

```
/*=====
=====
```

```
*Covance Study ID   : 000000106343
```

```
*Program Name       : t_disp.sas
```

```
*Purpose            : Descriptive Statistics of subject disposition - All Screened Subjects
```

Table 15.2.1.1

```
*Input Data         : adam.adsl, ADAM.adfa
```

```
*Output Data        : tflds.T_15_02_01_01
```

```
*Macros Called       : %m_printto, %mnum, %m_logchk, %outrtf
```

```
*Programmed by      : L.Ma
```

```
*Creation Date       : 2015-05-20
```

```
*=====
=====
```

*Modification History

```
*Date      Initials  No. Reason;
```

```
*=====
=====*/
```

```
options notes nosource;
```

```
proc datasets lib=work nolist memtype=data kill; quit;
```

```
options notes source source2 nofullstimer validvarname=upcase missing=' ';
```

```
ods _all_ close;
```

```
ods listing;
```

```
%m_printto;
```

```
options spool;
```

```
*=====;
```

```
* Overall part ;
```

```
*=====;
```

```
data adsl;
```

```
    set adam.adsl;
```

```
    if not missing(dtestdtm) then testfl='Y';
```

```
run;
```

```
data adfa;
```

```
    set adam.adfa;
```

```
run;
```

```
data adfa1;
```

```
    merge adfa adsl(keep=usubjid testfl);
```

```
    by usubjid;
```

```
run;
```

```
proc freq data=adfa1(where=(scrffl='Y' and SAFBFL='N' and paramcd='WILLABL' and aval=2));
```

```
    table parcat1*testfl /noprint out=willths(where=(parcat1='THS 2.2' ) rename=(count=total));
```

```
run;
```

```
data willths(keep=statusn statusss total);
```

```

set willths;

if total=. then total=0;

status="Unwilling to use THS 2.2 Menthol";

statusn=4;

run;

proc freq data=adsl;

    *overall screened;

    tables studyid / noprint out=scrn (rename=(count=total) );

    *Screen failures;

    tables scrffl / noprint out=sfl(where=(scrffl='Y')rename=(count=total));

    *Screening failures, without product test;

    table scrffl*SAFBFL / noprint out=noprod(where=(scrffl='Y' and
SAFBFL='N')rename=(count=total));

    *Screening failures, with product test;

    table scrffl*SAFBFL / noprint out=prod(where=(scrffl='Y' and SAFBFL='Y')rename=(count=total));

    *Screening failures, with product test who Completed safety follow-up;

    tables scrffl*SAFBFL*DISFUCAT / noprint out=fup_c(where=(scrffl='Y' and SAFBFL='Y' and
DISFUCAT='') rename=(count=total));

    tables scrffl*DSREAS / noprint out=sfl_rsn(where=(scrffl='Y') rename=(count=total));

    *enrolled;

    tables enrfl / noprint out=enr(where=(enrfl='Y')rename=(count=total));

    *enrolled not randomized;

```

```

tables enrfl*enfl / noprint out=enr_nr(where=(enrfl='Y' and enfl='Y') rename=(count=total));

*enrolled not randomized who completed safety follow-up;

tables enfl*DISFUCAT / noprint out=enr_nrc(where=(enfl='Y' and DISFUCAT^='Discontinued
follow-up') rename=(count=total));

*enrolled randomized;

tables enrfl*randfl / noprint out=enr_r(where=(randfl='Y' and enrfl='Y') rename=(count=total));

run;

data _null_;

    set scrn;

    call symput('n', strip(put(total,best.)));

run;

%put n=&n.;

*reason for screen failure;

data sfl_rsn;

    set sfl_rsn ;

    if dsreas="Entry criteria not met" then do; statusn=7; statuss=' Entry criteria not met'; output;
end;

    else if dsreas="Withdrawal by subject" then do; statusn=8; statuss=' Withdrawal by subject';
output; end;

    else if dsreas="Other" then do; statusn=10; statuss=' Other'; output; end;

    keep statusn statuss total;

run;

data dum;

```

```

length status $100;

/* create a row with Completed safety follow-up as no data for this one. */
statusn=5; status=' Completed safety follow-up'; total=.; output;

statusn=5.5; status=''; total=.; output;

statusn=6; status='Reason for screen failure'; total=.; output;

statusn=9; status=' Adverse events'; total=.; output;

statusn=10.5; status=''; total=.; output;

run;

*set together;

data overall;

length status $100;

set sfl(in=a) noprod(in=b) prod(in=c) willths(in=d) fup_c(in=e) enr(in=f) enr_nr(in=g)
enr_nrc(in=h) enr_r(in=i);

if a then do; statusn=1; status='Screen failures'; output; end;

if b then do; statusn=2; status=' Screening failures, without product test'; output; end;

if c then do; statusn=3; status=' Screening failures, with product test'; output; end;

if d then do; statusn=4; status=' Unwilling to use THS 2.2'; output; end;

if e then do; statusn=5; status=' Completed safety follow-up'; output; end;

if f then do; statusn=11; status='Enrolled'; output; end;

if g then do; statusn=12; status=' Enrolled not randomized'; output; end;

if h then do; statusn=13; status=' Enrolled not randomized who completed safety follow-up';
output; end;

if i then do; statusn=14; status=' Randomized'; output; end;

