



# The ePCT Ecosystem

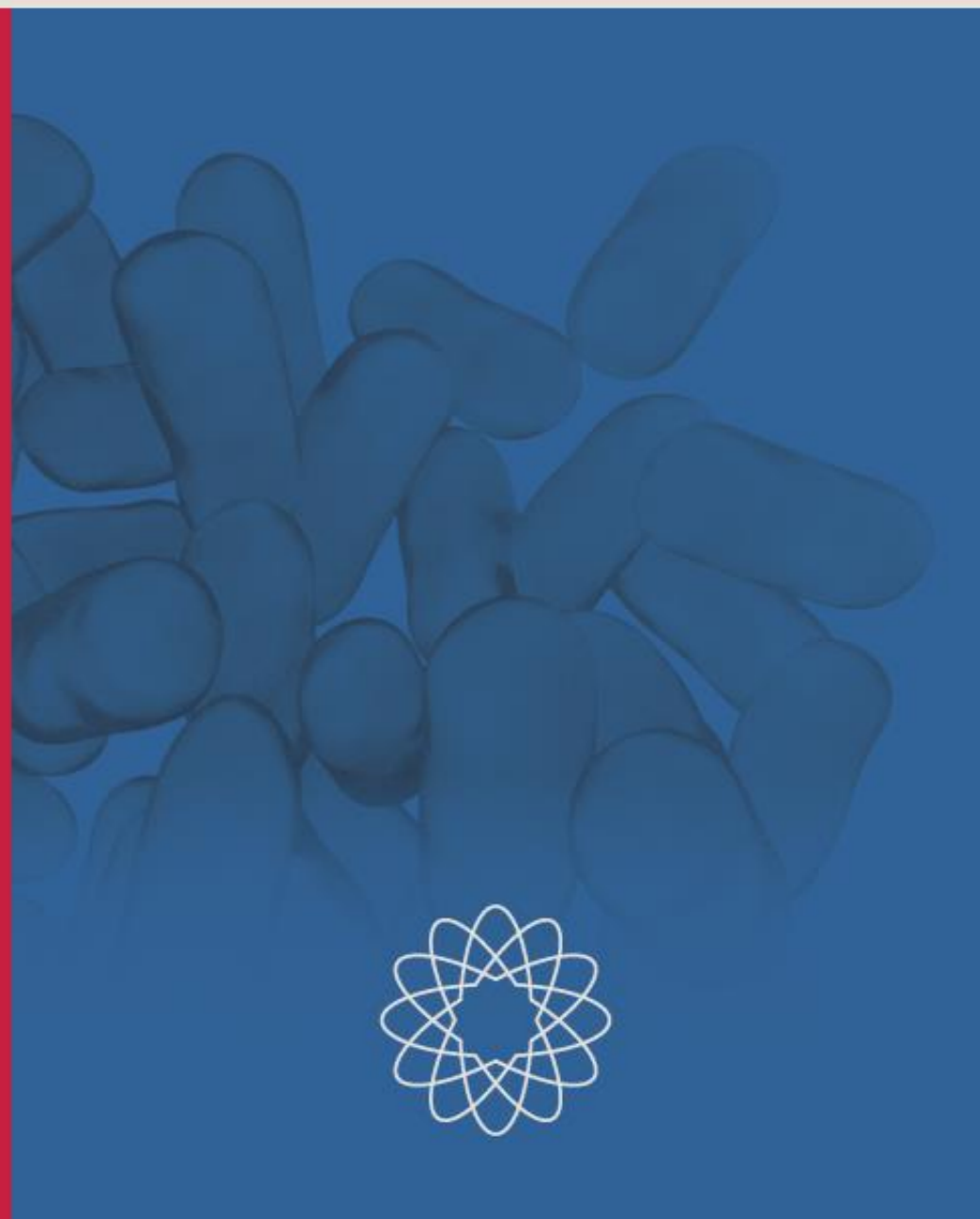
