NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

NIH Collaboratory Coordinating Center Overview and Goals

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Today's Presentation

1. What Are the Goals of the Collaboratory Coordinating Center?
2. How Are We Doing It?
3. How Do We Share What We Have Learned?
4. Conclusions

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What Are the Goals of the Coordinating Center?

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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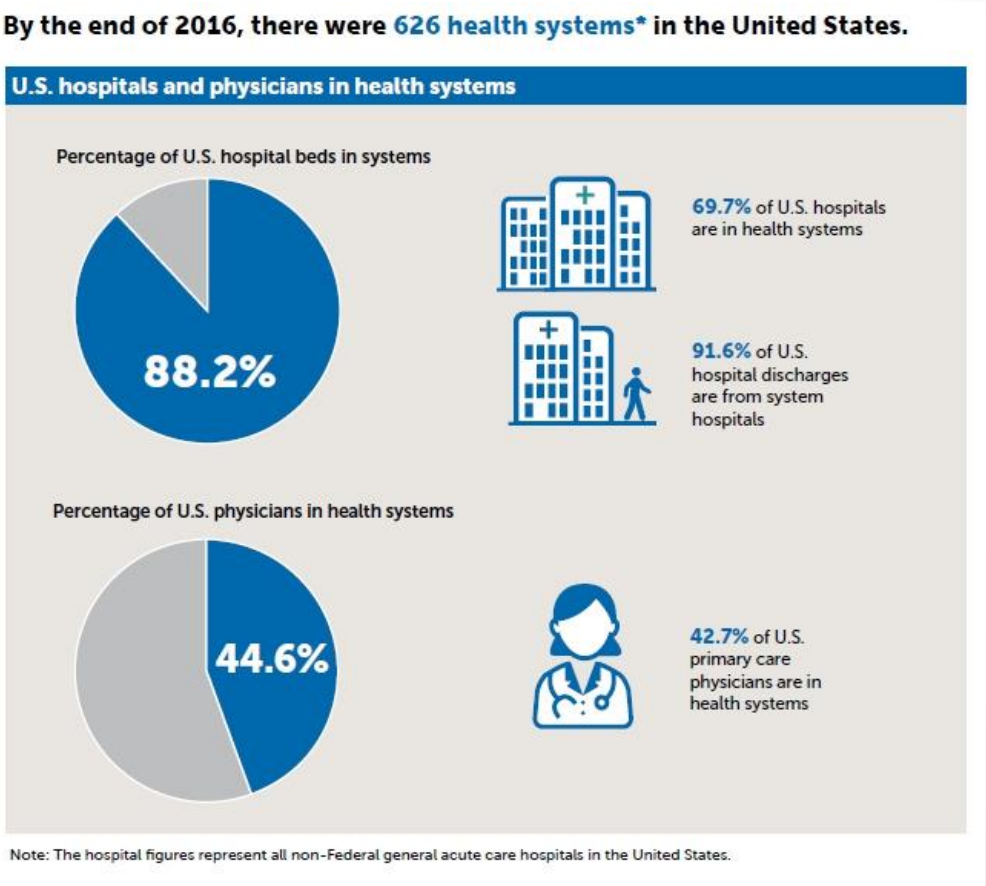
Increasing System-ness

Hospitals and physicians in US health systems

2000: 5810 hospitals

2016: 626 health systems

2020: ?



