

Participant Diversity in Stroke-Related Medical Device Trials: Historical Context and Ongoing Challenges

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Abstract: Despite an acknowledgement of the ethical and clinical importance of recruiting diverse populations into clinical trials, there is a continued under enrollment of patients with diverse demographic characteristics within the field of Neurology and more specifically, in stroke-related device trials. Efforts on the part of the United States Congress, the National Institutes of Health, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services over the last several decades have attempted to increase trial participant diversity with varying success. This historical context provides an important lens for analyzing diversity proposals and their bearing on device trials in the field of stroke neurology. Despite economic and logistical challenges, recruitment of appropriately diverse clinical trial populations through policy change and community engagement is critical to continuing to advance health equity goals.