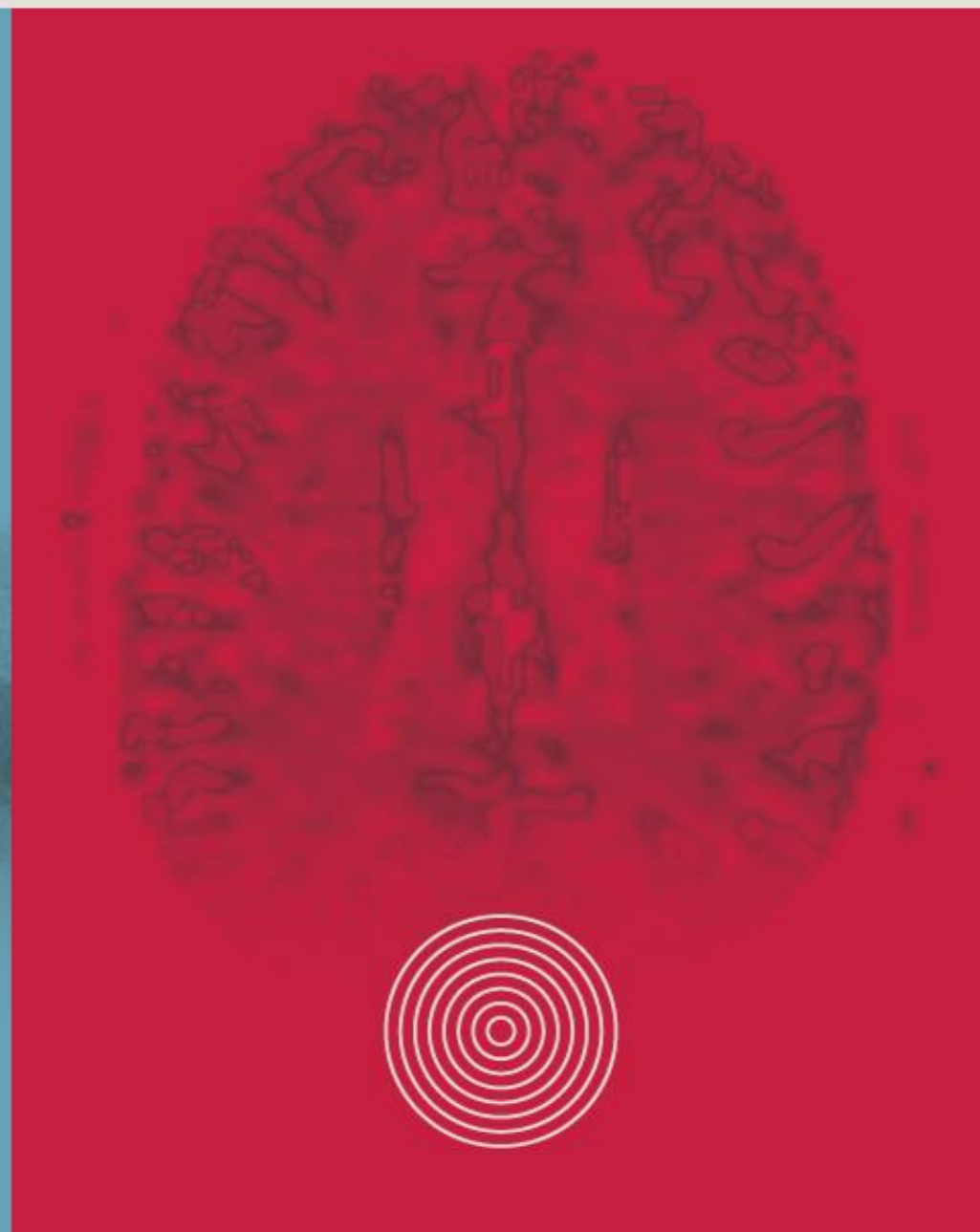
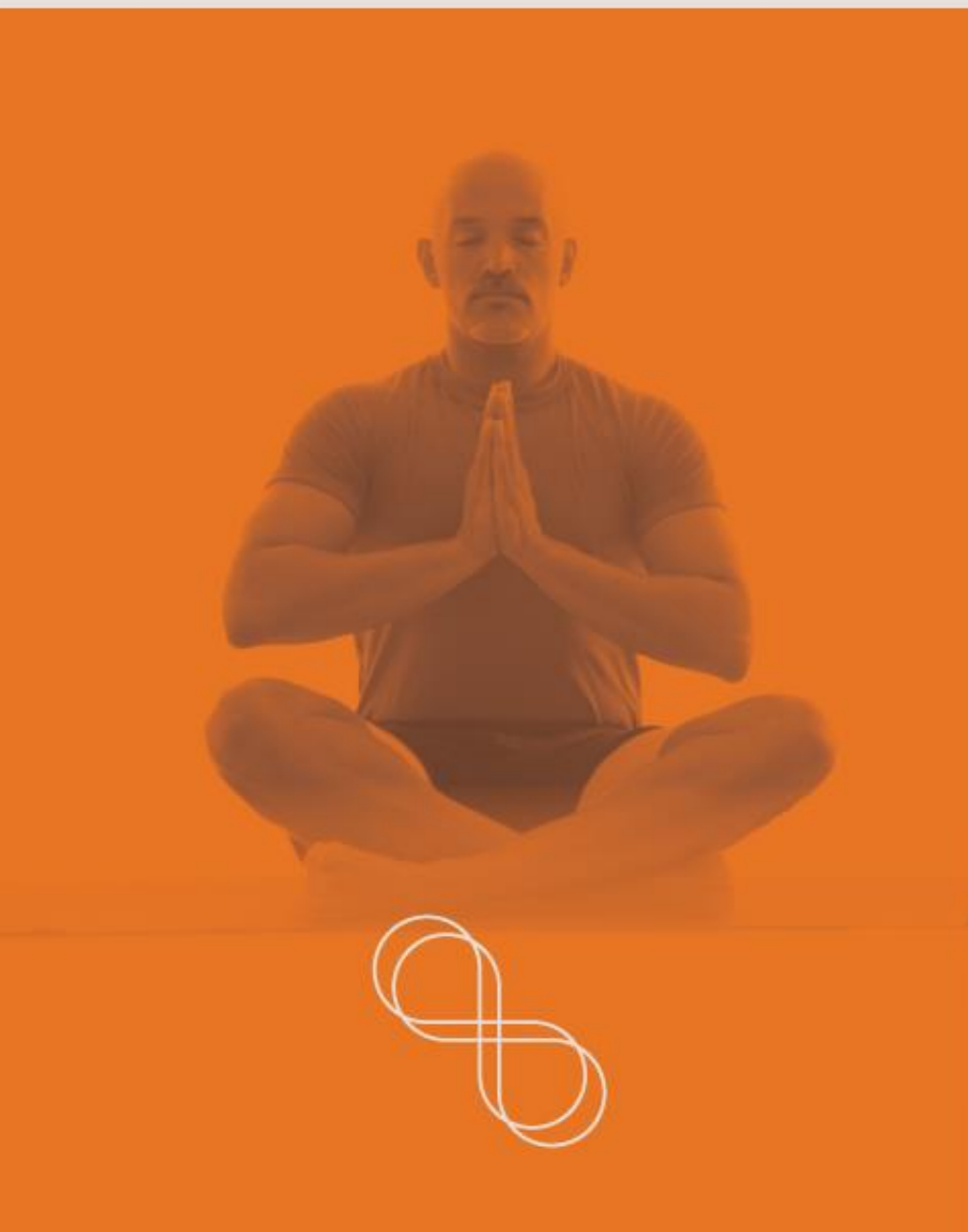
## A Learning Health Care System - Are We Building One?

