

```

options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
* macro to save output and log to appropriate areas ;
%_mprintto;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106326;
%put NOTE: Client Protocol ID : ZRHM-PK-05-JP;
%put NOTE: Program Name : d_2ADQSSYM.sas;
%put NOTE: Purpose : create ADQSSYM dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADQSSYM SDTM.QS ADAM.ADSL;
%put NOTE: Output : ADAM.ADQSSYM;
%put NOTE: Macros Called : _MPRINTTO _SCRAMBLE;
%put NOTE: ;
%put NOTE: Programmed by : cvn_kbooth;
%put NOTE: Creation Date : 2014-04-14;
%put NOTE: SAS Version : 9.3;
%put NOTE: ;
%put NOTE: == Latest Run
=====;
%put NOTE: Run by : &sysuserid;
%put NOTE: Date/Time :
%sysfunc(putn(%sysfunc(date()),e8601da.))T%sysfunc(putn(%sysfunc(time()),
e86011z.));
%put NOTE: ;
%put NOTE: == Modification History
=====;
%put NOTE: Date Initials No. Reason;
%put NOTE: 22Apr2014 KB 1) Amended AWRANGE to only populate for
non-blanks;
%put NOTE: 22Apr2014 KB 2) Added formats to AVISITN ATPT ATPTN;
%put NOTE: 05Aug2014 KB 3) Amended AWRANGE for if AWLO is
missing;
%put NOTE: 05Aug2014 KB 4) Added DEVN;
%put NOTE: 05Aug2014 KB 5) Added EXNOTRFL and NICOGR2 variables
to keep;
%put NOTE: 05Aug2014 KB 6) Amended format of AVISITN and ATPTN;
%put NOTE: 07Aug2014 KB 7) Amended Day 4 due to SDTM update;
%put NOTE: 08Aug2014 KB 8) AMended key variables;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

*=====;
* START OF PROGRAM CODE ;
*=====;
*****;
* bring in ADSL ;
*****;

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data adsl;
    set adam.adsl;
    keep studyid usubjid subjid: siteid age sex: race height weightb1
bmi ucpdgr1 ucpdgrln nicogr1 nicogrln NICOGR2 NICOGR2N /* 5) KB 05Aug2014
*/
    targr1 targrln enrfl scrfl complfl saffl pprotfl randfl trt:
trt01: tr01: tr02: dthfl enfl exfl fupfl analgr1 analgrln EXNOTRFL; /* 5)
KB 05Aug2014 */
run;

*****;
* bring in QS ;
*****;

data qs;
    set sdtm.qs(where = (qscat = 'COUGH ASSESSMENT QUESTIONNAIRE'));
    format paramcd $8. parcat1 $200. avisit ATPT $40. paramn parcatln
8. aval best. param $100. avalc $50. adt date9. /* 2) KB 22Apr2014 */
    adm dtetime13. atm time5. AVISITN ATPTN /*BEST.*/8. ; /* 2) KB
22Apr2014 */ /* 6) KB 05Aug2014 */
    * parameter variables ;
    parcat1 = propcase(qscat);
    parcatln = 1;

    paramcd = qstestcd;
    param = propcase(qstest, '.');

    if qstestcd = 'COUGH24' then paramn = 1;
    else if qstestcd = 'COUIMP' then paramn = 2;
    else if qstestcd = 'COUINT' then paramn = 3;
    else if qstestcd = 'COURFEQ' then paramn = 4;
    else if qstestcd = 'COUSPUT' then paramn = 5;
    else if qstestcd = 'COUOTH' then paramn = 6;
    else put 'USER WARN' 'ING: check parameter names as paramn not
allocated:' qstestcd = ;

    * analysis variables ;
    if qstestcd = 'COUINT' then do;
        if qsstresc='VERY MILD' then aval=1;
        if qsstresc='MILD' then aval=2;
        if qsstresc='MODERATE' then aval=3;
        if qsstresc='SEVERE' then aval=4;
        if qsstresc='VERY SEVERE' then aval=5;
    end;
    else if qstestcd = 'COURFEQ' then do;
        if qsstresc='RARELY' then aval=1;
        if qsstresc='SOMETIMES' then aval=2;
        if qsstresc='FAIRLY OFTEN' then aval=3;
        if qsstresc='OFTEN' then aval=4;
        if qsstresc='ALMOST ALWAYS' then aval=5;
    end;
    else if qstestcd = 'COUSPUT' then do;
        if qsstresc='NO SPUTUM' then aval=0;
        if qsstresc='A MODERATE AMOUNT OF SPUTUM' then aval=1;

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        if qsstresc='A LARGE AMOUNT OF SPUTUM' then aval=2;
        if qsstresc='A VERY LARGE AMOUNT OF SPUTUM' then aval=3;
    end;
    else aval = qsstresn;
    avalc = propcase(qsstresc, '.');

    * visit details ;
    avisit = propcase(visit);
    avisitn = visitnum;

    * baseline flag;
    ablfl = qsbflfl;

    * dates;
    if length(qsdtc) gt 10 then do;
        adtm = input(qsdtc,e8601dt.);
        adt = datepart(adtm);
        atm = timepart(adtm);
    end;
    else if length(qsdtc) = 10 then adt = input(qsdtc, yymmdd10.);

    IF ATPT='' THEN ATPT=''; /* 2) KB 22Apr2014 */
    IF ATPTN=. THEN ATPTN=.; /* 2) KB 22Apr2014 */

    keep usubjid qsseq param: parcat: aval: ablfl avisit: adt: atm
    qsstat qsreasnd qsdtc qsdym epoch qstpt ATPT ATPTN; /* 2) KB 22Apr2014 */
run;

proc sort data = qs;
    by usubjid paramn avisitn adtm;
run;

* end of exposure flag;
proc sort data = qs out = eos(where = (not missing(avalc)));
    by usubjid paramn avisitn adtm;
run;

data eos2(keep = usubjid paramn avisitn aeoe fl);
    set eos;
    by usubjid paramn;
    format aeoe fl $2.;
    if last.paramn then do;
        aeoe fl = 'Y';
        output;
    end;
run;

*merge back onto data;
data qs2;
    merge qs eos2;
    by usubjid paramn avisitn;
    format anl01fl $2.;

    * determine if any unscheduled;

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        if index(lowercase(avisit),'unscheduled') or paramcd = 'QSALL' then
anl01fl = ' ';
        else if last.avisitn and first.avisitn = 0 then anl01fl = ' ';
        else if paramcd ne 'COUGH24' and qsstat='NOT DONE' then anl01fl='';
        else anl01fl = 'Y';
        if anl01fl = ' ' then put 'Check reason for exclusion from
analysis: ' usubjid = param = avisit = ;
run;

*****;
* Combine ADSL and QS data *;
*****;
* treatment period;
*_mtotper;

data slqssym;
    merge adsl qs2(in = a);
    by usubjid;
    if a;          * only include subjects with data ;
    format aperiod trtan trtpn aday DEVN 8. trta trtp $40. aperiodc $8.
