

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

```
| Covance Study Number   : 000000106343          |
```

```
| Program Name           : t_comp.sas             |
```

```
| Purpose                : Summary of Compliance  |
```

```
| Input Data             : ADAM.ADSL              |
```

```
| Output Data            : tflds.T_15_2_5_2 & RTF  |
```

```
| Macros Called          : m_printto, m_logchk     |
```

```
| Originally Performed by : kpothuri              |
```

```
| Date                   : 30Apr2015              |
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|                       |
```

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```
| Modification History          |
```

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```
| Modified by      :          |
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| Modification Date :          |
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| Modification Description :    |
```

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

```
ods _all_ close;
```

```
ods listing;
```

```
%m_printto(route=YES);
```

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

```

* START OF PROGRAM CODE                                ;

*=====;

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

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

/* Standard - leave this */

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;

/*Column header numbers*/

data adsl;

    set adam.adsl(where=(fasfl='Y'));

run;

proc sort data=adsl nodupkey out=adsl1;

    by trt01pn trt01p subjid;

run;

proc sql noprint;

```

```

create table period as

select distinct trt01pn, trt01p, count(compp1fl) as pd1, count(compp2fl) as pd2,
count(compp3fl) as pd3, count(compp4fl) as pd4, count(cmppovfl) as overall_fas
from adsl1

group by trt01pn, trt01p;

run;

data count;

    set period;

    if trt01p = "THSm2.2" then do;

        trt01p = "THS";

        trt=0.2;

    end;

    if trt01p = "mCC" then trt=1.2;

    if trt01p = "SA" then trt=2.2;

run;


data _null_;

    set count;

    call symput ("pd1_" || compress(trt01p), put(pd1,8.));

run;

%put &pd1_SA &pd1_THS &pd1_mCC;


data _null_;

    set count;

    call symput ("pd2_" || compress(trt01p), put(pd2,8.));

```

```

run;

%put &pd2_SA &pd2_THS &pd2_mCC;


data _null_;

    set count;

    call symput ("pd3_" || compress(trt01p), put(pd3,8.));

run;

%put &pd3_SA &pd3_THS &pd3_mCC;


data _null_;

    set count;

    call symput ("pd4_" || compress(trt01p), put(pd4,8.));

run;

%put &pd4_SA &pd4_THS &pd4_mCC;


data _null_;

    set count;

    call symput ("tot_" || compress(trt01p), put(overall_fas,8.));

run;

%put &tot_SA &tot_THS &tot_mCC;


proc freq data=adsl1 noprint;

    table comp1fl*trt01p*trt01pn/out=f_exc_1 (drop=percent);

    table comp2fl*trt01p*trt01pn/out=f_exc_2 (drop=percent);

    table comp3fl*trt01p*trt01pn/out=f_exc_3 (drop=percent);

```

```

table comp4fl*trt01p*trt01pn/out=f_exc_4 (drop=percent);

table cmp4povfl*trt01p*trt01pn/out=f_exc_all (drop=percent);

run;

%macro comp (fset=, pd=, pct=, denom1=, denom2=, denom3=, dset=);

    data &dset (drop=count pct rename=(&pd=comp npct=&pct));

        set &fset;

        if trt01pn=3 then pct=(count/&denom1)*100;

        if trt01pn=4 then pct=(count/&denom2)*100;

        if trt01pn=5 then pct=(count/&denom3)*100;

        npct=put(count,8.) || " (" || compress(put(round(pct,.01),5.1)) || ")";

    run;

%mend comp;

%comp (fset=f_exc_1, pd=COMPP1FL, pct=npct1, denom1=&pd1_SA, denom2=&pd1_THS,
denom3=&pd1_mCC, dset=pd1);

%comp (fset=f_exc_2, pd=COMPP2FL, pct=npct2, denom1=&pd2_SA, denom2=&pd2_THS,
denom3=&pd2_mCC, dset=pd2);

%comp (fset=f_exc_3, pd=COMPP3FL, pct=npct3, denom1=&pd3_SA, denom2=&pd3_THS,
denom3=&pd3_mCC, dset=pd3);

%comp (fset=f_exc_4, pd=COMPP4FL, pct=npct4, denom1=&pd4_SA, denom2=&pd4_THS,
denom3=&pd4_mCC, dset=pd4);

%comp (fset=f_exc_all, pd=cmp4povfl, pct=npct_ovr, denom1=&tot_SA, denom2=&tot_THS,
denom3=&tot_mCC, dset=pd_ovr);

proc sort data=pd1; by trt01p trt01pn comp; run;

proc sort data=pd2; by trt01p trt01pn comp; run;

