Product Quality Outcomes Analytics Update
Car Buying Parameters

1. Safety
2. Effectiveness
3. Reliability
4. Satisfaction
5. Usability
6. Availability
7. Compatibility
How Do You Buy Your Car?

- Consumer Reports
- JD Power
- Edmunds
- Kelly Blue Book
- CarFax
- TrueCar
- ...

- These tools support purchasing decisions.
- They do not recommend the best car for you!

Source: KBB.com
Creating a Marketplace for Quality

“Develop A Medical Device Quality Dashboard To Guide Strategic Procurement Decisions”
**Product Quality Dashboard 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.
Phase I Dashboard

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.

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.

Rankings by Product
Displays a table of KPI rankings by company and product, similar to third dashboard.
# Phase II Project Charter

## Objectives
Develop a medical device quality dashboard to guide purchasing decisions

## Project Scope

<table>
<thead>
<tr>
<th>Included</th>
<th>Future Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>• Collaborations with GPOs or 3rd party data analysts to ensure adoption</td>
</tr>
<tr>
<td>• Identify and analyze registry data on safety and effectiveness</td>
<td></td>
</tr>
<tr>
<td>• Identify and analyze hospital data on reliability, patient perspective and physician preference</td>
<td></td>
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<tr>
<td>• Establish analytical methods and revise dashboards</td>
<td></td>
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<tr>
<td>• Alignment with MDIC CfQ maturity model work</td>
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</table>

If there is sufficient bandwidth:

• Coordinate with NEST program
• Gather and analyze patient perspective data

## Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Goal</th>
<th>Unit of Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry data sources</td>
<td>2</td>
<td>Number of registries accessed for safety and effectiveness data</td>
</tr>
<tr>
<td>Hospital Collaborations</td>
<td>2</td>
<td>Number of hospitals providing data for the dashboard</td>
</tr>
<tr>
<td>Phase II completion date</td>
<td>12/31/18</td>
<td>Analytical methods defined and dashboards revised</td>
</tr>
</tbody>
</table>
Phase 2 Goal

• Develop a standardized method for calculating, analyzing and presenting the Seven Dimensions of Quality
  – Consistency allows for a fair comparison of devices
  – Standard calculation for each Quality Dimension
  – Supports Evidence Based decision making
  – Level the playing field for device comparison
THE VALUE OF ANALYTICS IN VALUE BASED HEALTHCARE

PERSPECTIVES FROM KEY STAKEHOLDERS IN THE HEALTHCARE ECOSYSTEM
Drivers for PQOA

• The primary drivers for Healthcare today are improving the quality of patient outcomes, enhancing patient-centered care and adopting initiatives that control costs while maximizing patient benefit.

• Healthcare stakeholders, including physicians, clinicians and supply chain professionals utilize data to make value-based procurement decisions for medical devices to ensure and improve patient access to high quality devices.

• The integrity of these decisions depends upon the accuracy and completeness of unbiased analysis of underlying data to support patient care decisions.

Data is Foundational

- Improving the quality of patient outcomes, enhancing patient-centered care and adopting initiatives that control costs depends on unbiased quality and outcomes, data is foundational.
  - Value analysis, medical, clinical, and supply chain professionals will use the data to guide strategic sourcing decisions.
  - It could assist manufacturers target device performance, user-interface, etc., or complications that may be corrected in the next revision or generation of product development.
  - Regulators could use evidence-based data to evaluate a company’s commitment to Quality/Product Quality.
  - Patients/consumers could provide input to decisions for device selection based on data.

The Value Of Analytics

“Using real world data, real world evidence, real world performance, gives us a lot more visibility into where we, as an agency and a collective ecosystem, need to target resources to respond to issues, drive improvement, drive better education, and increase awareness.”

Francisco (Cisco) Vicenty - Program Manager for Case for Quality, Office of Compliance, CDRH, FDA

“The real promise of the analytics project is the ability to make information available to care providers, physicians, and also patients, and, where appropriate, to use this information to help them achieve the best possible outcomes.”

Stephanie Christopher - Program Director
Medical Device Innovation Consortium (MDIC)

Source: The Value of Analytics in Value-Based Healthcare, 2018, Axendia Inc.,
The Value Of Analytics

“The biggest value is patient outcomes. In today's value-based healthcare environment, it is the patient, and no longer the supply, that is at the center. Evidence-based data helps guide procurement decisions within an organization as to which product works best, with the patient population they care for, to produce the best outcome at the most appropriate cost is the ultimate goal. This is what AHRMM calls cost, quality, and outcomes (CQO)

Michael Schiller – CMRP, Senior Director
Association for Healthcare Resource & Materials Management (AHRMM)

“While it's uncomfortable talking about results and bringing the scrutiny of results into a public forum it's absolutely necessary to help entities really figure out that they do have to improve their quality.”

