Enhancing the Collection, Analysis and Availability of Demographic Subgroup Data

Public Meeting: February 29, 2016

9:00 – 9:10 am **Welcome**
Barbara Buch, MD, Center for Biologics Evaluation and Research (CBER), FDA Safety and Innovation Act (FDASIA) Section 907 Steering Committee Chair

9:10 – 9:20 am **Opening Remarks** *"The Shifting Paradigm and FDA's Current Thinking"*
Robert Califf, MD, MACC, Commissioner of Food and Drugs

9:20 – 10:30 am **Progress in Data Quality, Participation, and Transparency at FDA**
Moderator: Barbara Buch, MD, CBER
Center for Biologics Evaluation and Research (CBER)
Barbara Buch, MD, CBER
Center for Devices and Radiological Health (CDRH)
Kathryn (Katie) O'Callaghan, Acting Senior Advisor, Strategic Partnerships, CDRH
Center for Drug Evaluation and Research (CDER)
John Whyte, MD, MPH, Director of Professional Affairs and Stakeholder Engagement (PASE), CDER
Office of Women's Health (OWH)
Marsha Henderson, MCRP, Assistant Commissioner for Women's Health
Office of Minority Health (OMH)
Jonca Bull, MD, Assistant Commissioner for Minority Health

10:30 – 10:45 am **Kick-Off** *"Ancestry NOT Race or Ethnicity, Moving Towards Precision Medicine"*
Charles Rotimi, PhD, Chief and Senior Investigator, Metabolic, Cardiovascular and Inflammatory Disease Genomics Branch
Director, Center for Research on Genomics and Global Health, National Human Genome Research Institute, National Institutes of Health (NIH)

10:45-10:55 am **Break**

10:55 – 12:10 pm **Panel 1: Challenges and Solutions**
Moderator: Kathryn (Katie) O'Callaghan, CDRH
Panelists:
Government Perspectives
- Cara James, PhD, Director, Office of Minority Health at the Centers for Medicare and Medicaid Services (CMS)
- Janine Clayton, MD, Director, Office of Research on Women's Health, NIH

*Members of the public who have signed up to speak

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10:55 – 12:10 pm **Continued**

Public-Private Partnership Perspective

- Jamie Roberts, MA, CCRP, MPH[c] Senior Clinical Project Manager Clinical Trials Transformation Initiative

Community Research Perspective

- Carol Horowitz, MD, MPH, Associate Professor Population Health Science and Policy, Associate Professor Medicine, General Internal Medicine, Mount Sinai

Industry Perspective

- Kara Haas, MD, MPH, FACS, RAC, Director, Global Regulatory Affairs Policy and Intelligence, Medical Devices, Johnson & Johnson, AdvaMed

12:10 – 12:40 pm **Public Session***

12:40 – 1:40 pm **Lunch (on your own)**

1:40 – 2:55 pm **Panel 2: The Future**

Moderator: John Whyte, MD, MPH, Director of PASE, CDER

Panelists:

- Allison Kalloo, Patient Perspective, Founder, #iParticipate
- Robert Temple, MD, Deputy Center Director for Clinical Science, CDER
- Lisa LaVange, PhD, Director, Office of Biostatistics, Office of Transitional Sciences, CDER
- Rita Redberg, MD, MSc, Professor and Director, Women's Cardiovascular Services, University of California, San Francisco
  Advisor, Women's Heart Alliance
- Jocelyn Ulrich, MPH, Assistant Vice President, Science & Regulatory Advocacy, PhRMA

2:55 – 3:05 pm **Break**

3:05 – 3:35 pm **Public Session***

3:35 – 3:45 pm **Closing Remarks and Wrap Up**

Barbara Buch, MD, FDA FDASIA Section 907 Steering Committee Chair

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