```
/*Evaluation of FLuorometholone as Adjunctive MEdical Therapy for Trachomatous Trichiasis Surgery: The FLAME Randomized
Controlled Clinical Trial*/
/*purpose: summarize visual acuity change over time in study eyes by treatment groups*/
/*Note: raw datasets in SAS library 'in' corresponds to the shared data file in xlsx format, their relationship are as below:
in.EYEEXAM_BASELINE - BE
in.EYEEXAM_W4 - WE
in.EYEEXAM_M6 - month 6 record in ME
in.EYEEXAM_m12 - month 12 record in ME
in.surgery - SI*/

/*set up SAS library, TLF path, TLF title, format catalog which will be used in later analysis*/
%include "setup.sas";
libname in "&_root_in";
libname fm "&_root_fm";
libname data "&_root_data";
%let TLF_path = &_root_output\tb7_visual_acuity.rtf;
%let TLF_title = Table 7:  Visual acuity change over time in study eyes by treatment groups;

OPTIONS FMTSEARCH=(fm.fmsurgery fm.fmexamm6 fm.fmbaseexam fm.fmexamw4 fm.fmelig);

/*set up variable format for visualization*/
proc format;
        value gf  0 = "Placebo" 1 = "FML";
        value ynf 0 = "No" 1 = "Yes";
        value yno 1='No' 2='Yes';
        value pval (default=8)
                low - <0.00095 = '<0.001'
```

```
                0.00095 - <0.0095 = [8.3]
                0.0095 - <0.045 = [8.2]
                0.045 - <0.0495 = [8.3]
                0.0495 - <0.04995 = [8.4]
                0.04995 - <0.05 = '~<0.05'
                0.05 = '0.05'
                0.05< - <0.05005 = '~>0.05'
                0.05005 - <0.0505 = [8.4]
                0.0505 - <0.055 = [8.3]
                0.055 - 0.99 = [8.2]
                0.99< - high = [8.2];
run;

/*combine covariate for analysis*/
data rand;
        set data.rand;
        if reye_eligibel=1 then do; eye='OD'; output; end;
        if leye_eligibel=1 then do; eye='OS'; output; end;
run;
data EYEEXAM_BASELINE;
set in.EYEEXAM_BASELINE;
run;
data EYEEXAM_W4;
set in.EYEEXAM_W4;
run;
data EYEEXAM_M6;
set in.EYEEXAM_M6;
```

```
run;
data EYEEXAM_m12;
set in.EYEEXAM_m12;
run;
%proc_reshape(indata=WORK.EYEEXAM_BASELINE,memname="EYEEXAM_BASELINE",outdata=EYEEXAM_BASELINE_);
%proc_reshape(indata=WORK.EYEEXAM_W4,memname="EYEEXAM_W4",outdata=EYEEXAM_W4_);
%proc_reshape(indata=WORK.EYEEXAM_M6,memname="EYEEXAM_M6",outdata=EYEEXAM_M6_);
%proc_reshape(indata=WORK.EYEEXAM_M12,memname="EYEEXAM_M12",outdata=EYEEXAM_M12_);

proc sql;
	create table data.tbl7_data as
	select r.subjid, r.eye, r.treat,
	a.beva as va_baseline, b.weva as va_w4, c.meva as va_m6, d.meva as va_m12,
	case when a.subjid^='' then 1 end as have_baseline,
	case when b.subjid^='' then 1 end as have_w4,
	case when c.subjid^='' then 1 end as have_m6,
	case when d.subjid^='' then 1 end as have_m12,
	case when a.beva>1 then 1 when .<a.beva<=1 then 0 end as blind_baseline,
	case when b.weva>1 then 1 when .<b.weva<=1 then 0 end as blind_w4,
	case when c.meva>1 then 1 when .<c.meva<=1 then 0 end as blind_m6,
	case when d.meva>1 then 1 when .<d.meva<=1 then 0 end as blind_m12,
	b.weva-a.beva as w4_diff,
	c.meva-a.beva as m6_diff,
	d.meva-a.beva as m12_diff,
	/*to meet requirement of HIPAA, name (sisiname2) and certification (sisicert2) of surgeon is removed from the public
shared dataset*/
	sisicert2,sisiname2,
```

```
        /*for surgeon that only have a small number of surgery (<50), cluster them into 1 group*/
        case when sisicert2 in (/*surgeon license removed*/) then 'Other'
                else sisicert2 end as sisicert3
from rand as r
left join EYEEXAM_BASELINE_ as a on r.subjid=a.subjid and r.eye=a.eye
