Our definition of medical device quality consists of seven domains

1. **Safety**: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.

2. **Effectiveness**: Device produces the effect intended by the manufacturer relative to the medical condition(s).

3. **Reliability**: Device system or component is able to function under stated conditions for a specified period of time.

4. **Patient Satisfaction**: Device was perceived to meet or exceed patient expectations of usability and outcome.

5. **Usability**: Device minimizes the risk of user errors by patients or clinicians.

6. **Availability**: Device is available to fill first request orders.

7. **Compatibility**: Device is compatible with related devices or drugs, the use environment or relevant standards.
Dashboards

Assignment of Gold (G), Silver (S), and Bronze (B) rankings to a company’s KPI assuming that KPI values follow a normal distribution (lower score is better)

Dashboard 1

Overview
Intended to orient user and explains the quality domains, the data sources, KPIs, and gold, silver, bronze rankings. Also describes and explains how rankings are portrayed visually.

Rankings by Data Source
Displays a table of KPI rankings by company and at individual data source level. Each source is identified whether quality of data is high, medium, low.

Dashboard 2

Rankings by Manufacturer
Collapses the individual data sources and displays a table of KPI rankings by company. Individual data sources are aggregated using weighted average.

Dashboard 3

Rankings by Product
Displays a table of KPI rankings by company and product, similar to third dashboard.

Dashboard 4
NEW ADDITION: Assessment of the Value of Electronic Health Records Data for Identifying Implantable Cardiac Lead Failures

**Title:** Assessment of the Value of Electronic Health Records Data for Identifying Implantable Cardiac Lead Failures

**Technology of Interest:** Cardiac Device Leads

**Disease Area:** Cardiovascular

**Duration:** 12 months

**Network Collaborator(s):** STAR CRN

The primary objective of this study is to examine the feasibility of establishing a generalizable and efficient process for determining medical device reliability. The study will specifically focus on implantable leads (i.e. electrodes) for permanent cardiac pacemakers and defibrillators using different data sources, including electronic health record (EHR) data, CMS claims data, device manufacturer databases, and the U.S. Food and Drug Administration (FDA)’s Medical Device Adverse Event Reports (MAUDE) database. The leads examined in this study are Class III devices.

The ability to mobilize vast amounts of patient data from the EHR holds tremendous potential for evaluating the effectiveness and safety of medical devices through observational studies and pragmatic trials. However, test cases of the value of EHR data for such purposes and the superiority of EHR over other extant data are lacking. This study will determine the degree to which existing EHR data can be harnessed to determine device reliability, using cardiac leads as a test case. The study will also triangulate several different data sources to examine device reliability to determine the strengths and limitations of these different sources and will further examine the value of PCORnet as a national resource to address a wide range of issues related to medical device safety. Using EHR data, lead failures will be determined based on specific procedure codes found in the EHR after the date of implantation.

This study is an ideal NESTcc Test-Case, as NESTcc brings together key stakeholders from industry, academia, and the regulatory sphere around a common goal of improving methods for assessing device safety and effectiveness. As such, NESTcc facilitates the conduct of research through active matchmaking within its wide range of available Data Network sources.

Press Release: June 4, 2019
Activities and Next Steps

Data Collaborator: **STAR Clinical Research Network** (formerly Mid-South CRN)

Facilities: **Wake Forest Baptist Health (WFBH)**
**Vanderbilt University Medical Center (VUMC)**
*(potentially) University of North Carolina (UNC CH)*

Data sources: Electronic Health Records connected to CMS
Manufacturer’s reliability tracking data
MAUDE

1) WFBH finalizing contract with NESTcc (July 2019)
2) WFBH beginning process for IRB approval (July 2019)
3) Partnership with EP PASSION study team for Manufacturer participation
4) Seek funding through manufacturer grants to add UNC CH (July/August 2019)
5) Commission working group/team members for kick-off (target August/September)