

Comparison of Age-related Macular Degeneration Treatments Trials

Adverse Event Log					
ID. No.: Alpha Code: Clinic:					

AE (008.2)

09/22/2008

Instructions: Review all new or unresolved adverse events (currently on the Adverse Event Log in the CATT clinical database) with the patient. If the Serious Event Type is 3, 4, 5, 6, or 7, complete a Serious Adverse Event Initial Reporting Form for the first report or a Serious Adverse Event Follow-up Form for new additional information. If this is an ocular adverse event involving one eye, please check the R or L boxes; if this is an ocular adverse event involving both eyes check both the R and L boxes.

		Adverse Event Coding (NIH)	CATT AE Coding									
AE # (Record from database)	MedDRA Code	MedDRA Short Name	MedDRA Grade	Was E Serio	ous?	Serious Event Type	Tx for AE No Yes	Out- come	CATT Tx	Ocular AE Eye(s) R L	Start Date (MMDDYYYY)	Stop Date (MMDDYYYY)
										_		
Complete	d by:	Certification #:	Date Comp	oleted:								

CATT AE Code Table									
Grade	Serious Event Type	Outcome	CATT Treatment						
1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening/disabling 5 = Death	1 = None 2 = Congenital Anomaly 3 = Hospitalization 4 = Disability 5 = Medically Significant 6 = Life Threatening 7 = Death	1 = Not Recovered 2 = Recovered 3 = Resolved with Sequelae 4 = Recovering/ Resolving 5 = Fatal	1 = Treatment not changed 2 = Treatment Interrupted 3 = Treatment Withdrawn						