Day 1 Wrap Up

FDA-CERSI Patient Preference Workshop
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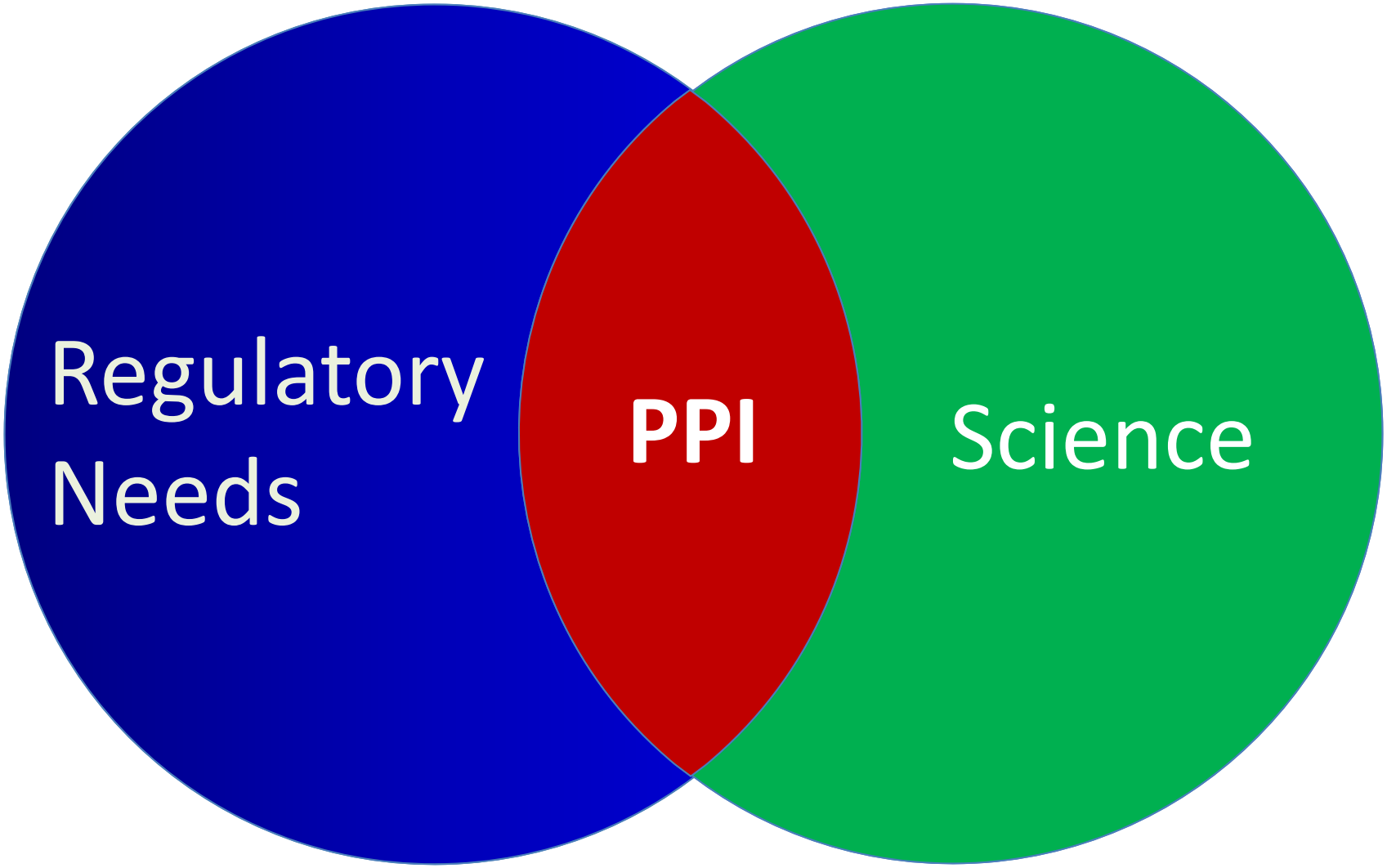
Patients are at the Heart of What We Do

Framework of PPI Uses in Medical Product Development

Development	Clinical Trial Design	Pre-Market Benefit-Risk Assessment	Post-Market
1. Identify unmet medical need 2. Understand what matters most to patients about their disease or treatment	1. Inform endpoint selection 2. Inform performance goal	1. Analysis of condition 2. Current treatment options 3. Patient perspective on benefit-risk tradeoffs	1. Inform interpretation of new data affecting benefit-risk assessment 2. Communicate benefit-risk information to patients

