

/*Evaluation of FLuorometholone as Adjunctive MEDical Therapy for Trachomatous Trichiasis Surgery: The FLAME Randomized Controlled Clinical Trial*/

/*purpose: generate descriptive statistics number for figure 1 flowchart*/

/*Note: raw datasets in SAS library 'in' corresponds to the shared data file in xlsx format, their relationship are as below:

in.eligibility - EL

in.ADHERENCE_W4 - TA

in.EQ5D_M12, in.EQ5D_M6, in.EQ5D_W4 - month 12, month 6 and week 4 record in EQ

in.EYEEXAM_M12, in.EYEEXAM_M6 - month 12 and month 6 record in ME

in.EYEEXAM_W4 - WE

in.EYEPAIN_M12, in.EYEPAIN_M6, in.EYEPAIN_W4 - month 12, month 6 and week 4 record in EP

in.HEALTHREVIEW_M12, in.HEALTHREVIEW_M6, in.HEALTHREVIEW_W4 - month 12, month 6 and week 4 record in FR

in.OSDI_M12, in.OSDI_M6, in.OSDI_W4 - month 12, month 6 and week 4 record in OSI

in.PRIMARY_END_M12, in.PRIMARY_END_M6, in.PRIMARY_END_W4 - month 12, month 6 and week 4 record in PE

in.SATISFACTION_SURGERY_M12, in.SATISFACTION_SURGERY_M6 - month 12 and month 6 record in SS

in.SURGERY - SI

in.VISUAL_FUNCTION_W4 - week 4 record in VF

in.exit - EX

*/

/*set up SAS library, TLF path, TLF title, format catalog which will be used in later analysis*/

%include "setup.sas";

libname in "&_root_in"; *** <--- Change the path based on the date ***;

libname fm "&_root_fm";

libname data "&_root_data";

OPTIONS FMTSEARCH=(fm.fmadherence fm.fmae fm.fmbaseexam fm.fmbaseline fm.fmdeath fm.fmelig fm.fmeq
fm.fmexamw6 fm.fmexamw4 fm.fmexit fm.fmeyepain fm.fmfu fm.fmosdi fm.fmpists_first fm.fmpists_secon
fm.fmpov fm.fmprimary fm.fmprotocal fm.fmrnd fm.fmsae fm.fmsaefp fm.fmsat fm.fmsurgery fm.fmvisual
fm.fmmiss);

option mprint;

proc format;

```
value gf 0 = "Placebo" 1 = "FML";
value visit 2='Surgery' 3='Week 4' 4='Month 6' 5='Month 12';
value inelig 1='Not sign consent form'
           2='Contraindications to use of test articles'
           3='Contraindications to the use of Azithromycin'
           4='Significant illness or condition'
           5='Severe / serious ocular pathology or medical condition'
           6='Condition requires ocular or systemic corticosteroid therapy'
           7='Both eyes not eligible for ocular reasons';
value ex12reas 1='Death'
              2='Lost to follow-up'
              3='Other';
```

