NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)

STAKEHOLDER ENGAGEMENT IN ePCTs FOR PEOPLE LIVING WITH DEMENTIA

Ellen Tambor, MA

On Behalf of the Stakeholder Engagement Team

Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **chat box** and send to everyone
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.
- Visit impactcollaboratory.org
- Follow us on Twitter: **@IMPACTcollab1**

IMPACT Stakeholder Engagement Team (SET)

Leader

- Gary Epstein-Lubow, MD

Associate Team Leader

- Katie Maslow, MSW

Executive Committee Members

- Louise Phillips, MD
- Ellen Tambor, MA

Administrative Core Liaisons

- Susan Mitchell, MD, MPH
- Jill Harrison, PhD

Core Support

- Laurie Herndon, MSN

Agenda

- Definitions and Rationale for Stakeholder Engagement in Research
- Importance of Engagement in ePCTs
- Special Considerations for Engagement in ePCTs for AD/ADRD
- Role of Stakeholder Engagement in the IMPACT Collaboratory

Stakeholder Engagement

Definitions*

Stakeholder: Responsible for or affected by health- and healthcare-related decisions

Engagement: Bi-directional relationship between the stakeholder and researcher

Who to Engage

Patients

- Includes advocates, family members, and family caregivers

Clinicians

- Clinical experts, clinician leaders, front-line clinicians (physicians, nurses and other direct care staff)

Other Stakeholders

- Administrators, payors, research funders, etc.

Concannon TW, Meissner P, Grunbaum JA, et al. A new taxonomy for stakeholder engagement in patient-centered outcomes research. J Gen Intern Med 2012;27:985–991.

Rationale for Engagement

Moral/Ethical Arguments

- Right of citizens to have a voice in the use of public funds
- Right of individuals to be involved in shaping research that pertains to them

"Nothing about us, without us"

Pragmatic Arguments

- Improving the quality, relevance, and usefulness of clinical research
- Increasing transparency, credibility, and trust in the clinical research enterprise

Importance of Engagement in ePCTs

- **Pragmatic Clinical Trial (PCT)**
  - "Designed for the primary purpose of **informing decision-makers** regarding the comparative balance of benefits, burdens and risks of a biomedical or behavioral health intervention at the individual or population level"*

PCTs must answer questions that are important to patients, clinicians, and other healthcare decision makers

- **Embedded PCT (ePCT)**
  - Pragmatic randomized clinical trials **embedded in routine health care**

ePCTs must be feasible to conduct in complex healthcare delivery settings where patient care is the top priority

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** Califf RM and Sugarman J. Exploring the ethical and regulatory issues in pragmatic clinical trials. Clin Trials. 2015;12(5):436-41.*

Engagement Throughout the ePCT Life Cycle

PLANNING the study

- Choosing a research question
- Designing the intervention
- Selecting outcome measures
- Determining inclusion/exclusion criteria
- Determining study requirements
- Designing study protocol to minimize burden to patients and clinicians
- Promoting/supporting the study
- Drafting/reviewing study materials
- Providing resources

CONDUCTING the study

- Developing recruitment strategies
- Promoting and assessing compliance with study requirements
- Serving as study champions
- Assisting with retention strategies
- Solving problems/removing barriers
- Considering privacy and data sharing issues
- Advising on analyses
- Interpreting study results

DISSEMINATING the results

- Determining key messages for different stakeholder groups
- Identifying avenues for dissemination
- Assisting with development of manuscripts and other dissemination materials
- Sharing findings via professional networks and social media
- Supporting implementation or de-implementation of intervention
- Considering changes to policies and guidelines

Fraser J, Moloney R, Tambor E, Tuzzio L. Building Partnerships to Ensure a Successful Trial: Stakeholder Engagement Throughout the PCT Life Cycle. In: Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials. Bethesda, MD: NIH Health Care Systems Research Collaboratory. Available at: https://rethinkingclinicaltrials.org/chapters/engaging-stakeholders/stakeholder-engagement-throughout-the-pct-life-cycle/.

Stakeholder Engagement in ePCTs for AD/ADRD

Special Considerations for Engaging:

- People living with dementia (PLWD) and their family caregivers
- Healthcare system stakeholders

Special Considerations for Engaging PLWD

Matching Capacity
- Cognitive symptoms
- Strengths and preferences
- Familiarity with research
- Symptom progression

Accommodating Heterogeneity
- Range in disease severity
- Race/ethnicity
- Socioeconomic status
- Geography

Engagement Approaches
- Flexibility
- Preparation and support
- Meeting logistics
- Timelines

Engaging Caregivers
- Caregiver burden
- Caregivers as proxy respondents
- Caregivers as independent stakeholders

