

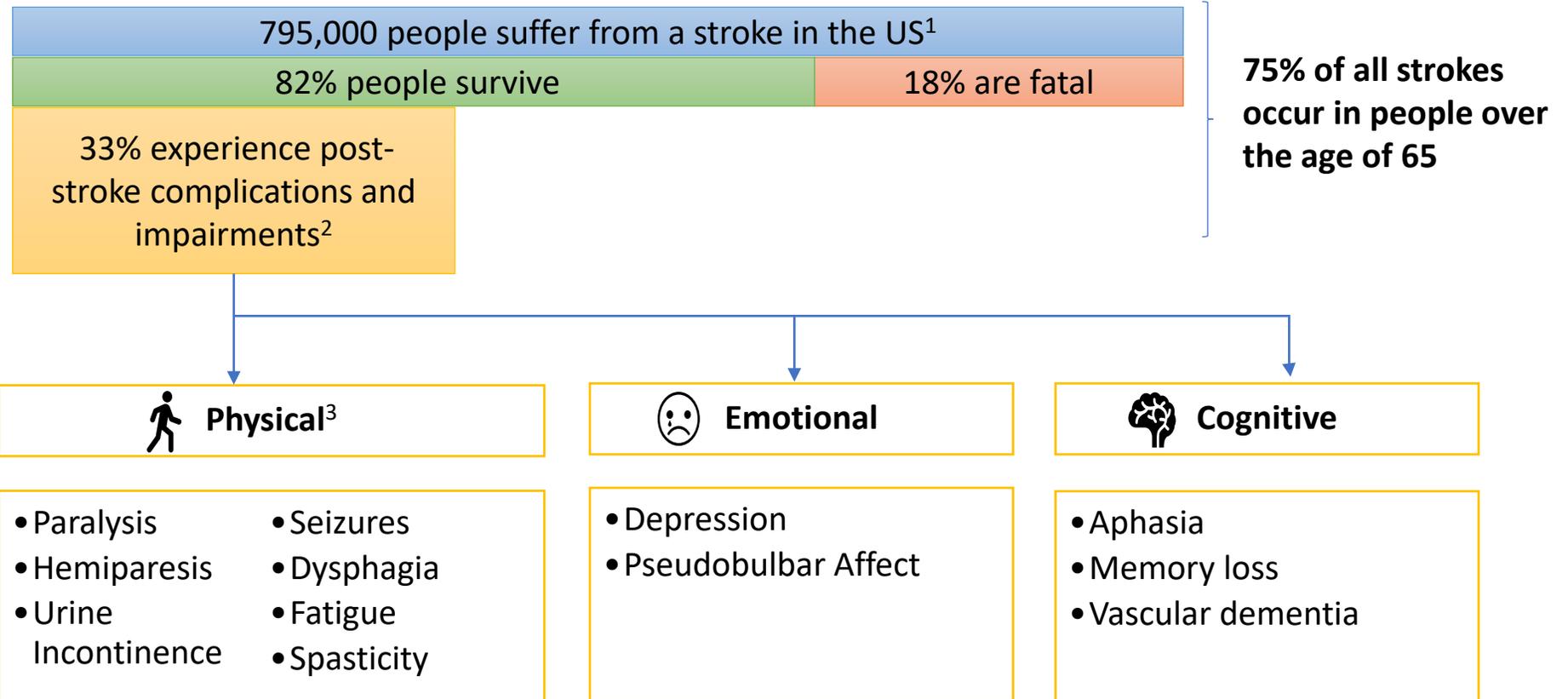
NONO
CHANGE EVERYTHING

CMS ICD-10 Coordination and
Maintenance Committee Meeting
09/10/2019

	Topic	Objectives
1	Stroke Statistics	Review the prevalence and implications of stroke on the US population
2	Current Stroke Care	Review and understand the complete stroke patient journey and treatment paradigm
3	Nerinitide (NA-1)	Introduce nerinitide (NA-1) and rationale for new ICD-10-PCS code
4	Clinical Study	Introduce ongoing clinical study of NA-1
5	Regulatory Timeline	Review the regulatory status of nerinitide
6	Conclusion	Summarize impact of nerinitide and rationale for new ICD-10 PCS code