PPI: Science Meets Regulatory Needs



Relevance to diverse stakeholders

Patient

Development of patient-centric endpoints for clinical trials

Incorporation of the patient voice

Provider

Patient-oriented education to empower and help patients become a partner in their treatment decisions

Pharma

Design clinical trials that are meaningful to the lung cancer patient, leading to increased patient recruitment

Regulatory

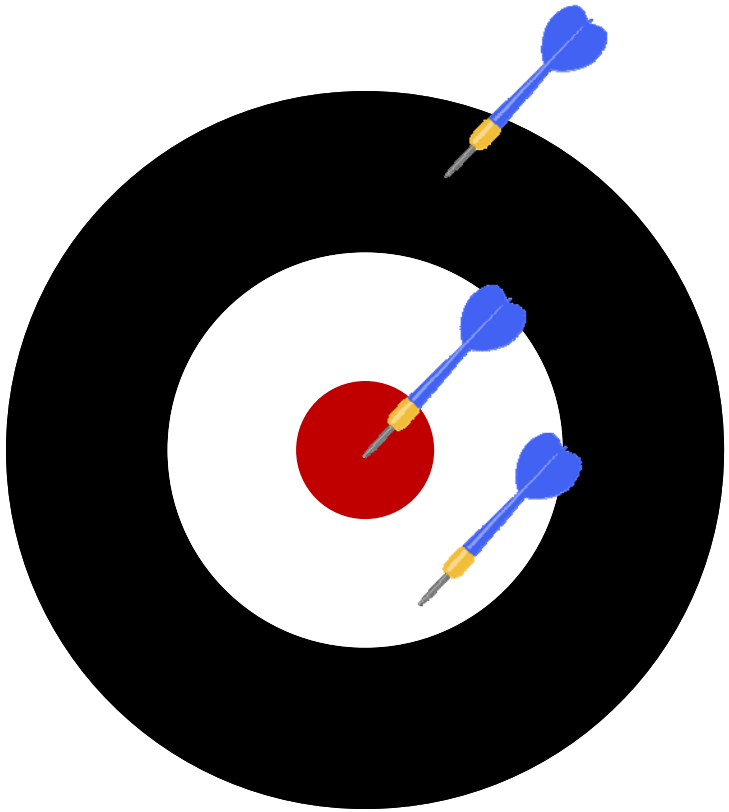
Lay informational groundwork for patient-centered regulatory process

Preference Sensitive Areas

What makes a topic preference sensitive?

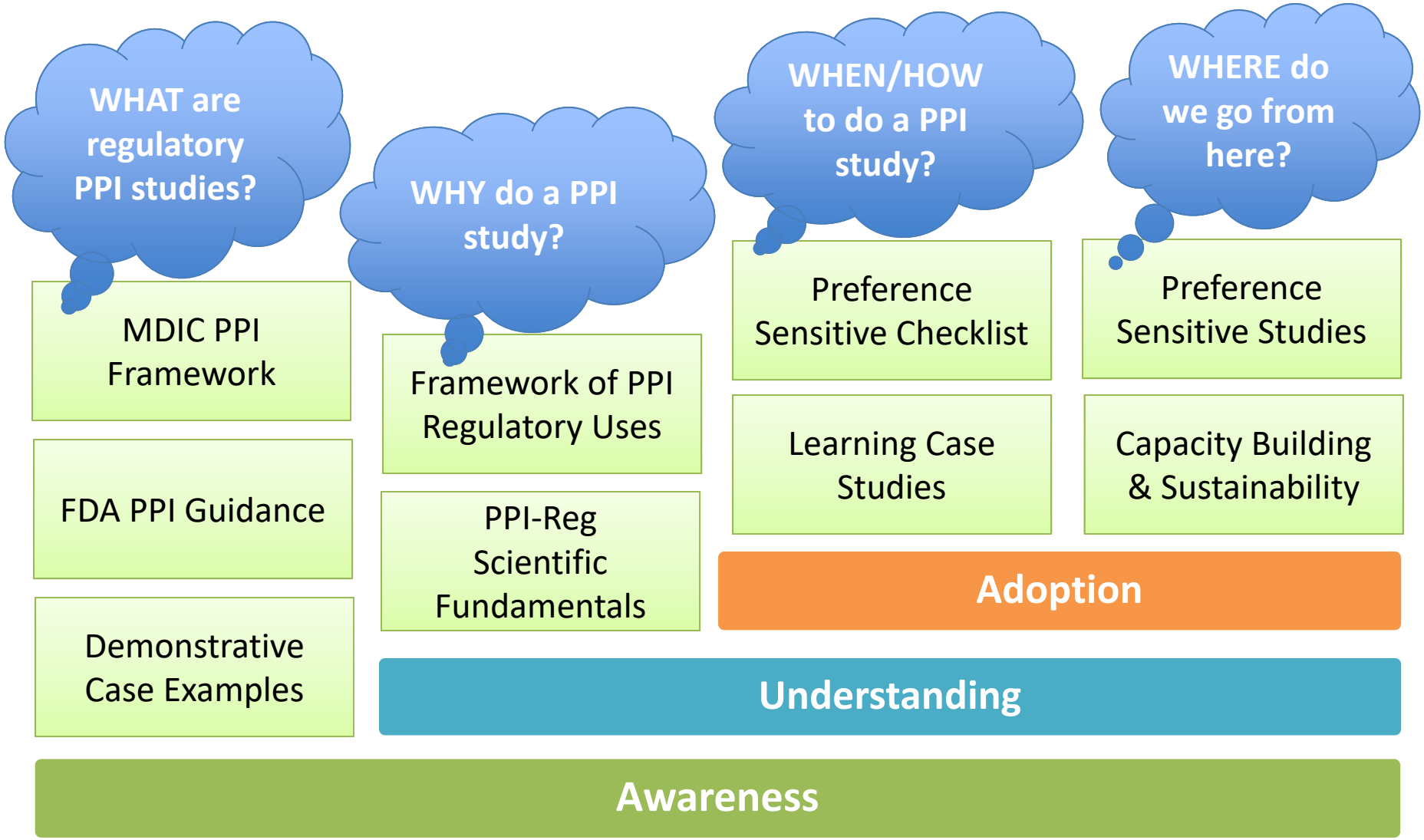
For which conditions might decision-making be enhanced by data from a patient preference study?