Michael Ruhlen – MD, MHCM, FAAP, VP Division of Medical Education,
Atrium Health

Source: The Value of Analytics in Value-Based Healthcare, 2018, Axendia Inc.,
Challenges Accessing Data

“Medical device manufacturers have not been open to broadly sharing information or data that they have. Couple of reasons for this, first there is a concern that information provided would be misunderstood and used incorrectly by litigators. The second, is that information could be misrepresented and used by your competitors.”

Garth Conrad – VP Quality
BD Peripheral Intervention

“Manufacturers are naturally reluctant to share information that may be the source of competitive advantage or reveal weaknesses in products. Healthcare providers have major concerns over patient privacy and potential connection to liability and litigation matters. Registries and other data repositories have invested significant time and money in collecting what they have and are reluctant to share without compensation or help in fulfilling their particular mission.”

Nathan Soderborg – PhD, Principal Scientist, Statistical and Data Sciences
Exponent

Source: The Value of Analytics in Value-Based Healthcare, 2018, Axendia Inc.,
Opportunities To Leverage Data

“We need to shift the dynamic with industry around data sharing in order to enable a lot more trust and engagement around performance issues. This shift needs to happen, so that we can get these analytic discussions started, improve the use of the data, and then work to enhance that data with real world sources afterwards.”

Francisco (Cisco) Vicenty - Program Manager for Case for Quality, Office of Compliance, CDRH, FDA

“Unique Device Identification (UDI) is one of those decoder keys that will allow for cross platform analysis of information. It should link the full life-cycle of a product from manufacturing all the way through the electronic patient record.”

Garth Conrad – VP Quality
BD Peripheral Intervention

“Once [UDI] data is captured within a hospital's EHR, and resides downstream in device registries and claims, we can begin to assess device performance and determine the best medical device to be used for a specific patient population to deliver the best outcomes. It is here that we achieve access to unbiased data.”

Michael Schiller – CMRP, Senior Director
Association for Healthcare Resource & Materials Management (AHRMM)

“As with any change initiative we need the support of all stakeholders to accomplish our project. This includes industry, FDA, health-care providers, VACs and in the case of our pilot project, data collaborators from NEST.”

Garth Conrad – VP Quality
BD Peripheral Intervention

“My desire would be able to work collaboratively with manufacturers on developing a foundation of trust around data. Their concern, and understandably so, is that product performance is being gauged on one variable when there are other variables at play.”

Michael Schiller – CMRP, Senior Director
AHRMM

Source: The Value of Analytics in Value-Based Healthcare, 2018, Axendia Inc.,
“I know the good intentions of industry and I know nobody ever wants to go out and produce a faulty thing that's going to hurt someone. They don't want to do that for all the right reasons because their goal really is to improve human health. I wholeheartedly know that now, and deeply appreciate their work. I'm not sure that I would have known that until I got engaged with this effort.”

Michael Ruhlen – MD, MHCM, FAAP, VP Division of Medical Education, Atrium Health

“…we need to raise this discussion to a higher level of stakeholders in each of the affected communities—leadership and executives among manufacturers, healthcare providers, payers, regulatory agencies, and data collectors.”

Nathan Soderborg – PhD, Principal Scientist, Statistical and Data Sciences Exponent

NESTcc Submission

National Evaluation System for Health Technology Coordinating Center (NESTcc)

Second Round of Call for Concepts: An Invitation to Submit Concepts for Real-World Evidence Test-Cases

Comparative Reliability Study

We propose to evaluate medical device reliability of knee implants or cardiac rhythm devices (CRD). However, we are open to exploring current initiatives where data exists in the areas of implanted devices, non-implanted devices, reusable, or single use medical devices using Real World Data sources offered by one or more of NESTcc’s initial set of data network partners (Duke University Health System, HealthCore, Kaiser Permanente, Mayo Clinic, Mercy, OneFlorida, PEDSnet, Vanderbilt University, Weill-Cornell Medical Center, Yale New Haven Health System). We will select the device in partnership with our data network partner to assure mutual interest and capacity to provide the data.
NESTcc Submission
Comparative Reliability Study

B. Alignment

NESTcc’s mission is “to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE), and innovative research.” By developing the methodology to assess medical device reliability using real-world evidence, we will make it easier for patients, physicians and hospitals to assess and understand the reliability of their medical device and in doing so, we will realize NEST’s vision to accelerate the adoption of new medical technologies by utilizing innovation research techniques at different points in the medical device development lifecycle.

Our prior attempts to measure medical device reliability depended on adverse event reports and recalls. These data sources are unreliable due to reporting differences across industry and challenging to use because of poor device identification information. Real World Evidence would eliminate the reporting disparities by providing consistent information on devices used to treat specific conditions. Real World Evidence provides both the number of times a device has a reliability failure but also the total number of times the device is used. This critical denominator or market share information is missing from adverse events and recall data. Using NESTcc’s initial set of partners may allow us to connect failure information with UDI or internal hospital device identification sources.