```

```
proc sort data=pd3; by trt01p trt01pn comp; run;

proc sort data=pd4; by trt01p trt01pn comp; run;

proc sort data=pd_ovr; by trt01p trt01pn comp; run;
```

```
data pd_all;

    merge pd1 pd2 pd3 pd4 pd_ovr;

    by trt01p trt01pn comp;
```

```
run;
```

```
proc freq data=adsl1 noprint;

    table cmpcp1fl*trt01p*trt01pn/out=f_pp_1 (drop=percent);

    table cmpcp2fl*trt01p*trt01pn/out=f_pp_2 (drop=percent);

    table cmpcp3fl*trt01p*trt01pn/out=f_pp_3 (drop=percent);

    table cmpcp4fl*trt01p*trt01pn/out=f_pp_4 (drop=percent);

    table cmpcovfl*trt01p*trt01pn/out=f_pp_all (drop=percent);
```

```
run;
```

```
%macro comp_pp (fset=, pd=, pct=, denom1=, denom2=, dset=);

    data &dset (drop=count pct rename=(&pd=comp npct=&pct));

        set &fset;

        where trt01pn in (3,4);

        if trt01pn=3 then pct=(count/&denom1)*100;

        if trt01pn=4 then pct=(count/&denom2)*100;

        npct=put(count,8.) || " (" || compress(put(round(pct,.01),5.1)) || ")";

run;
```

```
%mend comp_pp;

%comp_pp (fset=f_pp_1, pd=cmpcp1fl, pct=npct1, denom1=&pd1_SA, denom2=&pd1_THS, dset=pp1);

%comp_pp (fset=f_pp_2, pd=cmpcp2fl, pct=npct2, denom1=&pd2_SA, denom2=&pd2_THS, dset=pp2);

%comp_pp (fset=f_pp_3, pd=cmpcp3fl, pct=npct3, denom1=&pd3_SA, denom2=&pd3_THS, dset=pp3);

%comp_pp (fset=f_pp_4, pd=cmpcp4fl, pct=npct4, denom1=&pd4_SA, denom2=&pd4_THS, dset=pp4);

%comp_pp (fset=f_pp_all, pd=cmpcovfl, pct=npct_ovr, denom1=&tot_SA, denom2=&tot_THS,
dset=pp_ovr);
```

```
proc sort data=pp1; by trt01p trt01pn comp; run;

proc sort data=pp2; by trt01p trt01pn comp; run;

proc sort data=pp3; by trt01p trt01pn comp; run;

proc sort data=pp4; by trt01p trt01pn comp; run;

proc sort data=pp_ovr; by trt01p trt01pn comp; run;
```

```
data pp_all;

    merge pp1 pp2 pp3 pp4 pp_ovr;

    by trt01p trt01pn comp;

run;
```

```
data all;

length comp comp1 $75;

    set pd_all(in=a) pp_all(in=b);
```

```
    if a then do;

        label="exc";

        seq=1;

    end;
```

```

if b then do;
    label="pp";
    seq=2;
end;

if comp="Y" then do; comp="    Yes"; comp1="    Yes"; ny=1; end;
if comp="N" then do; comp="    No"; comp1="    No"; ny=2; end;

if trt01pn=4 then trt=1;
if trt01pn=5 then trt=2;
if trt01pn=3 then trt=3;

if npct1="" then npct1='    0 (0.0)';
if npct2="" then npct2='    0 (0.0)';
if npct3="" then npct3='    0 (0.0)';
if npct4="" then npct4='    0 (0.0)';
if npct_ovr="" then npct_ovr='    0 (0.0)';

run;

proc sort data=all; by trt seq ny; run;

data count_1 (drop=pd1 pd2 pd3 pd4 overall_fas);
length comp comp1 $75;

set count;

npct1=put(pd1,8.0);
npct2=put(pd2,8.0);
npct3=put(pd3,8.0);

```



```

npct4=put(pd4,8.0);

npct_ovr=put(overall_fas,8.0);


if trt01pn=3 then do; comp="SA - N"; comp1="SA - N"; end;

if trt01pn=4 then do; comp="THSm2.2 - N"; comp1="THSm2.2 - N"; end;

if trt01pn=5 then do; comp="mCC - N"; comp1="mCC - N"; end;

run;


data tot;

    set all count_1;

run;

proc sort data=tot; by trt seq comp; run;


data dummy1;

length comp comp1 $75;

    trt=0.5; comp=" Exclusive product use${super (1)} - n(%)";

        comp1=" Exclusive product use - n(%)"; output;

    trt=1; seq=1.5; comp=" PP criterion${super (2)} - n(%)";

        comp1=" PP criterion - n(%)"; output;

    trt=1.5; seq=.; comp=" Exclusive product use${super (1)} - n(%)";

        comp1=" Exclusive product use - n(%)"; output;

    trt=2.5; seq=.; comp=" Abstinent${super (1)} - n(%)";

        comp1=" Abstinent - n(%)"; output;

    trt=3; seq=1.5; comp=" PP criterion${super (2)} - n(%)";

        comp1=" PP criterion - n(%)"; output;