April 22, 2020

**Cathy Meyers, MD**

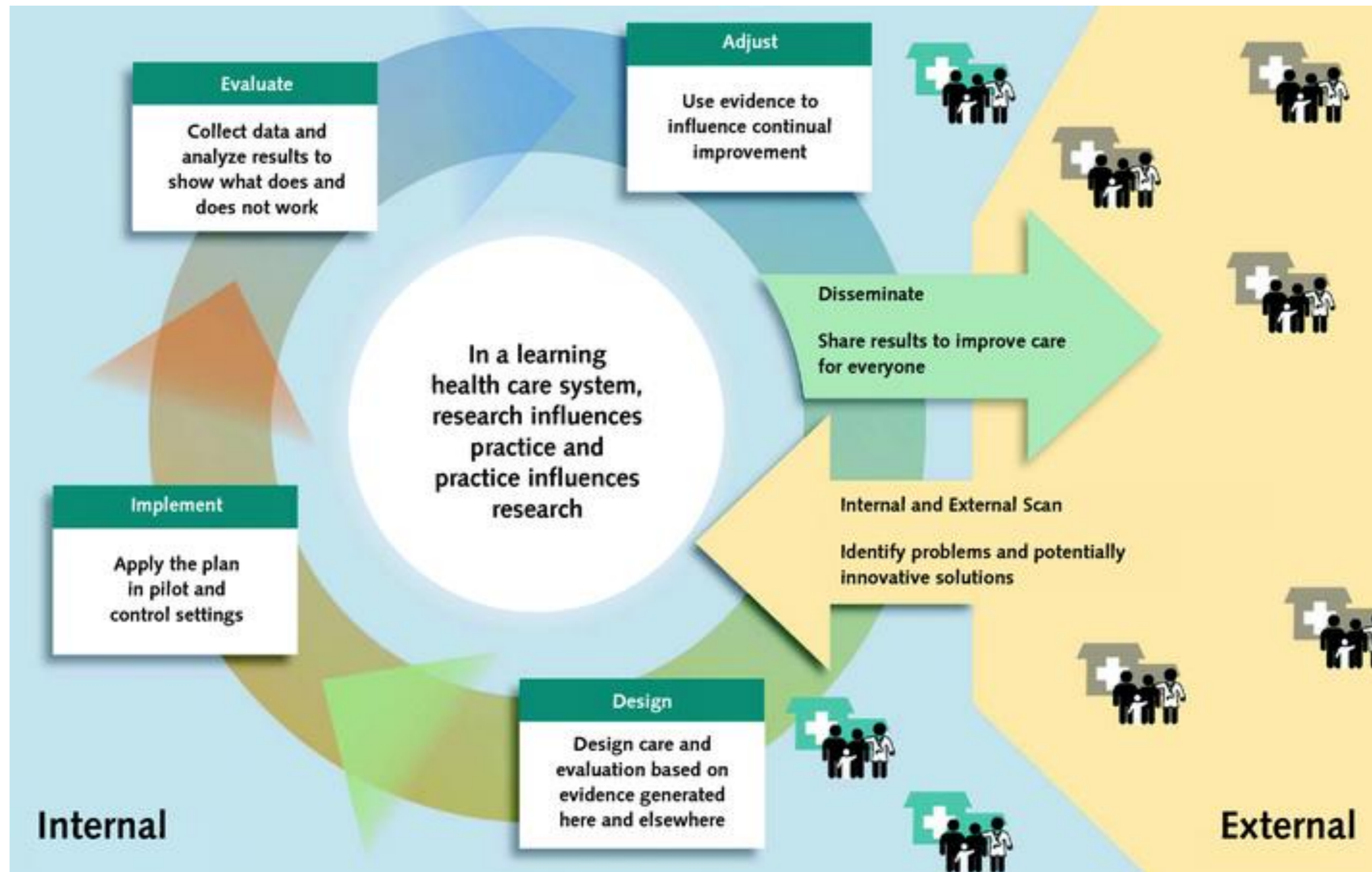
**NIH/NCCIH**

**Director, Office of Clinical & Regulatory Affairs**





# The Learning Health Care System



*Ann Intern Med.* 2012;157(3):207-210



SOUNDING BOARD

**Transforming Evidence Generation to Support Health  
and Health Care Decisions**

Robert M. Califf, M.D., Melissa A. Robb, M.S.(Reg.Sci.), B.S.N., Andrew B. Bindman, M.D.,  
Josephine P. Briggs, M.D., Francis S. Collins, M.D., Ph.D., Patrick H. Conway, M.D.,

**Key Activities**

1. Strategic, organizational and technical aspects for making data available to clinicians and patients for clinical decision making
2. Leverage and extend digital health and data for efficient high-quality research – trials and observational work
3. Demonstration Projects to leverage government and private organization resources



# Learning Health System Core Principles

- Systems that create research embedded in practice
- **Methods that answer questions**
- **New approaches for efficient design, analysis, conduct**
- Frameworks for autonomy, privacy, confidentiality & security
- Configure, store and use data, addressing consent & privacy



