NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

NIH Collaboratory: Research Transformation in Progress

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Today's Presentation

1. Collaboratory story and highlights
2. What are we working on now?
3. What should be next?

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Collaboratory Story and Highlights

Millions

Patients **walk through the doors** of hospitals and clinics each year **with questions** about their health and their care.

?

How do we **study their experiences** to **find answers** and **create solutions** that **change care** and **improve outcomes**?

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The Collaboratory Story

Initiated through the NIH Common Fund in 2012

Goal: Strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations as research partners

Vision: Support the design and execution of innovative pragmatic clinical trial Demonstration Projects to establish best practices and proof of concept

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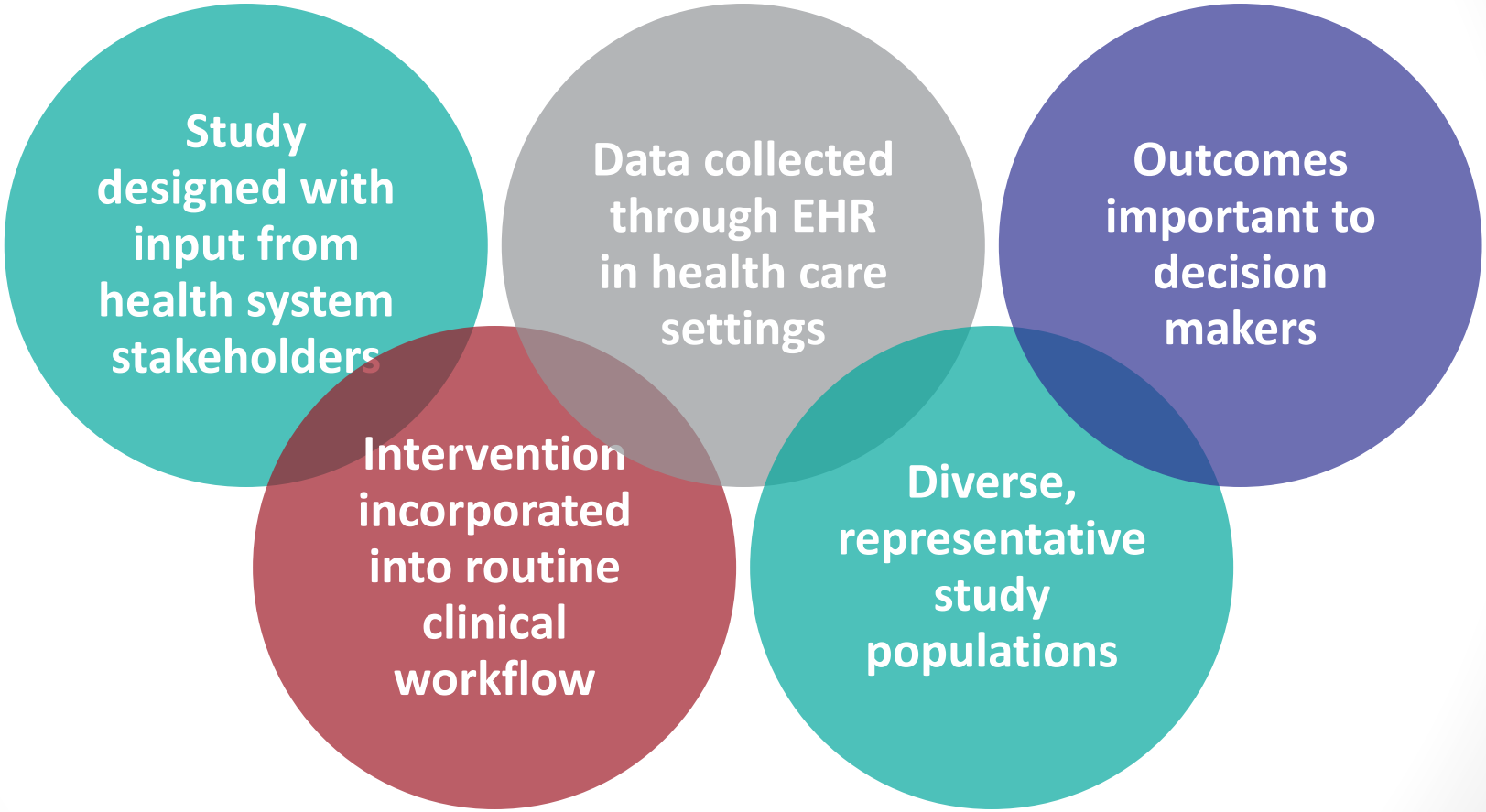
Embedded PCTs Bridge Research into Clinical Care



