; run;

data ar1;
length  MAAEFL $1.;
        merge ADSL (in=ina) faco (in=inface rename = (MAAEFL = _MAAEFL));
        by studyid usubjid;
        if ina and inface;
        if faobj in ('Erythema','Swelling') and index(upcase(fatest), 'OCCURRENCE')
> 0 and FAORRES = 'Y' then delete;
        MAAEFL = _MAAEFL;
        drop _MAAEFL;
run;

/*proc freq data=ar1; tables faobj*fatest /list missing; run;

proc freq data=ar1; tables faobj*fatest*faorres /list missing; where faobj in
('Erythema','Swelling'); run;*/

proc freq data=ar1; tables fatpt /list missing; run;

proc print data=ar1; where fatpt = 'DAY 0'; var usubjid faobj fatest faorres fatpt
fadtc; run;


data ar2;
        merge adsl (in=ina) vs (in=invs drop=subjid);
        by studyid usubjid;
        if ina and invs;
        if vscat = 'REACTOGENICITY' and . < vstptnum <= 7;
;
run;

data takp;
        set ar2;
        where medtakp = 'Y';
        length PARAM $200;
        if medtakp = 'Y' then param = 'Prevent Pain or Fever from Occurring';
```

```
run;

data takt;
        set ar2;
        where medtakt = 'Y';
        length PARAM $200;
        if medtakt = 'Y' then param = 'Treat Pain or Fever already Occurred';
run;

data tak;
        set ar2;
        where medtak = 'Y';
        length PARAM $200;
        if medtak = 'Y' then param = 'Medication Taken Today for Pain or Fever';
run;

data ar2;
        set ar2 takp takt tak;
run;

/*proc print data=ar2; where usubjid = 'mRNA-1273-P201-US203-1095' and VSTESTCD =
'TEMP'; var usubjid vstestcd vstest vstpt vsseq vsstresn vsstresu; run;*/

/*proc freq data=ar2; tables vscat*vstestcd*vsstresu /list missing; run;*/

data ar3;
        set ar1(in=ar1 rename=(domain=_domain lymphevl=_lymphevl srevl=_srevl))
ar2(in=ar2 rename=(medtakp=_medtakp medtakt = _medtakt medtak = _medtak));


*** PARAMCD/PARAM ***;
        length PARAMCD $8 PARAM $200;
        if ar1 then do;
                if faobj = 'Rash' and fatestcd ne 'SEV' then param = 'Rash
Occurrence';
                else if faobj = 'Solicited Rash' then param = 'Rash';
                else if faobj = 'Underarm Gland Swelling or Tenderness' and
fatestcd = 'SEV' then param = 'Underarm Gland Swelling or Tenderness';
                else if faobj = 'Nausea/Vomiting' and fatestcd = 'SEV' then param =
'Nausea/Vomiting';
                else if faobj = 'Lymphadenopathy' then param = 'Lymphadenopathy
Occurrence';
                else if faobj in ('Erythema','Swelling') and upcase(fatest) =
'OCCURRENCE INDICATOR' then param = strip(faobj)||' Longest Diameter (mm)';
                else if faobj in ('Erythema','Swelling') and index(upcase(fatest),
'INTENSITY' ) > 0  then param = strip(faobj)||' Longest Diameter (mm)';
                else if faobj in ('Erythema','Swelling') and upcase(fatest)
='LONGEST DIAMETER' then param =strip(faobj)||' '||strip(propcase(fatest))||'
('||strip(FAORRESU)||')';
                else if faobj in ('Fever')  then param = 'Fever (C)';
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```
                else param = strip(faobj);
        end;
        if ar2 then do;
                if missing(param) then do;
                        if vstestcd = 'TEMP' and ~missing(vsstresu) then param =
'Fever'||' ('||strip(vsstresu)||')';
                        if vstestcd = 'VSALL' or (vstestcd = 'TEMP' and
missing(vsstresu)) then param = 'Fever (C)';
                end;
        end;

        paramcd = strip(put(param, $pamcd.));

        *** SRCDOM, SRCSEQ, SRCVAR ***;
        length SRCDOM $20 SRCVAR $50;
        if ar1 then do;
                SRCDOM = strip(_domain);
                SRCSEQ = faseq;
                SRCVAR = 'FASTRESC';
        end;
        if ar2 then do;
                SRCDOM = strip(domain);
                SRCSEQ = vsseq;
                SRCVAR = 'VSSTRESN';
        end;
        if paramcd in ('MEDTAKP' 'MEDTAKT' 'MEDTAK') then SRCVAR =
cats("SUPPVS.QVAL where QNAM='",paramcd,"'");


