PATIENT-FOCUSED DRUG DEVELOPMENT

Using Methods from PFDD Guidance 1 and Guidance 2 as Tools for Including Patient Experience Data in Clinical Trials: Lessons Learned about Data Collection and Analysis

July 25, 2022

11:00 a.m. **Welcome**

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

11:05 a.m. **Opening Remarks**

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

11:10 a.m. **Session I: Data Collection**

Objective

Provide a focused overview of data collection and analysis with an emphasis on practical implementation

11:10 a.m. **Leveraging Social Media to Capture the Patient Experience**

Selena Daniels, Division of Clinical Outcome Assessment (DCOA), Office of New Drugs (OND), CDER, FDA

11:20 a.m. **Data Collection and Analyses: A Regulatory Perspective**

11:20 a.m. Michelle Campbell, Office of Neuroscience (ON), OND, CDER, FDA

11:30 a.m. Lili Garrard, Division of Biostatistics III (DBIII), Office of Biostatistics (OB), Office of Translational Sciences (OTS), CDER, FDA

11:40 a.m. **Inclusive Research: Managing Barriers to Self-Report**
Naomi Knoble, DCOA, OND, CDER, FDA

11:50 a.m. **Session II: Ideas in Practice**

11:50a.m. **Development of Research Study Materials: Lessons Learned**
Robyn Carson, AbbVie

12:05 p.m. **Reflections on the Utilization of Social Media Data: An Industry Perspective**
Tom Willgoss, Roche

12:20 p.m. **Sanfilippo Syndrome Study of Caregiver Treatment Priorities and Unmet Need**
Cara O'Neill, Cure Sanfilippo Foundation

12:35 p.m. Session III: Question and Answer
Moderator: Robyn Bent, PFDD, CDER FDA
Panelists:

- Selena Daniels, DCOA, OND, CDER, FDA
- Naomi Knoble, DCOA, OND, CDER, FDA
- Michelle Campbell, ON, OND, CDER, FDA
- Lili Garrard, DBIII, OB, OTS, CDER, FDA
- Robyn Carson, AbbVie
- Tom Willgoss, Roche
- Cara O'Neill, Cure Sanfilippo Foundation

1:00 p.m. End