

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

```
| Covance Study Number   : 000000106343          |
| Program Name           : t_hba1c_pp.sas         |
| Purpose                 : Program to table 14.2.4.29.1 |
| Input Data              : ADAM.ADSL, ADAM.adlb    |
|                         |                         |
| Output Data             : T_14_02_04_29_01       |
| Macros Called           :                       |
| Originally Performed by :Sree Bikki             |
| Date                    : 12MAY2015              |
|                         |                         |
```

```
|=====
=====|
```

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

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

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

```
run;
```

```
%m_printto;
```

```
%macro table (paramcd= , tfl =, title = );
```

```
proc sql;
```

```
select count(distinct usubjid) into: N1THS from adam.adsl(where=(trt01pn = 4 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1MCC from adam.adsl(where=(trt01pn = 5 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1SAA from adam.adsl(where=(trt01pn = 3 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N2THS from adam.adsl(where=(trt01pn = 4 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2MCC from adam.adsl(where=(trt01pn = 5 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2SAA from adam.adsl(where=(trt01pn = 3 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N3THS from adam.adsl(where=(trt01pn = 4 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N3MCC from adam.adsl(where=(trt01pn = 5 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N3SAA from adam.adsl(where=(trt01pn = 3 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01pn = 4 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01pn = 5 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01pn = 3 and pprot4fl = "Y"));
```

```
quit;
```

```
%let tflno=&tfl.;
```

```
/* Standard - leave this */
```

```
%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;
```

```
data adlb_1;
```

```
set adam.adlb;
```

```
where (pprot1fl = "Y" and 101<=avisitn <= 106) or (pprot2fl = "Y" and avisitn = 130) or (pprot3fl = "Y"  
and avisitn = 160) or (pprot4fl = "Y" and avisitn in (190, 191));
```

```
if paramcd in &paramcd and anl01fl = "Y";
```

```
run;
```

```
data adlb_2;
```

```
set adam.adlb;
```

```
if paramcd in &paramcd and anl01fl = "Y";
```

```
if ablfl = "Y" and pprot1fl = "Y" then do;
```

```
  avisitn = 10;
```

```
  avisit = "Baseline";
```

```
  apuper = 1;
```

```
  apuperc = "Period 1";
```

```
  output;
```

```
end;
```

```
if ablfl = "Y" and pprot2fl = "Y" then do;
```

```
  avisitn = 10;
```

```
  avisit = "Baseline";
```

```
  apuper = 2;
```

```
  apuperc = "Period 2";
```

```
  output;
```

```
end;
```

```
if ablfl = "Y" and pprot3fl = "Y" then do;
```

```
  avisitn = 10;
```

```
  avisit = "Baseline";
```

```
  apuper = 3;
```

```
  apuperc = "Period 3";
```

```
  output;
```

```
end;
```

```
if ablfl = "Y" and pprot4fl = "Y" then do;
```

```
  avisitn = 10;
```

```
  avisit = "Baseline";
```

```
  apuper = 4;
```

```
apuperc = "Period 4";
```

```
output;
```

```
end;
```

```
run;
```

```
data adlb;
```

```
set adlb_1 adlb_2;
```

```
run;
```

```
proc sort data=adlb;
```

```
by trtpn trtp paramn param paramcd apuper apuperc avisitn avisit;
```

```
run;
```

```
/*GEOMEAN AN CI*/
```

```
proc means data=adlb(where=(aval ne .)) noprint;
```

```
var aval;
```

```
by trtpn trtp paramn param paramcd apuper apuperc avisitn avisit ;
```

```
output out=aval n =n mean = mean std = std median = median min = min max = max q1 = q1 q3 = q3 lclm  
= lclm uclm = uclm;
```

```
run;
```

```
/*for figure dataset t_15_02_04_29_01_F*/
```

```

data figure;

set aval;

logf=0;

keep lclm uclm paramcd param paramn avisit avisitn mean logf trtp trtpn ;

if apuper in (2,3,4) and avisitn=10 then delete;

run;