awlo awhi time8. awrange $50.; /* 4) KB 05Aug2014 */
    aday = adt - trtsdt + 1;
    * allocate treatment and period;
    if aday in (0 1) then aperiod=1;
    else if aday in (2 3) then aperiod=2;
    *_mperall(dvar1 = adtm, dvar2 = adt);
    if not missing(aperiod) then do;
        aperiodc = 'Period ' || put(aperiod,1.);
    end;

    if avisit='Day 0' then do;
        awlo=dhms(0,6,30,0);
        awhi=dhms(0,9,0,0);
        awrange=strip(put(awlo,time8.))||'-'||strip(put(awhi,time8.));
    end;
    else if avisit = 'Day 1' then do;
        awhi=tr01stm;
    end;
    else if avisit='Day 3' then do;
        awhi=tr02stm;
    end;
    else if avisit='Day 2' then do;
        awlo=tr01stm-dhms(0,0,5,0);
        awhi=tr01stm;
        awrange=strip(put(awlo,time8.))||'-'||strip(put(awhi,time8.));
    end;
    else if avisit=/'Day 4'/'Day 4/Discharge' THEN DO; /* 7) KB
07Aug2014 */
        awlo=tr02stm-dhms(0,0,5,0);
        awhi=tr02stm;
        awrange=strip(put(awlo,time8.))||'-'||strip(put(awhi,time8.));
    end;

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        IF MISSING(AWLO) AND MISSING(AWHI) THEN AWRANGE=''; /* 1) KB
22Apr2014 */

        IF NOT MISSING(AWHI) AND MISSING(AWLO) THEN
AWRANGE=STRIP('<')||STRIP(PUT(AWHI,TIME8.)); /* 3) KB 05Aug2014 */

        IF NOT MISSING(AWLO) AND ATM<AWLO THEN DEVN=(FLOOR((ATM-AWLO)/60));
/* 4) KB 05Aug2014 */
        ELSE IF NOT MISSING(AWHI) AND ATM>AWHI THEN DEVN=CEIL((ATM-AWHI)/60);
/* 4) KB 05Aug2014 */
        IF QSSTAT='NOT DONE' THEN CALL MISSING(DEVN); /* 4) KB 05Aug2014 */

run;

data slqssym2;
    set slqssym;
    format devwc $10.;

    if qsstat ne 'NOT DONE' then do;
        if atm<awlo then do;
            devwc=compress(put(floor((atm-awlo)/60),best.));
        end;
        else if atm>awhi then do;
            devwc=compress(put(ceil((atm-awhi)/60),best.));
        end;
    end;

    if not missing(devwc) then do;
        if index(devwc,'-')=0 then devwc=cats(cats('+',devwc),' min');
        else if index(devwc,'-') then devwc=cats(devwc,' min');
    end;
run;

*****;
* create output dataset ;
*****;

options replace;

data adqssym;
    set stdlib.adqssym slqssym2;

    drop trt01p: trt01a: trt02p: trt02a: qstpt ablf1 aeofl;
run;

proc sort data = adqssym out = adam.adqssym(label= 'Symptoms
Questionnaire Analysis Dataset');
/*    by usubjid avisitn;*/
    BY USUBJID AVISITN PARAMCD; /* 8) KB 08Aug2014 */
run;

options noreplace;

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%_scramble(set=adqssym, id=usubjid subjid subjidn age sex sexc sexn race
dthfl height weightbl bmi ucpdgr1 ucpdgrln nicogr1
        nicogrln targr1 targrln analgr1 analgrln, dates=devwc
trtsdtm trtsdt trtsday trtedtm trtedt trteday tr01sdt tr01stm tr01sdm
tr01edt tr01etm tr01edtm
        tr02sdt tr02stm tr02sdm tr02edt tr02etm tr02edtm,
        nullc=trtp trta trtseqp trtseqa trtstmf tr01stmf tr02stmf,
nulln=trtpn trtan trtseqpn trtseqan, nullcc=7, nullnc=4);

proc printto; run;
*=====;
* END OF PROGRAM CODE ;
*=====;

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