When does a patient preference study add value?



Capacity Building

Toolkit for Appropriate Adoption of PPI for Regulatory Uses



"The FDA's work requires us to establish objective, consistent criteria on which we base our decisions. But ultimately, the criteria we use to judge benefit and risk turn on the parameters that matter to patients.

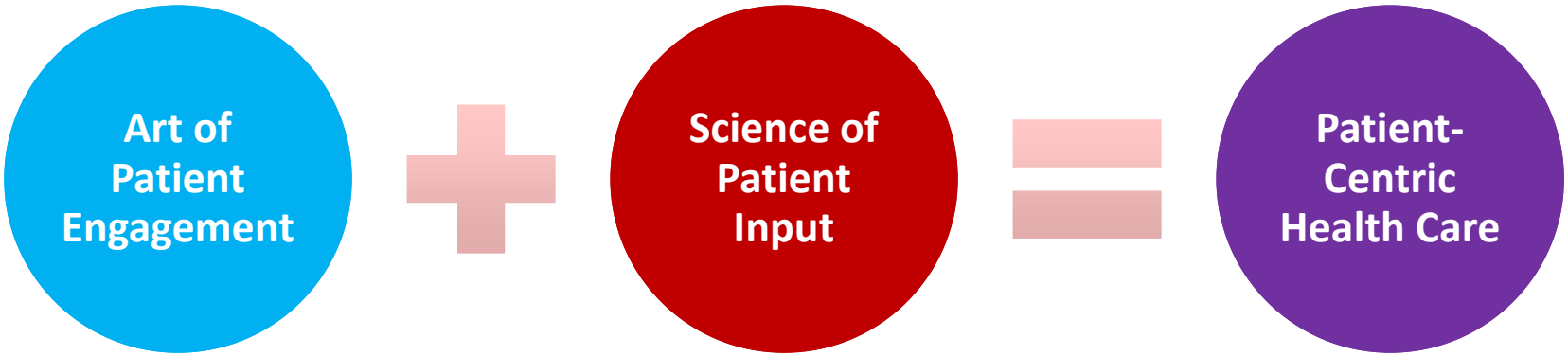
"Involving the end-user – the patient – in identifying health priorities and outcomes desired from health interventions is critically important.

"The bottom line is this: When assessing whether valid scientific evidence shows that a device's probable benefit outweighs its likely risks, the FDA can also consider rigorous, systematically gathered patient preference information as a part of the totality of the evidence from clinical and nonclinical testing. "

- ***FDA Commissioner Scott Gottlieb****, Oct 11, 2017*

Shared Goal

Improve patient health by better understanding patient needs, experiences and preferences



Thank You

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