```

```

/*end for figure dataset t_15_02_04_29_02_F*/

```

```

data aval1;

set aval;

if lclm ne . then lclmx = 0.01*floor(100*lclm);

if uclm ne . then uclmx = 0.01*ceil(100*uclm);

length median1 Q2575 Minmax Meansd CIAM n1 $50.;

median1 = strip(put(round(median, 0.01), 15.1));

q2575 = strip(put(round(q1, 0.01), 15.1))||", "||strip(put(round(q3, 0.01), 15.1));

minmax = strip(put(round(min, 0.1), 15.0))||", "||strip(put(round(max, 0.1), 15.0));

if std ne . then meansd = strip(put(round(mean, 0.01), 15.1))||" ("||strip(put(round(std, 0.001),
16.2))||")";

else if std = . then meansd = strip(put(round(mean, 0.01), 15.1))||" (NA)";

if nmiss(lclmx, uclmx) = 0 then ciam = strip(put(lclmx, 15.1))||", "||strip(put(uclmx, 15.1));

else if lclmx ne . and uclmx = . then ciam = strip(put(lclmx, 15.1))||", NA";

else if lclmx = . and uclmx ne . then ciam = "NA, "||strip(put(uclmx, 15.1));

```

```
else if lclmx = . and uclmx = . then ciam = "NA, NA";
```

```
n1 = strip(put(n, best.));
```

```
run;
```

```
/**missing calculation*/
```

```
data results03;
```

```
length missc $30;
```

```
set aval1;
```

```
/*period 1*/
```

```
if trtpn=3 and apuper = 1 then do;
```

```
if &n1saa.=n then
```

```
missc="";
```

```
else
```

```
missc=strip(put(((&n1saa.- n), 8.)) || ' (' || strip(put((((&n1saa.-n)*100)/&n1saa., 8.1)) || "));
```

```
end;
```

```
else if trtpn=4 and apuper = 1 then do;
```

```
if &n1ths.=n then
```

```
missc="";
```

```
else
```

```
missc=strip(put(((&n1ths.- n), 8.)) || ' (' || strip(put((((&n1ths.-n)*100)/&n1ths., 8.1)) || "));
```

```
end;
```

```
else if trtpn=5 and apuper = 1 then do;
```

```
if &n1mcc.=n
```

```
then missc="";
```

```

else
missc=strip(put((&n1mcc.-n), 8.)) || ' (' || strip(put(((&n1mcc.-n)*100)/&n1mcc., 8.1)) || ")";

end;

/*period 2*/

if trtpn=3 and apuper = 2 then do;

if &n2saa.=n then

missc="";

else

missc=strip(put((&n2saa.- n), 8.)) || ' (' || strip(put(((&n2saa.-n)*100)/&n2saa., 8.1)) || ")";

end;

else if trtpn=4 and apuper = 2 then do;

if &n2ths.=n then

missc="";

else

missc=strip(put((&n2ths.- n), 8.)) || ' (' || strip(put(((&n2ths.-n)*100)/&n2ths., 8.1)) || ")";

end;

else if trtpn=5 and apuper = 2 then do;

if &n2mcc.=n

then missc="";

else

missc=strip(put((&n2mcc.-n), 8.)) || ' (' || strip(put(((&n2mcc.-n)*100)/&n2mcc., 8.1)) || ")";

end;

/*      period 3*/

if trtpn=3 and apuper = 3 then do;

if &n3saa.=n then

missc="";

```



```

else
missc=strip(put((&n3saa.-n), 8.)) || ' (' || strip(put(((&n3saa.-n)*100)/&n3saa., 8.1)) || ")";

end;

else if trtpn=4 and apuper =3 then do;

if &n3ths.=n then

missc="";

else

missc=strip(put((&n3ths.- n), 8.)) || ' (' || strip(put(((&n3ths.-n)*100)/&n3ths., 8.1)) || ")";

end;

else if trtpn=5 and apuper = 3 then do;

if &n3mcc.=n

then missc="";

else

missc=strip(put((&n3mcc.-n), 8.)) || ' (' || strip(put(((&n3mcc.-n)*100)/&n3mcc., 8.1)) || ")";

end;

/*period 4*/

if trtpn=3 and apuper =

4 then do;

if &n4saa.=n then

missc="";

else

missc=strip(put((&n4saa.- n), 8.)) || ' (' || strip(put(((&n4saa.-n)*100)/&n4saa., 8.1)) || ")";

end;

else if trtpn=4 and apuper =4 then do;

if &n4ths.=n then

missc="";

