Stroke template

A [age] year old [male/female] suffered an acute ischemic stroke and was enrolled in SHINE on [date of enrollment with an initial NIHSS of [baseline score]. The patient was admitted to the [ICU/stroke unit/floor]. On [date], the patient was determined to have a new ischemic stroke. The new ischemic stroke was [an extension of the enrollment stroke/separate from the enrollment stroke] in the judgment of the clinical investigator. [Include details on patient's current status.] The patient subsequently [recovered/did not recover but is alive/died].

Event name guidance

***Worsening from the enrollment stroke without evidence of a new stroke: Stroke in Evolution

***Worsening from the enrollment stroke associated with additional areas of ischemic infarct: Ischemic Stroke

***Use a specific clinical event name. Please do not use worsening of stroke.

For questions regarding completing SAE reporting or narrative template, contact SHINE site manager – arthrama@med.umich.edu or 734-936-2454.