

Experts discuss improving enrollment in acute stroke trials

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Clinical trials are a critical step in improving treatments and care for acute stroke patients, and enrolling a large and diverse patient population in trials helps push research forward.

At the Stroke Treatment Academic Industry Roundtable XII meeting in



March, stroke physicians, researchers, industry representatives and members of the National Institute of Neurological disorders and Stroke and the U.S. Food and Drug Administration discussed the current status of enrolling patients in acute stroke trials and the most pressing issues impacting enrollment.

The meeting's review and recommendations were recently published in the journal *Stroke*, led by corresponding author Joseph Broderick, MD, professor in the University of Cincinnati's Department of Neurology and Rehabilitation Medicine in the College of Medicine, director of the UC Gardner Neuroscience Institute and a UC Health physician.

Meeting members discussed enrollment issues including:

- The need for emergency consent in the U.S. and other countries due to the time-sensitive nature of treatments being tested for acute stroke patients
- Designing patient eligibility criteria in order to maximize both overall enrollment numbers and a diverse and representative patient sample that represents the broader population
- Investigator, study coordinator and pharmacist's availability outside of business hours
- Delays in sites opening trials due to contractual and other issues

"In conclusion, enrollment of participants is the lifeblood of acute stroke trials and is the rate-limiting step for testing an exciting array of new approaches to improve patient outcomes," Broderick and his colleagues wrote. "In particular, efforts should be undertaken to broaden the medical community's understanding and implementation of emergency consent procedures and to adopt designs and processes that are easily incorporated into standard workflow and that improve trials' efficiencies and execution.



"Research and actions to improve enrollment in ongoing and future trials will improve <u>stroke</u> outcomes more broadly than any single therapy under consideration," the authors continued.

More information: Joseph P. Broderick et al, Enhancing Enrollment in Acute Stroke Trials: Current State and Consensus Recommendations, *Stroke* (2023). DOI: 10.1161/STROKEAHA.123.044149

Provided by University of Cincinnati

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