Special Considerations for Engaging Healthcare Stakeholders

Diverse Care Settings

- Hospital
- Nursing Home
- Adult Day Center
- In-Home Care

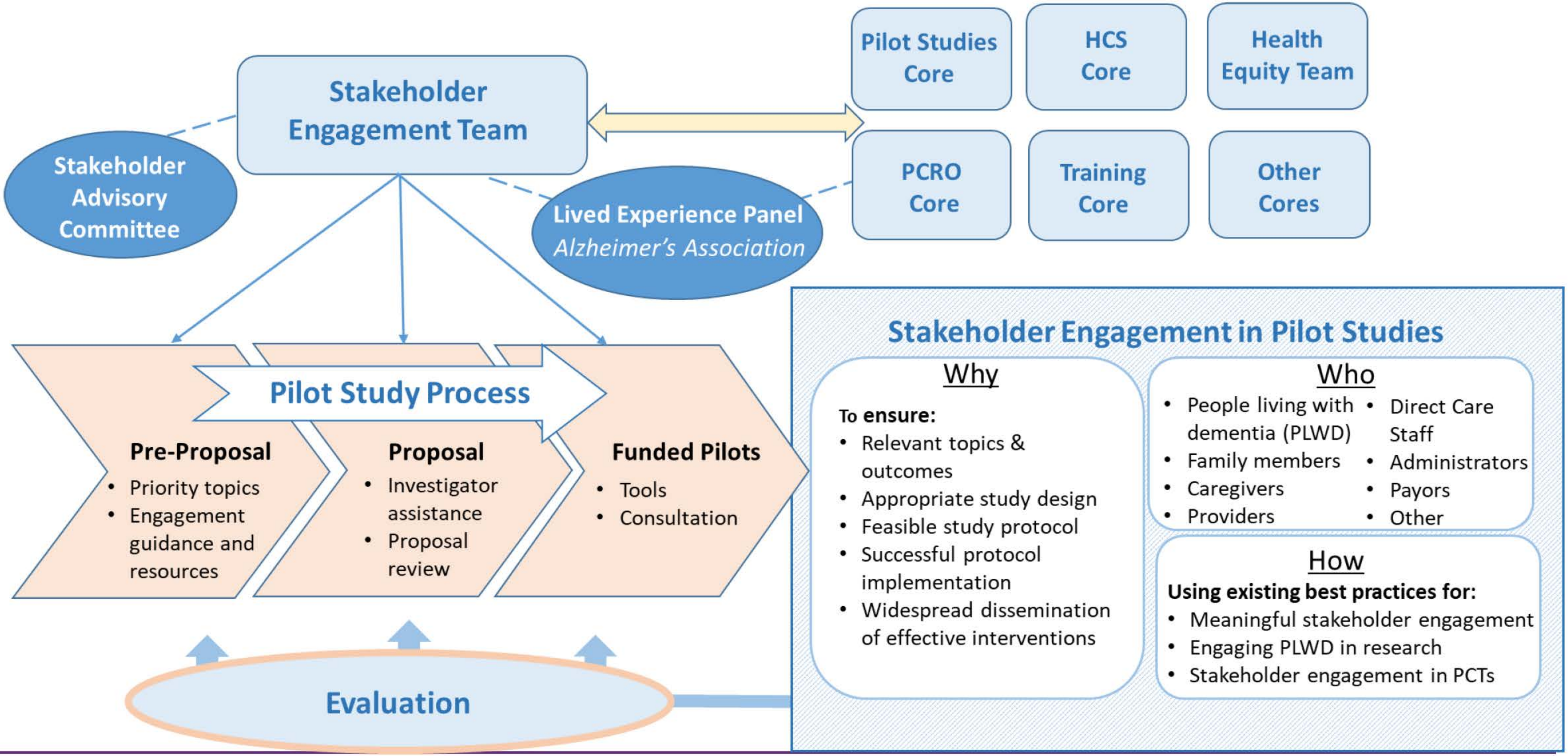
Diverse Professional Roles

- Physician
- Nurse
- Medical/Nursing Assistant
- Physical Therapist
- Occupational Therapist

Clinician and Other Care Provider Burden

- Complex care needs of PLWD
- Shortage of dementia-capable work force
- Staff turnover
- Nursing home crises (COVID-19)

Stakeholder Engagement in the IMPACT Collaboratory



Stakeholder Engagement Team

Stakeholder Advisory Committee

Lived Experience Panel
Alzheimer's Association

Pilot Studies Core

HCS Core

Health Equity Team

PCRO Core

Training Core

Other Cores

Pilot Study Process

Pre-Proposal
- Priority topics
- Engagement guidance and resources

Proposal
- Investigator assistance
- Proposal review

Funded Pilots
- Tools
- Consultation

Evaluation

Stakeholder Engagement in Pilot Studies

Why

To ensure:
- Relevant topics & outcomes
- Appropriate study design
- Feasible study protocol
- Successful protocol implementation
- Widespread dissemination of effective interventions

Who

- People living with dementia (PLWD)
- Family members
- Caregivers
- Providers
- Direct Care Staff
- Administrators
- Payors
- Other

How

Using existing best practices for:
- Meaningful stakeholder engagement
- Engaging PLWD in research
- Stakeholder engagement in PCTs

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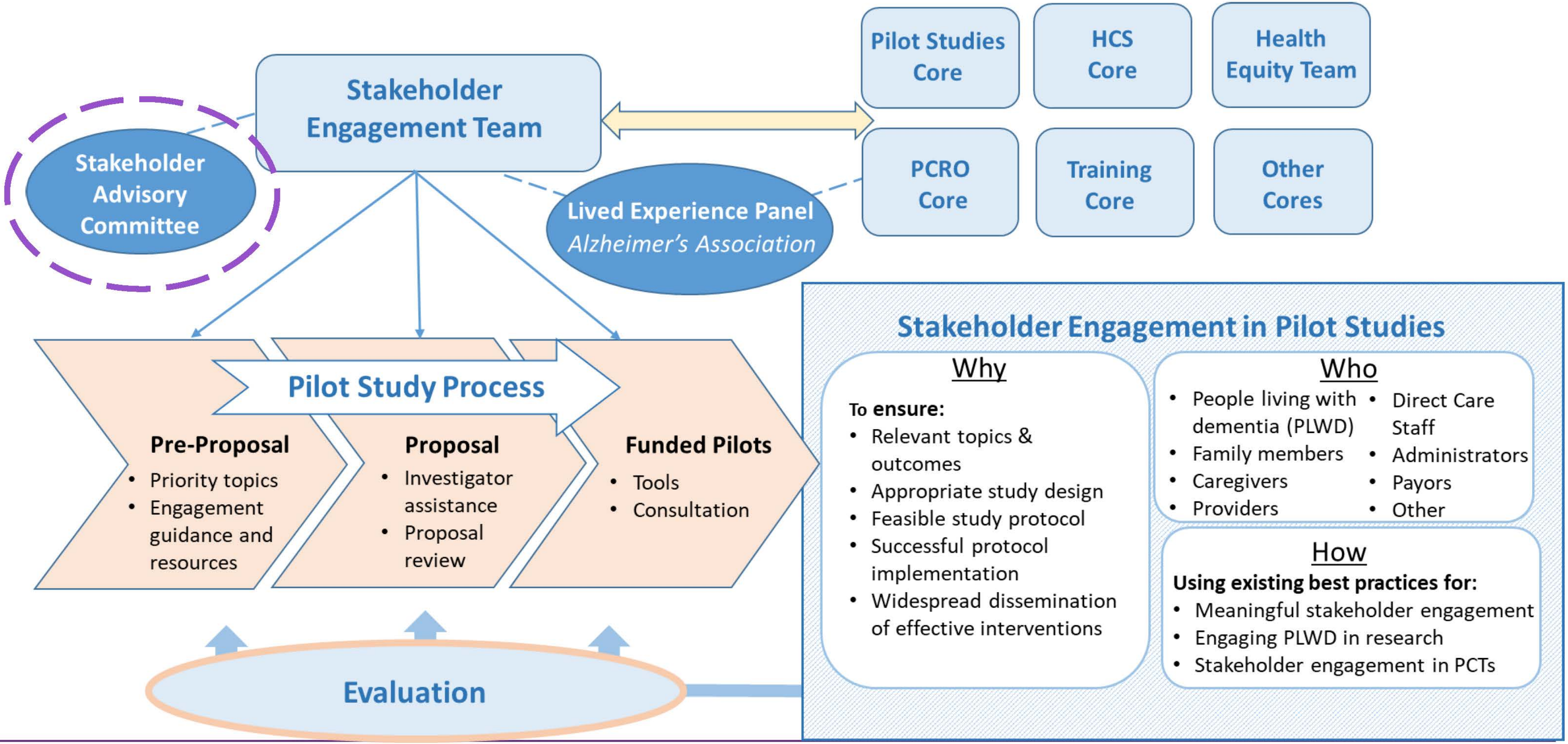

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Stakeholder Advisory Committee

Role:

Advise the IMPACT Collaboratory about stakeholder engagement activities, strategies to assist investigators with stakeholder engagement, and priority topics for the development of guidance materials.