        *** ATPT ***;
        length ATPT $50;
        if ar1  then do;
            if FAEVAL='STUDY SUBJECT'  then atpt=strip(FATPT);
            if FAEVAL='INVESTIGATOR'   then atpt=strip(FATPT);
        end;

        if ar2 then atpt=strip(VSTPT);

        if ATPT = 'DAY 1' and  FAEVAL='INVESTIGATOR' and PARAMCD not in ('RASH'
'LYMPHOCC' ) then ATPT = 'DAY 1, AFTER VACCINATION (AT HOME)';

        *** ATPTN ***;
        if ATPT = 'DAY 1, 30 MINS AFTER VACCINATION (AT STUDY CLINIC)' then ATPTN =
1.05;
        if ATPT = 'DAY 1, 1 HOUR AFTER VACCINATION (AT STUDY CLINIC)' then ATPTN =
1.1;
        else if ATPT = 'DAY 1, AFTER VACCINATION (AT HOME)' then ATPTN = 1.2;
        else if index(ATPT,'DAY') > 0 then ATPTN = input(substr(ATPT,index(ATPT,
'DAY')+4),best.);
```

```
        if ATPT = 'DAY 0' then do;
                ATPTN = .;
                put 'ALERT_C: subject with DAY 0 ' USUBJID ' ' SRCDOM ' ' SRCSEQ '
' ATPT;
        end;

        *** ATPTREF ***;
        length ATPTREF $50;
        if ar1 then do;
                if index(upcase(fatptref),'DOSE 1') > 0 and index(upcase(fatptref),
'OL') = 0 then ATPTREF = 'Vaccination 1';
                else if index(upcase(fatptref),'DOSE 2') > 0 and
index(upcase(fatptref), 'OL') = 0 then ATPTREF = 'Vaccination 2';
        else if index(upcase(fatptref), 'DOSE 1 OL')> 0 then ATPTREF  = 'OL
Vaccination 1';
        else if index(upcase(fatptref), 'DOSE 2 OL')> 0 then ATPTREF  = 'OL
Vaccination 2';
        end;
        if ar2 then do;
                if index(upcase(vstptref),'DOSE 1') > 0 and index(upcase(vstptref),
'OL') = 0 then ATPTREF = 'Vaccination 1';
                else if index(upcase(vstptref),'DOSE 2') > 0 and
index(upcase(vstptref), 'OL') = 0 then ATPTREF = 'Vaccination 2';
        else if index(upcase(vstptref), 'DOSE 1 OL')> 0 then ATPTREF  = 'OL
Vaccination 1';
        else if index(upcase(vstptref), 'DOSE 2 OL')> 0 then ATPTREF  = 'OL
Vaccination 2';
        end;

        *** ATPTGR1, ATPTGR1N ***;
        length ATPTGR1 $50;
        if index(ATPT, 'DAY 1') > 0  then ATPTGR1 = 'DAY 1';
        else ATPTGR1 = strip(ATPT);

        if not missing(ATPTGR1) then ATPTGR1N = input(substr(ATPTGR1,
index(ATPTGR1,'Day')+4), best.);
        if ATPTGR1 = 'DAY 0' then ATPTGR1N = .;



    *** Numeric of FADTC, VSDTC ***;
    %iso2sas(isodate = fadtc, datec = fadtc9, daten =fadtn, timec = fatmc);
    %iso2sas(isodate = vsdtc, datec = vsdtc9, daten =vsdtn, timec = vstmc);

        *** ADT, ATM, ADTM, ADY ***;
        if ar1 then do;
                adt = fadtn;
                atm = input(fatmc,time5.);
                if not missing(fadtc9) and not missing(fatmc) then adtm =
input(fadtc,E8601DT.);
```

```
                ady = fady;
        end;
        if ar2 then do;
                adt = vsdtn;
                atm = input(vstmc, time5.);
                if not missing(vsdtc9) and not missing(vstmc) then adtm =
input(vsdtc,E8601DT.);
                ady = vsdy;
        end;

        *** AVAL, AVALC ***;
        length AVALC $100;
        if ar1 then do;
                avalc = strip(fastresc);
                if faobj in ('Erythema','Swelling') and index(upcase(fatest),
'OCCURRENCE')>0 then do;
                        if faorres = 'N' then aval = 0;
                        else aval = fastresn;
                end;
                else aval = fastresn;
        end;
        if ar2 then do;
                if paramcd in ('MEDTAKP' 'MEDTAKT' 'MEDTAK') then do;
                        avalc = 'Y';
                end;
                else do;
                        aval = vsstresn;
                        avalc = strip(vsstresc);
                end;
        end;