Stroke is the leading cause of serious, long-term disability in the US and 5th leading cause of death, and reduces mobility in more than half of survivors age 65 and over

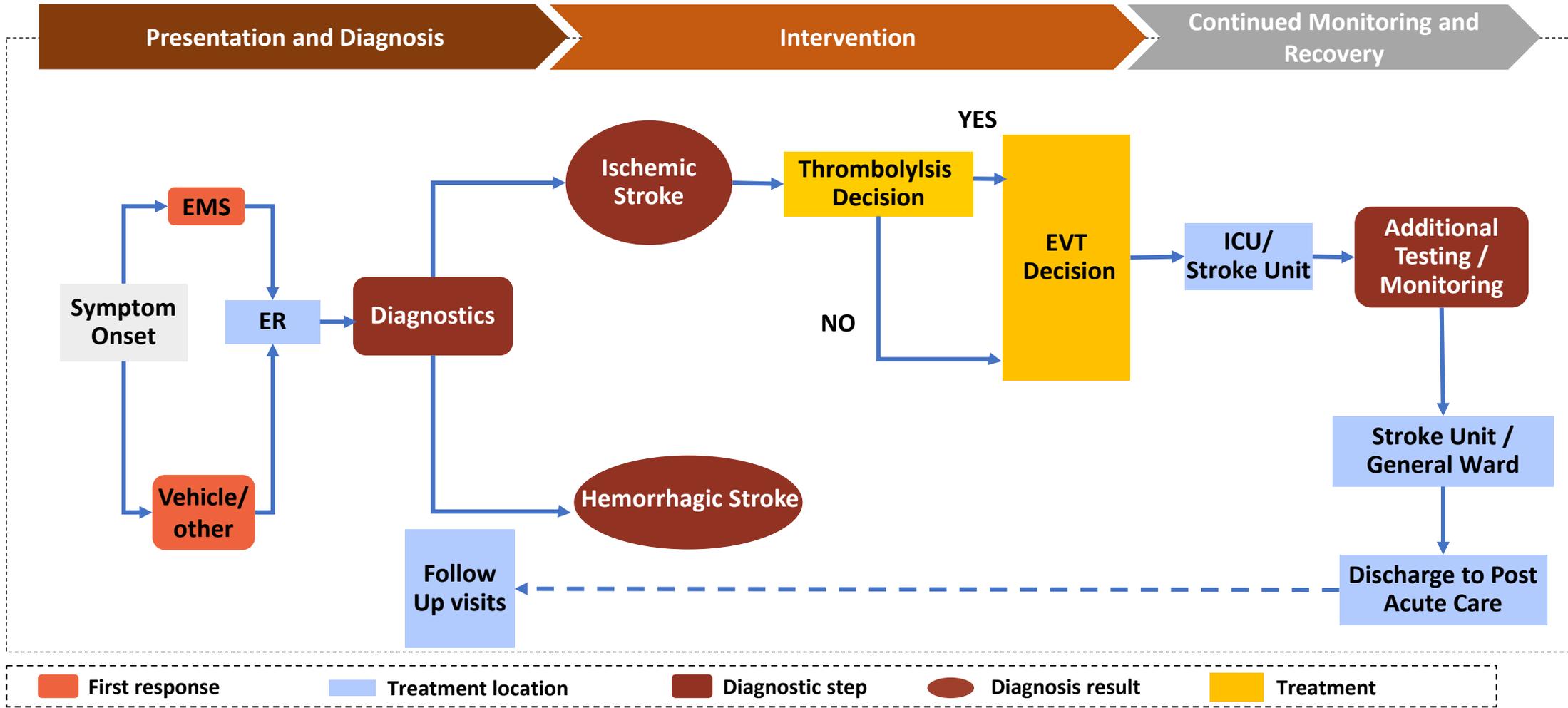


Sources:

1. Stroke Fact Sheet. Center for Disease Control (CDC). Updated Sept 2017. Accessed May 2019.
2. Lui, S.W. Elderly Stroke Rehabilitation: Overcoming the Complications and Its Associated Challenges. Current Gerontology and Geriatrics Research. June 2018.
3. Vincent, Y. Incidence, Prevalence, Costs, and Impact on Disability of Common Conditions Requiring Rehabilitation in the United States. American Congress of Rehabilitation Medicine. 2014.