```

```
        keep statusn statusss total;
run;
```

```
data overall2;

        set overall sfl_rsn dum;

        order=1;

run;
```

```
proc sort data=overall2 out=overall2;

        by statusn;

run;
```

```
data overall3;

        retain statusn statusss tot order;

        length tot $100;

        set overall2;

        if nmiss(total) then tot="";

        else tot=strip(put(total, 8.)) || ' (' || strip(put((total*100)/&n., 8.1)) || "%";

        if statusss=" Adverse events" and tot="" then tot="0";

        if statusss=' Completed safety follow-up' and tot="" then tot="0";

        keep statusn statusss tot order;

run;
```

```
*=====;
```

```

* By trt group part                                ;

*=====;

/*get N for column header */

data adsl;

    set adam.adsl(where=(not missing(trt01an)));

    output;

    if randfl="Y" then do;

        trt01an=100;

        trt01a='Overall Randomized';

        output;

    end;

run;


proc freq data=adsl(where=(trt01an in (3 4 5 100))) noprint;

    table trt01an*trt01a/ out =tot(drop=percent rename=(count=total));

run;


data tot2;

    set tot;

    call symput('trt' || compress(put(trt01an,best.)), compress(put(total,best.)));

run;


*** completed part ***;

```

*create completed for each period flag;

data adsl1;

set adsl;

if randfl='Y' and index(disccat, 'Discontinued Period 1')=0 then compl1fl='Y';

if randfl='Y' and index(disccat, 'Discontinued Period 1')=0 and index(disccat, 'Discontinued Period 2')=0 then compl2fl='Y';

if randfl='Y' and index(disccat, 'Discontinued Period 1')=0 and index(disccat, 'Discontinued Period 2')=0 and index(disccat, 'Discontinued Period 3')=0 then compl3fl='Y';

if randfl='Y' and disccat = 'Completed' then compl4fl='Y';

run;

*get completed no for each period;

proc freq data=adsl1;

tables trt01an*compl1fl / noprint out=tot_c1(where=(compl1fl='Y'));

tables trt01an*compl2fl / noprint out=tot_c2(where=(compl2fl='Y'));

tables trt01an*compl3fl / noprint out=tot_c3(where=(compl3fl='Y'));

tables trt01an*compl4fl / noprint out=tot_c4(where=(compl4fl='Y'));

run;

*** discontinued part ***;

proc freq data= adsl(where=(trt01an in (3 4 5 100)));

/* completed*/

completed safety follow-up;

tables trt01an*randfl*DISFUCAT/noprint out=tot_cs(where=(randfl='Y' and DISFUCAT^='Discontinued follow-up'));


```

/*      discontinued*/;/;

tables trt01an*randfl*complfl / noprint out=tot_d(where=(randfl='Y' and complfl = 'N'));

tables trt01an*randfl*disccat / noprint out=tot_d1(where=(randfl='Y' and disccat =
'Discontinued Period 1 with randomized product use'));

tables trt01an*randfl*disccat / noprint out=tot_d2(where=(randfl='Y' and disccat =
'Discontinued Period 2'));

tables trt01an*randfl*disccat / noprint out=tot_d3(where=(randfl='Y' and disccat =
'Discontinued Period 3'));

tables trt01an*randfl*disccat / noprint out=tot_d4(where=(randfl='Y' and disccat =
'Discontinued Period 4'));

/*      discontinued, without randomized product use*/

tables trt01an*randfl*disccat / noprint out=tot_dwo(where=(randfl='N' and
disccat='Discontinued Period 1 without randomized product use' ));

/*      discontinued safety follow-up*/

tables trt01an*randfl*DISFUCAT/noprint out=tot_ds(where=(randfl='Y' and
DISFUCAT='Discontinued follow-up'));

run;

*get completed each period no by trt group;

proc sql;

    select count into :trtc1 - :trtc4

    from tot_c4;

run;

%macro mnum(dsn=, out=, status=, statusn=);

proc transpose data=&dsn.(drop=percent rename=(count=total)) out=sum prefix=_;

    id trt01an;