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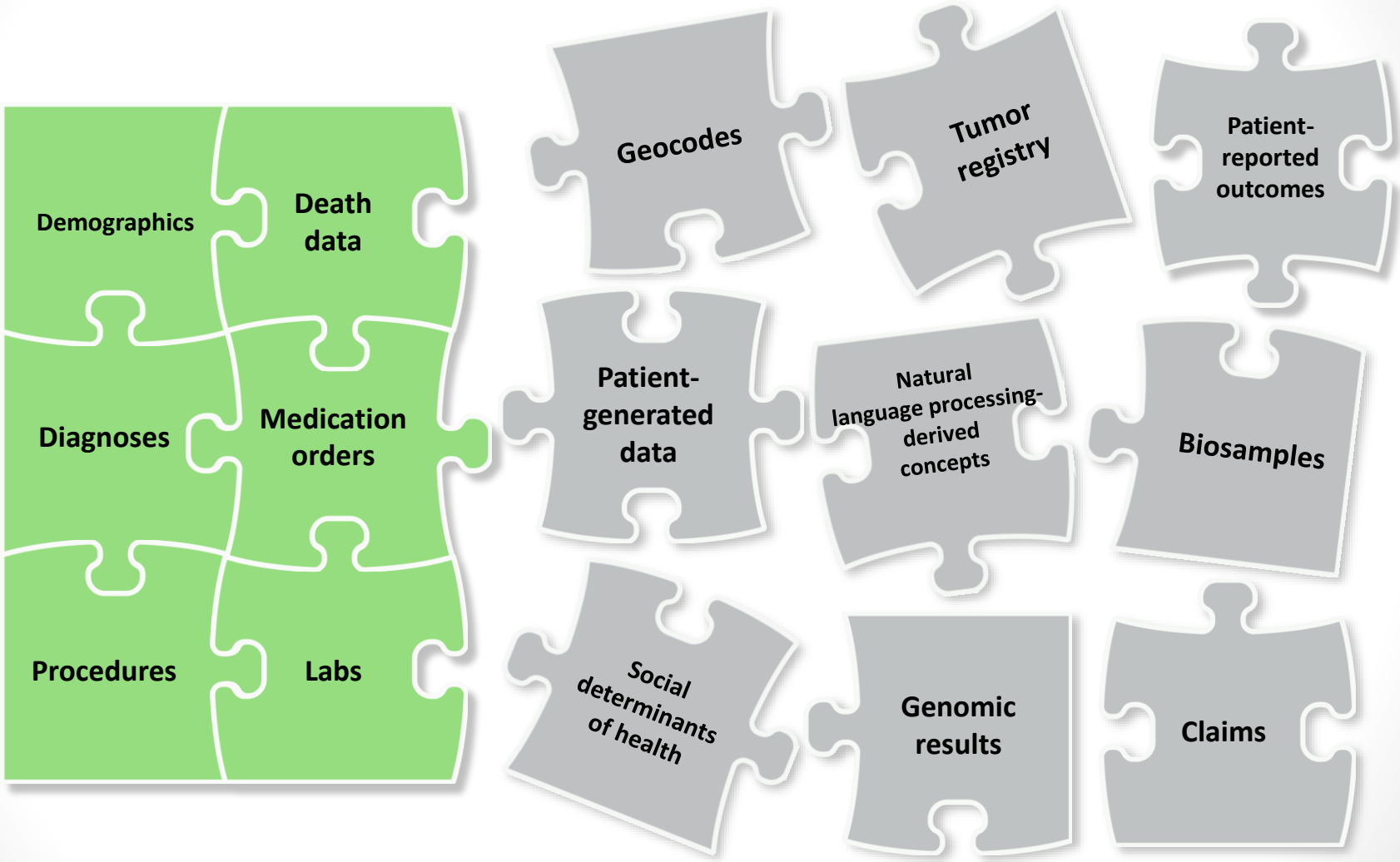
Data Everywhere