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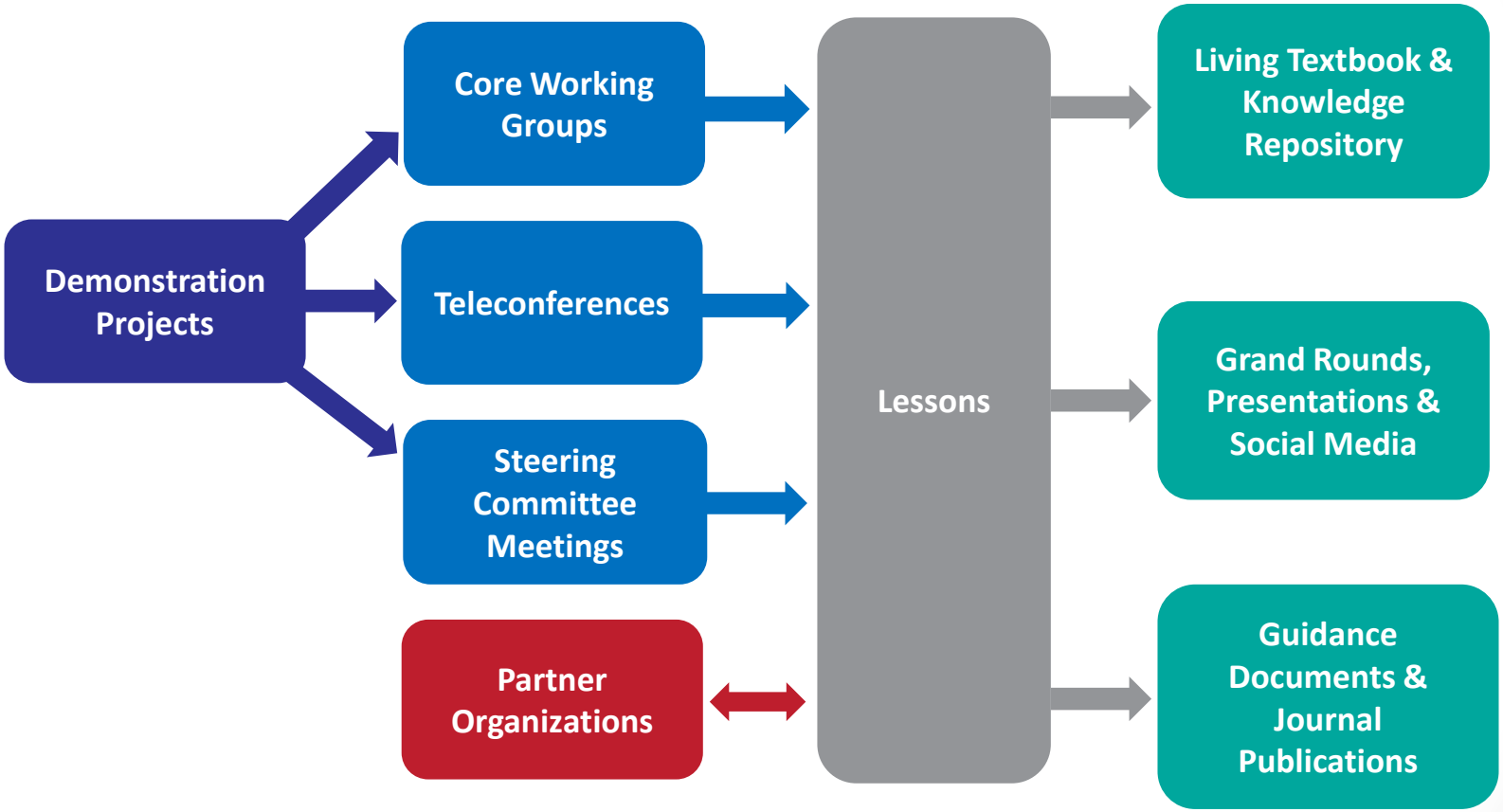
Collaboratory Opportunities

- Amazing opportunity to use new information and clinical learning to inform and change the system
- The Collaboratory effort provides a fascinating vantage point for the transformation
  - Tremendous progress and opportunity
  - Show how to overcome the hurdles or speed bumps

