NEST Coordinating Center
An initiative of MDIC

TEST-CASE

Johnson & Johnson Leverages NESTcc for Evaluation of Cardiac Ablation Catheters

EHR Data Feasibility Research Designed to Lead to Label Expansion Study

PROJECT OVERVIEW

Johnson & Johnson sought to determine the reliability and relevance of EHR data as evidence demonstrating the safety and effectiveness of radiofrequency (RF) catheters for expanding indications for use, specifically to treat ventricular tachycardia (VT) and persistent atrial fibrillation (AFib).

NESTcc paired the Johnson & Johnson team with three Network Collaborators – Mercy in St. Louis, Mo., Mayo Clinic in Rochester, Minn., and Yale New Haven Hospital in New Haven, Conn. – as each site had used the device of interest and had specific expertise to capture required EHR system data and evaluate associated outcomes.

DESIGN AND EXECUTION

The design of the feasibility study consisted of five parts: Defining the data elements, identifying devices, abstracting device data, identifying patient populations, and evaluating and validating codes and algorithms for identifying data elements. The duration of the project from kickoff to completion was 11 months.

Early in the project, the Test-Case team formed workgroups to refine methodological approaches captured in a standardized and pre-defined protocol, project goals, and institutional strengths. Through an iterative process, Network Collaborators and the Johnson & Johnson team worked through challenges including outcome identification, identification of the indication of the procedure in which the device was used, linking device usage with diagnosis type cohorts, and data validation.

The project team found that identifying unique devices in the EHR entails substantial effort with each health care system using a different approach. To identify the device of interest used during an ablation procedure, Network Collaborators used a combination of HCPCS and site-specific EHR charge codes, as well as manufacturer numbers and UDIs captured in point-of-care and supply-chain inventory-management systems. Data analysts at each Network Collaborator queried their EHR systems to match codes against patient medical histories (including encounter diagnoses, problem lists and procedures) to identify the study population.

TEST-CASE SNAPSHOT

Device Class
III

Device Category
Traditional

Regulatory Pathway
PMA

Total Product Life Cycle
Label Expansion

Disease Type
Cardiology

Data Type
EHR

Study Type
Retrospective

Duration
11 months

Result
Advancing to label expansion study

NETWORK COLLABORATOR EXPERTISE

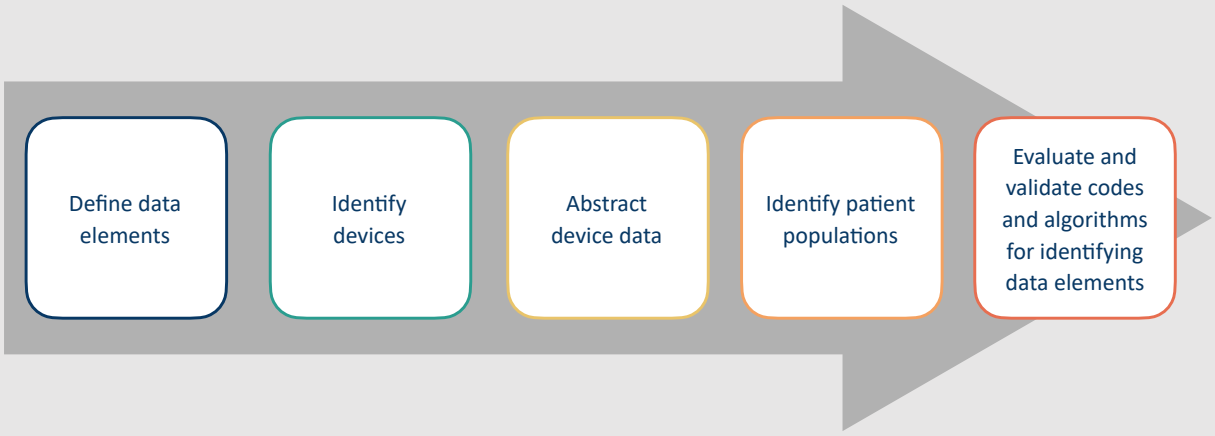
Mercy
Expansive work with UDIs

Mayo Clinic
Maintains internal ablation registry

Yale New Haven Hospital
Participates in NCDR AFib ablation registry

For more information, please contact us at 202.559.2938 or nestcc@mdic.org

NESTcc Test-Case: Feasibility Study Design



Source: Johnson & Johnson

NESTcc ROLE

In addition to connecting the Test-Case sponsor with the Network Collaborators best positioned to lead the study, NESTcc managed the contracting process, developed and tracked key milestones and deliverables, and coordinated regular communication among parties involved in the project.

NESTcc also facilitated engagement between the project team and the U.S. Food and Drug Administration (FDA) throughout the Test-Case process to discuss the use and analysis of RWE for regulatory purposes.

"We had all the right expertise on board – the multi-stakeholder, multi-disciplinary approach is absolutely essential."

Joseph Drozda, Jr., M.D.
Director of Outcomes Research, Mercy

OUTCOMES AND NEXT STEPS

The Test-Case process demonstrated the expertise of Mercy, Mayo Clinic, and Yale New Haven Hospital in developing distributed data network studies, as well as the importance of multidisciplinary input (epidemiology, clinical/ medical, regulatory affairs, and informatics) in driving a project forward. The scientific findings of the Test-Case will be submitted for publication by Mercy later this year.

For the Johnson & Johnson team, the results of the feasibility study have laid the groundwork for a label expansion study, which the company is co-sponsoring. The goal of the study will be to support a label expansion submission to FDA's Center for Devices and Radiological Health later this year. Based on publicly available information, no other product to date has received an indication expansion solely using RWE generated from EHR system databases.

"The Test-Case evaluated data relevance and reliability to assess if real-world data would be 'fit for purpose' for regulatory submission supporting a potential study for label expansion."

Paul Coplan, ScD, MBA
VP and Head of Medical Device Epidemiology and Real-World Data Sciences, Johnson & Johnson

For more information, please contact us at 202.559.2938 or nestcc@mdic.org