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The NIH 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 healthcare 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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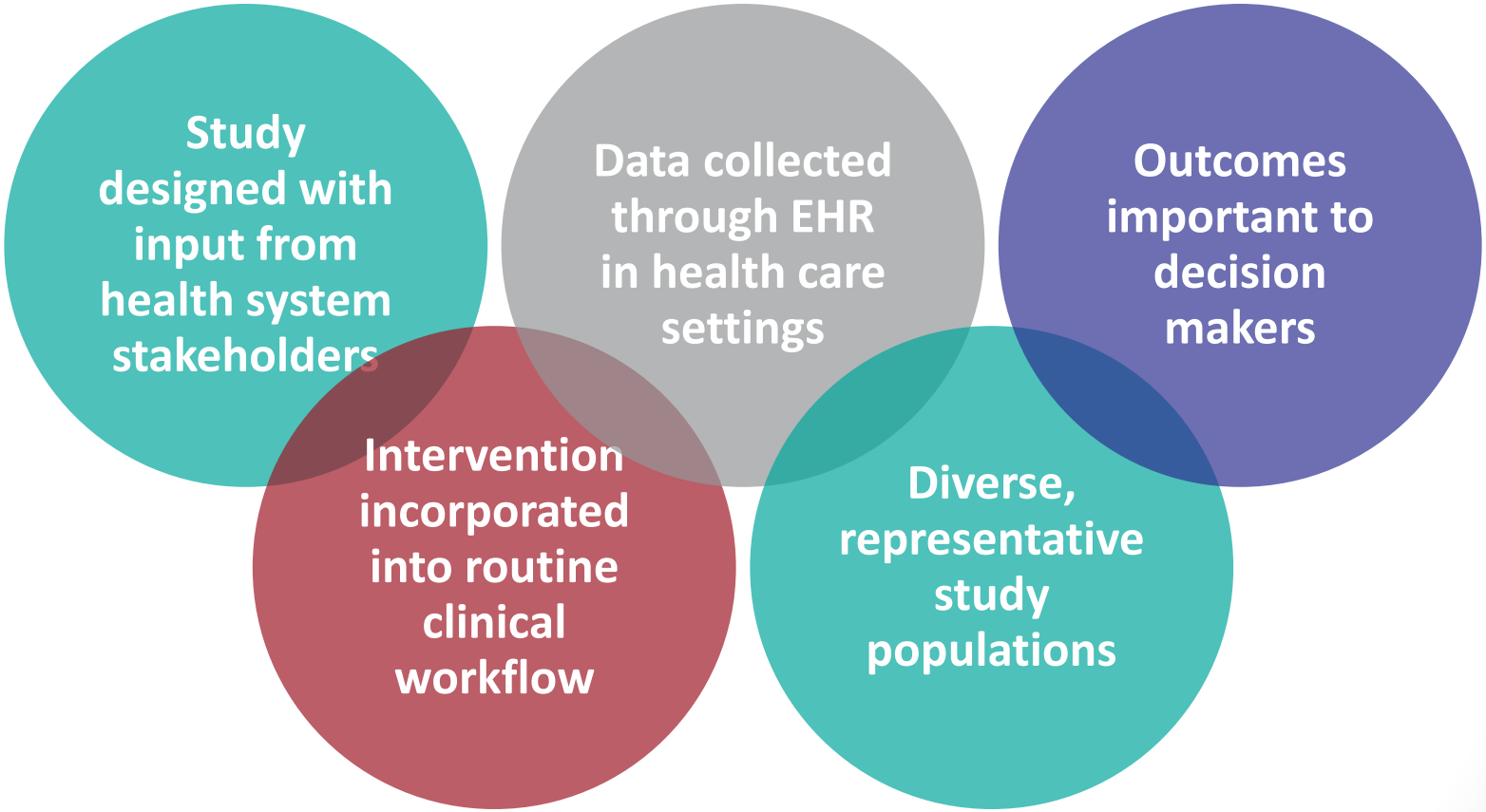
Embedded PCTs Bridge Research Into Clinical Care



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How Are We Doing It?

Structure of the Coordinating Center

Collaboratory Structure

Advisory Panel

NIH Project Officers

Demonstration Projects

Steering Committee

Core Workgroups

Coordinating Center

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Core Working Groups

- Guide and support Demonstration Projects
- Disseminate knowledge
- Chair from Coordinating Center and representatives from NIH and Demonstration Projects