Flow of Information



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What's been contributed

- Significant body of knowledge on ethical & regulatory issues in PCTs
  - Consulted with OHRP
  - Conducted research on clinician & participant attitudes
  - Published special journal issue on challenges & best practices
- Biostatistical guidance in area of cluster randomized trials
- Created functional distributed research network
- Established policies and culture for data sharing
- Developed resources and guidance to support re-use of EHR data, integration of patient-reported outcomes, and partnerships with healthcare systems
- Shared case studies from our Demonstration Projects

NIH Collaboratory Publications

80 total publications
in peer-reviewed journals

NIH Collaboratory Presentations

>150

total conference
presentations
or symposia

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NIH Collaboratory Presentations

Academy Health

Statistical Issues in Clinical Trials

PMI

OHA Transformation Center

Am Society Bioethics

>150

Seattle Symposium on Data Analytics

NCURA

NIH

ASCP

Natl Advisory Council for Nursing Home Research

ISPOR

PRIM&R

total conference presentations or symposia

IOM

ENAR

HMORN

ACOS

AMWA

RSA

ASNR

Health Systems Partnerships

PMR Sports Medicine

AMIA

Joint Summits

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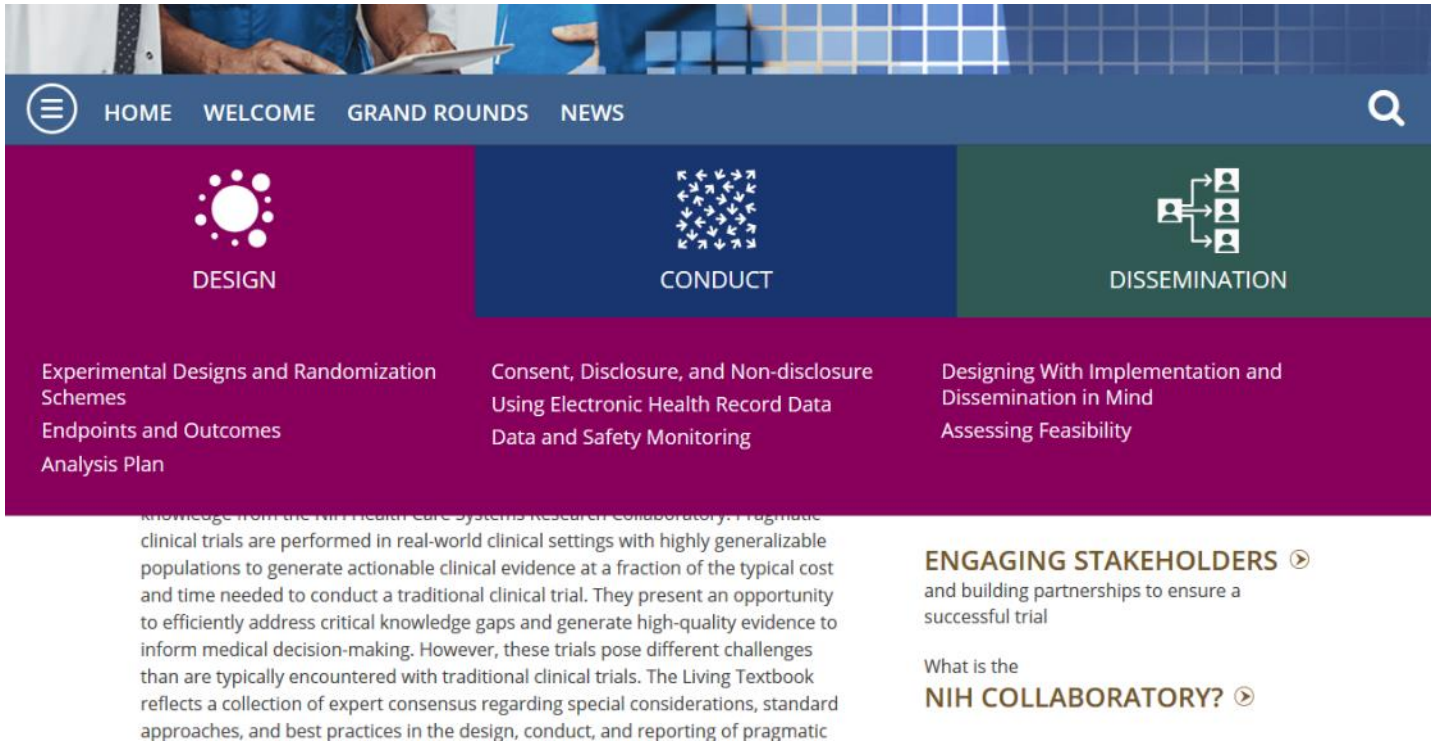
The Living Textbook *of Pragmatic Clinical Trials*