NONO Stroke patient flow overview



ER: Emergency Room; EMS: Emergency Medical Services; EVT: Endovascular Therapy; ICU: Intensive Care Unit

Sources:

- 2018 Guidelines for Management of Acute Ischemic Stroke. AHA/ASA Guidelines
- Heart Disease and Stroke Statistics- 2018 Update: A Report From the American Heart Association. 2018.



Nerinitide is an emergency drug aimed at reducing functional disability in patients with acute ischemic stroke

- **Indication:** Acute ischemic stroke (AIS)
- **Drug Class:** Post-synaptic Density 95 (PSD-95) Inhibitor
- **Administration:** Nerinitide is administered as soon as possible following symptom onset as a single IV dose of 2.60 mg/kg prior to the initiation of endovascular thrombectomy (EVT)
- **Mechanism of Action:** Nerinitide targets PSD-95, a synaptic scaffolding protein that links NMDA glutamate receptors to neurotoxic signaling pathways which lead to cell death from ischemic insults
- **Outcomes:** Aims to extend the window of eligibility for stroke patients to receive EVT benefits and reduce ischemic damage

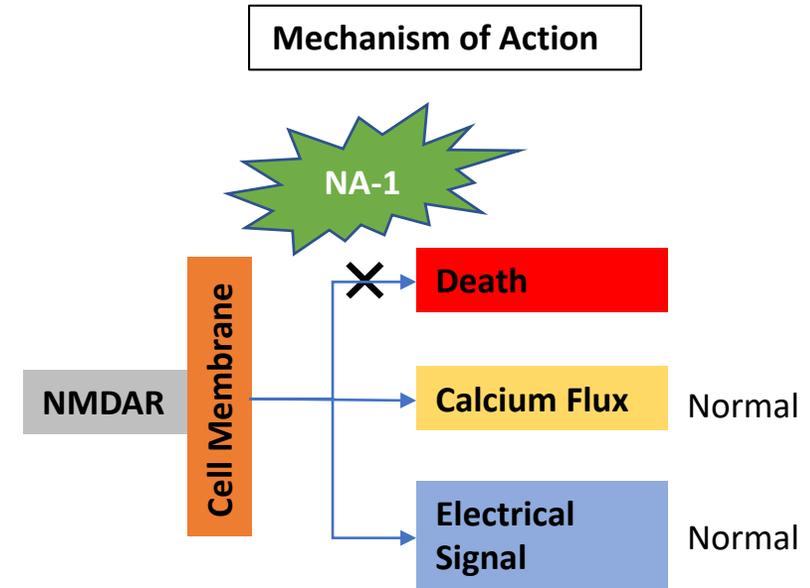


Figure 1: Effect of NA-1 on NMDAR Functions

➤ There are no existing ICD-10-PCS codes that describe the administration of nerinitide or PSD-95 antagonists.

