Duke | Robert J. Margolis, MD Center for Health Policy

Opportunities and Gaps in Real-World Evidence for Medical Devices

Duke-Robert J. Margolis, MD, Center for Health Policy Main Conference Room
1201 Pennsylvania Ave. NW Suite 500 ● Washington, DC 20004
April 26, 2017

Overall Workshop Objective: Obtain detailed multi-stakeholder and expert input on specific questions regarding the current landscape of real-world evidence (RWE) of medical devices throughout the total product lifecycle. Participants will identify areas where there has been movement in scaling and expanding best practices as well as identifying methodological, technical, and/or data gaps that are slowing or preventing the development and/or expansion of RWE generation for medical devices.

9:00 a.m. **Welcome and Meeting Objectives**

- Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

9:10 a.m. **Opening Statements**

- Jeffrey Shuren, U.S. Food and Drug Administration
- Bill Murray, Medical Device Innovation Consortium

9:30 a.m. **Session I: Review of Landscape Analysis Process**

Session Objective: This session briefly outlines NESTcc's process for the development of the landscape analysis. The discussion will solicit broad feedback on process and planned next steps, as well as provide suggestions about other potential study areas for NESTcc to consider as it continues to develop the landscape analysis.

- Moderator
  - Adrian Hernandez, Duke Clinical Research Institute
- Presenters
  - Dawn Bardot, Medical Device Innovation Consortium
  - Chandan Karnik, Deloitte Consulting, LLP
- Moderated Group Discussion

10:15 a.m. **Session II: Current Uses and Opportunities to Expand the Application of Real-World Evidence (RWE)**

Session Objective: This session includes presentations of several short case studies on ways that companies are making use of RWE outside of regulatory purposes and throughout the total product lifecycle. The discussion will focus on less-well-known areas where RWE has been useful, particularly in the early-IDE space, as well as how to determine fit-for-purpose for various data sources.

- Moderator
  - Gregory Daniel, Duke-Margolis Center for Health Policy
- Presenters
  - Darrell Johnson, Medtronic
  - Jesse Berlin, Johnson & Johnson
- Responders
  - Mitchell Krucoff, Duke Clinical Research Institute
  - Owen Faris, U.S. Food and Drug Administration
- Moderated Group Discussion

11:45 a.m. **Lunch**

1:15 p.m. **Session III: Current Gaps in Using RWE**

Session Objective: There are several well-known challenges in the collection of real-world data (RWD). This session includes two brief presentations highlighting the progress made on structured data capture and device identification. The goal of both the panel and the group discussion is to focus on these and other significant gaps, the underlying reasons these gaps still exist, and what gaps should be prioritized during the early development of NESTcc's RWE landscape and ecosystem.

- Moderator
  - Adrian Hernandez, Duke Clinical Research Institute
- Presenters
  - James Tcheng, Duke University
  - Karen Conway, GHX
- Responders
  - Nancy Dreyer, QuintilesIMS
  - Joseph Drozda, Mercy Health
  - Danica Marinac-Dabic, U.S. Food and Drug Administration
  - Larry Wood, Edwards Lifesciences
- Moderated Group Discussion

2:45 p.m. **Break**

3:00 p.m. **Session IV: Identifying High-Value Opportunities for Stakeholders**

Session Objective: The goal of this session is to identify key priorities of the stakeholder groups for the use of RWD for medical devices. A panel discussion of the short and long-term priorities for individual stakeholder groups will start this session. The subsequent moderator discussion will focus on the value of RWE, the landscape analysis, and NESTcc to the different stakeholders, as well as how NESTcc might prioritize development to deliver optimal value to critical stakeholders.

- Moderator
  - Gregory Daniel, Duke-Margolis Center for Health Policy
- Panel Discussion
  - William Crown, OptumLabs
  - Anna McCollister-Slipp, Scripps Translational Science Institute
  - Philip Goodney, Dartmouth-Hitchcock Medical Center
- Moderated Group Discussion

3:45 p.m. **Next Steps and Closing Remarks**

- Gregory Daniel, Duke-Margolis Center for Health Policy

4:00 p.m. **Adjourn**

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