



Hilton Washington DC/Rockville Hotel & Executive Meeting Center

The workshop is being co-sponsored by the NCATS Cures Acceleration Network Review Board, NCATS Drug Development Partnership Programs, Food and Drug Administration, and Reagan-Udall Foundation for the FDA.

December 5, 2019

- 7:30 am** Registration
- 8:00 am** Welcoming remarks
Importance of the Issue and Context
Christopher Austin, *Director, NCATS/NIH/HHS*
- 8:15 am** Call to Action
Impact on Patients and the Healthcare System
Shira Strongin, *Founder of Sick Chicks*
- 8:30 am** Meeting Objectives
Structure of Workshop and Break-out Sessions
Heather Stone, *Policy Analyst, FDA/HHS* and Bobbie Ann Mount, *Program Officer, NCATS/NIH/HHS*
- 8:45 am** Background
Regulatory pathways for applications submitted to the FDA
Katherine Schumann, *Deputy Director (Acting), Division of Regulatory Policy, Office of New Drug Policy, OND/CDER/FDA*
- Panel discussion
Moderator: Matthew Fedowitz, Shareholder, Buchanan Ingersoll & Rooney PC
- Kurt Karst, Director, Hyman, Phelps, and McNamara
 - James Czaban, Chair, FDA Practice Group, DLA Piper Global Law Firm
- 9:45 am** Pre-clinical (not used off-label)
Hypothesis-Driven Research
Moderator: Christine Colvis, Drug Development Partnership Programs Director, NCATS/NIH/HHS
- Don Lo, Therapeutic Development Branch Director, NCATS/NIH/HHS
 - Scott Weir, Director, Institute for Advancing Medical Innovation, University of Kansas
- 10:20 am** Break
- 10:45 am** Pre-clinical to Clinical Translation (some human data is available)
Moderator: Noel Southall, Informatics Leader, NCATS/NIH/HHS
- Robert Anderson, Head of Regulatory Affairs, Emmes Corporation
 - Tudor Oprea, Chief, Translational Informatics Division, UNM School of Medicine
 - David Cavalla, Founder, Numedicus
- 11:45 am** Summary: Understanding the Overarching Problems and Opportunities
- Harry Selker, Executive Director, Tufts Medical Center
 - Frank Weichold, Director, Science and Innovation, FDA/HHS

- Vikas Sukhatme, co-Founder GlobalCures and Director and co-Founder of The Morningside Center for Innovative and Affordable Medicine, Emory University

12:15 pm Lunch

1:30 pm Chasing My Cure
David Fajgenbaum, *Executive Director, Castleman Disease Collaborative Network*

1:50 pm The Clinical Experience Spectrum
Moderator: Kenneth Gersing, Informatics Director, NCATS/NIH/HHS

- Jacqueline Corrigan-Curay, Director, CDER Office of Medical Policy, FDA/HHS
- Clare Thibodeaux, Director of Scientific Affairs, Cures Within Reach
- Patroula Smpokou, Clinical Team Leader, Rare/Genetic Diseases, FDA/HHS
- Joseph Ross, Professor of Medicine and Public Health, Yale University
- Matt Might, Director, Hugh Paul Precision Medicine Initiative

3:10 pm Launch CURE app

3:20 pm Break

3:40 pm The Economics of Off-Patent Repurposing
Moderator: Andrew Lo, Director, Laboratory for Financial Engineering, MIT

- Choe Sung Hee, Director, Faster Cures (Milken Institute)
- Barbara Handelin, CEO, Audacity Therapeutics

4:20 pm Use of payment data for identifying repurposing candidates

- Shari Ling, Deputy Chief Medical Officer, CMS/HHS
- Ed Pezalla, Subject Matter Expert, Aetna
- Fran Cunningham, Director, Center for Medication Safety, Department of Veterans Affairs

5:00 pm Closing
G. Lynn Marks, *Retired Senior Vice President of Research & Development, GlaxoSmithKline*

December 6, 2019

- 7:30 am** Registration
- 8:30 am** Breakout Process Overview & Logistics
*Samantha Jonson, Special Assistant to the Director, NCATS/NIH/HHS and Jamie Zigterman,
Scientific Program Analyst, NCATS/NIH/HHS*
Breakout Group Locations
Breakout Group 1 = Regency Room
Breakout Group 2 = Roosevelt Room
Breakout Group 3 = Madison Room
Breakout Group 4 = Jefferson Room
Breakout Group 5 = Eisenhower Room
- 8:45 am** 4 x 4 Panel
- 9:10 am** Breakout Session 1
Prioritize problems
- 10:15 am** Break
- 10:45 am** Breakout Session 2
Identify solutions
- 11:45 am** Individual Breakout Recaps
- 12:15 pm** Lunch
- 1:30 pm** Breakout Session 3
Discuss collaborative solutions
- 2:30 pm** Create Breakout Reports
- 3:00 pm** Break
- 3:30 pm** Breakout Reports to Main Group
- 4:30 pm** Closing Remarks