```

```
trt=1.1; seq=.; comp=""; comp1=""; output;  
trt=2.1; seq=.; comp=""; comp1=""; output;  
trt=3.1; seq=.; comp=""; comp1=""; blank=""; output;  
run;
```

```
proc sort data=dummy1; by trt seq comp; run;
```

```
data all_2;  
    merge tot dummy1;  
    by trt seq comp comp1;
```

```
run;
```

```
proc sort data=all_2 out=final; by trt seq ny; run;
```

```
data final_1;
```

```
    set final;
```

```
    npct1_=npct1;
```

```
    npct2_=npct2;
```

```
    npct3_=npct3;
```

```
    npct4_=npct4;
```

```
    npct_ovr_=npct_ovr;
```

```
if trt in (0.2,1.2,2.2) then do;
```

```
    comp='\b ' || strip(comp) || '\b0';
```

```
    npct1='\b ' || strip(npct1) || '\b0';
```

```
    npct2='\b ' || strip(npct2) || '\b0';
```

```

        npct3='\b ' || strip(npct3) || '\b0';

        npct4='\b ' || strip(npct4) || '\b0';

        npct_ovr='\b ' || strip(npct_ovr) || '\b0';

    end;

    if trt <= 2.1 then page=1;

    else if trt <= 3.1 then page=2;

run;

data final_1;

    set final_1 end=last;

    by page;

    if last then call symputx("page", page);

run;

%put &page;

%let tflno = %str(T_15_02_05_02);

data tflds.&tflno;

set final_1;

run;

/* Standard - leave this */

options number nodate orientation=landscape missing=' ';

```

```

ods escapechar='$';

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

%let linebot = \brdrb\brdrs\brdrw30;


/* Standard - macro for paging */

%macro outrtf(blankn=130, halfblk=N);

%if &halfblk=N %then %let halfblk=;

%else %if &halfblk=Y %then %let halfblk=\~;


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;

%let wd=0;

ods proclabel = ' ';


data comp;

set final_1 end=eof;

```

where page=&i;

/* Amend title as needed */

_firtitl="Table 15.2.5.2 Summary of Compliance by Period and Overall - FAS";

_upcas=(length("Path: &TFLpath.")-
length(compress("Path:&TFLpath.",'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 listing close;

* most set up in template others below;

* title arial 12pt bold with 12pt paragraph space below;

* all headers to be arial 11pt bold;

* data arial 10pt;

* headers to be central, text values left aligned and numeric centered around decimal point;

/* Update with your variables as needed */

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

```
column page comp ("Confinement&linebot" npct1) blank ("Ambulatory&linebot" npct2 npct3
npct4) npct_ovr;
```

```
define page / order order = internal noprint;
```

```
define comp /"Period" display style(column)={asis=on just=left cellwidth=2.5cm}
style(header)={just=left} "";
```

```
define blank /display " " style(column)=[just=left cellwidth=0.2cm];
```

```
define npct1 /"Period 1" display style={just=c cellwidth=1.4cm}
style(header)={just=center} ;
```

```
define npct2 /"Period 2" display style={just=c cellwidth=1.4cm}
style(header)={just=center};
```

```
define npct3 /"Period 3" display style={just=c cellwidth=1.4cm}
style(header)={just=center};
```

```
define npct4 /"Period 4" display style={just=c cellwidth=1.4cm}
style(header)={just=center};
```

```
define npct_ovr /"Overall FAS" display style={just=c cellwidth=1.4cm}
style(header)={just=center};
```

```
break after page / page;
```

```
compute before page / style={protectspecialchars=off};;
```

```
line "&linetop";
```

```
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;

compute after _page_/ style={just=left protectspecialchars=off pretext="&linetop."};

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

    line '[1]: No use of any nicotine or tobacco-containing product other than the assigned
product. However, in the SA arm, NRT use is allowed during the study.';

    line 'In the SA arm, 100% abstinence also requires CO breath test <=10 ppm (apart from
at Day 1). (Criterion for compliant population)';

    line '[2]: No use of more than 2 CC during a single day within any time period and no use
of on average more than 0.5 CC per day over the exposure period.';

    line 'Note: Percentages are based on the number of subjects (N) in the FAS for each arm
and period (first row of each arm).';

    line ";

    line 'Appendix 15.3.2.1.1 15.3.2.1.2 15.3.2.1.3';

    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(blankn=36, halfblank=N);

```

ods listing;

*=====;

* END OF PROGRAM CODE ;

*=====;

%m_logchk;