OBJECTIVE

• To support a national surveillance system that monitors patient, provider, and procedure characteristics and associated outcomes for patients receiving transcatheter valve therapies using standardized data elements. This surveillance system was designed to help assess and improve quality of care, and to promote research based on registry collected data.

• The secondary objective of the registry is to serve as a scalable data infrastructure for post market studies.

UTILITY FOR POST MARKET DATA COLLECTION

• New and high risk medical devices traditionally have stand-alone new enrollment Post Approval Studies (PAS) mandated with their approval.
• These stand alone studies are costly and time consuming.
• TVT has allowed for standardized post market surveillance of these devices across manufacturers and eliminated the need for stand alone PAS.
• Data analysis can be done independently removing any potential conflicts of interest that exist when industry studies its own devices.
• More than a dozen surveillance projects are conducted under TVT.

UTILITY FOR PRE-MARKET DATA COLLECTION

• The ongoing data collection facilitated the approval of a device for an expanded indication
• Because of data collected through TVT the U.S. was able to be the first in the world to approve a transcatheter device for mitral valve-in-valve treatment
• Additionally, Industry has relied on TVT to imbide IDE studies.

MDEpiNet
Transcatheter Valve Therapy (TVT) Registry
Epidemiologic Evaluation and Research Branch (EERB) 1
Division of Epidemiology, Office of Surveillance and Biometrics, Center for Devices and Radiological Health
U.S. Food and Drug Administration, Silver Spring, MD

TVT REGISTRY PUBLICATIONS