Session 1: Fundamental Concepts and Regulatory Context of PPI to Support Medical Product Development and Evaluation

Chair: Anindita Saha
Overcoming Barriers in Conducting PPI Studies

WHAT are regulatory PPI studies?

MDIC PPI Framework

FDA PPI Guidance

Demonstrative Case Examples

WHY do a PPI study?

HOW/WHEN to do a PPI study?

WHERE do we go from here?

Adoption

Understanding

Awareness
Session 1: Objectives

Fundamental Concepts and Regulatory Context of PPI to Support Medical Product Development and Evaluation

• Provide framework of how PPI can be used in regulatory decision making
• What are the pros and cons of doing PPI studies from the perspective of FDA, patients, industry and academics
Session 1: Speakers

• FDA Perspective on Patient Preference Information in Medical Product Evaluation
  – Anindita Saha (FDA/CDRH) and Million A. Tegenge (FDA/CBER)
• Industry Perspective on PPI to Support Medical Product Development and Evaluation
  – Bennett Levitan (Janssen R&D)
• Academic Perspective on Patient Preference Research
  – John F. P. Bridges (Johns Hopkins University)
• Patient Perspective on Landscape
  – K. Kimberly McCleary (FasterCures)
• Discussion and Q&A