

Alliance (Native)

<u>INVESTIGATORS</u>	<ul style="list-style-type: none">• Robert Cubeddu, MD-Principal Investigator• Mazen Albaghdadi, MD -Sub Investigator• Luis Paz, MD-Sub Investigator• Brian Solomon, MD Sub-Investigator• David Axline, MD Sub-Investigator• Hany Elmahdy, MD Sub-Investigator
<u>Trial Objective</u>	<ul style="list-style-type: none">• To establish the safety and effectiveness of the Edwards SAPIEN X4 Transcatheter Heart Valve (THV) in subjects with symptomatic, severe, calcific aortic stenosis (AS)
<u>Randomization</u>	<ul style="list-style-type: none">• All patients who meet study Inclusion/exclusion receive study device
<u>Key Inclusion</u>	<ul style="list-style-type: none">• Severe, calcific AS defined as:<ul style="list-style-type: none">-AVA\leq1.0 cm² or-AVAi\leq 0.6 cm²/m² if BMI <30 kg/m² ; OR-AVAi\leq 0.5cm²/m² if BMI \geq 30 kg/m²• NYHA Function class \geq II
<u>Key Exclusion</u>	<ul style="list-style-type: none">• Pre-Existing mechanical or bioprosthetic valve in any position• Severe aortic regurgitation (>3+)• Severe mitral regurgitation (>3+) or \geq Moderate mitral stenosis• Need for mitral, Tricuspid, or pulmonic valve intervention within the next 12 months• Left ventricular ejection fraction <20%