



# Real-World Evidence for Medical Devices: Lessons Learned from the NESTcc Test-Cases

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APRIL 27, 2022



@NESTccMedTech

## AGENDA

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### Presentation

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- Justin W. Timbie, Ph.D., The RAND Corporation

### Panel Discussion

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- Sandra Siami, MPH, NESTcc/MDIC (Moderator)
- Paul Coplan, ScD, MBA, MPH, Johnson & Johnson
- Adrian Hernandez, M.D., MHS, Duke Clinical Research Institute
- Joseph Ross, M.D., MHS, Yale School of Medicine
- Art Sedrakyan, M.D., Ph.D., Weill Cornell Medicine/MDEpiNet
- Justin W. Timbie, Ph.D., The RAND Corporation

### Attendee Q&A

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- Attendees are invited to submit questions throughout the workshop for response at the end of the session



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Submit written questions through the Zoom Q&A box at the bottom of your screen.

# NESTcc TEST-CASES

## 21 Total

NESTcc Test-Cases

- ✔ **Objective #1:** Explore the **feasibility** for medical device ecosystem stakeholders to work with RWD sources and NESTcc's initial set of Network Collaborators
  
- ✔ **Objective #2:** Help identify areas where NESTcc could **play a role in creating efficiencies**

NESTcc's Test-Cases reflect the diversity of types of medical devices available and the different use of data in pre- and post-market settings

### THERAPEUTIC AREA

- 👤 Cardiology
- 👤 Cardiovascular
- 👤 Dental
- 👤 Dermatology
- 👤 ENT
- 👤 Mental health
- 👤 Oncology
- 👤 Orthopedics
- 👤 Respiratory
- 👤 Urology

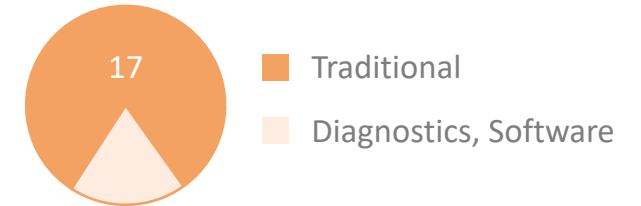
### PATHWAY

- 🏠 510(k)
- 🏠 PMA

### CLASS

- ⊕ Class II
- ⊕ Class III

### DEVICE TYPE



### TPLC STAGE



<sup>1</sup>Not pictured, The Women's Health Technology Coordinated Registry Network (WH-CRN)

# Key Findings on use of Real-World Data in the NESTcc Test-Cases

Interim Report



# RAND Conducted an Independent Assessment of Test-Cases Completed through August 2021

## ASSESSMENT GOALS

Synthesize key lessons on the use of real-world data (RWD)



Gather stakeholder views on the strength of the evidence



Identify ways to help stakeholders generate real-world evidence (RWE)



# Assessment Included Review of Test-Case Deliverables and Interviews

**14 Test-Cases**



**44 Interviews**



**21 Test-Cases Total**

Remaining 7 will be complete in September 2022

**31 Network Collaborators**

Research organizations with access to RWD sources and analytical expertise

**13 Submitting Organizations**

Medical device manufacturers and other stakeholders with research questions



# Test-Case Teams Identified Several Keys To Success

**Using data from manufacturers to identify the target population**

**Using rich clinical data from registries to enhance EHR data**

**Standardizing EHR data using common data models**

**Combining the expertise of physician researchers and data scientists**

# Many Test-Case Teams Encountered Similar Challenges

**Identifying use of specific devices when UDIs were not available in RWD**

**Extracting key data elements from unstructured EHR fields**

**Granularity and reliability of diagnosis and procedure codes**

**Long-term follow-up of study endpoints**



# The Test-Cases Identified Opportunities to Improve Use of RWD

**Expand UDI capture in hospital and health system EHRs**

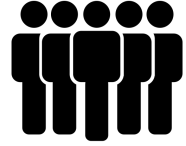
**Develop libraries of computable phenotypes and endpoints**

**Expand use and breadth of common data models**

**Create more linkages between EHRs, registries, and claims**



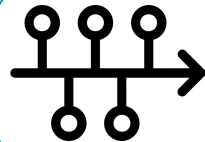
# Test-Cases Established Proof of Concept and Identified Priorities for Follow-On Studies



Larger sample sizes



Additional validation of endpoints



More complete follow-up



Greater alignment across sites







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## PANEL DISCUSSION

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**Sandra Siami, MPH**  
MDIC/NESTcc



**Paul Coplan, ScD, MBA, MPH**  
Johnson & Johnson



**Adrian Hernandez, M.D., MHS**  
Duke Clinical Research Institute



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Yale School of Medicine



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