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/*Evaluation of FLuorometholone as Adjunctive MEdical Therapy for Trachomatous Trichiasis Surgery: The FLAME Randomized
Controlled Clinical Trial*/
/*purpose: Comparison of eye infection between randomized treatment group by visit*/
/*Note: raw datasets in SAS library 'in' corresponds to the shared data file in xlsx format, their relationship are as below:
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\tbl8_infection_analysis.rtf;
%let TLF_title = Table 8: Comparison of eye infection between randomized treatment group by visit;

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

/*set up variable format for visualization*/
proc format;
        value gf  0 = "Placebo" 1 = "FML";
        value ynf 1='Yes' 0='No';
        value yno 1='No' 2='Yes';
        value pval (default=8)
                low - <0.00095 = '<0.001'
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                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 used for analysis;
data fas;
        set data.fas;
        if reye_eligibel=1 then do; eye='OD'; output; end;
        if leye_eligibel=1 then do; eye='OS'; output; end;
run;

data EYEEXAM_W4;
set in.EYEEXAM_W4;
run;
data EYEEXAM_M6;
set in.EYEEXAM_M6;
run;
data EYEEXAM_m12;
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set in.EYEEXAM_m12;
run;

%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.tbl8_data as
	select r.subjid, r.eye, r.treat,
		a.wecorninf as corninf_w4, a.weconjinf as conjinf_w4, a.weotherinf as otherinf_w4,
		case when a.subjid^='' then 1 else 0 end as w4fl,
		b.mecornealinf as corninf_m6, b.meconjinf as conjinf_m6, b.meotherinf as otherinf_m6,
		case when b.subjid^='' then 1 else 0 end as m6fl,
		c.mecornealinf as corninf_m12, c.meconjinf as conjinf_m12, c.meotherinf as otherinf_m12,
		case when c.subjid^='' then 1 else 0 end as m12fl,
		case when a.wecorninf=1 or a.weconjinf=1 or a.weotherinf=1 then 1
			when a.wecorninf=0 or a.weconjinf=0 or a.weotherinf=0 then 0
			else . end as infection_w4,
		case when b.mecornealinf=1 or b.meconjinf=1 or b.meotherinf=1 then 1
			when b.mecornealinf=0 or b.meconjinf=0 or b.meotherinf=0 then 0
			else . end as infection_m6,
		case when c.mecornealinf=1 or c.meconjinf=1 or c.meotherinf=1 then 1
			when c.mecornealinf=0 or c.meconjinf=0 or c.meotherinf=0 then 0
			else . end as infection_m12,
		/*to meet requirement of HIPAA, name (sisiname2) and certification (sisicert2) of surgeon is removed from the
public shared dataset*/
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                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 fas as r
        left join EYEEXAM_W4_ as a on r.subjid=a.subjid and r.eye=a.eye
        left join EYEEXAM_M6_ as b on r.subjid=b.subjid and r.eye=b.eye
        left join EYEEXAM_M12_ as c on r.subjid=c.subjid and r.eye=c.eye
        left join in.surgery as d on r.subjid=d.subjid;
quit;
data data.tbl8_data;
        format corninf_w4 conjinf_w4 otherinf_w4
                corninf_m6 conjinf_m6 otherinf_m6
                corninf_m12 conjinf_m12 otherinf_m12 8.;
        set data.tbl8_data;
run;

/*calculate descriptive statistics, hypothesis test and build model*/
/*w4*/
proc sql noprint;
select count(*) into :t0_eye
                from data.tbl8_data
                where treat = 0 and w4fl=1;
select count(*) into :t1_eye
                from data.tbl8_data
                where treat = 1 and w4fl=1;
quit;
```

```
%put &t0_eye;
%put &t1_eye;

%stat_char(input=data.tbl8_data,output=tab_w4_1,unit=eye,variable=corninf_w4,min=2,max=2,cohort=treat,ref=Placebo,qu
estionlabel=,tab_order=1,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=0,gee_multinomial=0,rever
se=0,chi=0,fisher=2,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_w4_2,unit=eye,variable=conjinf_w4,min=2,max=2,cohort=treat,ref=Placebo,qu
estionlabel=,tab_order=2,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,rever
se=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_w4_3,unit=eye,variable=otherinf_w4,min=2,max=2,cohort=treat,ref=Placebo,qu
estionlabel=,tab_order=3,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,rever
se=0,chi=0,fisher=0,surgeon=1,surgeon_cluster=1,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_w4_4,unit=eye,variable=infection_w4,min=2,max=2,cohort=treat,ref=Placebo,q
uestionlabel=,tab_order=4,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,reve
rse=0,chi=0,fisher=0,surgeon=1,surgeon_cluster=1,surg_bar=0,diffs=0,event=0);

data header;
answerlabel='Number of eyes';cohort_0="&t0_eye";cohort_1="&t1_eye";tab_order=0;
run;

data tab_w4;
        length answerlabel sectionlabel cohort_0 cohort_1 $200;
        set header tab_w4_:;
        if tab_order=1 then answerlabel='Corneal Infection#';
        if tab_order=2 then answerlabel='Conjunctival Infection*';
        if tab_order=3 then answerlabel='Other Infection**';
        if tab_order=4 then answerlabel='Overall Infection**';
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```
        section_order=1;
        sectionlabel='Week 4';
run;