www.rethinkingclinicaltrials.org

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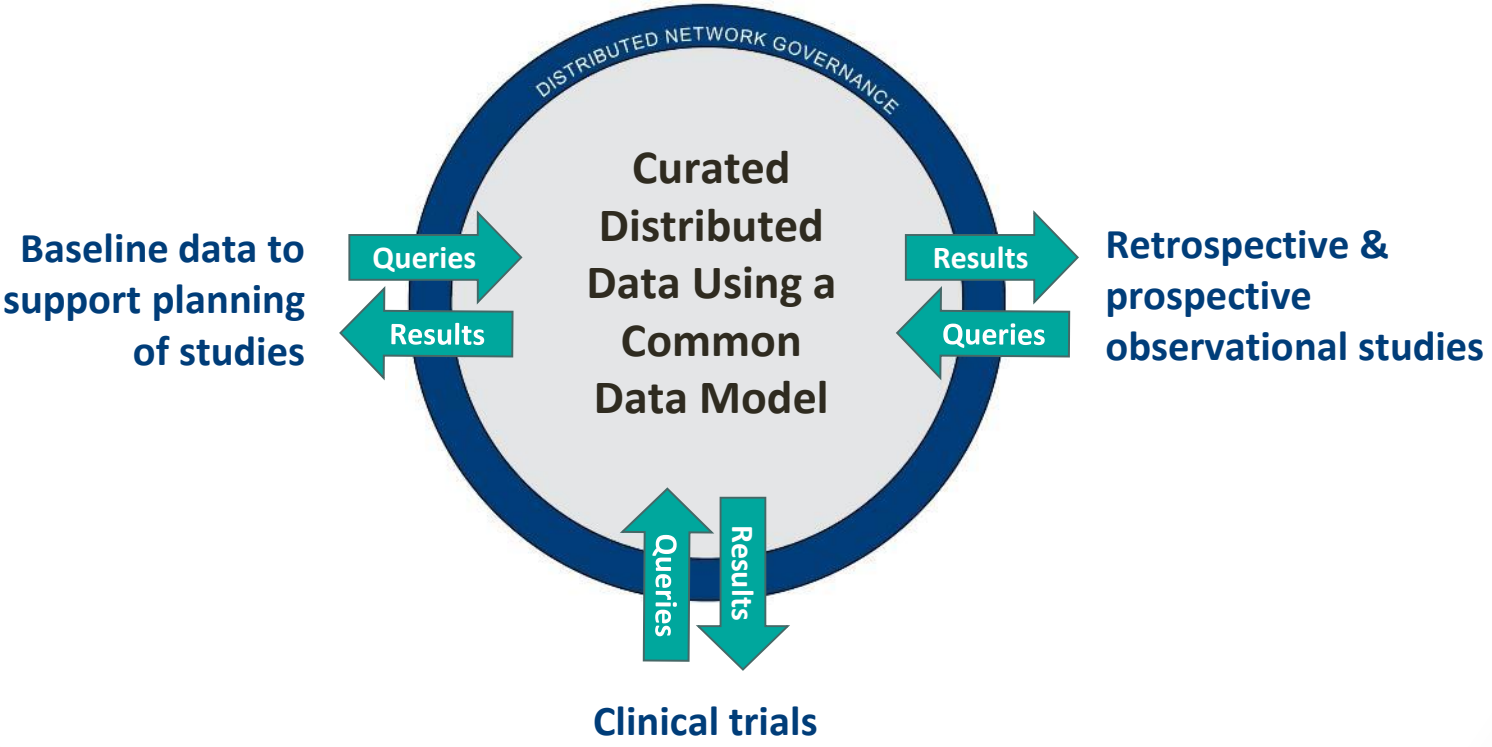
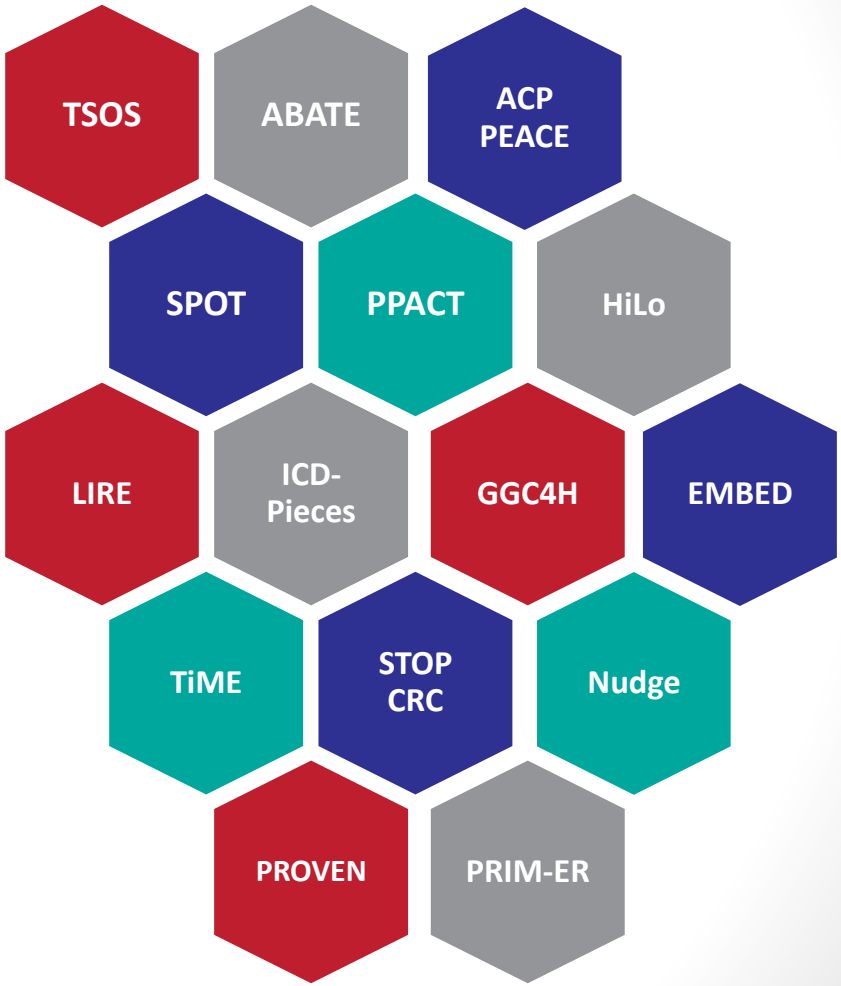
Distributed Research Network