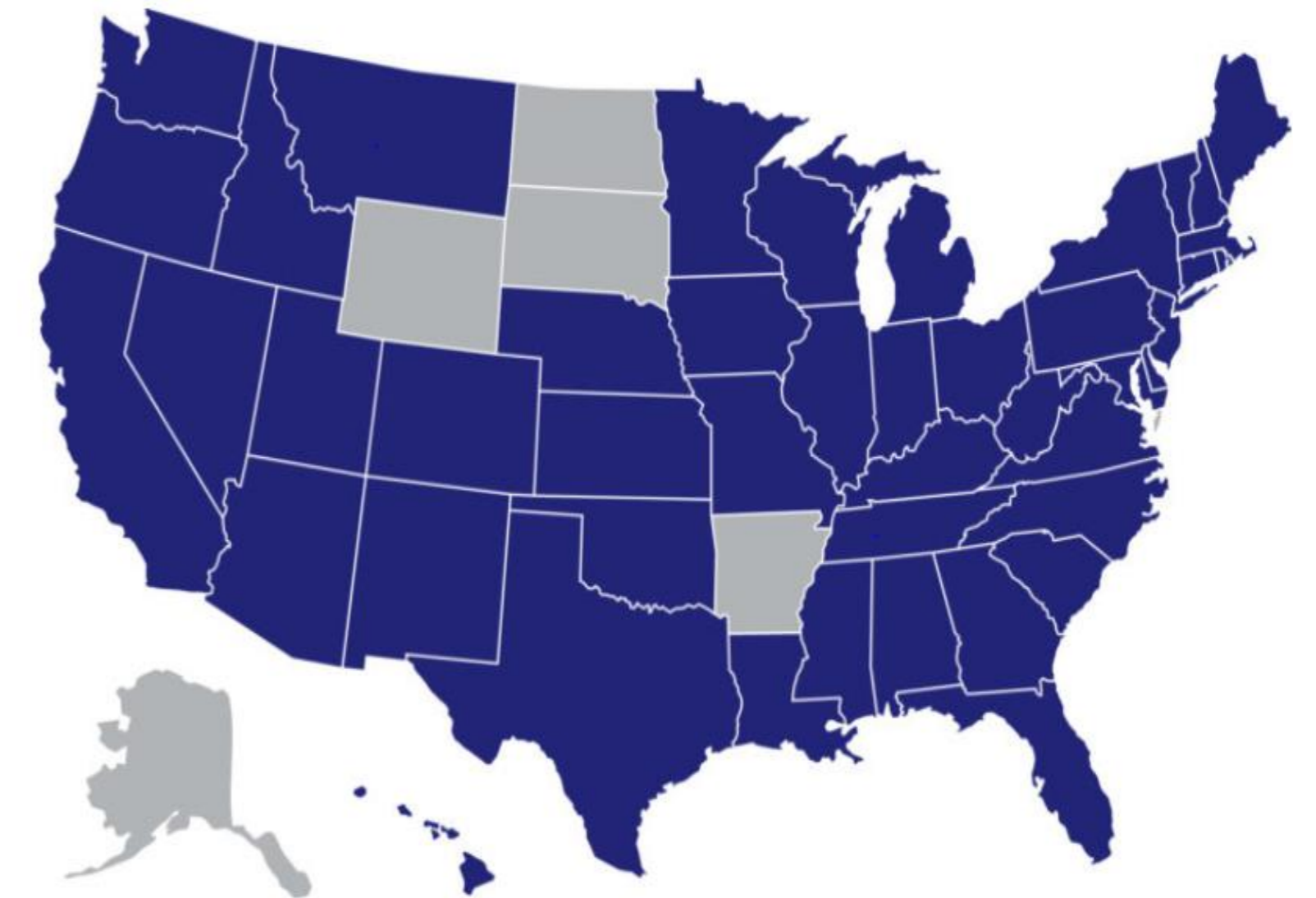


## One Approach....

# NIH Health Care Systems Research Collaboratory

**Goal:** To strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners.

**Aim:** To provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research. Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to health practice.



And now there are other approaches ....



# Methods That Answer Questions

- Dissemination of information
  - Research methods
  - Interventions
  - Research results
  - Large data sets



By Robert B. Giffin and Janet Woodcock

# Comparative Effectiveness Research: Who Will Do The Studies?

DOI: 10.1377/hlthaff.2010.0669  
HEALTH AFFAIRS 29,  
NO. 11 (2010): 2075-2081  
©2010 Project HOPE—  
The People-to-People Health  
Foundation, Inc.

2010

Trends in the Explanatory or Pragmatic Nature of Cardiovascular Clinical Trials Over 2 Decades

Original Investigation

Invited Commentary

## Consequences of Slow Progress Toward Pragmatism in Randomized Clinical Trials It Is Time to Get Practical

Fatima Rodriguez, MD, MPH; Robert M. Califf, MD; Robert A. Harrington, MD

2019

## Evidence from Pragmatic Trials during Routine Care — Slouching toward a Learning Health System

Gregory E. Simon, M.D., M.P.H., Richard Platt, M.D., and Adrian F. Hernandez, M.D., M.H.S.

2020

