



Masking Guidelines

Masking

- BEACON, GLEAM and GLIMMER are all **double-masked studies**.
 - Subjects and masked staff at investigational sites must remain unaware to which treatment arms subjects have been assigned and which treatment was administered.
- Why do we have sham injections?
 - Treatment frequency is not identical in the KSI-301 and aflibercept arms, so sham injections are used on non-treatment visits to mask the regimens.
- A minimum of two investigators are required per site
 - Evaluating Physician, who will remain masked
 - Treating (Injecting) Physician (and designated unmasked assistants, as needed) who will be unmasked to subjects' treatment assignments and will administer all injections (KSI-301, aflibercept and sham). Also responsible for the immediate post-injection assessments vision check for counting fingers and post-injection IOP check.

Masking Status by Roles and Responsibilities of Site Personnel

- Unmasked Personnel
 - Injecting Physician
 - Unmasked Assistant(s)
- Masked Personnel
 - Evaluating Physician
 - Study Coordinator
 - Photographer
 - Visual Acuity Examiner (VAE)
 - Monitor/CRA
 - Pharmacist
- Masking takes effect as of patient randomization.
 - Pre-randomization assessments include Screening as well as Day 1 pre-injection assessments and are therefore unmasked.

Masking Grid

(all the details will be reviewed at your SIV)

Assessment/Activity	Study Team Member					
	Same Rules Apply to All			VAE	Same Rules Apply to Both	
	Masked Investigator	Coordinator	Photographer		Unmasked Injector	Unmasked Assistant
Consent	Y	Y	Y	N	Y	Y
Medical and Ocular History	Y	Y	Y	N	Y	Y
Vital Signs	Y	Y	Y	Y	Y	Y
BCVA	Y	Y	Y	Y	Y	Y
Ophthalmic Exam (including Tonometry)	Y	Y	Y	Y	Y	Y
Imaging (FA/OCT/CFP)	Y	Y	Y	Y	Y	Y
Blood draw and processing	Y	Y	Y	Y	Y	Y
Access EDC	Y	Y	Y	N	Y	Y
Register/Randomize subject in IRT	Y	Y	Y	N	Y	Y
↑ Before Randomization						
↓ After Randomization						
BCVA	N	N	N	Y	N	N
Pre-injection Ophthalmic Exam	Y	Y	Y	N	N	N
Pre-Injection Tonometry	Y	Y	Y	Y	N	N
Injection or Sham Procedure	N	N	N	N	Y	N
Post- Injection assessments (vision check, IOP)	N	N	N	N	Y	Y
Imaging (FA/OCT/CFP)	Y	Y	Y	N	N	N
Assess AE/SAE relationship (study drug/inj. procedure)	Y	N	N	N	N	N
Blood draw and processing	Y	Y	Y	Y	Y	Y
Vital Signs	Y	Y	Y	Y	Y	Y
Access EDC	Y	Y	Y	N	*N	N
Allocate Drug in IRT	Y	Y	Y	N	Y	Y
Receive drug and confirm in IRT	Y	Y	Y	N	Y	Y

*If PI is the Unmasked Injector, they can access EDC for final data review & signature.