run;

```
/*Screened # of patients*/
title 'Screened # of patients';
proc sql;
select count(distinct screening_id) as screening_n
from in.eligibility;
quit;
```

```
/*not enrolled due to reason of */
title 'not enrolled due to reason of';
proc sql;
create table ineligible_reason as
select screening_id,
       case when elconsent=0 then 1
            when eltestart=1 then 2
            when elazithro=1 then 3
            when elillness=1 then 4
            when elsevere=1 then 5
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        when elbaseline=1 then 6
        else 7 end as ineligible_reason format=inelig.

from in.eligibility2
where eeligible=0;

select distinct ineligible_reason,count(*) as n
from ineligible_reason
group by ineligible_reason
order by n desc;
quit;

/*enrolled and randomized # of patients*/
title 'enrolled and randomized # of patients';
proc freq data=data.rand noprint;
tables treat / out=pat_rand;
quit;
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;
proc freq data=rand noprint;
tables treat / out=eye_rand;
quit;
proc sql;
select coalesce(a.treat,b.treat) as treat format=gf.,
       a.count as pat_rand label='pat_rand',
       b.count as eye_rand label='eye_rand'
from pat_rand as a
full join eye_rand as b
on a.treat=b.treat;

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quit;
proc sql;
select 'Total' as treat,
      count(distinct subjid) as pat_rand label='pat_rand',
      count(*) as eye_rand label='eye_rand'
from rand;
quit;

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/*Visit completed and used for analysis*/
title 'Visit completed and used for analysis';
data all_visit(keep=subjid redcap_event_name form visit);
format form $200.;
set in.ADHERENCE_W4(in=a) in.EQ5D_M12(in=f) in.EQ5D_M6(in=g) in.EQ5D_W4(in=h) in.EYEEXAM_M12(in=k)
in.EYEEXAM_M6(in=l) in.EYEEXAM_W4(in=m)
in.EYEPAIN_M12(in=o) in.EYEPAIN_M6(in=p) in.EYEPAIN_W4(in=q) in.HEALTHREVIEW_M12(in=r) in.HEALTHREVIEW_M6(in=s)
in.HEALTHREVIEW_W4(in=t)
in.OSDI_M12(in=v) in.OSDI_M6(in=w) in.OSDI_W4(in=x) in.PRIMARY_END_M12(in=ab) in.PRIMARY_END_M6(in=ac)
in.PRIMARY_END_W4(in=ad)
in.SATISFACTION_SURGERY_M12(in=ag) in.SATISFACTION_SURGERY_M6(in=ah) in.SURGERY(in=ai)
in.VISUAL_FUNCTION_W4(in=aj);
if a then form='Week 4 Adherence Form';
if f then form = "Month 12 EQ-5D Form";
if g then form = "Month 6 EQ-5D Form";
if h then form = "Week 4 EQ-5D Form";
if k then form = "Month 12 Eye Exam Form";
if l then form = "Month 6 Eye Exam Form";
if m then form = 'Week 4 eye Exam Form';
if o then form = "Month 12 Eye pain impact";
if p then form = "Month 6 Eye pain impact";
if q then form = "Week 4 Eye pain impact";
if r then Form = "Month 12 Health Review";

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if s then Form = "Month 6 Health Review";
if t then Form = "Week 4 Health Review";
if v then Form = "Month 12 OSDI";
if w then Form = "Month 6 OSDI";
if x then Form = "Week 4 OSDI";
if ab then Form = "Month 12 Primary Endpoint";
if ac then Form = "Month 6 Primary Endpoint";
if ad then Form = "Week 4 Primary Endpoint";
if ag then form = "Month 12 Satisfaction";
if ah then form = "Month 6 Satisfaction";
if ai then form='Surgery Form';
if aj and index(upcase(redcap_event_name),'VISIT_3') then form='Week 4 Visual Function';
if aj and index(upcase(redcap_event_name),'VISIT_4') then form='Month 6 Visual Function';
if aj and index(upcase(redcap_event_name),'VISIT_5') then form='Month 12 Visual Function';
if ai then visit=2;
else if index(upcase(redcap_event_name),'VISIT_3') then visit=3;
else if index(upcase(redcap_event_name),'VISIT_4')>0 then visit=4;
else if index(upcase(redcap_event_name),'VISIT_5')>0 then visit=5;
if index(upcase(redcap_event_name),'BASELINE')>0 then delete;
run;
proc sql;
select distinct treat format=gf.,visit format=visit.,
               count(distinct a.subjid) as pat_visit,
               count(distinct a.subjid||b.eye) as eye_visit

from all_visit as a
left join rand as b
on a.subjid=b.subjid
group by visit,treat
order by treat,visit;
quit;

```

```
/*reason of exit*/  
title 'reason of exit';  
proc sql;  
create table exit_reason as  
select subjid,  
       case when ex12reas in (2,3,4,5) then 2  
             when ex12reas=6 then 3  
             else ex12reas end as ex12reas format=ex12reas.  
from in.exit  
where ex12month^=1;
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select distinct treat,ex12reas,count(*)  
from exit_reason as a  
left join data.rand as b  
on a.subjid=b.subjid  
group by treat,ex12reas;  
quit;
```

```
/*number of patient completing the study - the same as # of patients and eyes in month 12*/  
title 'number of patient completing the study';  
proc sql;  
select distinct treat format=gf.,  
       count(distinct a.subjid) as pat_complete,  
       count(*) as eye_complete  
from in.exit(where=(ex12month=1)) as a  
left join rand as b  
on a.subjid=b.subjid  
group by treat;  
quit;
```