/*m6*/
proc sql noprint;
select count(*) into :t0_eye
                from data.tbl8_data
                where treat = 0 and m6fl=1;
select count(*) into :t1_eye
                from data.tbl8_data
                where treat = 1 and m6fl=1;
quit;
%put &t0_eye;
%put &t1_eye;

%stat_char(input=data.tbl8_data,output=tab_m6_1,unit=eye,variable=corninf_m6,min=2,max=2,cohort=treat,ref=Placebo,qu
estionlabel=,tab_order=1,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=0,gee_multinomial=0,rever
se=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_m6_2,unit=eye,variable=conjinf_m6,min=2,max=2,cohort=treat,ref=Placebo,qu
estionlabel=,tab_order=2,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,rever
se=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_m6_3,unit=eye,variable=otherinf_m6,min=2,max=2,cohort=treat,ref=Placebo,q
uestionlabel=,tab_order=3,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=0,gee_multinomial=0,reve
rse=0,chi=0,fisher=2,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
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```
%stat_char(input=data.tbl8_data,output=tab_m6_4,unit=eye,variable=infection_m6,min=2,max=2,cohort=treat,ref=Placebo,
questionlabel=,tab_order=4,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,re
verse=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);

data header;
answerlabel='Number of eyes';cohort_0="&t0_eye";cohort_1="&t1_eye";tab_order=0;
run;

data tab_m6;
        length answerlabel sectionlabel cohort_0 cohort_1 $200;
        set header tab_m6_1-tab_m6_4;
        if tab_order=1 then answerlabel='Corneal Infection';
        if tab_order=2 then answerlabel='Conjunctival Infection*';
        if tab_order=3 then answerlabel='Other Infection#';
        if tab_order=4 then answerlabel='Overall Infection*';
        section_order=2;
        sectionlabel='Month 6';
run;

/*m12*/
proc sql noprint;
select count(*) into :t0_eye
                from data.tbl8_data
                where treat = 0 and m12fl=1;
select count(*) into :t1_eye
                from data.tbl8_data
                where treat = 1 and m12fl=1;
```

```
quit;
%put &t0_eye;
%put &t1_eye;

%stat_char(input=data.tbl8_data,output=tab_m12_1,unit=eye,variable=corninf_m12,min=2,max=2,cohort=treat,ref=Placebo,
questionlabel=,tab_order=1,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=0,gee_multinomial=0,re
verse=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_m12_2,unit=eye,variable=conjinf_m12,min=2,max=2,cohort=treat,ref=Placebo,
questionlabel=,tab_order=2,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,re
verse=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_m12_3,unit=eye,variable=otherinf_m12,min=2,max=2,cohort=treat,ref=Placebo
,questionlabel=,tab_order=3,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=0,gee_multinomial=0,re
verse=0,chi=0,fisher=2,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);
%stat_char(input=data.tbl8_data,output=tab_m12_4,unit=eye,variable=infection_m12,min=2,max=2,cohort=treat,ref=Placeb
o,questionlabel=,tab_order=4,value_label=ynf,order_label=yno,id=subjid,self_denom=0,gee_binomial=1,gee_multinomial=0,r
everse=0,chi=0,fisher=0,surgeon=0,surgeon_cluster=0,surg_bar=0,diffs=0,event=0);

data header;
answerlabel='Number of eyes';cohort_0="&t0_eye";cohort_1="&t1_eye";tab_order=0;
run;
data tab_m12;
        length answerlabel sectionlabel cohort_0 cohort_1 $200;
        set header tab_m12_1-tab_m12_4;
        if tab_order=1 then answerlabel='Corneal Infection';
        if tab_order=2 then answerlabel='Conjunctival Infection*';
        if tab_order=3 then answerlabel='Other Infection#';
        if tab_order=4 then answerlabel='Overall Infection*';
```

```
        section_order=3;
        sectionlabel='Month 12';
run;

data data.tbl8_result;
set tab_w4 tab_m6 tab_m12;
if input(scan(cohort_0,1,'('),best.)=0 then cohort_0='0';
if input(scan(cohort_1,1,'('),best.)=0 then cohort_1='0';
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.tbl8_result nowd spanrows split='|' missing style(column)={background=white fontsize=9pt}

style(header)={background=white fontsize=9pt fontweight=medium};
        columns section_order sectionlabel tab_order answerlabel cohort_0 cohort_1 pvalue;
        define section_order  / ' ' order order=internal noprint;
        define sectionlabel / 'Visit' group left style(column)={cellwidth=1.8in} style(header)={just=l};
        define tab_order  / ' ' order order=internal noprint;
        define answerlabel / 'Infection' left style(column)={cellwidth=1.8in} style(header)={just=l};
        define cohort_0 / "Placebo" center style(column)={cellwidth=1.4in};
        define cohort_1 / "FLuorometholone" center style(column)={cellwidth=1.4in};
        define pvalue / 'P-value' center group style(column)={cellwidth=1.4in};
run ;
```

```
ods rtf text="~S={just=l font_size=9pt} #derived from Fisher’s exact test";
ods rtf text="~S={just=l font_size=9pt} *derived from generalized regression models that account for inter-eye correlation without adjusting for surgeon due to the small number of events";
ods rtf text="~S={just=l font_size=9pt} **derived from generalized regression models adjusting for surgeon that account for inter-eye correlation";

ods rtf close;

libname in clear;
libname fm clear;
```