Enables investigators to collaborate in the use of electronic health data while safeguarding protected health information



Demonstration Projects

- Collaboratory pragmatic trials conducted within health care systems to address questions of major public health importance
- Span multiple Institutes & Centers
- 1-year planning phase
- Implementation phase



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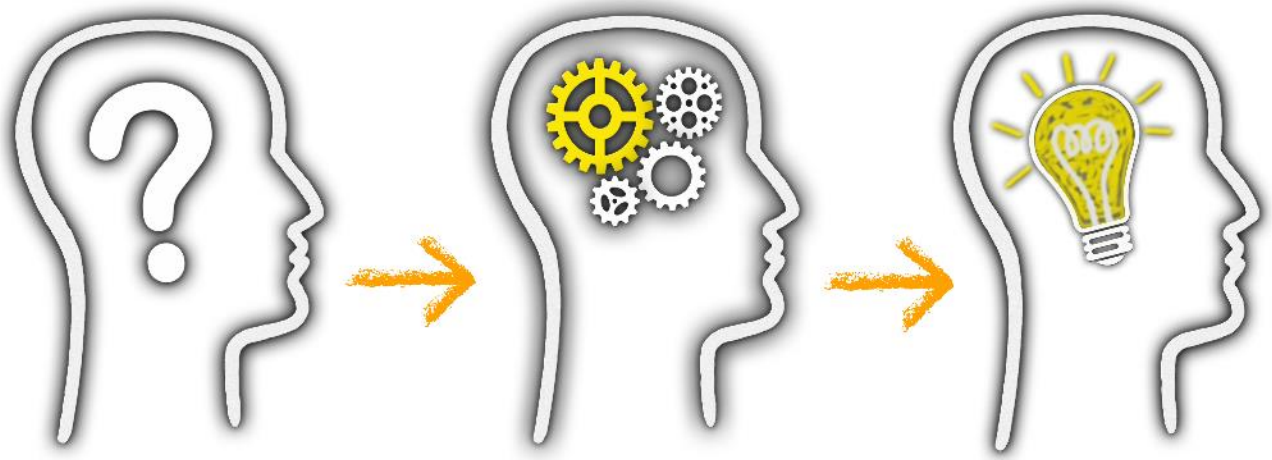
What our projects contribute…