Membership:

- People living with dementia (2)
- Alzheimer's Association
- National Alliance for Caregiving
- LEAD Coalition
- Association for Frontotemporal Degeneration
- Lewy Body Dementia Association
- Leading Age
- AARP
- AMDA: Society for Post-Acute and Long-Term Care Medicine
- American Geriatrics Society
- Centers for Medicare and Medicaid Services
- Veterans Administration

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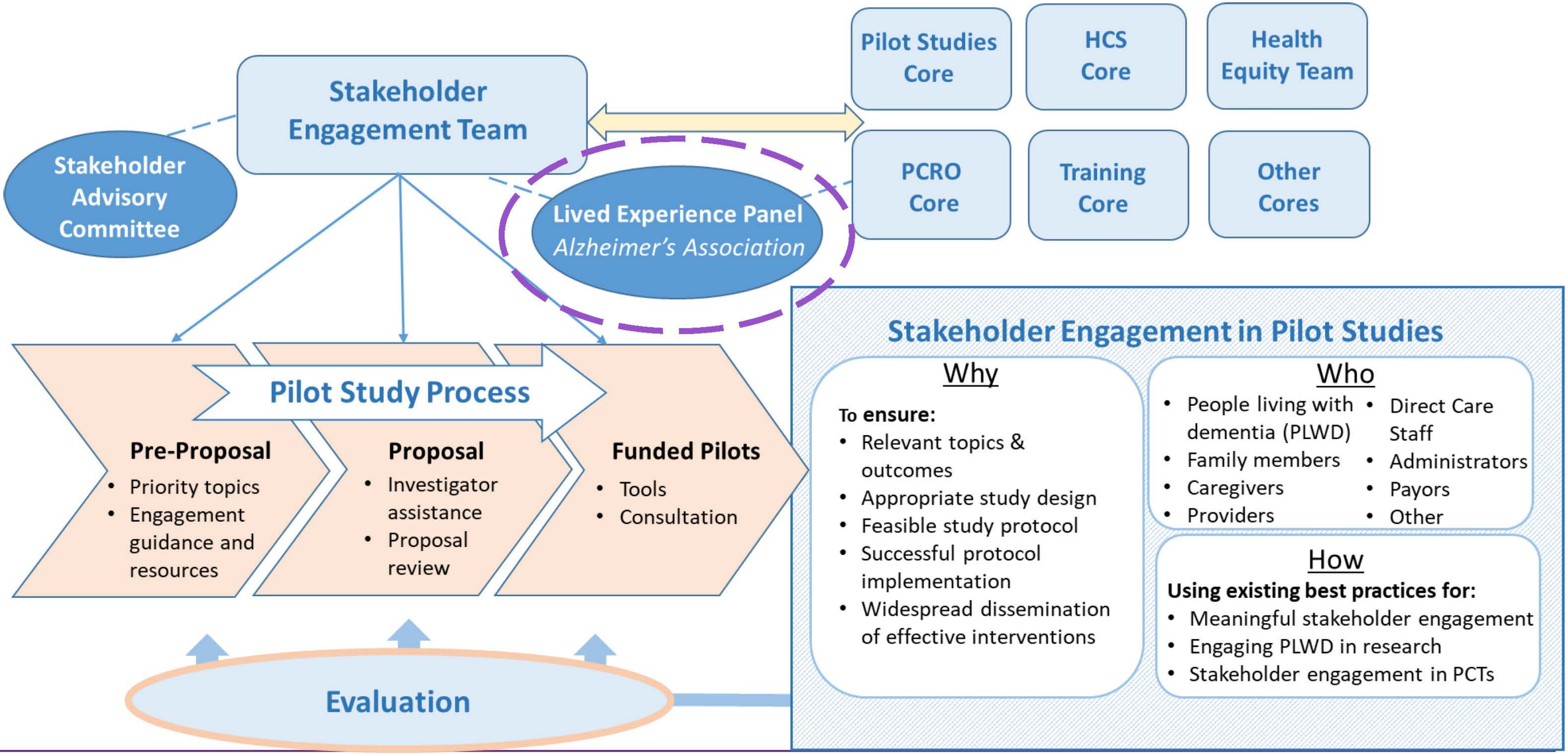

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Lived Experience Panel

Collaboration between IMPACT Collaboratory (PCRO and SET) and the Alzheimer's Association (AA)

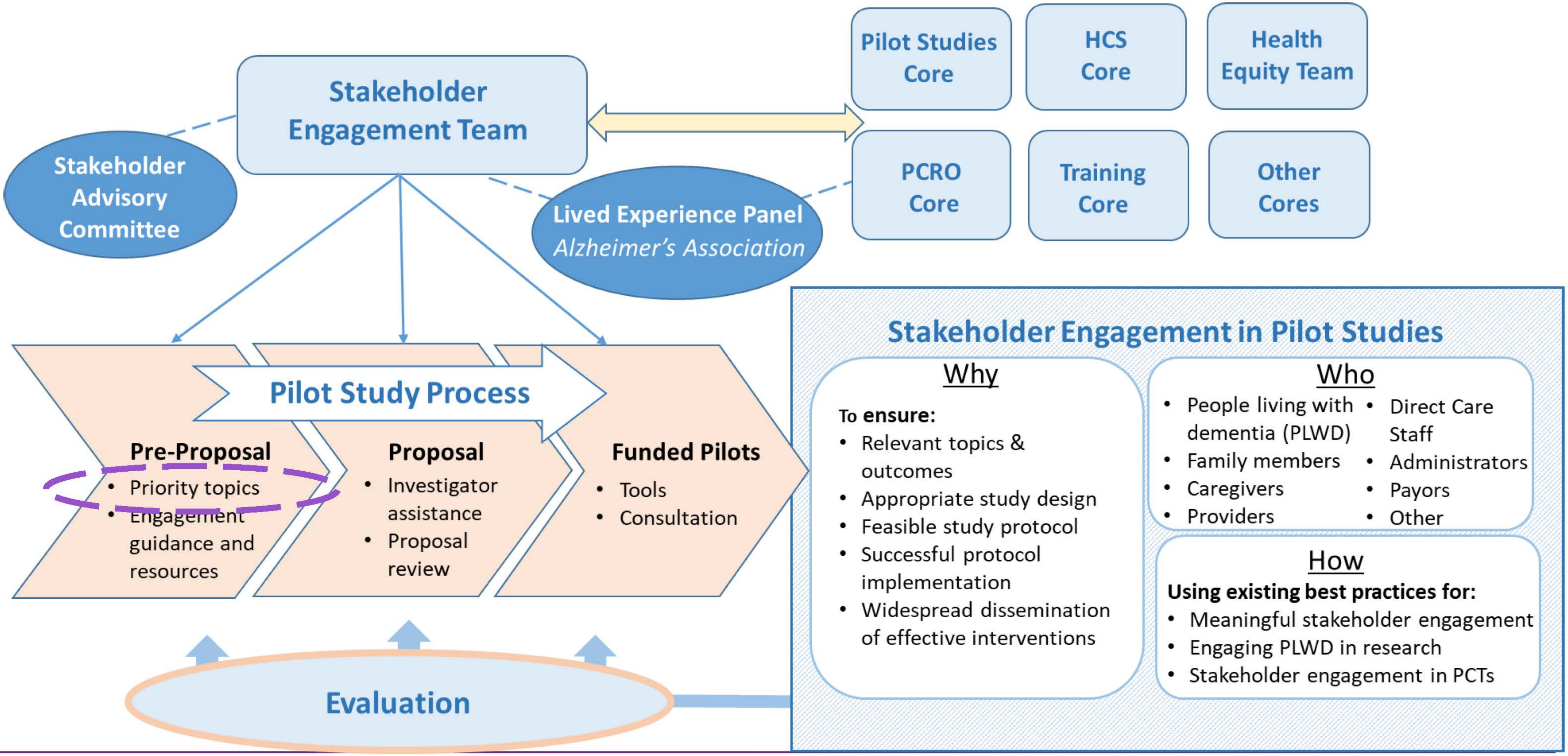
Role:

- Reflect on outcomes and relevance of pilot studies
- Identify high priority outcomes and gaps
- Review written documents

Panel Composition:

- **4** - Individuals living with a diagnosis of early stage Alzheimer's, Mild Cognitive Impairment (MCI) or other dementia
- **4** - Care partners/caregivers of an individual living with dementia
- **4** - Caregivers/family members who can represent the perspective of one or more individuals living in the middle or late stage

Stakeholder Engagement in the IMPACT Collaboratory



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Topic Prioritization

2017 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers

- Persons Living with Dementia Stakeholder Group “Top 6 Outcomes that Matter”
  1. Psychosocial care practices and behavioral strategies to address problematic symptoms
  2. Person-centered approaches to assessment and care planning
  3. Tailored resources and models of coordinated care
  4. Implications for use of the term “cognitive impairment” or “cognitive disorder” instead of “dementia”
  5. Implications on advocacy, stigma and reported prevalence rates as a result of consolidating disease names of all memory disorders
  6. Implications of financial burden on diagnosis, treatment, and research participation

Frank L, Shubeck E, Schicker M, et al. Contributions of persons living with dementia to scientific research meetings. Results from the National Research Summit on Care, Services, and Supports for persons with dementia and their caregivers. Am J of Geriatric Psychiatry. 2020;28(4):421-430.