        %macro ATOXGR();
                if index(upcase(FASTRESC),"GRADE 0") > 0 then ATOXGR = 'Grade 0';
                if index(upcase(FASTRESC),"GRADE 1") > 0 then ATOXGR = 'Grade 1';
                if index(upcase(FASTRESC),"GRADE 2") > 0 then ATOXGR = 'Grade 2';
                if index(upcase(FASTRESC),"GRADE 3") > 0 then ATOXGR = 'Grade 3';
                if index(upcase(FASTRESC),"GRADE 4") > 0 then ATOXGR = 'Grade 4';
        %mend;

        *** ATOXGR ***;
        length ATOXGR $20;
        if paramcd in ('ERYTHDIA','SWELLDIA') then do;
                if . < aval < 25 then ATOXGR = 'Grade 0';
                else if 25 <= aval <= 50 then ATOXGR = 'Grade 1';
                else if 51 <= aval <= 100 then ATOXGR = 'Grade 2';
                else if aval > 100 then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd = 'FEVER' then do;
```

```
                if . < aval < 38.0 then ATOXGR = 'Grade 0';
                else if 38.0 <= aval <  38.4 then ATOXGR = 'Grade 1';
                else if 38.4 <= aval <= 38.9 then ATOXGR = 'Grade 2';
                else if 38.9 <  aval <= 40.0 then ATOXGR = 'Grade 3';
                else if aval > 40 then ATOXGR = 'Grade 4';

                %ATOXGR();
        end;
        if paramcd in ('PAIN') then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                else if FASTRESC = 'DOES NOT INTERFERE WITH ACTIVITY' then ATOXGR =
'Grade 1';
                else if FASTRESC = 'REPEATED USE OF OVER-THE-COUNTER PAIN RELIEVER
> 24 HOURS OR INTERFERES WITH ACTIVITY' then ATOXGR = 'Grade 2';
                else if FASTRESC = 'ANY USE OF PRESCRIPTION PAIN RELIEVER OR
PREVENTS DAILY ACTIVITY' then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd in ('LYMPH') then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                else if FASTRESC = 'DOES NOT INTERFERE WITH ACTIVITY' then ATOXGR =
'Grade 1';
                else if index(FASTRESC,'REPEATED USE OF OVER-THE-COUNTER PAIN
RELIEVER > 24 HOURS OR INTERFER')>0 then ATOXGR = 'Grade 2';
                else if FASTRESC = 'ANY USE OF PRESCRIPTION PAIN RELIEVER OR
PREVENTS DAILY ACTIVITY' then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd in ('HEADACHE') then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                else if FASTRESC = 'NO INTERFERENCE WITH ACTIVITY' then ATOXGR =
'Grade 1';
                else if index(FASTRESC,'REPEATED USE OF OVER-THE-COUNTER PAIN
RELIEVER > 24 HOURS OR SOME INTERFER')>0 then ATOXGR = 'Grade 2';
                else if FASTRESC = 'ANY USE OF PRESCRIPTION PAIN RELIEVER OR
PREVENTS DAILY ACTIVITY' then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd in ('FATIGUE','MYALGIA','ARTHRALG') then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                if FASTRESC = 'NO INTERFERENCE WITH ACTIVITY' then ATOXGR = 'Grade
1';
                if FASTRESC = 'SOME INTERFERENCE WITH ACTIVITY' then ATOXGR =
'Grade 2';
                if FASTRESC = 'SIGNIFICANT; PREVENTS DAILY ACTIVITY' then ATOXGR =
'Grade 3';
```

```
                %ATOXGR();
        end;
        if paramcd = 'NAUSEA' then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                if FASTRESC= 'NO INTERFERENCE WITH ACTIVITY OR 1-2 EPISODES/24
HOURS' then ATOXGR = 'Grade 1';
                if FASTRESC= 'SOME INTERFERENCE WITH ACTIVITY OR >2 EPISODES/24
HOURS' then ATOXGR = 'Grade 2';
                if FASTRESC= 'PREVENTS DAILY ACTIVITY, REQUIRES OUTPATIENT IV
HYDRATION' then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd = 'CHILLS' then do;
                if FASTRESC = 'NONE' then ATOXGR = 'Grade 0';
                if FASTRESC = 'NO INTERFERENCE WITH ACTIVITY' then ATOXGR = 'Grade
1';
                if FASTRESC = 'SOME INTERFERENCE WITH ACTIVITY NOT REQUIRING
MEDICAL ATTENTION' then ATOXGR = 'Grade 2';
                if FASTRESC = 'PREVENTS DAILY ACTIVITY AND REQUIRES MEDICAL
ATTENTION' then ATOXGR = 'Grade 3';

