Coarctation Of the Aorta Stent Trials: What can we learn from the COAST/COAST II studies?

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Obtaining FDA approval for a new medical device in the USA can be a challenging task even for large corporations. For an academic clinician navigating these challenges can be overwhelming. This experience and the lessons learned from the COAST and COAST II pivotal FDA trials will be discussed. Specifically the use of Objective Performance Criteria and Severity of Illness Scores will be discussed. Also reviewed will be the lessons learned from the trial design.