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**

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**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](https://www.federalregister.gov/d/2019-01826) or go to [www.regulations.gov](http://www.regulations.gov) and search for docket number 2019-01826.