Enhancing the Incorporation of Patient Perspectives in Clinical Trials

March 18, 2019

8:00 a.m. **Registration**

9:00 a.m. **Welcoming Remarks**
Theresa Mullin, Center for Drug Evaluation and Research, FDA
Pamela Tenaerts, CTTI

9:10 a.m. **Keynote Presentation**
Donna Cryer, Global Liver Institute

9:30 a.m. Session I: Enhancing Awareness & Access

Ken Getz, Tufts Center for the Study of Drug Development *(moderator)*

9:35 a.m. **Patient Perspectives**
Donna Appell, Hermansky-Pudlak Syndrome Network
Steven Hall, Cystic Fibrosis Patient Advocate
Jamil Rivers, Breast Cancer Patient Advocate

9:55 a.m. **Case Examples**
Nancy Roach, Fight Colorectal Cancer
Ronnie Tepp, *All of Us* Research Program

10:25 a.m. **Discussion**
Richardae Araojo, Office of Minority Health, FDA
Luther T. Clark, Office of the Chief Patient Officer, Merck
Fabian Sandoval, Emerson Clinical Research Institute

11:20 a.m. **Lunch**

12:20 p.m. Session II: Design & Conduct of Patient Centric Trials

Pat Furlong, Parent Project Muscular Dystrophy *(moderator)*

12:25 p.m. **Patient Perspectives**
Melissa Beasley, Eosinophilic Esophagitis Patient Advocate
Len Schwartz, Parkinson's Foundation
Theresa Strong, Foundation for Prader-Willi Research

12:45 p.m. **Case Examples**
Mary Elmer, TransCelerate BioPharma Patient Experience Initiative
Joseph Kim, Eli Lilly

1:15 p.m. **Discussion**
Susan McCune, Office of Pediatric Therapeutics, FDA
Karlin Schroeder, Parkinson's Foundation

2:10 p.m. **Break**

2:20 p.m. Session III: Post Trial Communication & Engagement

Bray Patrick-Lake, Duke Clinical Research Institute *(moderator)*

2:25 p.m. **Patient Perspectives**
Carly Medosch, Chronic Illness Patient Advocate
Linnea Olson, Lung Cancer Patient Advocate

2:45 p.m. **Case Examples**
David Leventhal, Pfizer
Jessica Scott, Takeda

3:15 p.m. **Discussion**
Suzanne Schrandt, Arthritis Foundation
Michelle Tarver, Center for Devices and Radiological Health, FDA

4:10 p.m. Recapping Key Themes & Looking Forward

Donna Cryer, Global Liver Institute *(moderator)*

4:15 p.m. **Panel Discussion**
Michael Kurilla, National Center for Advancing Translational Sciences, NIH
Craig Lipset, Pfizer
Theresa Mullin, Center for Drug Evaluation and Research, FDA
Peter Saltonstall, National Organization for Rare Disorders
Pamela Tenaerts, CTTI
John Wilbanks, Sage Bionetworks

5:00 p.m. **Adjourn**

Docket Information
A docket is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. We encourage you to submit your written comments to the docket by May 20, 2019: https://www.federalregister.gov/d/2019-01826 or go to www.regulations.gov and search for docket number 2019-01826.