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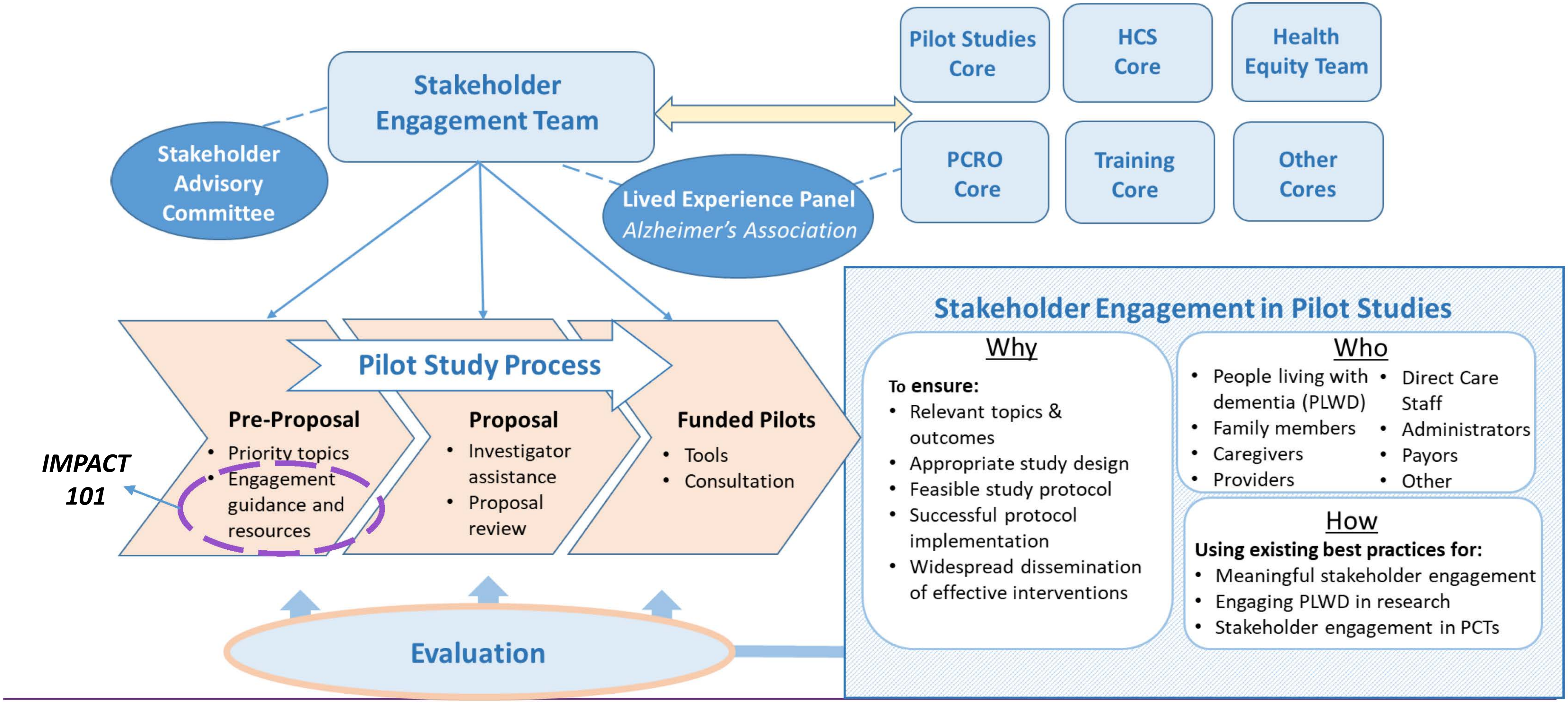

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IMPACT 101

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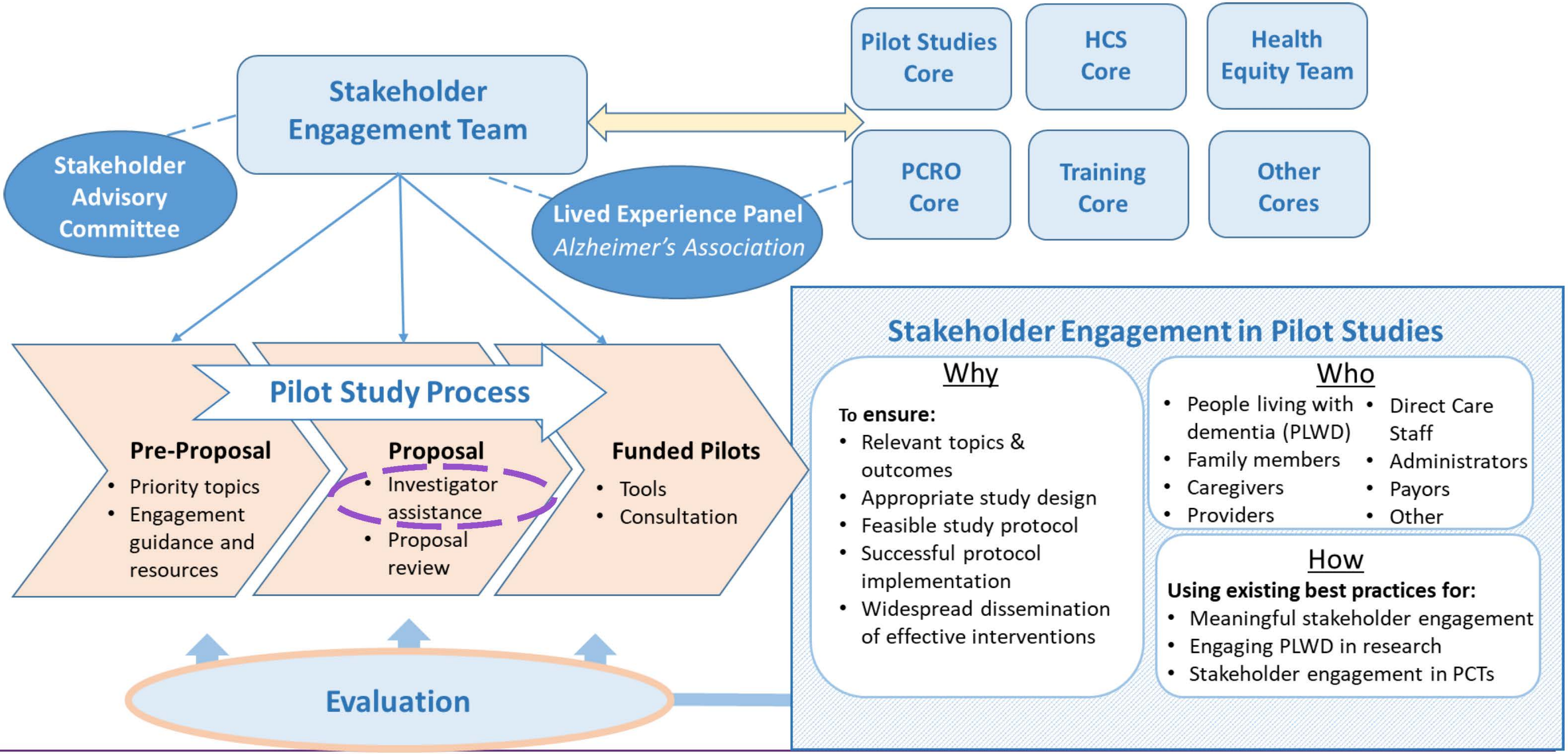

