

Patient-Focused Drug Development Consultation Meeting

July 18, 2013, 3:00 – 4:30 pm

FDA White Oak Campus, Silver Spring, MD

Building 51, Room 1300

Participants

FDA

Barbara Buch	Center for Biologics Evaluation and Research
Sara Eggers	Center for Drug Evaluation and Research (CDER)
Ray Ford	CDER
Andrea Furia-Helms	Office of Health and Constituent Affairs (OHCA)
Soujanya Giambone	CDER
Georgiann Ienzi	CDER
Theresa Mullin	CDER
Salina Prasad	OHCA
Andrea Tan	CDER
Graham Thompson	CDER
Pujita Vaidya	CDER

Patient Stakeholders

Martin Aimee	International Myeloma Foundation
Terrell Baptiste	Health and Medicine Counsel of Washington / Crohn's and Colitis Foundation of America
Theresa Barnes	Coalition for Pulmonary Fibrosis
Ronald Bartek	Friedreich's Ataxia Research Alliance
Cynthia Bens	Alliance for Aging Research/Accelerate Cure/Treatments for Alzheimer's Disease
Marc Boutin	National Health Council
Dane Christiansen	Health and Medicine Counsel of Washington / Pulmonary Hypertension Association
Mary Cathy Collet	Individual patient stakeholder
Terrie Cowley	The TMJ Association
Diane Dorman	National Organization for Rare Disorders
Lauren Ellis	Patient-Centered Outcomes Research Institute
Lori Frank	Patient-Centered Outcomes Research Institute
Eric Gascho	National Health Council
Richard Gelula	National Alopecia Areata Foundation
Steve Gibson	ALS Association
Carolyn Gondran	Individual patient stakeholder
Niva Haynes	National Psoriasis Foundation
Lori Hoffman	Sarcoma Foundation of America
Campbell Hutton	Juvenile Diabetes Research Foundation
Allison Kassir	King & Spalding / Muscular Dystrophy Association

Jim Kiefert	Us TOO, International
Janet Long	Health and Medicine Counsel of Washington / U.S. Hereditary Angioedema Association
Michael Manganiello	FasterCures
Kimberly McCleary	CFIDS Association of America
Paul Melmeyer	National Organization for Rare Disorders
Teri Robert	Alliance for Headache Disorders Advocacy / American Headache and Migraine Association
Jillian Roberts	National Health Council
Cynthia Rothblum	A-T Children's Project
Jennifer Sheridan	Parkinson's Action Network
Jennifer Singleterry	American Lung Association
Andrew Sperling	National Alliance on Mental Illness
Jamie Tucker	Parkinson's Action Network
Ryan Witt	Society for Participatory Medicine

Discussion Summary

FDA opened the meeting with several updates on the first three Patient-Focused Drug Development meetings held to date. The topics for the three meetings were chronic fatigue syndrome/myalgic encephalomyelitis, human immunodeficiency virus (HIV), and lung cancer. FDA described the structure of each meeting and summarized each meeting's topics and discussion. FDA relayed the feedback received from patients, patient representatives, and FDA staff who attended the meetings.

FDA discussed lessons learned from the past meetings, such as the successes in tailoring the meetings to best fit the needs and interests of the patient community and the FDA review divisions. FDA stressed that the role of patient stakeholders and advocacy groups have been crucial in holding successful meetings. FDA then led a discussion on how to further engage patients and patient stakeholders in advance of each Patient-Focused Drug Development meeting. Several advocates suggested working with advocacy groups and social media in advance of meetings in order to increase patient participation. FDA also solicited ideas from stakeholders for potential topics for future consultation meetings.

Marc Boutin from the National Health Council (NHC) provided a presentation on the NHC's Patient Stratification Tool. The tool provides a method for patient groups to systematically organize issues, stratify their patient population, and identify key topics of focus for examining disease impacts and treatment options for patients. The presentation addressed the NHC's goals behind developing the tool, including helping patient organizations ensure that their communications with FDA regarding benefit-risk are comprehensive.

The final presentation was given by Lori Frank, from the Patient-Centered Outcomes Research Institute (PCORI). Dr. Frank provided an overview of the founding, mission, and core duties of PCORI, and described key accomplishments to date. Dr. Frank also highlighted PCORI's national priorities for research: assessment of prevention, diagnosis, and treatment options; improving healthcare systems; communication and dissemination of research; addressing disparities; and accelerating patient-centered outcomes research and methodological research. The presentation concluded with a link to their website, www.pcori.org, and an invitation for patient and advocate attendees to engage PCORI directly.