                %ATOXGR();
        end;
        if paramcd = 'RASH' then do;
                %ATOXGR();
        end;
        if not missing(ATOXGR) then ATOXGRN = input(substr(ATOXGR,7,1), best.);

        *** CRIT1-CRIT4 ***;
        length CRIT1FL CRIT2FL CRIT3FL CRIT4FL $1 CRIT1 CRIT2 CRIT3 CRIT4 $20;
        if paramcd = 'FEVER' and not missing(aval) then do;
                if (9*aval/5)+32 > 104.1 then do;
                        CRIT4FL = 'Y';
                        CRIT4 = '> 104.1 degrees F';
                end;
                if (9*aval/5)+32 > 103.6 then do;
                        CRIT3FL = 'Y';
                        CRIT3 = '> 103.6 degrees F';
                end;
                if (9*aval/5)+32 > 103.1 then do;
                        CRIT2FL = 'Y';
                        CRIT2 = '> 103.1 degrees F';
                end;
                if (9*aval/5)+32 > 102.6 then do;
                        CRIT1FL = 'Y';
                        CRIT1 = '> 102.6 degrees F';
                end;
        end;
```

```
        *** PARCAT1 ***;
        length PARCAT1 $50;
        if ar1 then do;
           if FASCAT = 'ADMINISTRATION SITE' then PARCAT1 = 'LOCAL';
           else parcat1 = strip(fascat);
           if upcase(paramcd) = 'RASH' then parcat1 = 'SYSTEMIC';
           if upcase(paramcd) = 'LYMPHOCC' then parcat1 = 'LOCAL';
        end;
        if ar2 then do;
                parcat1 = strip(vsscat);
        end;

        *** PARCAT1N ***;
        if parcat1 = 'LOCAL' then PARCAT1N = 1;
        else if parcat1 = 'SYSTEMIC' then parcat1N = 2;

        ***ASTAT ***;
        length ASTAT $20;
        if ar1 then ASTAT = strip(fastat);
        if ar2 then ASTAT = strip(vsstat);

        *** LYMPHEVL, SREVLFL ***;
        length LYMPHEVL SREVLFL $1;
        if not missing(_LYMPHEVL) then LYMPHEVL = strip(_LYMPHEVL);
        if not missing(_SREVL) then SREVLFL = strip(_SREVL);

        *** LYMPHCOM, SRCOMM ***;
        if LYMPHCOM = '' then LYMPHCOM = strip(LYMPHCOM);
        if SRCOMM = '' then SRCOMM = strip(SRCOMM);

        if (ar1 and ASTAT = 'NOT DONE') or (ar2 and paramcd='FEVER' and ASTAT =
'NOT DONE') then delete;

        *** MEDTAKP, MEDTAKT, MEDTAK ***;
        length MEDTAKP MEDTAKT MEDTAK $1;
        if not missing(_MEDTAKP) then MEDTAKP = strip(_MEDTAKP);
        if not missing(_MEDTAKT) then MEDTAKT = strip(_MEDTAKT);
        if not missing(_MEDTAK) then MEDTAK = strip(_MEDTAK);

        if FAEVAL='STUDY SUBJECT' or (PARAMCD='FEVER' and FAEVAL='') then ANL01_CHK
= 0;
        else ANL01_CHK = 1;

        if AVALC = 'Y' then AVALC_CHK = 0;
        else AVALC_CHK = 1;

        format ADT Date9. ATM time5. ADTM datetime15.;

        drop _: fadtc9 fadtn fatmc vsdtc9 vsdtn vstmc ;
run;
```

```
*ANL02FL derivation;
proc sort data = ar3;
        by usubjid parcat1 paramcd atptref atptn descending ATOXGRN ANL01_CHK
AVALC_CHK adt adtm;
run;