```

```

else
missc=strip(put((&n4ths.- n), 8.)) || ' (' || strip(put(((&n4ths.-n)*100)/&n4ths., 8.1)) || ")";

end;

else if trtpn=5 and apuper = 4 then do;

if &n4mcc.=n

then missc="";

else

missc=strip(put((&n4mcc.-n), 8.)) || ' (' || strip(put(((&n4mcc.-n)*100)/&n4mcc., 8.1)) || ")";

end;

run;

proc sort data=results03 out=aval1;

by paramn param apuper apuperc avisitn avisit ;

run;

proc transpose data=aval1 out=aval_t prefix= trt_;

by paramn param apuper apuperc avisitn avisit ;

var n1 median1 q2575 minmax meansd ciam missc;

id trtpn;

run;

data aval_t;

length txt $200.;

set aval_t;

if upcase(_name_) = "N1" then do;

```

```
txtn = 1;

txt = "n";

end;

if upcase(_name_) = "MISSC" then do;

txtn = 2;

txt = "Missing, n (%)";

end;

else if upcase(_name_) = "MEDIAN1" then do;

txtn = 5;

txt = "Median";

end;

else if upcase(_name_) = "Q2575" then do;

txtn = 6;

txt = "Q25, Q75";

end;

else if upcase(_name_) = "MINMAX" then do;

txtn = 7;

txt = "Min, Max";

end;

else if upcase(_name_) = "MEANSD" then do;

txtn = 3;

txt = "Mean (SD)";

end;

else if upcase(_name_) = "CIAM" then do;

txtn = 4;
```

```
txt = "95% CI";
```

```
end;
```

```
run;
```

```
data aval_f;
```

```
set aval_t ;
```

```
run;
```

```
proc sort data=aval_f;
```

```
by paramn param apuper apuperc avisitn avisit txtn txt;
```

```
run;
```

```
proc sort data=adlb;
```

```
by trtpn paramn param apuper apuperc avisitn avisit ;
```

```
run;
```

```
proc means data=adlb(where=(pchg ne . and ablfl ne "Y")) noprint;
```

```
var pchg;
```

```
by trtpn paramn param apuper apuperc avisitn avisit ;
```

```
output out=chg n =n mean = mean std = std median = median min = min max = max q1 = q1 q3 = q3 lclm  
= lclm uclm = uclm;
```

```
run;
```

```

data chg1;

set chg;

if lclm ne . then lclmx = 0.01*floor(100*lclm);

if uclm ne . then uclmx = 0.01*ceil(100*uclm);

length median1 Q2575 Minmax Meansd CIAM n1 $50.;

median1 = strip(put(round(median, 0.01), 15.1));

q2575 = strip(put(round(q1, 0.01), 15.1))||", "||strip(put(round(q3, 0.01), 15.1));

minmax = strip(put(round(min, 0.1), 15.0))||", "||strip(put(round(max, 0.1), 15.0));

if std ne . then meansd = strip(put(round(mean, 0.01), 15.1))||" ("||strip(put(round(std, 0.001),
16.2))||")";

else if std = . then meansd = strip(put(round(mean, 0.01), 15.1))||" (NA)";

if nmiss(lclmx, uclmx) = 0 then ciam = strip(put(lclmx, 15.1))||", "||strip(put(uclmx, 15.1));

else if lclmx ne . and uclmx = . then ciam = strip(put(lclmx, 15.1))||", NA";

else if lclmx = . and uclmx ne . then ciam = "NA, "||strip(put(uclmx, 15.1));

else if lclmx = . and uclmx = . then ciam = "NA, NA";

n1 = strip(put(n, best.));

run;

```

```

/**missing calculation*/

```

```

data results04;

length missc $30;

set chg1;

