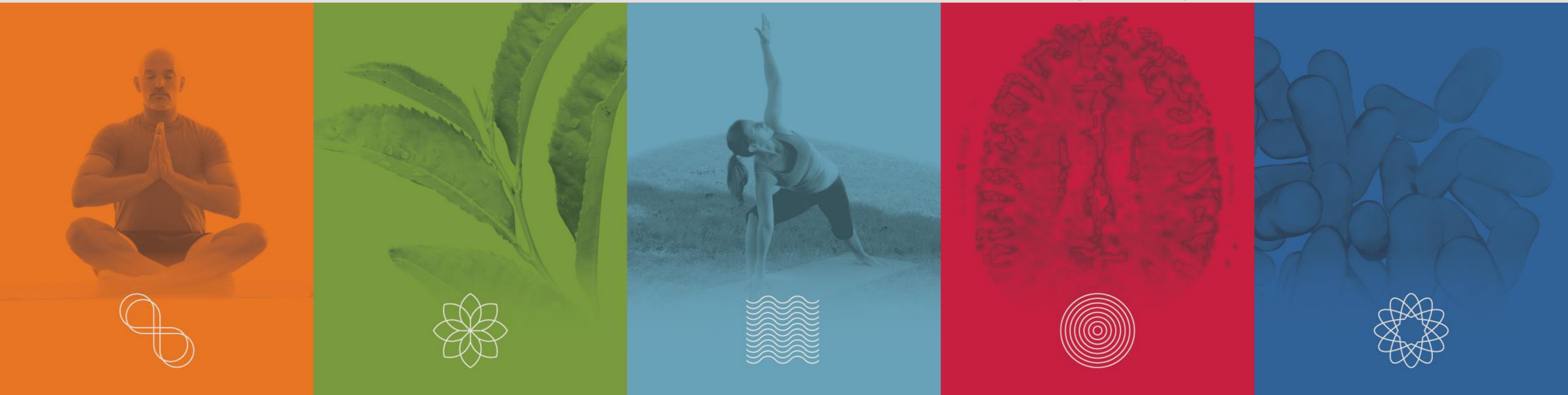




NIH Health Care Systems Research Collaboratory 2019 Steering Committee Meeting May 1, 2019 – KEYNOTE PANEL Perspectives on PCT – Real-World Evidence

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Director, NCCIH Office of Clinical & Regulatory Affairs



KEYNOTE PANELISTS

- **Dr. Richard Hodes, MD;** Director, National Institute on Aging, NIH
- **Dr. Jacqueline Corrigan-Curay, JD, MD;** Director, Office of Medical Policy, CDER/FDA
- **Dr. Joseph Chin, MD, MS;** Deputy Director, Coverage and Analysis Group, Center for Clinical Standards and Quality, CMS
- **Dr. Danny Almirall, PhD;** Associate Professor, Institute for Social Research, University of Michigan



Pragmatic Clinic Trials

- NIH Perspective
 - How has NIH addressed the need for PCT?
 - What are the challenges and opportunities for expanding its PCT portfolio?



Real-World Evidence

- CDER/FDA Perspective
 - How is real-world evidence from PCT most useful for FDA?
 - Are there opportunities or resources for researchers to work with FDA on developing PCT strategies for regulated products?



Real-World Evidence

- CMS Perspective
 - How could PCT be useful for CMS?
 - Are there opportunities in the NIH Collaboratory that could be leveraged?



Pragmatic Clinical Trials

- Implementation Science
 - Planning for Dissemination, Implementation and Sustainability – what are the opportunities?
 - Are researchers taking full advantage of opportunities? Why or why not?



Questions?

