Summary and Analysis of patient Disposition
Page 1 of 1
From Screening up to 24 Months
09:53 20JAN2009
Intent-to-treat patients

Protocol Violation Category Sub Category	Placebo (N=186) n (%)	Dula_0.75 (N=191) n (%)	Dula_1.5 (N=193) n (%)	Total (N=570) Overall n (%)	P-value*a
Lack of compliance to study drug					
Date of first study drug injection >= date of	21 (11.3)	17 (8.9)	19 (9.8)	57 (10.0)	.739
Overall subject-level treatment compliance <	80 (43.0)	51 (26.7)	80 (41.5)	211 (37.0)	.001
Important violations of inclusion/exclution criteria					
HbA1c not in specified range at visit 1	48 (25.8)	59 (30.9)	52 (26.9)	159 (27.9)	.511
Informed consent not done	3 (1.6)	4 (2.1)	4 (2.1)	11 (1.9)	.929
HbA1c missing at baseline	34 (18.3)	60 (31.4)	38 (19.7)	132 (23.2)	.004

Abbreviations: N = number of patients in specified treat arm; n = number og patients in specied category.
*a - overall p-values are from che-squered test.

Program From This Mock Shell Is Given Bellow

```
%let prgnm = fqpvla1;

options nocenter nodate nonumber mprint mlogic ps = 46 ls = 133 formchar = "|----|+|---+=|-/\<>*"
charcode;

%include "C:\Users\Desktop\SAS_ADS\LUMS\out2rtf.sas";

libname db "C:\Users\Desktop\SAS_ADS\ADS";
libname out "C:\Users\\Desktop\ADI\TFL_OUTPUT";

%let outfile = C:\Users\Desktop\ADI\TFL_OUTPUT;

*** User defined formats ***;
proc format;
*** Percentage Format ***;
 picture rnd_pct (round)
  0 - <99.95   = '(09.9)' (prefix = '(')
  99.95 - high = '(100)'  (prefix = '(');

*** P-value Format ***;
proc format;
 picture pvalj (round)
  0 - <0.001        = "<.001" (noedit)
  0.001 - <0.9995 = "0.999"  (prefix= '.')
  0.9995 - 1        = ">.999" (noedit)
  .               = " ";

value grp 1 = 'Lack of compliance to study drug'
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         2 = 'Important violations of inclusion/exclution criteria';

 value sgrpa 1 = 'Date of first study drug injection >= date of visit 3'
             2 = 'Overall subject-level treatment compliance < 75%';

 value sgrpb 1 = 'HbA1c not in specified range at visit 1'
             2 = 'Informed consent not done'
             3 = 'HbA1c missing at baseline';
run;
%macro fqpvla1 (rptnm = , pop = );

proc printto new log = "C:\Users\Desktop\ADI\SYSTEM_FILES\&prgnm..log";
run;

%put --------- Start of FQPVLA1 macro ---------;
****Getting inforation from subjinfo Ads****;

proc sort data = db.subjinfo out = subjinfo (keep = invid subjid trtsort trt country);
       by invid subjid;
       where &pop. = 1;
run;
*** N = Total number of patients in specied treatment arm ***;
proc sql noprint;
 select count(distinct subjid) into :n1  from subjinfo where trtsort = 1;
 select count(distinct subjid) into :n2  from subjinfo where trtsort = 2;
 select count(distinct subjid) into :n3  from subjinfo where trtsort = 3;
 select count(distinct subjid) into :n4  from subjinfo where trtsort in (1, 2, 3);
quit;

%let n1 = &n1;
%let n2 = &n2;
%let n3 = &n3;
%let n4 = &n4;

****Getting information from protvi Ads****;

data protvigrp;
       set db.protvi;
 if protvicatsnm = 'Lack of compliance to study drug' then do;
  grp=1;
  if protvirmrk = 'Date of first study drug injection >= date of visit 3' then sgrp = 1;
  else if protvirmrk = 'Overall subject-level treatment compliance < 75%' then sgrp = 2;
 end;
 else if protvicatsnm = 'Important violations of inclusion/exclution criteria' then do;
  grp=2;
  if protvirmrk = 'HbA1c not in specified range at visit 1' then sgrp = 1;
  else if protvirmrk = 'Informed consent not done' then sgrp = 2;
  else if protvirmrk = 'HbA1c missing at baseline' then sgrp = 3;
 end;
run;

proc sort data = protvigrp;
 by invid subjid;
run;

data pop;
       merge subjinfo (in=a) protvigrp (in=b);
       by invid subjid;
       if a and b;
run;

data pop_tot;
 set pop;
 output;
 trtsort = 4;
 output;
run;

proc sql noprint;
       create table summ as