```

```
/*period 1*/
```

```
if trtpn=3 and apuper = 1 then do;

                                if &n1saa.=n then

missc="";

                                else

missc=strip(put((&n1saa.- n), 8.)) || ' (' || strip(put(((&n1saa.-n)*100)/&n1saa., 8.1)) || ")";

                                end;

else if trtpn=4 and apuper = 1 then do;

                                if &n1ths.=n then

missc="";

                                else

missc=strip(put((&n1ths.- n), 8.)) || ' (' || strip(put(((&n1ths.-n)*100)/&n1ths., 8.1)) || ")";

                                end;

else if trtpn=5 and apuper = 1 then do;

                                if &n1mcc.=n

then missc="";

                                else

missc=strip(put((&n1mcc.-n), 8.)) || ' (' || strip(put(((&n1mcc.-n)*100)/&n1mcc., 8.1)) || ")";

                                end;

end;
```

```
/*period 2*/
```

```
if trtpn=3 and apuper = 2 then do;

                                if &n2saa.=n then

missc="";

                                else

missc=strip(put((&n2saa.- n), 8.)) || ' (' || strip(put(((&n2saa.-n)*100)/&n2saa., 8.1)) || ")";

                                end;

else if trtpn=4 and apuper = 2 then do;
```

[illegible]

```

else
missc=strip(put((&n3mcc.-n), 8.)) || ' (' || strip(put(((&n3mcc.-n)*100)/&n3mcc., 8.1)) || ")";

end;

/*period 4*/

if trtpn=3 and apuper =
4 then do;

if &n4saa.=n then

missc="";

else

missc=strip(put((&n4saa.- n), 8.)) || ' (' || strip(put(((&n4saa.-n)*100)/&n4saa., 8.1)) || ")";

end;

else if trtpn=4 and apuper =4 then do;

if &n4ths.=n then

missc="";

else

missc=strip(put((&n4ths.- n), 8.)) || ' (' || strip(put(((&n4ths.-n)*100)/&n4ths., 8.1)) || ")";

end;

else if trtpn=5 and apuper = 4 then do;

if &n4mcc.=n

then missc="";

else

missc=strip(put((&n4mcc.-n), 8.)) || ' (' || strip(put(((&n4mcc.-n)*100)/&n4mcc., 8.1)) || ")";

end;

run;

```



```

proc sort data=results04 out=chg1;

by paramn param apuper apuperc avisitn avisit ;

run;


proc transpose data=chg1 out=chg_t prefix= chg_;

by paramn param apuper apuperc avisitn avisit ;

var n1 median1 q2575 minmax meansd ciam missc;

id trtpn;

run;


data chg_t;

length txt $200.;

set chg_t;

if upcase(_name_) = "N1" then do;

txtn = 1;

txt = "n";

end;

if upcase(_name_) = "MISSC" then do;

txtn = 2;

txt = "Missing, n (%)";

end;

else if upcase(_name_) = "MEDIAN1" then do;

txtn = 5;

txt = "Median";

end;

```

```
else if upcase(_name_) = "Q2575" then do;

txtn = 6;

txt = "Q25, Q75";

end;

else if upcase(_name_) = "MINMAX" then do;

txtn = 7;

txt = "Min, Max";

end;

else if upcase(_name_) = "MEANSD" then do;

txtn =3;

txt = "Mean (SD)";

end;

else if upcase(_name_) = "CIAM" then do;

txtn = 4;

txt = "95% CI";

end;

run;


data chg_f;

set chg_t ;

run;


proc sort data=chg_f;

by paramn param apuper apuperc avisitn avisit txtn txt;
```

```
run;
```

```
proc sort data=aval_f;  
by paramn param apuper apuperc avisitn avisit txtn txt;  
run;
```

```
data final;  
length period $200.;  
merge aval_f chg_f(drop=_name_);  
by paramn param apuper apuperc avisitn avisit txtn txt;  
if apuper = 1 then do;  
period = "Period 1";  
THS = &N1THS;  
mcc = &N1mcc;  
sa = &N1saa;  
end;  
else if apuper = 2 then do;  
period = "Period 2";  
ths = &n2ths;  
mcc = &n2mcc;  
sa = &n2saa;  
end;  
else if apuper = 3 then do;
```

```

period = "Period 3";

ths = &n3ths;

mcc = &n3mcc;

sa = &n3saa;

end;

else if apuper = 4 then do;

period = "Period 4";

ths = &n4ths;

mcc = &n4mcc;

sa = &n4saa;

end;

if trt_3 = " " and trt_4 = " " and trt_5 = " " and chg_3 = " " and chg_4 = " " and chg_5 = " " then delete;

if txtn =2 and trt_3^= " " or trt_4^= " " or trt_5^= " " then do;

if trt_3 = " " then trt_3 = "0";

if trt_4 = " " then trt_4 = "0";

if trt_5 = " " then trt_5 = "0";

end;

if txtn =2 and avisitn ne 10 then do;

if chg_3 = " " then chg_3 = "0";

if chg_4 = " " then chg_4 = "0";

if chg_5 = " " then chg_5 = "0";

end;

run;