left join EYEEXAM_W4_ as b on r.subjid=b.subjid and r.eye=b.eye
left join EYEEXAM_M6_ as c on r.subjid=c.subjid and r.eye=c.eye
left join EYEEXAM_M12_ as d on r.subjid=d.subjid and r.eye=d.eye
left join in.surgery as s on r.subjid=s.subjid;
quit;

/*statistics calculation*/
/*baseline*/
%stat_char(input=data.tbl7_data,output=tab_1_1,unit=eye,variable=have_baseline,min=2,max=2,cohort=treat,ref=Placebo,q
uestionlabel=Baseline,tab_order=1,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=0,gee_multinomi
al=0,reverse=0,chi=0,fisher=0);
%stat_num(input=data.tbl7_data,output=tab_1_2,variable=va_baseline,cohort=treat,ref=Placebo,questionlabel=,tab_order=1
,id=subjid,gee_linear=1);
%stat_char(input=data.tbl7_data,output=tab_1_3,unit=eye,variable=blind_baseline,min=2,max=2,cohort=treat,ref=Placebo,q
uestionlabel=,tab_order=1,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=1,gee_multinomial=0,reve
rse=0,chi=0,fisher=0);
data tab_1;
length answerlabel cohort_0 cohort_1 $200;
set tab_1_1(in=a) tab_1_2(in=b) tab_1_3(in=c);
if b=0 or answer_order=2;
answer_order=_n_;
if a and cohort_0^='' then do; cohort_0=scan(cohort_0,1,'('); cohort_1=scan(cohort_1,1,'(');
```

```
                                                    answerlabel=' Number of study eyes'; end;
if b then answerlabel=' Visual acuity in logMAR: mean (SD)';
if c then answerlabel=' Visual acuity worse than 20/200*: Yes (%)';
run;

/*w4*/
%stat_char(input=data.tbl7_data,output=tab_2_1,unit=eye,variable=have_w4,min=2,max=2,cohort=treat,ref=Placebo,questi
onlabel=Week
4,tab_order=2,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=0,gee_multinomial=0,reverse=0,chi=0,
fisher=0);
%stat_num(input=data.tbl7_data,output=tab_2_2,variable=va_w4,cohort=treat,ref=Placebo,questionlabel=,tab_order=2,id=s
ubjid,gee_linear=1);
%stat_num(input=data.tbl7_data,output=tab_2_3,variable=w4_diff,cohort=treat,ref=Placebo,questionlabel=,tab_order=2,id=
subjid,gee_linear=1);
%stat_char(input=data.tbl7_data,output=tab_2_4,unit=eye,variable=blind_w4,min=2,max=2,cohort=treat,ref=Placebo,questi
onlabel=,tab_order=2,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=1,gee_multinomial=0,reverse=
0,chi=0,fisher=0);
data tab_2;
length answerlabel cohort_0 cohort_1 $200;
set tab_2_1(in=a) tab_2_2(in=b where=(answer_order=2)) tab_2_3(in=c where=(answer_order=2)) tab_2_4(in=d);
answer_order=_n_;
if a and cohort_0^='' then do; cohort_0=scan(cohort_0,1,'('); cohort_1=scan(cohort_1,1,'(');
                                                    answerlabel=' Number of study eyes'; end;
if b then answerlabel=' Visual acuity in logMAR: mean (SD)';
if c then answerlabel=' Change from baseline in logMAR: Mean (SD)';
if d then answerlabel=' Visual acuity worse than 20/200*: Yes (%)';
run;
```

```
/*m6*/
%stat_char(input=data.tbl7_data,output=tab_3_1,unit=eye,variable=have_m6,min=2,max=2,cohort=treat,ref=Placebo,questi
onlabel=Month
6,tab_order=3,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=0,gee_multinomial=0,reverse=0,chi=0,
fisher=0);
%stat_num(input=data.tbl7_data,output=tab_3_2,variable=va_m6,cohort=treat,ref=Placebo,questionlabel=,tab_order=3,id=s
ubjid,gee_linear=1);
%stat_num(input=data.tbl7_data,output=tab_3_3,variable=m6_diff,cohort=treat,ref=Placebo,questionlabel=,tab_order=3,id=
subjid,gee_linear=1);
%stat_char(input=data.tbl7_data,output=tab_3_4,unit=eye,variable=blind_m6,min=2,max=2,cohort=treat,ref=Placebo,questi
onlabel=,tab_order=3,value_label=ynf,order_label=yno,id=subjid,self_denom=1,gee_binomial=1,gee_multinomial=0,reverse=
0,chi=0,fisher=0);