LESSONS LEARNED

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JAMA Internal Medicine | Original Investigation

Effectiveness of a Mailed Colorectal Cancer Screening Outreach Program in Community Health Clinics
The STOP CRC Cluster Randomized Clinical Trial

Gloria D. Coronado, PhD; Amanda F. Petrik, MS; William M. Vollmer, PhD; Stephen H. Taplin, MD, MPH; Erin M. Keast, MPH; Scott Fields, MD; Beverly B. Green, MD, MPH

October 4-8 • San Diego, CA • www.idweek.org

IDWeek 2017™

Advancing Science, Improving Care

Daily Chlorhexidine Bathing in General Hospital Units – Results of the ABATE Infection Trial (Active BAThing to Eliminate Infection)

KIDNEYWEEK 2017

New Orleans, LA • Oct 31 - Nov 5

Primary Results of the Time to Reduce Mortality in End-Stage Renal Disease (TiME) Trial: A Pragmatic Trial Demonstration Project of the NIH Health Care Systems Research Collaboratory

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What are we working on now?

July 2018

NIH awards support

for **6** new

Demonstration Projects

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ACP PEACE *Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly*

- Cluster randomized trial testing whether clinician communication skills training and patient video decision aids will increase **advance care plan completion** in patients >65 with advanced cancer
- 4,500 patients in 36 oncology clinics across 3 systems

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HiLo *Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing Hemodialysis*

- Cluster randomized trial testing whether less stringent control of serum phosphate levels will yield **non-inferior rates of all-cause hospitalization** in patients with end-stage renal disease undergoing hemodialysis
- ~4,400 patients across >100 dialysis facilities

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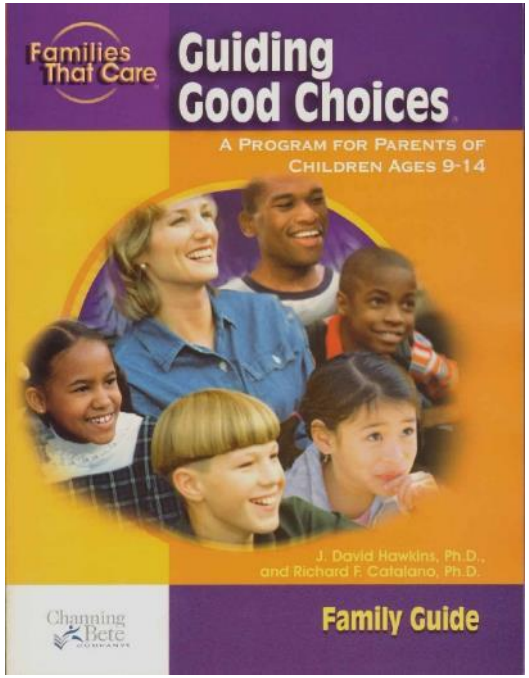
GGC4H *Guiding Good Choices for Health*

- Cluster randomized trial testing whether an anticipatory guidance curriculum for parents of early adolescents will reduce **behavioral health problems and health service utilization**
- 72 pediatricians across 3 health systems; ~4,500 families



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EMBED *Pragmatic Trial of User-Centered Clinical Decision Support to Implement EMergency Department-Initiated BuprenorphinE for Opioid Use Disorder*

- Cluster randomized trial testing the effect of user-centered computerized clinical decision support on rates of **emergency department–initiated buprenorphine/naloxone and referral for ongoing medication-assisted treatment** in patients with opioid use disorder

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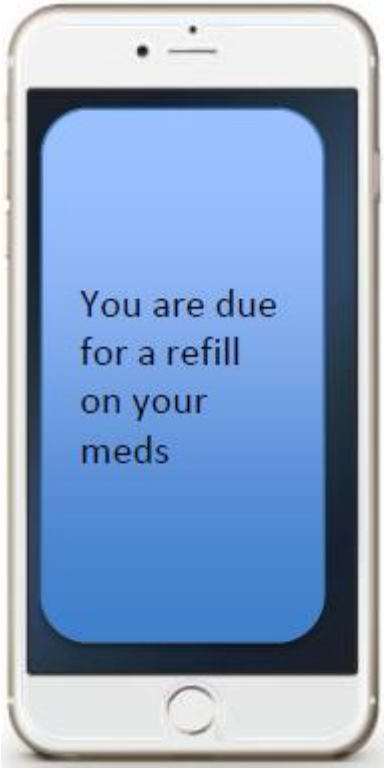
Nudge *Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications*

