Advancing the Science of Patient Input

NASEM Workshop
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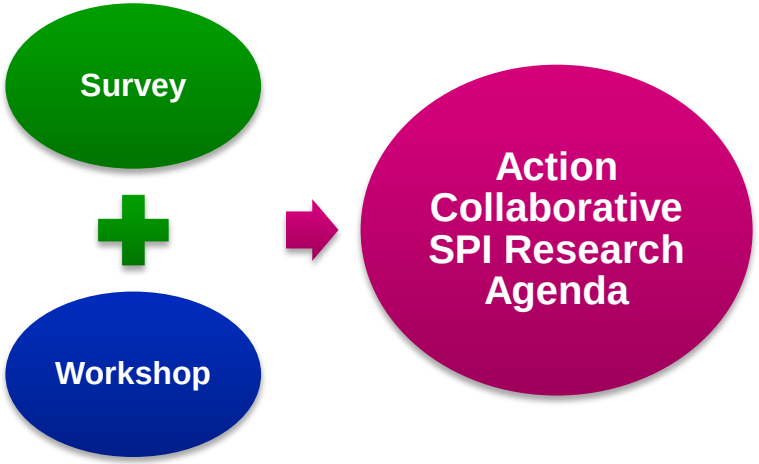
Welcome!

Background and Goals

- Part of an overarching Action Collaborative working group on the science of patient input
  - Launched in early 2017
  - In association with the Forum on Drug Discovery, Development, and Translation
- Action Collaborative looked at work ongoing in this field
  - Agreed to an in-depth assessment of gaps in knowledge and other barriers re: science of patient input
  - Want to build a research agenda for addressing them
- Collaborative's work phases:
  - Phase 1: Surveyed experts and thought leaders to inform the scope of this workshop
  - Phase 2: Planned and convened this workshop to inform Phase 3…
  - Phase 3: Developing an SPI research agenda



What we will address today

How your expertise can help

Session 1

Understanding Patient Experience with Disease or Medical Condition

Session 2

Patient Perspectives and Preferences on Benefit–Risk

Session 3

Patient Input on Clinical Trial Development and Continuous Improvement

- All medical products (drugs, biologics, devices)
- All methodologies (mixed, qualitative, and quantitative, existing and new)
- New data sources (e.g., social media, natural-language processing)

What is out of scope

And how to use it as a springboard for today

Out of Scope

- Disease-specific / fit-for-purpose applications of the science
- Development / validation of PROs
- Applications specific to regulatory decision-making, healthcare delivery, post-market decision making

Where We'll Focus

- What we can learn from disease-specific examples that applies more broadly
- What PROs can teach about developing and validating other methods
- Early and Clinical R&D applications (which will inevitably form the basis for later decision making)

Moving us forward

Where are the gaps and barriers?