data tab_3;
length answerlabel cohort_0 cohort_1 $200;
set tab_3_1(in=a) tab_3_2(in=b where=(answer_order=2)) tab_3_3(in=c where=(answer_order=2)) tab_3_4(in=d);
answer_order=_n_;
if a and cohort_0^='' then do; cohort_0=scan(cohort_0,1,'('); cohort_1=scan(cohort_1,1,'(');
                                                    answerlabel=' Number of study eyes'; end;
if b then answerlabel=' Visual acuity in logMAR: mean (SD)';
if c then answerlabel=' Change from baseline in logMAR: Mean (SD)';
if d then answerlabel=' Visual acuity worse than 20/200*: Yes (%)';
run;

/*m12*/
%stat_char(input=data.tbl7_data,output=tab_4_1,unit=eye,variable=have_m12,min=2,max=2,cohort=treat,ref=Placebo,quest
ionlabel=Month
```

```
12,tab_order=4,value_label=ynf,order_label=yno,id=subjid,self_denom=1,N=1,gee_binomial=0,gee_multinomial=0,reverse=0,
chi=0,fisher=0);
%stat_num(input=data.tbl7_data,output=tab_4_2,variable=va_m12,cohort=treat,ref=Placebo,questionlabel=,tab_order=4,id=
subjid,gee_linear=1,surgeon=1,diffs=1);
%stat_num(input=data.tbl7_data,output=tab_4_3,variable=m12_diff,cohort=treat,ref=Placebo,questionlabel=,tab_order=4,id
=subjid,gee_linear=1,surgeon=1,diffs=1);
%stat_char(input=data.tbl7_data,output=tab_4_4,unit=eye,variable=blind_m12,min=2,max=2,cohort=treat,ref=Placebo,ques
tionlabel=,tab_order=4,value_label=ynf,order_label=yno,id=subjid,self_denom=1,N=1,gee_binomial=1,gee_multinomial=0,rev
erse=0,chi=0,fisher=0,surgeon=1,surgeon_cluster=0,surg_bar=0,diffs=1,event=1);
data tab_4;
length answerlabel cohort_0 cohort_1 diffs $200;
set tab_4_1(in=a) tab_4_2(in=b where=(answer_order=2)) tab_4_3(in=c where=(answer_order=2)) tab_4_4(in=d);
answer_order=_n_;
if a and cohort_0^='' then do; cohort_0=scan(cohort_0,1,'('); cohort_1=scan(cohort_1,1,'(');
                                                    answerlabel=' Number of study eyes'; end;
if b then answerlabel=' Visual acuity in logMAR: mean (SD)';
if c then answerlabel=' Change from baseline in logMAR: Mean (SD)';
if d then answerlabel=' Visual acuity worse than 20/200*: Yes (%)';
run;

data data.tbl7_result;
        set /*tab_1 tab_2 tab_3*/ tab_4;
run;



/*table visualization*/
options nodate nonumber;
```

```
ods rtf file = "&TLF_path";
ods escapechar='~';
ods rtf text="~S={just=l font_size=10pt font_weight= bold} &TLF_title";
proc report data=data.tbl7_result nowd spanrows split='|' missing style(column)={background=white fontsize=9pt}

style(header)={background=white fontsize=9pt fontweight=medium};
        columns tab_order answer_order answerlabel cohort_0 cohort_1 diffs pvalue;
        define tab_order  / ' ' order order=internal noprint;
        define answer_order  / ' ' order order=internal noprint;
        define answerlabel / 'Visual acuity' left style(column)={cellwidth=1.8in asis=ON} style(header)={cellwidth=1.8in just=l};
        define cohort_0 / "Placebo" center style(column)={cellwidth=1.4in};
        define cohort_1 / "FLuorometholone" center style(column)={cellwidth=1.4in};
        define diffs / 'Difference (95% CI)' center group style(column)={cellwidth=1.4in};
        define pvalue / 'P-value#' center group style(column)={cellwidth=1.4in};
        compute after tab_order;
                line '' ;
         endcomp ;
run ;
ods rtf text="~S={just=l font_size=9pt} *worse than 20/200 corresponds to severe visual impairment per World Health
Organization criteria.";
ods rtf text="~S={just=l font_size=9pt} #From generalized regression models adjusting for surgeon that account for inter-eye
correlation.";
ods rtf close;
```