```

```
proc sql;

create table page as

select distinct apuper, apuperc, paramn, avisitn

from final

order by paramn, apuper, avisitn;

quit;
```

```
data page1;

set page;

by paramn apuper avisitn;

page =apuper;

run;
```

```
proc sql;

create table final_page as

select distinct a.*, b.page

from final as a

left join page1 as b

on a.paramn = b.paramn and a.avisitn = b.avisitn and a.apuper = b.apuper

order by paramn, apuper,avisitn, txtn;

quit;
```

```

data final_page;

set final_page end=last;

by paramn apuper avisitn txtn;

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

run;


data tflds.&tflno(keep=txt txtn avisitn avisit paramn param trt_3 trt_4 trt_5 chg_3 chg_4 chg_5);

set final_page;

run;


data tflds.T_15_02_04_29_01_F;

set figure;

run;


%put &page;

/* Standard - leave this */

options number nodate orientation=landscape /* papersize=&P_PGSIZE*/ 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;

/* Standard - macro for paging */

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

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

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

```

```

ods path stdlib.t106343 (read) ;

ods results off;

ods rtf toc_data/* contents*/
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_page end=eof;

    where page=&i;

    /* Amend title as needed */

    _firtitl="&title.";

    _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.)));

        call symput('period', strip(apuperc));

        call symput('param', strip(param));

        call symput('N3', strip(put(sa, best.)));

        call symput('N4', strip(put(th, best.)));

        call symput('N5', strip(put(mcc, 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 headsip nowd split = '$' %if &i=1 %then %do; contents=' ' %end;
%else %do; contents="" %end;;;

```

```

        column page paramn apuper avisitn avisit txtn txt ("THSm2.2$(N=&N4)&linebot" trt_4 chg_4 )
("mCC$(N=&N5)&linebot" trt_5 chg_5)

```

```

        ("SA$(N=&N3)&linebot" trt_3 chg_3);

```



```

        define paramn          / order order = internal noprint;

        define page            / order order = internal noprint;

        define avisitn        / order order = internal noprint;

        define apuper          / order order = internal noprint;

    define txtn / order order = internal noprint;

        define avisit          /"Timepoint" order order=internal style={just=left cellwidth=0.9cm}
style(header)={just=left} ;

        define txt             /"Statistic" display style={just=left cellwidth=1.9cm}
style(header)={just=left} ;

        define trt_3           /"Value" display style={JUST=c cellwidth=1.2cm}
style(header)={just=center} ;

        define trt_4           /"Value" display style={just=c cellwidth=1.2cm}
style(header)={just=center} ;

        define trt_5           /"Value" display style={just=c cellwidth=1.2cm}
style(header)={just=center};

        define chg_3           /"% Change(*)" display style={JUST=c cellwidth=1.2cm}
style(header)={just=center};

        define chg_4           /"% Change(*)" display style={just=c cellwidth=1.2cm}
style(header)={just=center};

        define chg_5           /"% Change(*)" display style={just=c cellwidth=1.2cm}
style(header)={just=center};

compute after avisitn;

        line " ";

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 " ";
```

```
line "Parameter (units):&param";
```

```
LINE "Product Use Time Period: &period";
```

```
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 'Note: Percentages are based on the number of subjects indicated in the column  
header (N).';
```

```
LINE 'Note: * % Change from baseline, where baseline is defined as the last assessment  
prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to  
10AM on Day 1 in the SA arm.';
```

```
line ' ';
```

```
line 'Appendix 15.3.3.2';
```

```
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, halfblk=N);
```

```
ods listing;
```

```
%mend table;
```

```
%table (paramcd = ("HBA1C"), tfl = %nrstr(T_15_02_04_29_01),title = %str(Table 15.2.4.29.1 Descriptive  
Statistics of HbA1c (%%)- PP Set));
```

```
%m_logchk2;
```