*** ANL02FL***;
data ar3_1 ar3_2;
    set ar3;
    if paramcd not in ('RASHOCC' 'LYMPHOCC') then output ar3_1;
    else output ar3_2;
run;


data ar3_1;
        set ar3_1(where = (~missing(atoxgrn)));
        by  usubjid parcat1 paramcd atptref atptn  descending ATOXGRN ANL01_CHK
AVALC_CHK adt adtm;
        if first.atptn then ANL02FL = 'Y';
run;


data ar3_2;
        set ar3_2;
        by  usubjid parcat1 paramcd atptref atptn descending ATOXGRN ANL01_CHK
AVALC_CHK adt adtm;
        if first.atptn then ANL02FL = 'Y';
run;

data ar3_anl02fl;
    set ar3_1 ar3_2;
    keep usubjid parcat1 paramcd atptref atptn adt adtm srcseq atoxgrn anl01_chk
avalc_chk anl02fl;
run;
proc sort data=ar3_anl02fl; by usubjid parcat1 paramcd atptref atptn adt adtm
srcseq; run;
proc sort data=ar3; by usubjid parcat1 paramcd atptref atptn adt adtm srcseq; run;


data ar3;
    merge ar3 ar3_anl02fl;
    by usubjid parcat1 paramcd atptref atptn adt adtm srcseq atoxgrn anl01_chk
avalc_chk;
run;
proc sort data = ar3;
    by usubjid parcat1 paramcd atptref atptn adt adtm srcseq;
run;
```

```
data adar;
        set ar3;
        by usubjid parcat1 paramcd atptref atptn adt adtm srcseq;
        retain aseq;
        if first.usubjid then aseq = 1;
        else aseq = aseq + 1;
run;


proc freq data=adar; tables param*paramcd /list missing; run;

*** ANL01FL***;
data adar1 adar2;
        set adar;
        if paramcd in ('RASHOCC','LYMPHOCC') then output adar1;
        else output adar2;
run;

data anl01fla;
        set adar1;
        if not missing(avalc);
        keep usubjid param atptref atptgr1 avalc adt aseq ANL01_CHK AVALC_CHK;
run;

proc sort data=anl01fla; by usubjid param atptref atptgr1 AVALC_CHK ANL01_CHK
avalc adt  aseq; run;

data anl01fla;
        set anl01fla;
        by usubjid param atptref atptgr1 AVALC_CHK  ANL01_CHK  avalc adt  aseq;
        if first.atptgr1;
        anl01fl = 'Y';
        keep usubjid param atptref atptgr1 avalc adt aseq anl01fl;
run;



proc sort data=anl01fla; by usubjid param atptref atptgr1 adt aseq avalc; run;

data anl01flb;
        set adar2;
        if not missing(atoxgrn);
        keep usubjid param atptref atoxgrn atptgr1 adtm adt aseq ANL01_CHK
AVALC_CHK;
run;

proc sort data=anl01flb; by usubjid param atptref atptgr1 descending atoxgrn
descending AVALC_CHK ANL01_CHK  adt ANL01_CHK adtm aseq; run;
```

```
data anl01flb;
        set anl01flb;
        by usubjid param atptref atptgr1 descending atoxgrn descending AVALC_CHK
ANL01_CHK adt  adtm  aseq;
        if first.atptgr1;
        anl01fl = 'Y';
        keep usubjid param atptref atptgr1 atoxgrn adtm adt aseq anl01fl;
run;

proc sort data=adar1; by usubjid param atptref atptgr1 adt aseq avalc; run;

data adar1;
        merge adar1(in=a) anl01fla(in=b);
        by usubjid param atptref atptgr1 adt aseq avalc;
        if a;
run;

proc sort data=adar2; by usubjid param atptref atptgr1 adtm adt aseq atoxgrn; run;

proc sort data=anl01flb; by usubjid param atptref atptgr1 adtm adt aseq atoxgrn;
run;

data adar2;
        merge adar2(in=a) anl01flb(in=b);
        by usubjid param atptref atptgr1 adtm adt aseq atoxgrn;
        if a;
run;

data adar;
        set adar1 adar2;
run;

proc freq data=adar; tables parcat1n*parcat1*paramcd /list missing; run;

proc freq data=adar; tables SRCDOM /list missing; run;

proc sort data=adar; by usubjid atptref; run;

%trta(dsname=adar);

proc freq data=adar; tables atptref*trta*trtan /list missing; run;

proc freq data=adar; tables srcdom*atptn*atpt /list missing; run;


%ADaM_Dataset_Update(
    ds=ADAR
   ,libin=WORK
   ,libout=output
```

```
,adsllib=ADB
,addcomvar=Y
,addseq=N
,dropinfmt=Y
,mapspecfile= &ADAM_SPEC
,maploc=&ADAM_SPEC_LOC
,debug=N);
```