U.S. FOOD & DRUG ADMINISTRATION

Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data

March 19, 2018

12:00 – 1:00 pm **Registration**

1:00 – 1:05 pm **Welcome**
Pujita Vaidya, Office Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

1:05 – 1:15 pm **Opening Remarks**
Theresa Mullin, Associate Director for Strategic Initiatives, CDER, FDA

1:15 – 1:30 pm **Introduction to CDER's External Resources or Information Related to Patients' Experience Webpage**
Pujita Vaidya, OSP, CDER, FDA

1:30 – 3:00 pm **Session I: Opportunities for Patient Stakeholders – FDA Perspective**
Objective: Identify areas where patient experience data might be particularly helpful to inform medical product development and regulatory decision making. This session will focus on providing an FDA panel's perspective on the types of information on the patient experience to collect and measure throughout medical product lifecycle and the varying formats for effective sharing of the collected patient experience data.

Moderator: Sara Eggers, OSP, CDER, FDA

FDA Presentations:

- Theresa Mullin, CDER, FDA
- Keith Flanagan, Transition Lead for Policy, Immediate Office, Office of New Drugs (OND), CDER, FDA

Moderated Panel Discussion

- Larissa Lapteva, Associate Director, Division of Clinical Evaluation, Pharmacology, and Toxicology, Office of Tissues and Advances Therapies, Center for Biologics Evaluation and Research (CBER), FDA
- Naomi Lowy, Associate Director for Regulatory Science, Office of Drug Evaluation I (ODE I), OND, CDER, FDA
- Susan McCune, Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA
- Laurie Muldowney, Associate Director for Medical Policy, Office of Translational Sciences, CDER, FDA
- Theresa Mullin, CDER, FDA
- Elektra Papadopoulos, Associate Director, Clinical Outcome Assessments Staff, OND, CDER, FDA
- Ellis Unger, Director, ODE I, OND, CDER, FDA

3:00 – 3:15 pm **Break**

3:15 – 4:30 pm **Session II: Opportunities for Patient Stakeholders – Stakeholder Perspective**
Objective: Seek input from patient stakeholders on how best to communicate FDA's current thinking on submitting proposed draft guidance relating to patient experience data. This session will provide perspectives from a panel of patient stakeholders on what questions would be most helpful for FDA to address in its forthcoming draft guidance on how to develop and submit a proposed draft guidance relating to patient experience data.

Moderator: Meghana Chalasani, OSP, CDER, FDA

Moderated Panel Discussion

- Jeff Allen, President and CEO, Friends of Cancer Research
- Marc Boutin, Chief Executive Office, National Health Council
- Annie Kennedy, Senior Vice President of Legislation and Public Policy, Parent Project Muscular Dystrophy
- Kimberly McCleary, Director, FasterCures
- Paul Melmeyer, Director of Federal Policy, National Organization for Rare Diseases
- Anne Pariser, Deputy Director, Office of Rare Diseases Research, National Center for Advancing Translational Sciences, National Institutes of Health
- Bray Patrick-Lake, Director of Stakeholder Engagement, Duke Clinical Research Institute
- Mary Jo Strobel, Executive Director, American Partnership for Eosinophilic Disorders

Facilitated Audience Discussion

4:30 – 4:50 pm **Open Public Comment**
Moderator: Pujita Vaidya, OSP, CDER, FDA

4:50 – 5:00 pm **Next Steps and Closing Remarks**
Theresa Mullin, CDER, FDA

Docket Information

We encourage you to submit your written comments to the public docket by May 18, 2018: https://www.regulations.gov/document?D=FDA-2017-N-6312-0001 or go to www.regulations.gov and search for: **proposed draft guidance relating to patient experience data.**