To improve medical device quality, industry needs to be able to objectively measure quality, compare quality of similar devices and correlate manufacturing practices with patient outcomes. Establishing individual partnerships with healthcare organizations isn’t feasible or cost effective. Using NESTcc’s initial set of partners provides the necessary infrastructure and expertise to explore use of Real World Data.

This test case supports the use of Real World Data throughout the Total Product Life cycle. We can use medical device reliability assessment to drive research, stimulate new designs, improve manufacturing processes and recognize when devices should no longer be on the market.
Mock Datasets for Collaboration With Tech Companies

- Reliability
- Availability
- Safety and Effectiveness
- Health Care Organizations
How Can You Help?

- Be a Change Agent!
- What are some options to overcome data access challenges?
- How to best address clinical use and patient accountability in device performance metrics?
- How can we best establish trust and collaboration across the ecosystem?
  - Providers
  - Clinicians
  - Manufacturers
  - Payers
  - FDA
  - Etc.
What are the Anticipated Connections between the Dashboard and the Maturity Model?

These slides have been prepared to show how the dashboard and maturity model could connect in the future. The slides are intended to inspire discussion and not meant as the complete description of all possibilities.
Coming Together

Maturity Model
- Program Creation
- Industry Assessment

Product Quality Dashboard
- Dashboard Creation
- Value Analysis Team Assessment

Device Quality
- Improved Patient Outcomes
Anticipated Connections between the Dashboard and the Maturity Model

• There are practice areas in the maturity model which will **benefit from input** from the Product Quality Outcomes Analytics Dashboard

• There are practice areas in the maturity model which will **drive changes** in medical device quality directly measureable with data from the Product Quality Outcomes Analytics Dashboard
Considering the Dashboard Domains as Inputs to specific Maturity Model Practices

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

Monitor and Control - Provides an understanding of the work progress so appropriate corrective actions can be taken when performance deviates significantly from plans. Increases the probability of meeting objectives by taking early actions to adjust for significant performance deviations.

Monitor and Control

• Knowledge of variations in the functioning time for medical devices can inform key areas of focus.
• The significance of observed performance deviations may be assessed through understanding of device reliability information.
Considering how the Maturity Model Practices could **Drive Measurable Change** within specific Dashboard Domains

**Process Quality Assurance** - Verifies and enables improvement of the quality of the performed processes and resulting work products. Increases the consistent use and improvement of the processes to maximize business benefit and customer satisfaction.

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

**Patient Satisfaction**: Device was perceived to meet or exceed patient expectations of usability and outcome.
Looking toward Correlation between Maturity Model Heat Map, Firm Internal Metrics and Product Quality Dashboard

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

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### Maturity Model Heat Map

<table>
<thead>
<tr>
<th>Category</th>
<th>Levels</th>
<th>Heat</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimating (EST)</td>
<td>1.1</td>
<td>S</td>
<td>82%</td>
</tr>
<tr>
<td>Planning (PLAN)</td>
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<td>82%</td>
</tr>
<tr>
<td>Monitor and Control (MVC)</td>
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<tr>
<td>Configuration Management (CM)</td>
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<tr>
<td>Managing Performance and Measure (MPM)</td>
<td>2.4</td>
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<td>82%</td>
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<tr>
<td>Requirements Development and Maintenance (RDM)</td>
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<tr>
<td>Process Quality Assurance (PQA)</td>
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<td>82%</td>
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<tr>
<td>Governance (G2V)</td>
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<td>P</td>
<td>82%</td>
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<tr>
<td>Implementation Infrastructure (II)</td>
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<td>82%</td>
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<tr>
<td>Product Integration (PI)</td>
<td>P</td>
<td>P</td>
<td>82%</td>
</tr>
<tr>
<td>Technical Solution (TS)</td>
<td>P</td>
<td>S</td>
<td>82%</td>
</tr>
</tbody>
</table>

### Firm Internal Metrics

- **Scope Definition**
  - Risk
  - Issue

### Product Quality Dashboard

<table>
<thead>
<tr>
<th>Design Phase</th>
<th>Design Transfer Phase</th>
<th>Manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>ISSUE</td>
<td>ISSK</td>
</tr>
<tr>
<td>ISSUE</td>
<td>ISSK</td>
<td>FISS</td>
</tr>
</tbody>
</table>

### Notes

From the drop-down menu, select the System(s) or Process(es) your facility uses to define:
1. Risk collection and management (Project management, supplier management); and
2. Issue collection and management (e.g. CAPA, Project Management, contracting).

Select as many as are relevant. You may also choose to type your own system or process instead.

Please fill in the following for the total sum of all your selections, respect to each phase:
1. Open/Closed: provide the number of open and closed risks/issus at the appropriate phase.
2. Mean time to resolution: provide the mean time (highest and lowest numbers added together a

### MDIC

Medical Device Innovation Consortium
Download the Report:

The Value of Analytics in Value-Based Healthcare
Perspectives from Key Stakeholders in the Healthcare Ecosystem


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Thank You