```

```

var total;

run;

data sum1(drop=_label_ _name_ );

    length status $100;

    length _3 _4 _5 _100 8;

    set sum;

    if _3=. then _3=.; if _4=. then _4=.; if _5=. then _5=.; if _100=. then _100=.;

    if nmiss(_3) then SA="0";

    else SA=strip(put(_3 , 8.)) || ' (' || strip(put((_3*100)/&trt3., 8.1)) || "%";

    if nmiss(_4) then THSm="0";

    else THSm=strip(put(_4, 8.)) || ' (' || strip(put((_4*100)/&trt4., 8.1)) || "%";

    if nmiss(_5) then mCC="0";

    else mCC=strip(put(_5, 8.)) || ' (' || strip(put((_5*100)/&trt5., 8.1)) || "%";

    if nmiss(_100) then Overall="0";

    else Overall=strip(put(_100, 8.)) || ' (' || strip(put((_100*100)/&trt100., 8.1)) || "%";

    order=2;

    status=&status.;

    statusn=&statusn.;

run;

data dum;

    length status $100;

```

```

length _3 _4 _5 8;

status="";

_3=.;

_4=.;

_5=.;

_100=.;

run;

data &out.;

length _3 _4 _5 _100 8;

set sum1;

by status;

if status="" then delete;

if _3=. then _3=.; if _4=. then _4=.; if _5=. then _5=.; if _100=. then _100=.;

keep statusn status THSm mCC SA Overall order;

run;

%mend mnum;

%mnum(dsn=tot_c1, out=pc1, status='Completed Period 1', statusn=15);

%mnum(dsn=tot_c2, out=pc2, status='Completed Period 2', statusn=16);

%mnum(dsn=tot_c3, out=pc3, status='Completed Period 3', statusn=17);

%mnum(dsn=tot_c4, out=pc4, status='Completed Period 4', statusn=18);

%mnum(dsn=tot_cs, out=pc_cs, status='Completed safety follow-up', statusn=19);

```

```

%mnum(dsn=tot_d, out=pd_d, status='Discontinued', statusn=20);

%mnum(dsn=tot_d1, out=pd1, status='Discontinued Period 1', statusn=22);

%mnum(dsn=tot_d2, out=pd2, status='Discontinued Period 2', statusn=23);

%mnum(dsn=tot_d3, out=pd3, status='Discontinued Period 3', statusn=24);

%mnum(dsn=tot_d4, out=pd4, status='Discontinued Period 4', statusn=25);

%mnum(dsn=tot_dwo, out=pdwo, status='Discontinued Period 1 without randomized product use',
statusn=21);

%mnum(dsn=tot_ds, out=pds, status='Discontinued safety follow-up', statusn=26);


*set together;

data compl;

    retain statusn status THSm mCC SA Overall order;

    set pc1 pc2 pc3 pc4 pc_cs pd_d pdwo pd1 pd2 pd3 pd4 pds;

run;


*delete row with all missing or 0 values;

data final;

    set overall3 compl;

    if index(status, 'Discontinued Period 1 without randomized product use') and order=2 and
THSm='0' and mCC='0' and SA='0' and Overall='0' then delete;

run;


*create blank row after "Discontinued" row per mock;

data dumf;

    length status $100;

    statusn=19.5; status=""; total=.; order=2; output;

```

```
run;
```

```
proc sort data=final out=final;
```

```
    by statusn;
```

```
run;
```

```
proc sort data=dumf out=dumf;
```

```
    by statusn;
```

```
run;
```

```
data final;
```

```
    set dumf(in=a) final;
```

```
    by statusn;
```

```
run;
```

```
/*output report data; */
```

```
%let tflno=T_15_02_01_01;
```

```
data tflds.T_15_02_01_01;
```

```
    set final ;
```

```
run;
```

```
data paging;
```

```
    set final;
```

```
if 26>=statusn>=15 then page=2;

else page=1;

call symput("page",compress(put(page,best.)));

run;
```

```
options number nodate orientation=landscape missing=' ';

ods escapechar='|';

%let linetop = \brdrt\brdrs\brdrw30; * needs to be 1.5pt so calculated in twips (1/20 pt) ;

%let linebot = \brdrb\brdrs\brdrw30;
```

```
%macro outrtf(blankn=130, halfbink=N);
```

```
%let TFL_Part=%scan(&_SASPROGRAMFILE,-3,%str(/));
```

```
data _null_;
```

```
tmp="&TFL_Part";
```

```
if tmp not in ("dev" "qc") then call symput("TFL_Part", "prod");
```

```
call symput('TFLpath', compress("&_SASPROGRAMFILE", ""));
```

```
call symput('TFLprg',reverse(scan(strip(reverse(compress("&_SASPROGRAMFILE", ""))),1,"/")));
```

```
run;
```

```
%if &halfbink=N %then %let halfbink=;
```

```
%else %if &halfbink=Y %then %let halfbink=~;
```

```

ods path stdlib.t106343 (read) ;

ods results off;

ods rtf toc_data file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf"
style=t106343 startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

%do i=1 %to &page;


title ;

footnote;


data comp;

    set paging end=eof;

        where page=&i;


/* Amend title as needed */

        _firtitl="Table 15.2.1.1 Summary of Subject Disposition - All Screened Subjects";
        _upcas=(length(_firtitl)-length(compress(_firtitl,'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
len=&blankn.-length("(Page &i of &page)");


        if eof then do;

            call symput('_FSRTITL', trim(left(_firtitl)));

            call symput('_blankn', compress(put(len,best.)));

        end;

