

# Comparison of Age-related Macular Degeneration Treatments Trial

Data Dictionary for data table: si.csv

## Serious Adverse Event Initial Reporting Form

Variable	Description	Type	Units	Coded values
alpha_code	Subject identifier	Char		
aeseqq	AE #	Num		
aecode	MedDRA Code	Num		
PT	Preferred Adverse Event Term	Char		
SOC	System Organ Class	Char		
report	Is this an initial or follow-up report?	Num		1=Initial 2=Follow-up
masking	Was study masking broken?			0=No 1=Yes
days_to_onset	Number of days from randomization to onset date	Num		
days_to_notification	Number of days from randomization to notification date	Num		
aesev	Severity (intensity) of event	Num		1=Mild, little clinical significance (Grade 1) 2=Moderate, causing some limitation; minimal/no intervention required (Grade 2) 3=Severe (Grade 3) 4=Life threatening or Disabling (Grade 4) 5=Death
aeserious	Seriousness of event	Num		1=Non Serious 2=Congenital Anomaly 3=Hospitalization 4=Disability 5=Medically Significant 6=Life Threatening 7=Death
expected	Was this an expected event?	Num		0=No 1=Yes
attribution2	Ophthalmologist's Attribution of Causality	Num		1=Unrelated to study drug 2=Unlikely related to study drug 3=Possibly related to study drug 4=Probably related to study drug 5=Definitely related to study drug 6=Related to Injection Procedure 7=Not assessable

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Variable	Description	Type	Units	Coded values
morelikely	If attribution is unrelated or unlikely is there another more likely explanation?	Num		0=No 1=Yes
otherexplanation	Specify other explanation	Char		
studydrug	Was the study drug discontinued?			0=No 1=Yes
eventabate	Did the event abate after discontinuation of the study drug	Num		0=No 1=Yes
drugreintroduced	Was the study drug reintroduced	Num		0=No 1=Yes
reappear	Did the event reappear after reintroduction of the study drug?	Num		0=No 1=Yes
medicationstaken	Were concomitant medications taken at time of event?	Num		0=No 1=Yes
aeout	Outcome of event	Num		1=Not Recovered 2=Recovered 3=Resolved with Sequelae 4=Recovering/Resolving 5=Fatal
days_to_resolution	Number of days between randomization and resolution	Num		
checkunknowndate	Check if resolution date unknown	Num		0=Not checked 1=Checked