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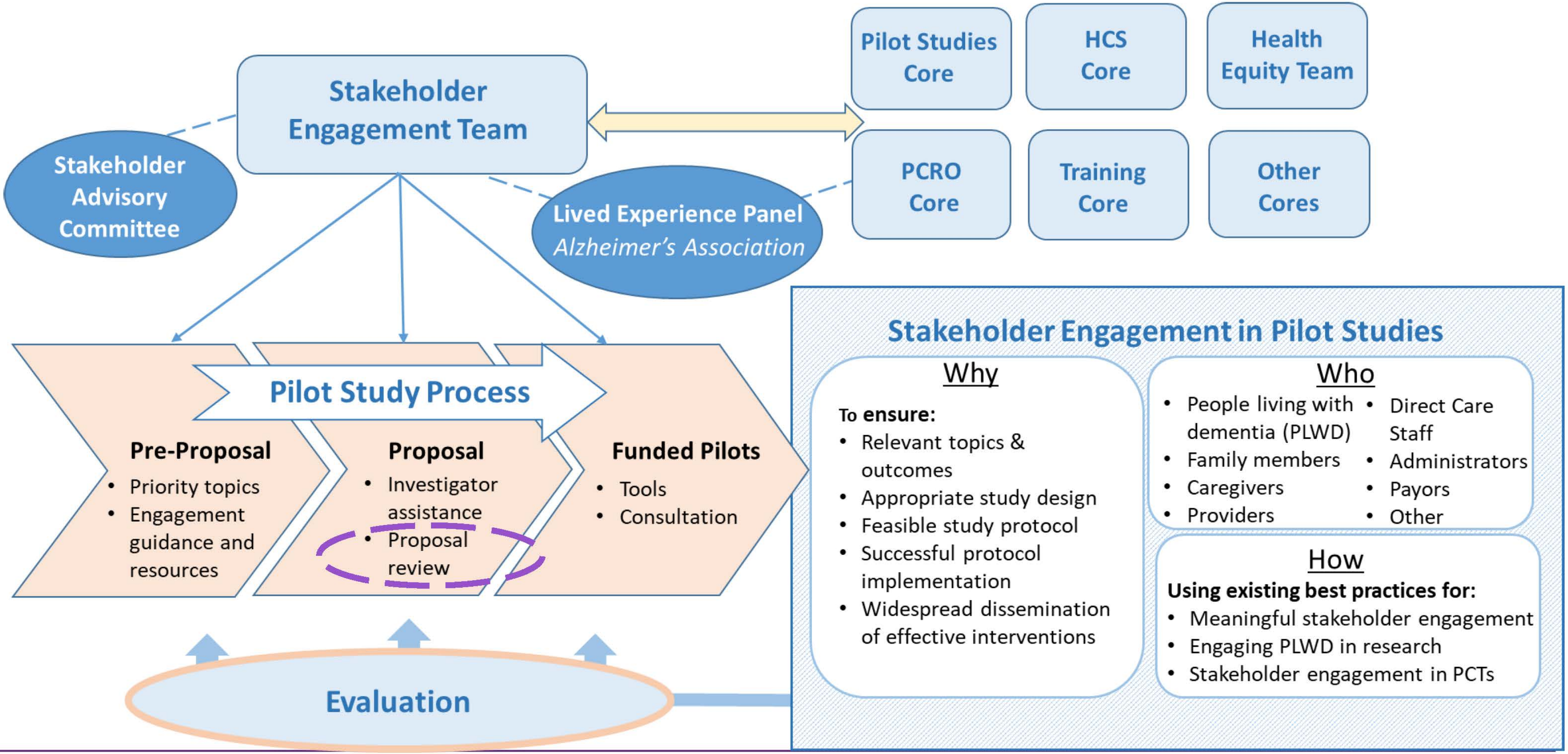

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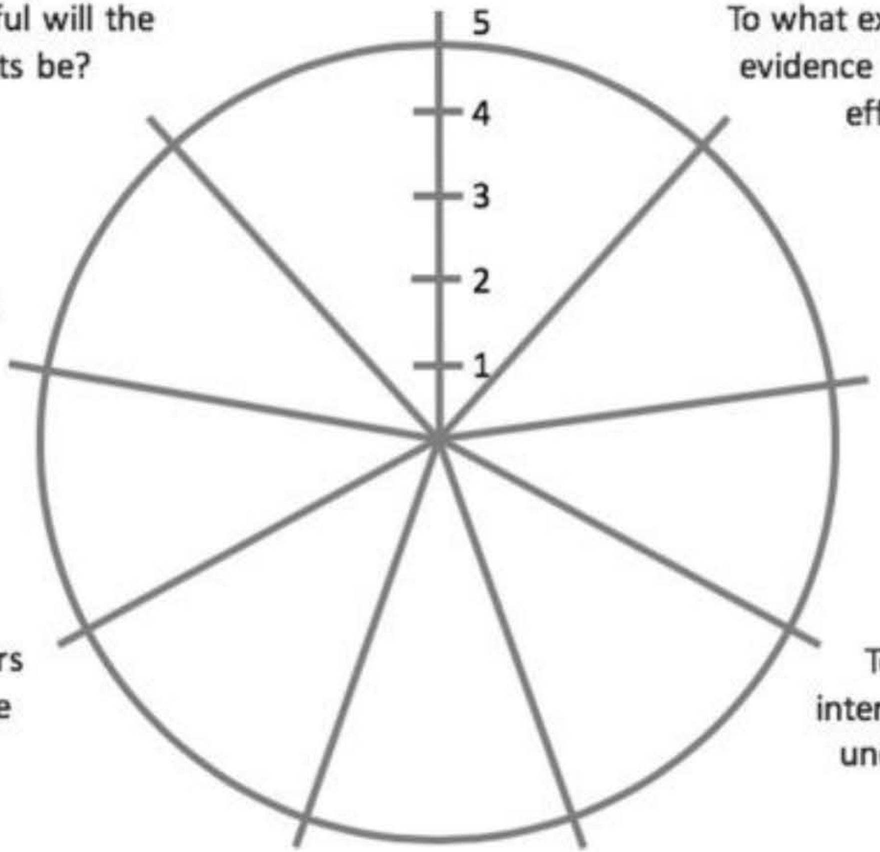
RAPT Model

Readiness Assessment for Pragmatic Trials



Implementation protocol
Is the protocol sufficiently detailed to be replicated?

Evidence
To what extent does the evidence base support efficacy?

Risk
Is it known how safe the intervention is?

