



Public Webinar

**Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments – Draft Guidance**

September 9, 2022

<https://fda.yorkcast.com/webcast/Play/e6fa3566822e4a18a367afb91283ae761d>

**12:00 p.m. Welcome**

Shannon Cole, Patient-Focused Drug Development (PFDD), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

**12:02 p.m. Opening Remarks**

Theresa Mullin, Office of the Center Director (OCD), CDER, FDA

**12:07 p.m. Introduction**

David Reasner, Division of Clinical Outcome Assessment (DCOA), Office of New Drugs (OND), CDER, FDA

**12:25 p.m. Roadmap to Patient-Focused Outcome Measurement in Clinical Trials**

**12:25 p.m. What is the COA Roadmap?**

Fraser Bocell, Division of All Hazards Response, Science and Strategic Partnerships (DAHRSSP), Office of Strategic Partnerships and Technology Innovation (OST), Center for Devices and Radiological Health (CDRH), FDA

**12:50 p.m. Clinician Perspective on the Roadmap**

Michelle Tarver, OST, CDRH, FDA

**1:00 p.m. Overview of the Evidence-Based Rationale to Justify a COA's Use**

Lili Garrard, Division of Biometrics III (DBIII), Office of Biostatistics (OB), Office of Translational Sciences (OTS), CDER, FDA

**1:15 p.m. Q&A**

**Moderator:** Shannon Cole, PFDD, CDER, FDA

**Panelists:**

- David Reasner, DCOA, OND, CDER, FDA
- Fraser Bocell, DAHRSSP, OST, CDRH, FDA
- Michelle Tarver, OST, CDRH, FDA
- Lili Garrard, DBIII, OB, OTS, CDER, FDA

**1:25 p.m. Break**

**1:35 p.m. Advanced Discussion of Evidence-Based Rationale**

**1:35 p.m. Detailing Each Component**

Lili Garrard and Monica Morell, DBIII, OB, OTS, CDER, FDA

**2:20 p.m. MiCOAS Example**

RJ Wirth, Vector Psychometric Group, LLC

**2:45 p.m. Q&A**

**Moderator:** Shannon Cole, PFDD, CDER, FDA

**Panelists:**

- Lili Garrard, DBIII, OB, OTS, CDER, FDA
- Monica Morell, DBIII, OB, OTS, CDER, FDA
- David Reasner, DCOA, OND, CDER, FDA
- Fraser Bocell, DAHRSSP, OST, CDRH, FDA
- Michelle Tarver, OST, CDRH, FDA
- RJ Wirth, Vector Psychometric Group, LLC

**3:00 p.m. Conclusion / End**