

Overview of FLAME data

July 18, 2025

This export site provides a total of 23 data files for FLAME in excel format. The data are from 2663 patients who are screened, and 2410 participants among the 2663 who were enrolled into the trial and randomized.

23 data files are derived from case report forms completed at the clinical centers. Dataset names correspond to the form names (see table below). Annotated versions of the forms are provided with embedded variable names that are used as column headings for the excel files.

#	Case Report Form Name	Dataset name
1	Adverse Event Log	AE
2	Baseline Eye Examination Form	BE
3	Patient Death Form	DD
4	Baseline Information Form	DS
5	Protocol Deviation and Unanticipated Event Form	DV
6	Eligibility Form	EL
7	Eye Pain Impact Questionnaire	EP
8	EQ-5D Form	EQ
9	Exit Form	EX
10	Follow Up Health Review Form	FR
11	Month 6 & 12 Eye Examination Form	ME
12	Missed Visit Form	MV
13	Ocular Surface Disease Index	OSI
14	Primary Endpoint Assessment Form	PE
15	First Post-Operative Visit Complications Form	FPO
16	Second Post-Operative Visit Complications Form	SPO
17	Randomization and Initial Treatment Form	RT
18	Serious Adverse Event Initial Reporting Form	SAE
19	Surgery Information Form	SI
20	Satisfaction with TT Surgery	SS
21	Treatment Adherence Form	TA
22	Visual Function Questionnaire	VF
23	Week 4 Eye Examination Form	WE

In eligibility form, information for 2663 screened patients is provided. For adverse event log, serious adverse event initial reporting form, missed visit form, patient death form, protocol deviation and unanticipated event form, information is recorded when events happen. All other forms are required for 2410 enrolled patients as long as they are in the study.

To meet the requirement of HIPAA, date in this study is shown as days from informed consent date, all age over 89 are aggregated into a single category of age ≥ 90 .

To help the statistical analysis, derived variables are calculated from collected data based on defined algorithm, and are included in the data file as below:

Dataset Name	Variable Name	Variable Label
OSI	osi_symp	OSDI ocular symptoms score (0-100, higher is worse)
	osi_vision	OSDI visual-related function (0-100, higher is worse)
	osi_trigger	OSDI environmental trigger (0-100, higher is worse)
	osi_total_score	OSDI total score (0-100, higher is worse)
TA	taadherence	Treatment adherence rate (Patient-level)
EP	eppainscore_r	Total pain score of right eye (5-20, higher is worse)
	eppainscore_l	Total pain score of left eye (5-20, higher is worse)
EQ	eqsevindex	EQ-5D severity index (0-25, higher is worse)