Feasibility
To what extent can the intervention be implemented under existing conditions?

Measurement
To what extent can outcomes be captured?

Cost
How likely is the intervention to be economically viable?

Acceptability
How willing are providers likely to be to adopt the intervention?

Alignment
To what extent does the intervention align with external stakeholders' priorities?

Impact
How useful will the results be?

Baier, Jutkowitz, Mitchell, McCreedy and Mor, 2019

RAPT Model

Readiness Assessment for Pragmatic Trials

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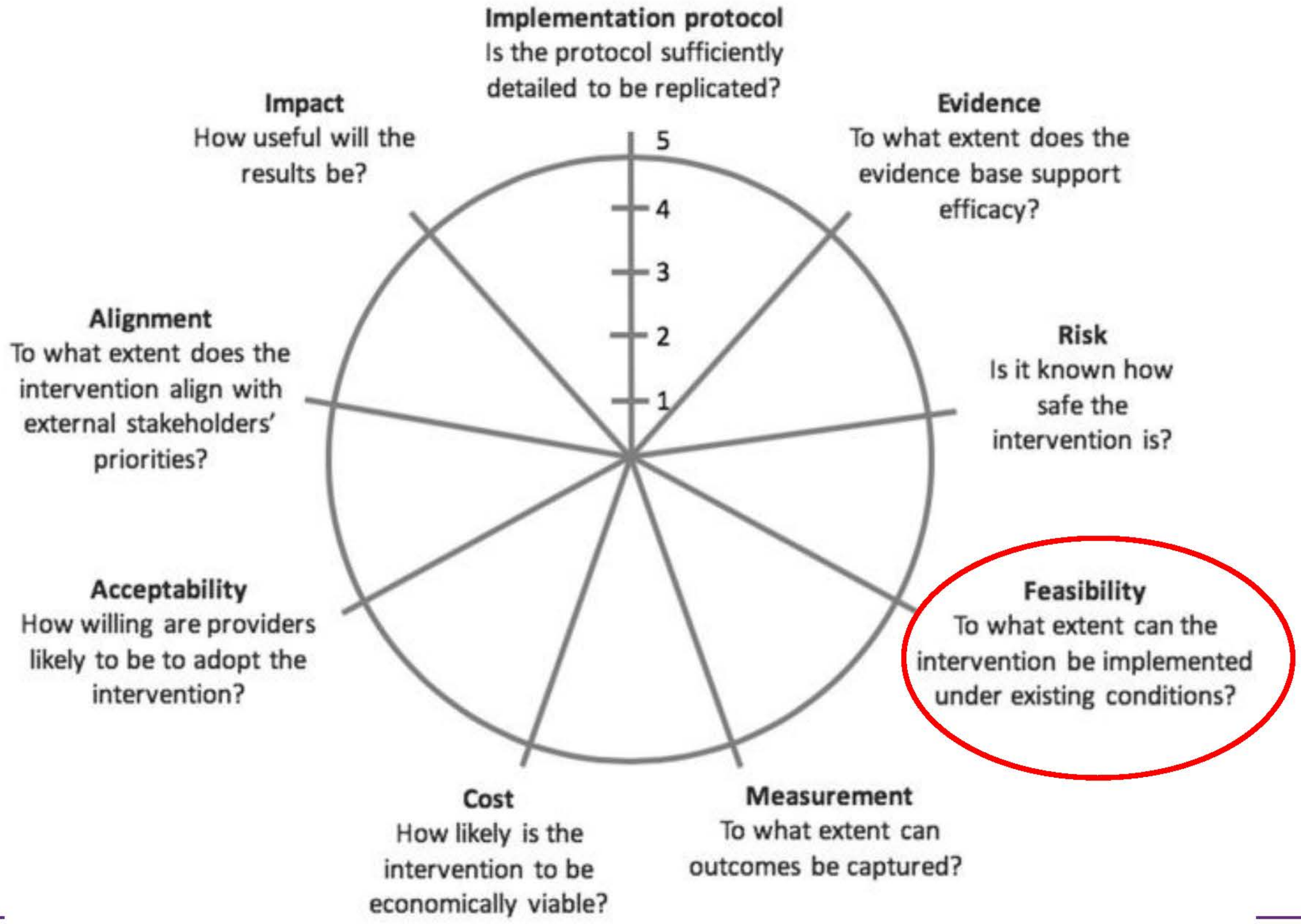

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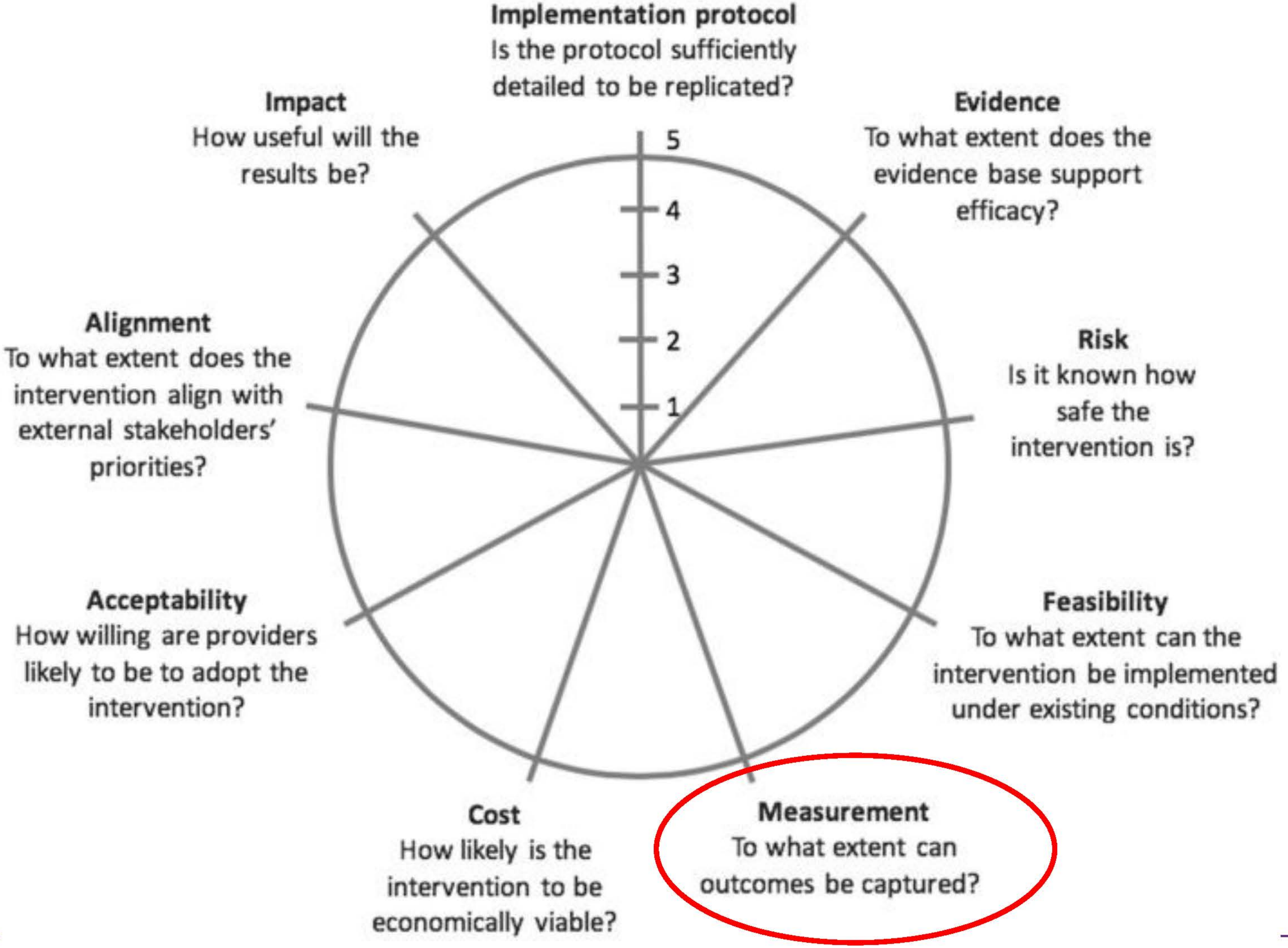