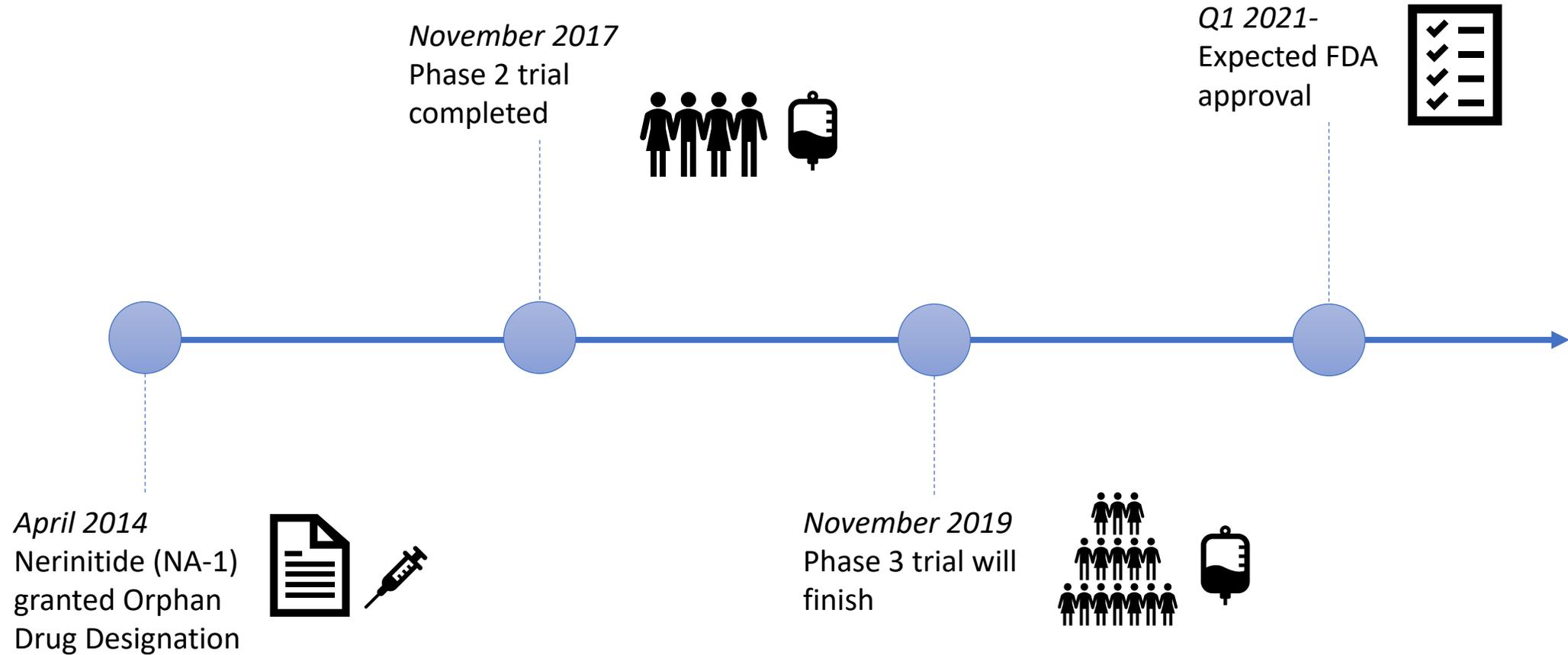


The Phase 3 trial, ESCAPE-NA1, intends to further establish safety and efficacy of NA-1 in AIS patients

Study Elements	Description
Trial Design	Phase III, randomized, multicenter, blinded, placebo-controlled, parallel group, single-dose design
Primary Objective	To determine safety and efficacy of the neuroprotectant NA-1 in reducing disability in patients with acute ischemic stroke (AIS) with a small established infarct core with good collateral circulation who are selected for endovascular revascularization
Estimated Enrollment	1,120 participants
Administration	Single IV dose of 2.6 mg/kg of NA-1 or placebo within 30 mins of randomization
Primary Outcome	Overall proportion of subjects experiencing a favorable functional outcome 90 days post randomization, defined as a score of 0 to 2 on the modified Rankin Scale (mRS)
Secondary Outcomes	<ul style="list-style-type: none">• Reduction of functional dependence analyzed across the whole distribution of scores on the mRS at Day 90 or the last rating• Proportion of subjects with good neurological outcome, as defined by a score of 0-2 on the NIHSS at Day 90 or the last rating• Proportion of subjects with functional independence in activities daily living, as defined by a score of ≥ 95 on the BI at Day 90 or the last rating• Reduction in mortality rate, as defined by event rate (%) for mortality over the 90 day study period• Proportion of subjects with functional independence, as defined by a score of 0-1 on the mRS at Day 90 or the last rating
Start Date	March 1, 2017
End Date	<i>November 2019</i>



FDA approval of nerinitide is expected in early 2021





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Conclusion

- Nerinitide is an emergency drug aimed at reducing functional disability in patients with acute ischemic stroke (AIS) undergoing thrombectomy
- There are no existing ICD-10-PCS codes that describe the administration of nerinitide
- Existing ICD-10-PCS codes for treatment of AIS that describe thrombolytic class drugs and thrombectomy devices are not applicable to PSD-95 antagonists
- A unique ICD-10-PCS code for nerinitide ensures distinct tracking of drug utilization and corresponding patient outcomes to better inform treatment of this medical emergency



Questions

