Duke | MARGOLIS CENTER *for* Health Policy

# Public Workshop: Evaluating Inclusion and Exclusion Criteria in Clinical Trials

The National Press Club • Washington, DC
April 16, 2018

**8:15 a.m.** **Welcome and Introductions**
*Mark McClellan, Duke-Margolis Center for Health Policy*

**8:20 a.m.** **FDA Opening Remarks**
- *Robert Temple, U.S. Food and Drug Administration*

**8:30 a.m.** **Keynote: Rationale for Inclusion and Exclusion Criteria**
- *Deidra Crews, Johns Hopkins University*

**8:45 a.m.** **Session I: Historical Application of Inclusion and Exclusion Criteria and Recent Federal Activities**
*Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*

**Presentation: FDA Analysis of Inclusion and Exclusion Criteria in Regulatory Trials**
- *Kaveeta Vasisht, U.S. Food and Drug Administration*

**Presentation: CMS Perspectives on Evidence for Coverage**
- *Kate Goodrich, Centers for Medicare & Medicaid Services*

**Presentation: Highlights from the June 2017 NIH Workshop, "Inclusion Across the Lifespan"**
- *Marie Bernard, National Institutes of Health*

**Presentation: Report from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)**
- *Catherine Spong, National Institutes of Health*

**10:00 a.m.** **Session IIa: What Leads to Underrepresentation?**
*Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*

**Presentation: Inclusion of Children, Infants and Adolescents**
- *Robert "Skip" Nelson, Johnson & Johnson*

**Panelists:**
- *Kathleen Neville, Arkansas Children's Hospital*
- *Donna Cryer, Global Liver Institute*
- *Katy Hayward, ViiV*

**Panel Discussion**

**10:45 a.m.** **Break**

**11:00 a.m.** **Session IIb: What Leads to Underrepresentation?**
*Moderator: Gregory Daniel, Duke-Margolis Center for Health Policy*

**Presentation: Inclusion of Older Adults and Patients with Multiple Chronic Conditions**

- *Anand Parekh, Bipartisan Policy Center*

**Panelists:**

- *Mark Supiano, University of Utah*
- *Kumar Budur, AbbVie*
- *Meryl Comer, Geoffrey Beene Foundation Alzheimer's Initiative*
- *Dawn Corbett, National Institutes of Health*

**Panel Discussion**

**11:45 a.m.** **Lunch**

**12:45 p.m.** **Session III: Morning Synthesis Discussion**
*Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*

**Panelists:**

- *Newell McElwee, Boehringer Ingelheim*
- *Rebecca Dresser, Washington University in St. Louis*
- *C. Daniel Mullins, University of Maryland*
- *Mary Woolley, Research!America*
- *Mary Thanh Hai, U.S. Food and Drug Administration*
- *Doug Peddicord, ACRO*

**Panel Discussion**

**2:00 p.m.** **Session IV: Inclusion of Patients with Organ Dysfunction in Phase III Trials**
*Moderator: Issam Zineh, U.S. Food and Drug Administration*

**Presentation: Utility of PK/PD Approaches**

- *Raj Madabushi, U.S. Food and Drug Administration*

**Panelists:**

- *Thomas Nolin, University of Pittsburgh*
- *Brian Corrigan, Pfizer*
- *Yaning Wang, U.S. Food and Drug Administration*

**Panel Discussion**

**2:45 p.m.** **Break**

**3:00 p.m.** **Session V: Innovative Methods and Designs**
*Moderator: Gregory Daniel, Duke-Margolis Center for Health Policy*

**Presentation:**

- *Rajeshwari Sridhara, U.S. Food and Drug Administration*

**Panelists:**

- *Craig Lipset, Pfizer*
- *Richard Simon, R Simon Consulting*
- *Scott Berry, Berry Consultants*
- *Jim Smith, U.S. Food and Drug Administration*

**Panel Discussion**

**3:50 p.m.** **Session VI: Utilizing Data from Expanded Access**
*Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*

**Presentation:**

- *Richard Moscicki, Pharmaceutical Research and Manufacturers of America*

**Panelists:**

- *Tammy Phinney, Biogen*
- *Joshua Sharfstein, Johns Hopkins University*
- *Pat Furlong, Parent Project Muscular Dystrophy*

**Panel Discussion**

**4:35 p.m.** **Closing Remarks**
*Mark McClellan, Duke-Margolis Center for Health Policy*

Funding for this workshop was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.