- Patient-level randomized pragmatic trial comparing the effects of digital interventions (text messages and chat bot) on **medication adherence** in patients with chronic CV conditions
- 3 health systems



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PRIM-ER *Primary Palliative Care for Emergency Medicine*

- Cluster randomized trial testing the effects of implementing primary palliative care in emergency medicine on **healthcare utilization and survival**
- 35 emergency departments across 18 health systems

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Summary of New Projects

Study	Population	Intervention	Outcome
ACP PEACE	Patients with advanced cancer	Clinician communication skills training and patient video decision aids for advanced care planning	Advance care plans completion; medical orders for resuscitation preferences; palliative care consultations; hospice use
HiLo	Patients undergoing hemodialysis	Liberalizing serum phosphate target	Rate of hospitalization
GGC4H	Parents of early adolescents	Anticipatory guidance curriculum	Behavioral health problems; health service utilization
EMBED	Patients with opioid use disorder	User-centered computerized clinical decision support	Rate of emergency department–initiated buprenorphine/naloxone; referral for ongoing medication assisted treatment
Nudge	Patients with chronic CV conditions	Text messages and chat bot	Adherence to CV medications
PRIM-ER	Older adults (>65 years)	Palliative care education; simulation-based workshops; clinical decision support; provider audit and feedback	Healthcare utilization and survival

Sharing Challenges & Solutions

Collaboratory videos & interviews

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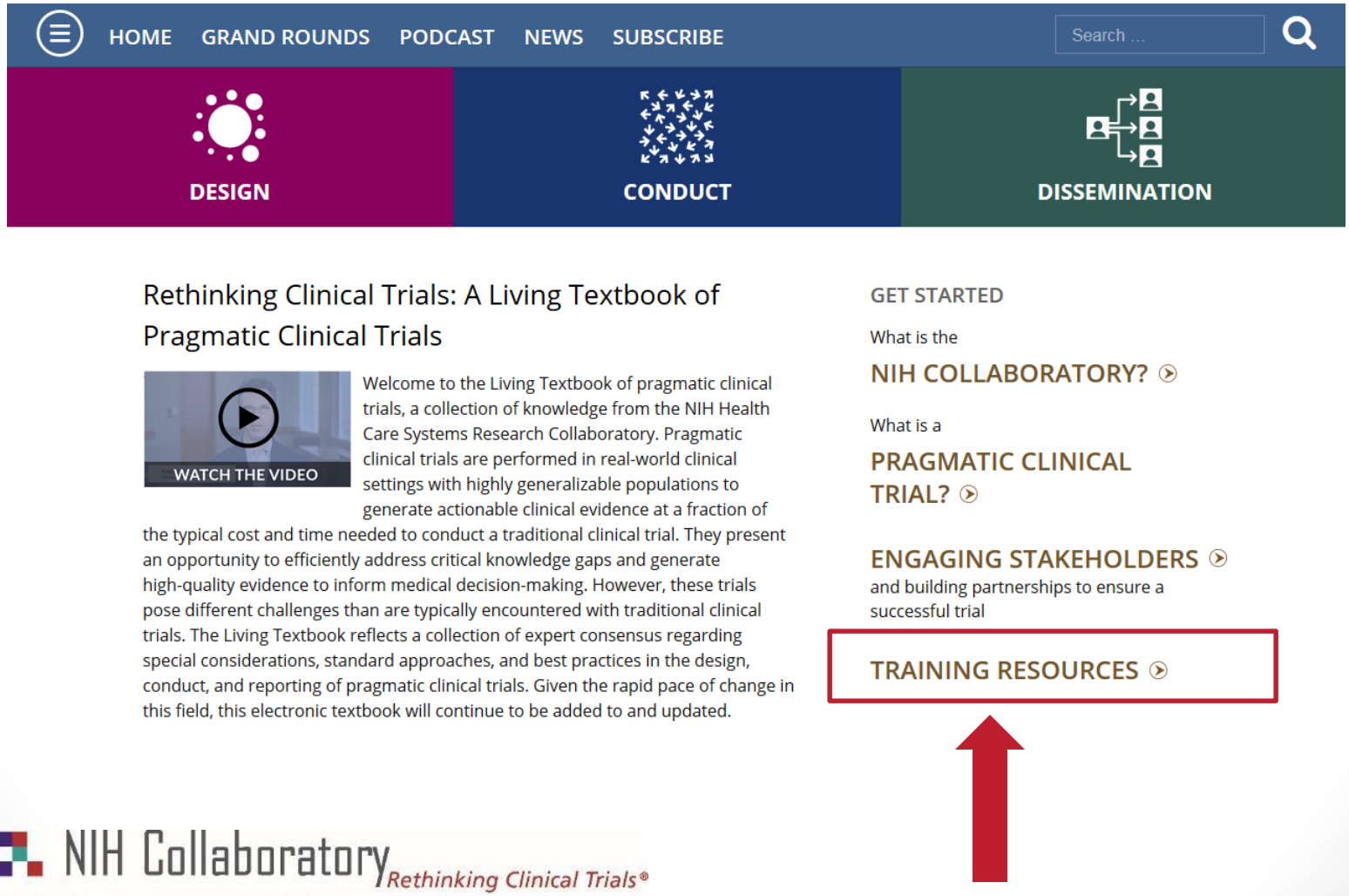
Training Resources for Investigators