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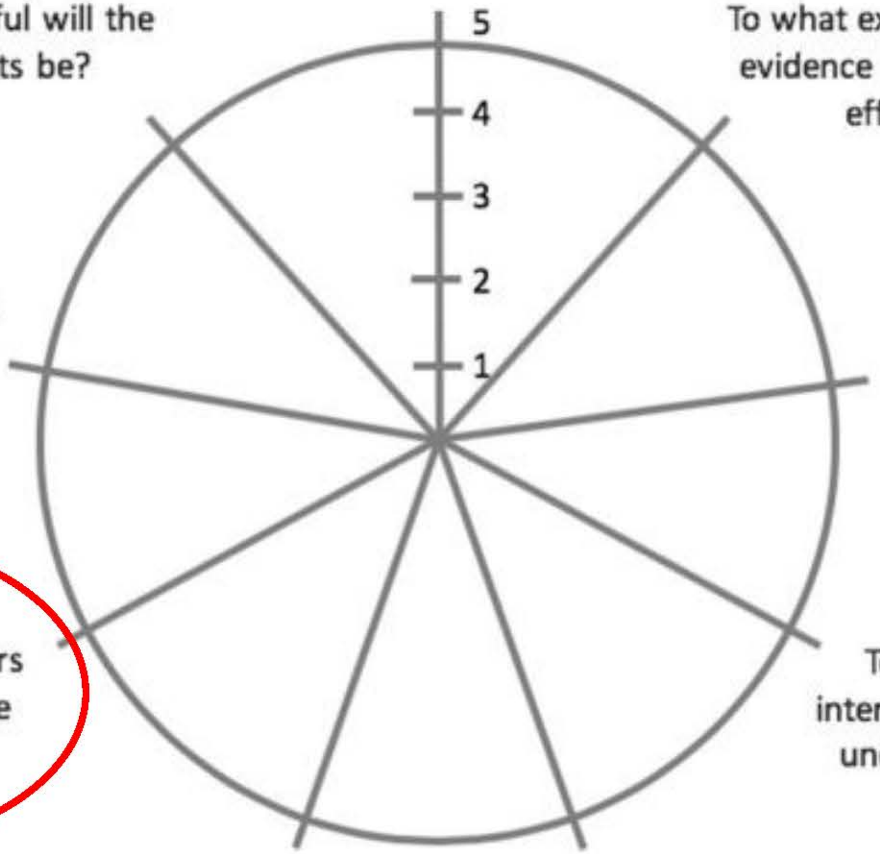

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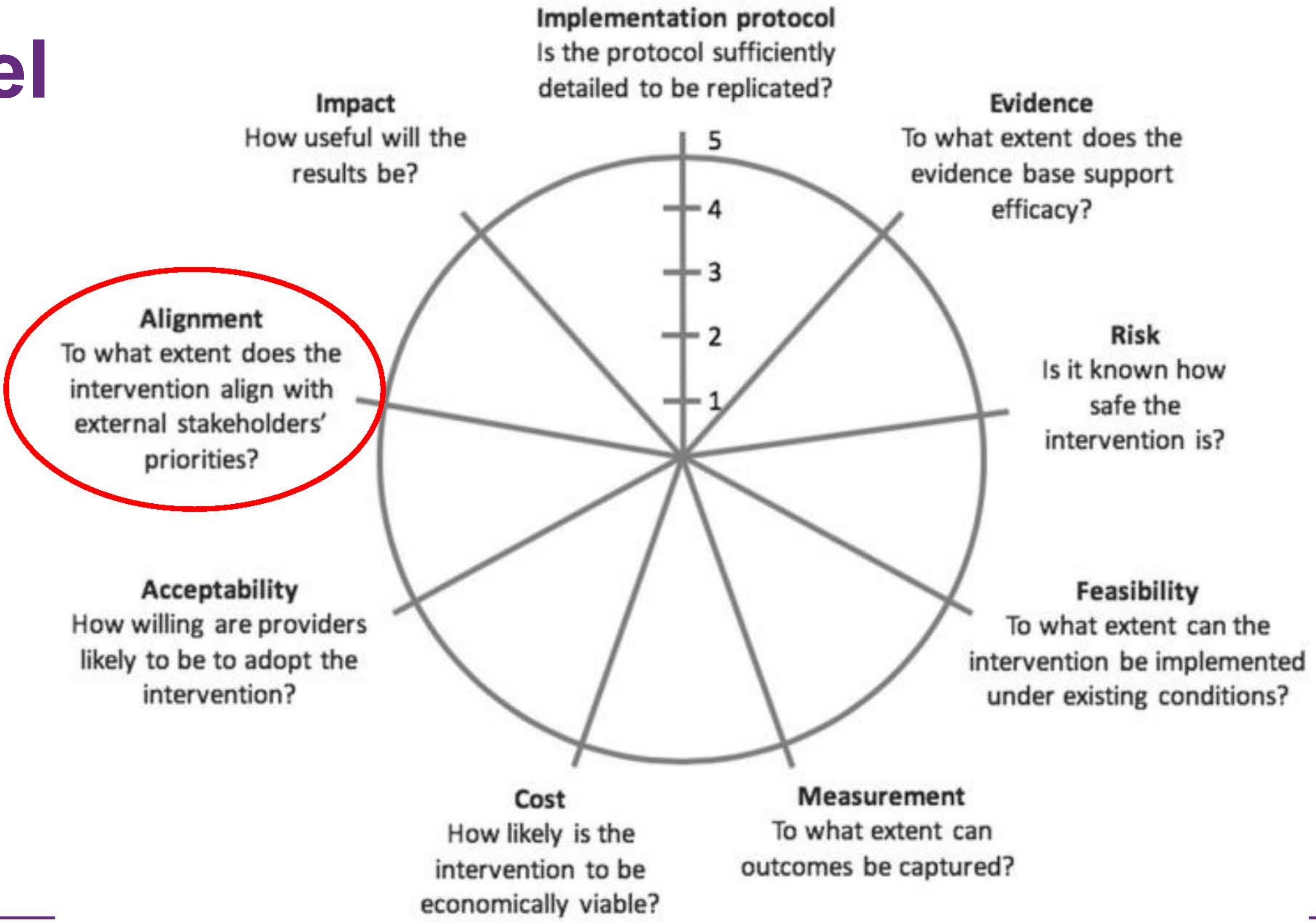

