

# Public Meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization Panel 2 – Patient Perspectives

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# Other NHC Members Include:

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- Providers
- Researchers
- Family Caregivers
- Biopharmaceutical
- Device
- Diagnostic
- Generic Drug
- Payers



# PDUFA VI

- Enhanced Benefit-Risk Framework
- **Patient-Engagement Guidances**
- Enhancing RWE
- Biomarkers and Surrogate Endpoints
- Combination of Product Review
- Rare Disease Drug Development
- FDA Hiring and Retention

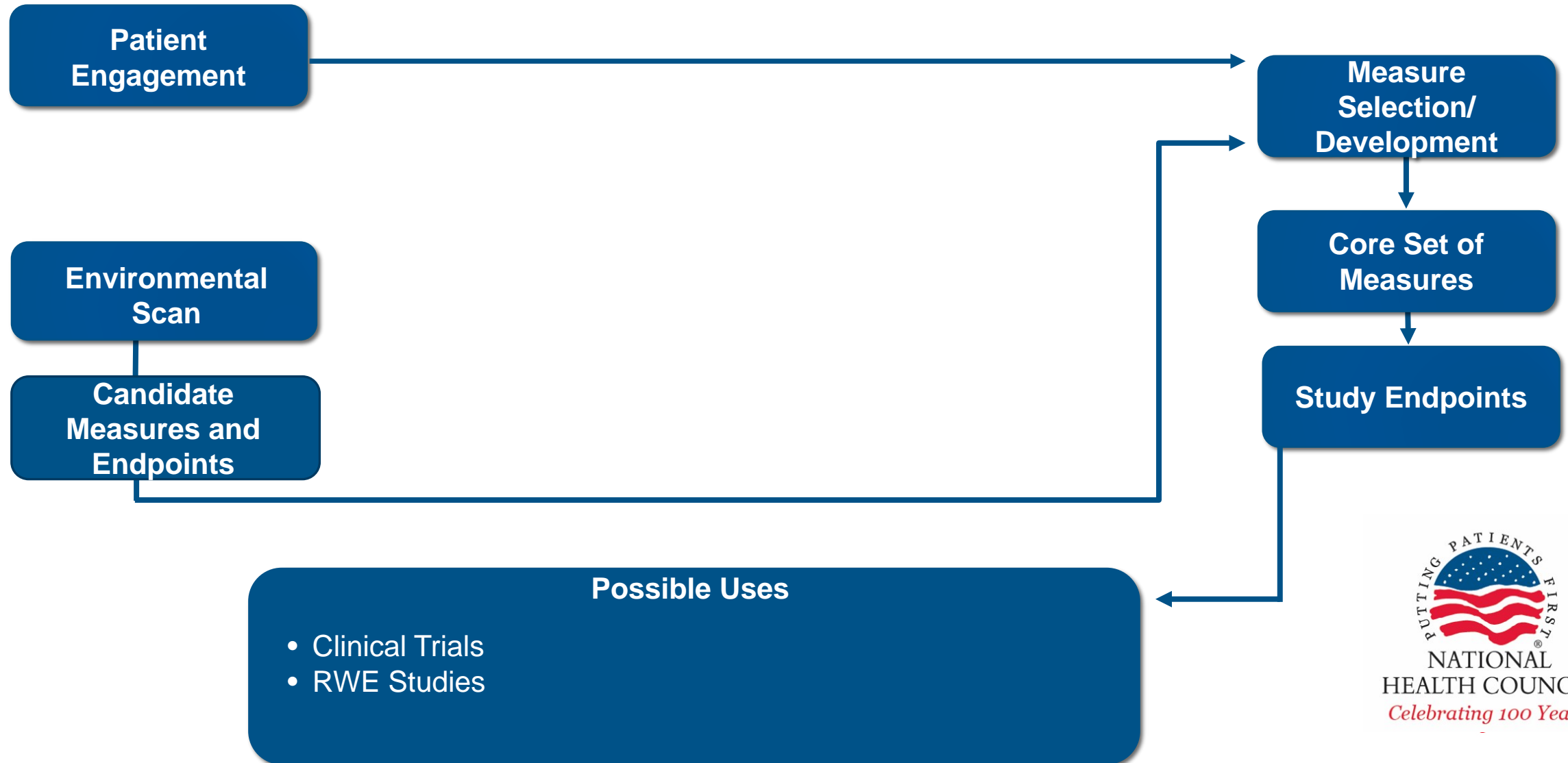


# PDUFA VII

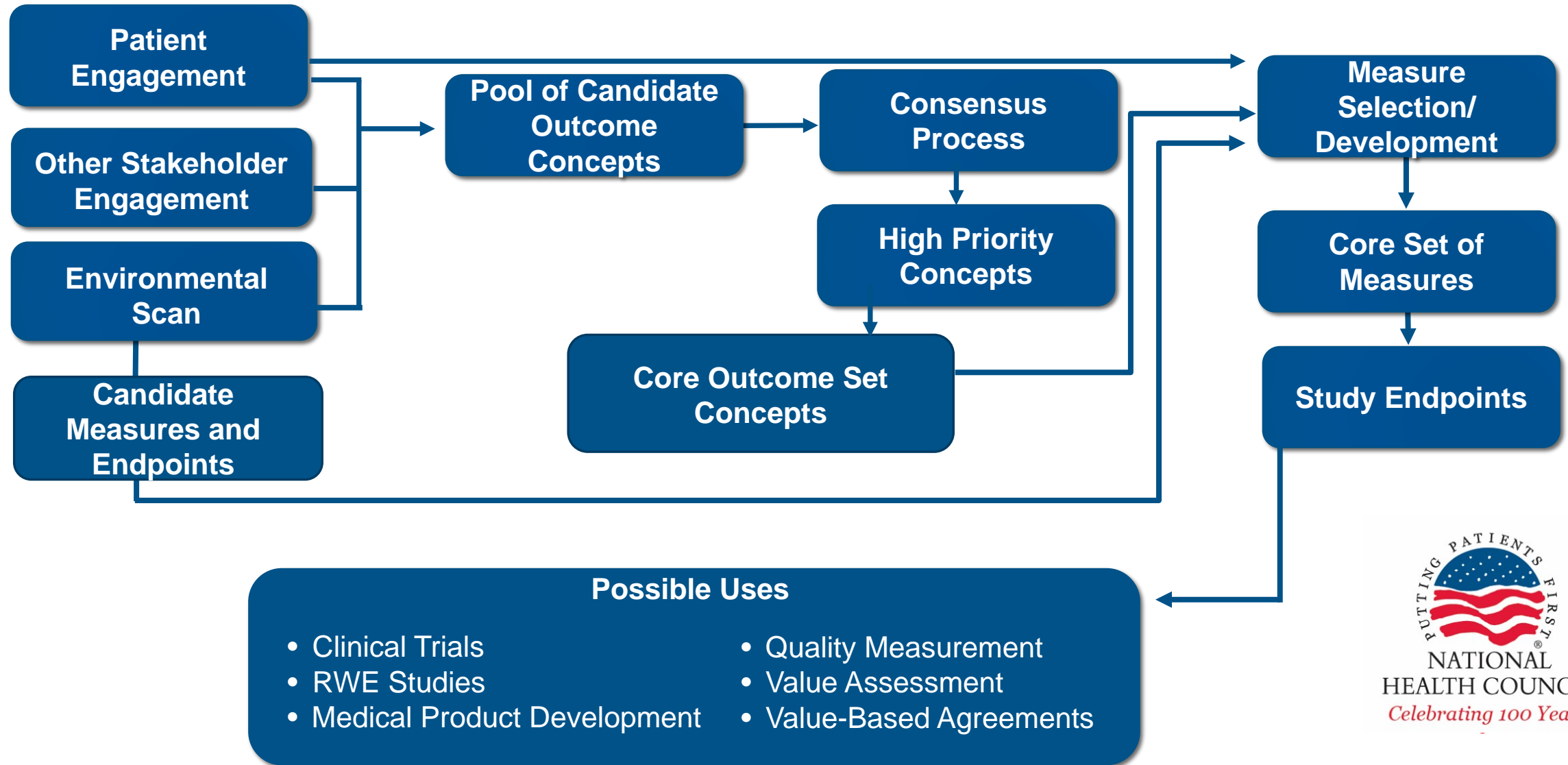
- Digital Clinical Trials
- RWE
- Knowledge Management System
- Increasing FDA Staff Capacity
- **Patient-Centered Core Outcome Sets**



# Core Outcome Sets



# Patient-Centered Core Outcome Sets



# What is the Goal? What is Needed?

Goals	Needs
<ul style="list-style-type: none"><li>• <b>Patient centricity as the core</b></li><li>• <b>COSs serving as a foundation for a wide range of health care activities</b><ul style="list-style-type: none"><li>• Research</li><li>• Clinical trials/drug development</li><li>• Care provision</li><li>• Quality measurement</li><li>• Real-world evidence</li><li>• Policy</li><li>• Value-based payment/contracts/agreements</li><li>• Other</li></ul></li></ul>	<ul style="list-style-type: none"><li>• <b>Get on the same page:</b> Standardize terms, methods, approaches (but not overly prescriptive)</li><li>• <b>Collaboration:</b> Multi-stakeholder, multi-disciplinary</li><li>• <b>Flexibility:</b> Allow and support innovation and advancement in measurement and methods</li><li>• <b>Infrastructure:</b> Convene stakeholders to determine infrastructure needs</li></ul>





# Thank you!

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