

Trial Innovation Network Expression of Interest:  
CREATIVITY

<b>Study Title</b>	Anticoagulation for Stroke and Dementia Prevention in Atrial Myopathy	
<b>Funding I/C</b>	NHLBI	
<b>Study Description</b>	Atrial myopathy (characterized by abnormalities in left atrial function and size) is independently associated with higher risk of ischemic stroke and dementia. We hypothesize that a direct oral anticoagulant can significantly reduce the risk of a composite of ischemic stroke, mild cognitive impairment, dementia, and all-cause death in older adults with atrial myopathy and without prior ischemic stroke, mild cognitive impairment or dementia, or atrial fibrillation.	
<b>Study Design</b>	CREATIVITY is a Phase 3 multicenter double blind randomized controlled trial. The aim of CREATIVITY is to determine whether a direct oral anticoagulant can significantly reduce the risk of a composite of ischemic stroke, mild cognitive impairment, dementia, and all-cause death in older adults with atrial myopathy and without prior ischemic stroke, mild cognitive impairment or dementia, or atrial fibrillation. There will be 2 arms: one arm receiving a direct oral anticoagulant and the other arm receiving a placebo. Participants will be randomly assigned to the 2 arms.	
<b>IRB</b>	Vanderbilt University Medical Center sIRB	
<b>Coordinating Center</b>	Vanderbilt Clinical Coordinating Center	
<b>Study Length</b>	Plan to submit a UG3/UH3 grant proposal to the NHLBI. The UG3 phase is 1 year and the UH3 phase is 6 years for a total duration of 7 years or 84 months. 2-year recruitment period; participants followed minimum 36 months and maximum 60 months.	
<b>Study Enrollment #</b>	1000	
<b>Eligibility Criteria</b>	<p><b><u>Inclusion Criteria</u></b></p> <p>-Older adults aged ≥65 years with LA reservoir strain &lt;27% and CHA<sub>2</sub>DS<sub>2</sub>-VASc ≥3</p>	<p><b><u>Exclusion Criteria</u></b></p> <p>-Prior ischemic stroke, mild cognitive impairment or dementia, or atrial fibrillation</p>
<b>Total # of Sites</b>	20	
<b>Site Requirements</b>	<p><u>Study sites will need to have the following at their site to be considered:</u></p> <ul style="list-style-type: none"> <li>• Clinical 2-D ECHOS</li> <li>• Tech available for training and measuring LA reservoir strain</li> <li>• Research coordinator familiar with cardiac clinical trials</li> </ul>	
<b>Site Investigator Qualifications</b>	<p><u>Site Investigators should have the following:</u></p> <ul style="list-style-type: none"> <li>• Practicing ABIM board-certified cardiologist</li> <li>• Prior cardiac clinical trial experience as Co-I or PI</li> </ul>	
<b>Key Timeline Dates:</b>	<p><u>The following dates are projections and subject to change:</u></p> <p><b>Site Selection Decisions:</b> June 2026  <b>Site Selection Notifications:</b> July 2026  <b>Enrollment begins:</b> January 2027  <b>Last Patient/Last Visit:</b> January 2032  <b>Study Closure:</b> July 2032</p>	