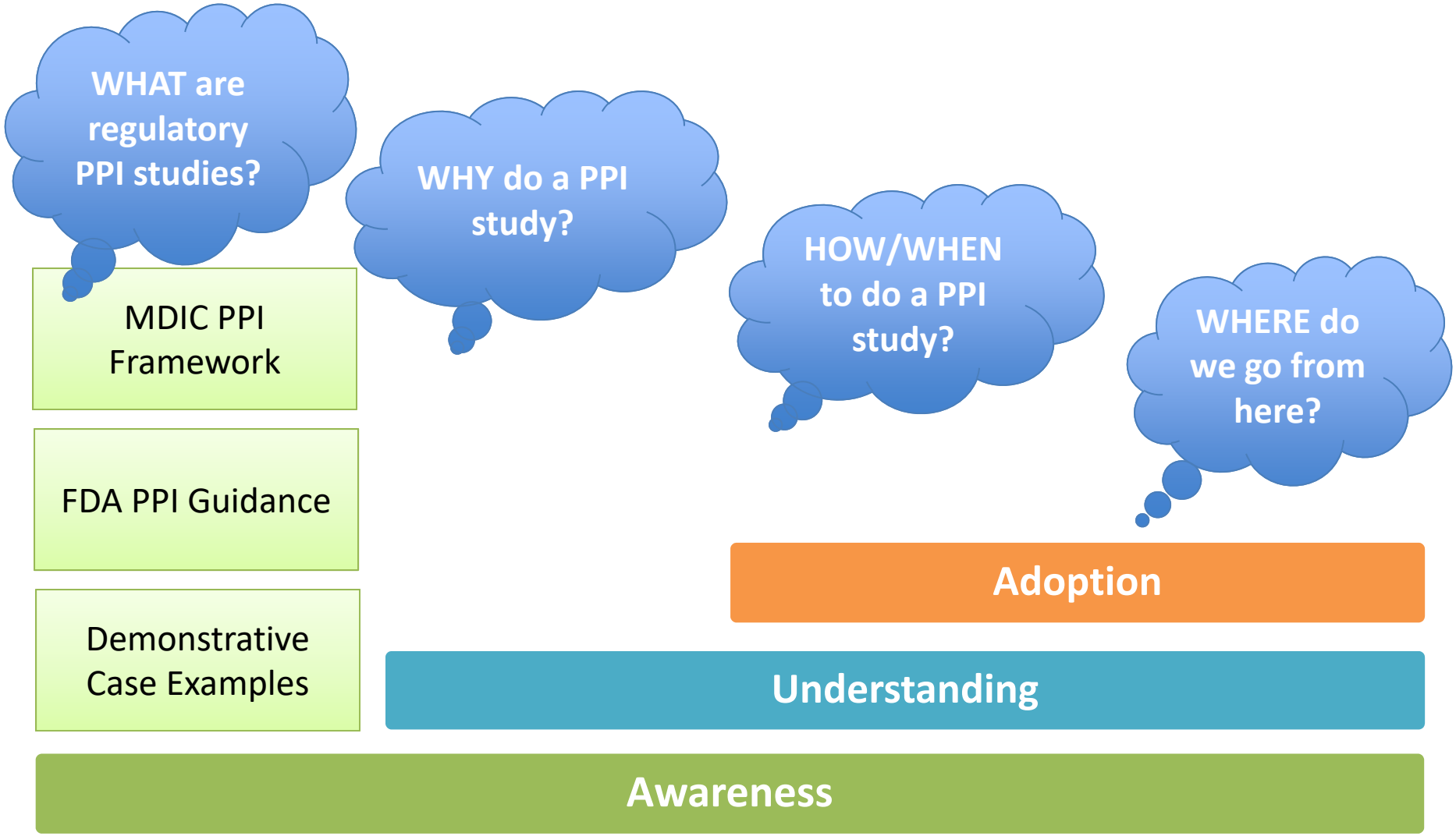
U.S. FOOD & DRUG ADMINISTRATION

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



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