```

```

drop _firtitl _upcas len;

run;

ods proclabel = ' ';

ods listing close;

proc report data = comp headline headskip nowd split = '$' %if &i=1 %then %do; contents=' ' %end;
%else %do; contents=" %end;;

    %if &i=1 %then %do;

        column page statusn (" | S={just=left}Status$" status$) ("Overall Screened$(N=&n.)$n(%)"
tot);

        define page      / order order = internal noprint;

        define statusn    / order order = internal noprint;

        define status$    / display style={just=left cellwidth=7cm} style(header)={just=l} "";

        define tot        / display style={just=c cellwidth=3cm} style(header)={just=center} "";

        *indent status per mock;

        compute status$;

        if statusn in (5 7 8 9 10 ) then call define(_col_, "style", "style=[indent=40]" );

            else if statusn in (2 3 6 12 13 14) then call define(_col_, "style",
"style=[indent=15]");

        endcomp;

    %end;

%else %do;

        column page statusn (" | S={just=left}Status$" status$)("THSm2.2$(N=&trt4)$n(%)"
THSm)

        ("mCC$(N=&trt5.)$n(%)" mCC) ("SA$(N=&trt3.)$n(%)" SA)
("Overall$Randomized$(N=&trt100.)$n(%)" Overall);

```



```

define page      / order order = internal noprint;

define statusn   / order order = internal noprint;

define statuss   / display style={just=left cellwidth=7cm} style(header)={just=l} "";

define THSm      / display style={just=c cellwidth=2cm} style(header)={just=c} "";

define mCC       / display style={just=c cellwidth=2cm} style(header)={just=c} "";

define SA        / display style={just=c cellwidth=2cm} style(header)={just=c} "";

define Overall   / display style={just=c cellwidth=2cm} style(header)={just=c} "";

*indent status per mock;

compute statuss;

if statusn in (22 23 24 25 26) then call define(_col_, "style", "style=[indent=15]");

endcomp;

%end;

compute before page / style={just=left protectspecialchars=off};

line "&linetop";

endcomp;

compute after page / style={just=left protectspecialchars=off};

line "&linebot";

endcomp;

compute before _page_ / style={just=left protectspecialchars=off};

line "\b\fs24\sa24&_FSRTITL." ; * \b = bold, \fs24 is font size 12pt, \sa24 is space after 12pt;

line "&linebot";

endcomp;

```

```
%let line4=%NRBQUOTE(Note: Percentages for disposition prior to randomization are based on
the number of subjects screened. Percentages for 'Completed safety follow-up' under);
```

```
%let line5=%NRBQUOTE('Screening failures, with product test' are based on the number of
subjects who screen failed with the product test. Percentages for disposition after randomization);
```

```
%let line6=%nrstr(are based on the number of subjects randomized indicated in the column
header (N), apart from the Overall column where only percentages of completed and discontinued refer
to the total number of subjects randomized.);
```

```
compute after _page_/ style={just=left protectspecialchars=off};
```

```
line 'Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 =
Tobacco Heating System 2.2 Menthol.';
```

```
line 'Note: Discontinued refers to randomized subjects who discontinued from the study
before the planned discharge at Day 91; Completed at Period X Visit';
```

```
line 'refers to randomized subjects who did not discontinue the study before the completion of
study assessments at Period X Visit.';
```

```
line "&line4.";
```

```
line "&line5.";
```

```
line "&line6.";
```

```
line 'Note: Period 1 to Period 4 refers to the confinement, 30, 60, and 90 day periods,
respectively.';
```

```
line "Appendix 15.3.1.8"; /*John email on 5-28-2015*/
```

```
line "Study ID: ZRHM-REXA-08-US   Program: &TFLprg   Status: &status"
&_blankn.*"\~\~" "&sysdate" &_blankn.*"\~\~" "(Page &i of &page)";
```

```
endcomp;
```

```
run;
```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

```
ods path sashelp.tmplmst (read);
```

```
%mend outrtf;
```

```
%outrtf(blankn=36, halfblank=N);
```

```
ods listing;
```

```
%m_logchk;
```

```
/****** END OF FILE t_disp.sas *****/
```