

Alliance (AVIV)

<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 who are at high or greater surgical risk with a failing aortic bioprosthetic valve
<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">• Failing Aortic bioprosthetic valve demonstrating \geq moderate stenosis and/or \geq moderate insufficiency• NYHA Functional class \geq II
<u>Key Exclusion</u>	<ul style="list-style-type: none">• Failing valve has moderate or severe paravalvular regurgitation• Surgical or transcatheter valve in the mitral position• 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%