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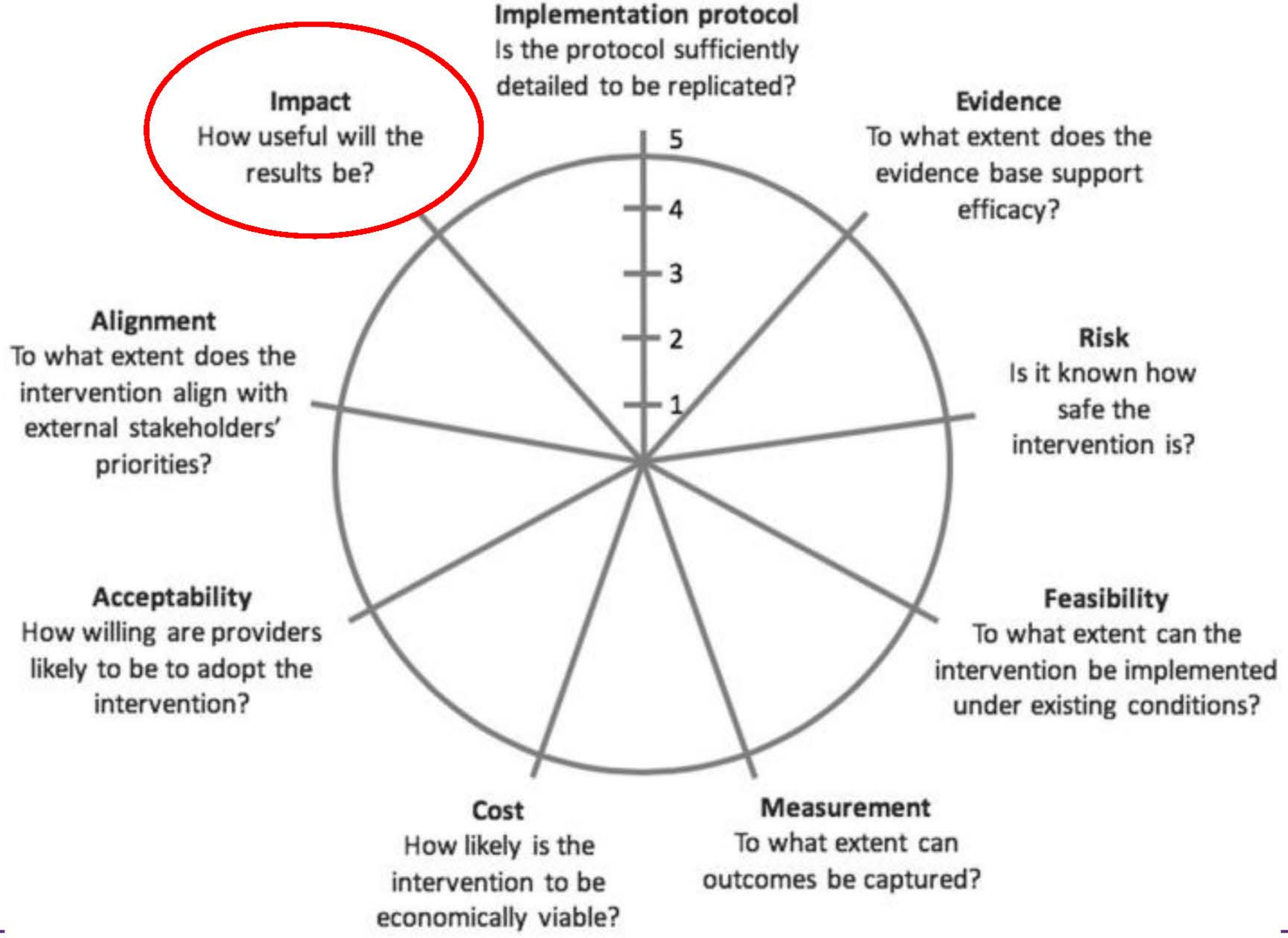

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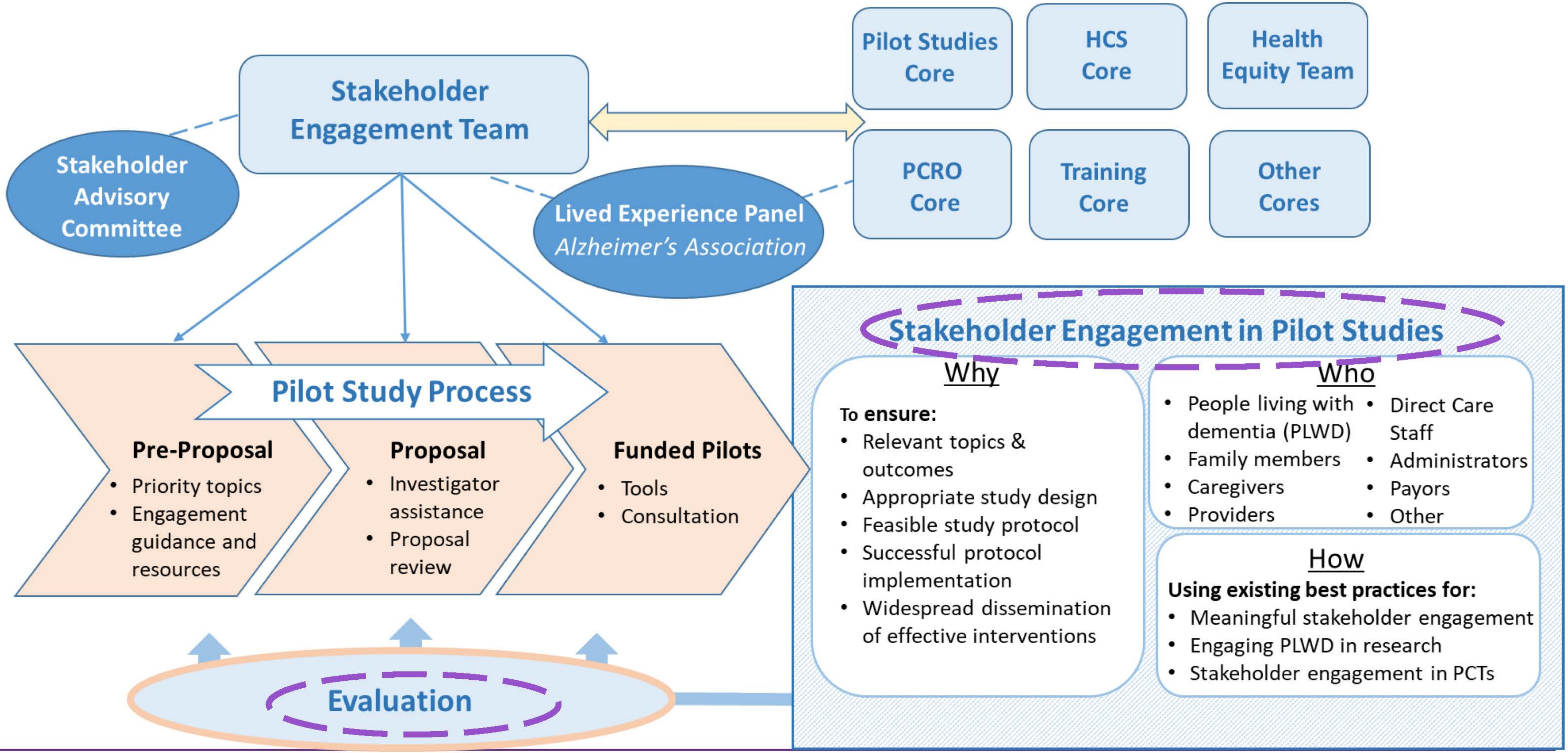

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Questions?