

M-CERSI Conference on Patient-Focused Drug Development

Thank you for your interest in the M-CERSI Conference on Patient-Focused Drug Development, a conference by the University of Maryland, with planning members from the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), Food and Drug Administration, academia, and industry.

The M-CERSI Conference on Patient-Focused Drug Development will be held on **Monday, March 9, 2015** at the Hyatt Regency Hotel in Bethesda, MD. The conference will provide a forum for all patient-focused drug development (PFDD) stakeholders to gather for an open dialogue. Patients, caregivers, and patient advocacy groups, as well as regulators from the Food and Drug Administration (FDA); researchers from academia, industry, and other agencies; payers; and other stakeholders will come together to discuss the following topics:

- Definition of PFDD
- Essential components that need to be included in successful PFDD
- Current initiatives, such as those of the FDA, patient advocacy groups, and pharmaceutical companies
- Challenges to achieving PFDD and methods to overcome those challenges
- Recommendations on a plan of action that includes a description of stakeholders' roles to move PFDD forward

Conference deliverables will include a "Patient Engagement Rubric" for PFDD.

For more information, please visit www.pharmacy.umaryland.edu/patient_focused_drug_development.



Registering by mail? Please detach this form and submit it to the address below. All participants can also register online at www.pharmacy.umaryland.edu/patient_focused_drug_development.



Patient-Focused Drug Development

University of Maryland School of Pharmacy
 Attn: Sharese Essien
 20 Penn Street
 HSF II, Room 503B
 Baltimore, MD 21201

Please note that there is no cost to register for this event.

Please provide the following information:

Name _____

Address _____

Phone _____

Email _____

Title and Company/School/Agency _____

Please indicate highest degree obtained:

- High School Master's Degree
 Bachelor's Degree Doctorate

Please indicate which category best describes you:

- Faculty, Staff, Student from the University of Maryland, Baltimore or College Park Campus
 M-CERSI Industrial Consortia Member
 Federal Government Employee
 Other Participant

CONFERENCE AGENDA

March 9, 2015

Time	Activity
8:30-9:00 a.m.	Registration and Continental Breakfast
9:00-9:15 a.m.	<p>Welcome James Polli, PhD Shangraw/Noxell Endowed Chair in Industrial Pharmaceutics Co-Principal Investigator, Center for Excellence in Regulatory Science and Innovation University of Maryland School of Pharmacy</p> <p>Introduction and Objectives Eleanor Perfetto, PhD, MS Professor, Department of Pharmaceutical Health Services Research University of Maryland School of Pharmacy</p> <p>Pat Furlong Founding President and CEO Parent Project Muscular Dystrophy (PPMD)</p>
9:15-11:00 a.m.	<p>FDA Activities in Patient-Focused Drug Development Moderator: Sara Eggers, PhD (FDA)</p> <ul style="list-style-type: none"> • How FDA defines PFDD • Current FDA activities in PFDD • PRO's in PFDD • Future Directions <p>An Overview of FDA's Patient-Focused Drug Development Initiative Theresa Mullin, PhD Director, Office of Strategic Programs Food and Drug Administration</p> <p>The Role of Patients in Health Outcomes Assessment Ashley Slagle, PhD Study Endpoint and Labeling Division Food and Drug Administration</p> <p>TBD Richard Klein Director, Patient Liaison Program Food and Drug Administration</p>
11:00-11:15 a.m.	Break

CONFERENCE AGENDA

March 9, 2015

Time	Activity
11:15-1:00 p.m.	<p>Patient Engagement in Patient-Focused Drug Development Moderator: Pat Furlong (PPMD)</p> <ul style="list-style-type: none">• Patient and Patient Advocate definition of PFDD• View of Patient and Advocacy Roles within PFDD• Current Activities in PFDD• Future Directions <p>Dialogue on Patient Engagement in Drug Development Marc Boutin, JD Chief Executive Officer National Health Council</p> <p>Patient-Focused Drug Development: Exploring from a Patient-First Perspective Sally Okun, RN Vice President, Advocacy, Policy & Patient Safety PatientsLikeMe</p> <p>Tom Murphy PatientsLikeMe Patients Advocate for ALS</p> <p>Patient Organization Action Steps to Engage in New Therapy Development Christine Brown, MS Executive Director National PKU Alliance</p>
1:00-2:00 p.m.	<p>Lunch with Keynote Speaker</p> <p>George Vradenburg Convener The Global CEO Initiative on Alzheimer's Disease</p>

CONFERENCE AGENDA

March 9, 2015

Time	Activity
2:00-3:00 p.m.	<p>How Companies Are Preparing for Patient-Focused Drug Development Moderator: Lisa Egbuina-Davis, MD, MPH, MBA, Co-Founder and Director, ROI Squared, and Senior Advisor, Avalere Health</p> <ul style="list-style-type: none">• Industry Definition of PFDD• Industry Current Activities• Industry View of Its Role• Future Directions <p>Pharma's Role in Getting Patients Ready to Partner in Development Anne Beal MD, MPH Chief Patient Officer Sanofi</p> <p>Patient-centricity: Making Stone Soup Roslyn Schneider, MD, MSc Global Patient Affairs Pfizer</p> <p>Patient Focused Drug Development: The Time is Now Jorie Gatlin, MD VP & Head of Regulatory A&P and Risk Management Novartis</p>
3:00-3:15 p.m.	Break
3:15-4:45 p.m.	<p>Panel Discussion: Future Directions and Opportunities for Collaboration How do we create a model for Patient-Focused Drug Development that will meet the needs of Patients, Drug Regulators, Drug Developers, and Payers?</p> <p>Moderator: Eleanor Perfetto, PhD, MS (UMSOP) Participants: Murray Ross, PhD (Kaiser-Permanente), Robert Epstein, MD, MS (Epstein Health, LLC), Marc Boutin, JD (National Health Council), Kristin Van Goor, PhD (PhRMA), Theresa Mullin, PhD (FDA), Suzanne Schrandt, JD (PCORI).</p>
4:45-5:00 p.m.	<p>Closing Remarks and Adjourn Eleanor Perfetto, PhD, MS and Pat Furlong</p>