 select grp, sgrp, trtsort, count(distinct subjid) as sn from      pop_tot
       group by grp, sgrp, trtsort order by grp, sgrp, trtsort;
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```
quit;

data dummy (where = ((grp = 1 and sgrp in (1, 2)) or grp = 2));
 do grp = 1 to 2;
  do sgrp      = 1 to 3;
   do trtsort = 1 to 4;
    sn = 0;
    output;
   end;
  end;
 end;
run;

data summ_dummy;
       merge dummy (in=a) summ (in=b);
       by grp sgrp trtsort;
       if a;
run;

proc transpose data = summ_dummy out = summ_trans prefix = trt;
 by grp sgrp;
 var sn;
 id trtsort;
run;

*** Getting Chisq P-value ***;
data pdata;
 set summ_dummy;
 where trtsort ^= 4;
 resflg = 1;
 wcnt = sn;
 output;
 resflg = 0;
/* if trtsort = 1 then wcnt = &n1. - sn;*/
/* else if trtsort = 2 then wcnt = &n2. - sn;*/
/* else if trtsort = 3 then wcnt = &n3. - sn;*/
 wcnt = input(symget(cats('n', trtsort)), 8.) - sn;
 output;
run;

ods listing close;
ods output chisq = pvalues;
proc freq data = pdata;
       by grp sgrp;
 tables trtsort*resflg / chisq;
 weight wcnt;
run;
ods output close;
ods listing;

data p_values(keep = grp sgrp prob);
       set pvalues;
       where statistic = 'Chi-Square';
run;

data summ_comb;
 merge summ_trans p_values;
 by grp sgrp;
run;

data final;
       set summ_comb;
 length c1 $400 c3 - c6 $20;
  if grp = 1 then c1 = '   ' || strip(put(sgrp, sgrpa.));
  else if  grp = 2 then c1 = '   ' || strip(put(sgrp, sgrpb.));
 c2 = put(trt1, 4.) || ' ' || put(trt1*100/&n1., rnd_pct.);
 c3 = put(trt2, 4.) || ' ' || put(trt2*100/&n2., rnd_pct.);
 c4 = put(trt3, 4.) || ' ' || put(trt3*100/&n3., rnd_pct.);
 c5 = put(trt4, 4.) || ' ' || put(trt4*100/&n4., rnd_pct.);
 c6 = put(prob, pvalj.);

 if grp = 1 then mgrp = 1;
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```
 else if grp = 2 then mgrp = 2;
 pbrk = 1;
run;

data out.&rptnm. (keep = c1 - c6);
 set final;
run;

ods listing close;

options pageno = 1;

filename tmpfile temp;

proc printto new print = tmpfile;
run;

ods listing;

title;
footnote;

proc report data = final headline headskip nowd missing split = '^';
 columns pbrk mgrp grp c1 - c6;

 define pbrk / group order = data noprint;
 define mgrp / group order = data noprint;
 define grp / group order = data noprint;
 define c1 / display 'Protocol Violation Category^ Sub Category' width = 48 spacing = 0;
 define c2 / display "Placebo^(N=&n1)^n (%)" width = 16 spacing = 1 center;
 define c3 / display "Dula_0.75^(N=&n2)^n (%)" width = 16 spacing = 1 center;
 define c4 / display "Dula_1.5^(N=&n3)^n (%)" width = 16 spacing = 1 center;
 define c5 / display "Total^(N=&n4)^n (%)" width = 16 spacing = 1 center;
 define c6 / display "Overall^P-value*a" width = 16 spacing = 1 center;

 break after mgrp / skip;
 break after mgrp / skip;

 compute before mgrp;
 length txt $100;
  if mgrp = 1 then  txt = 'Lack of compliance to study drug';
  else if mgrp = 2 then  txt = 'Important violations of inclusion/exclution criteria';
       line @1 txt $100.;
 endcomp;

 %if %upcase(&rptnm.) = FQPVLA11 %then %let tit3 = Intent-to-treat patients;

 compute before _page_;
  line @1 "Summary and Analysis of patient Disposition
Page_X___of_Y__";
  line @1 "From Screening up to 24 Months
&systime. &sysdate9.";
  line @1 "&tit3";
  line @1 " ";
  line @1 133*'-';
 endcomp;


 compute after pbrk;
  line @1 133*'-';
  line @1 "Abbreviations: N = number of patients in specified treat arm; n = number og patients
in specied category.";
  line @1 "*a - overall p-values are from che-squered test.";
 endcomp;
run;

proc printto print = print log = log;
run;

%out2rtf (in = tmpfile, out = &outfile.\&rptnm..rtf, orient = l, center = );

filename tmpfile clear;
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%put --------- End of FQPVLA1 macro ---------;

%mend fqpvla1;

%fqpvla1 (rptnm = fqpvla11, pop = subjitt);
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