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Partner Organizations

Grand Rounds
- Shared PCORnet/ Collaboratory forum
- Frequent presentations by partner organizations

Collaboration on
- Workshops
- Regulatory/ethics publications

Shared tools & resources
- Links to external resources in Living Textbook

NIH Collaboratory Newsletter

Subscribe to this convenient monthly wrap-up:

www.rethinkingclinicaltrials.org/newsletter-subscribe/

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News From the NIH Collaboratory

Welcome to the NIH Collaboratory E-Newsletter! The newsletter is intended to provide a convenient monthly wrap-up of NIH Collaboratory news, along with featured stories and a look at what's coming in the month ahead. We hope you'll find it useful, and we'd love to hear your feedback. **Please let us know what you think.**

QUICK LINKS

Living Textbook

Grand Rounds Hub

Recent News

Reflections From the Patient-Reported Outcomes Core: Dr. Kevin Weinfurt, chair of the Patient-Reported Outcomes (PRO) Core, shares the successes of the first 5 years of the Core and looks ahead to the coming years: "We need to determine when PROs are essential, supporting, or not at all informative for the clinical questions. This gets at the value proposition: When are they of value and to whom?"

NCI Announces Training Institute in Dissemination and Implementation Research in Cancer: The National Cancer Institute is accepting applications for a Training Institute in Dissemination and Implementation Research in Cancer (TIDIRC). Designed for investigators at all levels, this cancer-focused training program will consist of a 4-month online course and a 2-day in-person training. The application window will close on February 9.

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What should be next?

Value of Pragmatic Clinical Trials

- Embedded Research Leverages Health Systems
  - What are the fixed costs being leveraged?
    - Large?
  - What are the variable costs?
    - Small?
- What's the net value?
  - Potential return of investment
- What's the ideal state for economies of scale?
  - Multiple trials can achieve highest value

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Expanded Education and Training

- Training for new investigators/NIH Staff on PCT methods
- Publicly available training materials, such as handouts , slides, videos, Living Textbook chapters/additions, or other content to be made available on the Collaboratory website.

Regulatory & Ethics

- Ethical and practical issues associated with incidental findings
  - Planned Administrative Supplement application
- Data safety and monitoring
- Nested Studies

Stakeholder Engagement

- Further stakeholder engagement
  - Empirical studies
  - How to build relationships with health systems
  - Address barriers with health system leaders
  - Healthcare plans
  - Clinicians

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Sustainability for embedded PCTs

- Define what's needed
  - What will it take for health systems to make this routine as opposed to the exception?
- Establishing a roadmap for eliminating barriers
  - Regulatory/Ethics
  - Engagement
  - Costs
  - Data silos
  - Others….

Conclusions

Conclusions

- Take advantage of continued interest in real world evidence and learning health systems
- Multiple lessons learned from rethinking research integrated with practice
- Cost-effective, large-scale research is possible and we have the charge to scale it…
  - By learning, sharing, and helping the ecosystem evolve

For More Information

Living Textbook

- **Comprehensive, searchable information on design, conduct & dissemination of embedded PCTs**
- **www.rethinkingclinicaltrials.org**

Knowledge Repository

- **Archives for the Living Textbook including presentations, videos, stakeholder interviews, guidance documents & more**

Twitter

- **@Collaboratory1**
- **@PCTGrandRounds**

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