Biostatistics and Study Design

Electronic Health Records

Health Care Systems Interactions

Patient-Reported Outcomes

Regulatory/Ethics

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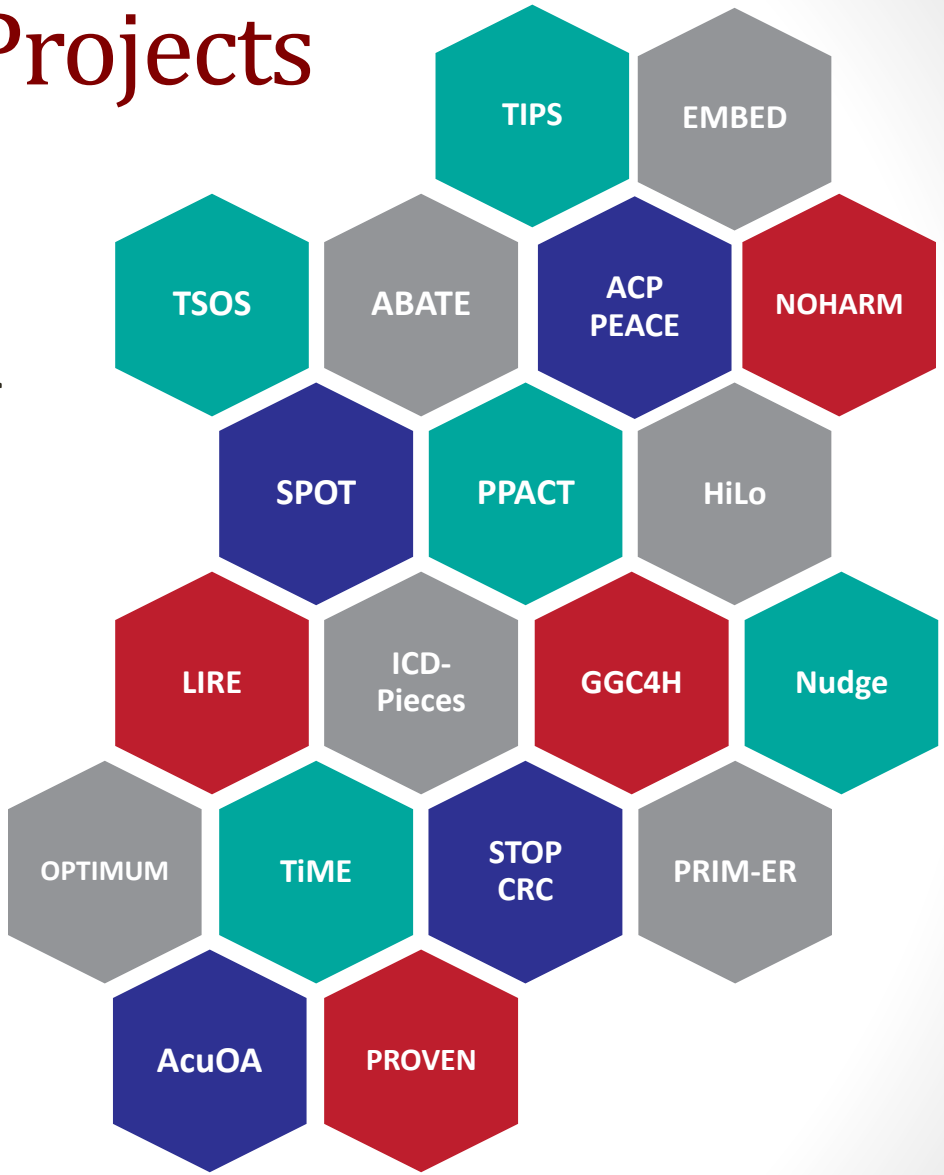
How Are We Doing It?

Demonstration Projects

Demonstration Projects

- Pragmatic trials embedded in healthcare systems to address questions of major public health importance
- Projects span multiple NIH Institutes, Centers, and Offices
- One-year planning phase followed by implementation phase



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Completed Demonstration Projects

Project	Population	Intervention	Outcome
ABATE	Non-ICU patients	Decolonization strategies	MRSA and VRE clinical cultures
PPACT	Nonmalignant chronic pain	Multidisciplinary behavioral care management	Brief Pain Inventory
STOP CRC	Adults aged 50-75 years	Direct mail CRC screening program (FIT kit)	CRC screening rates
TiME	Patients initiating dialysis	Dialysis session of at least 4.25 hours	All-cause mortality, hospitalization

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Ongoing Projects

Project	Population	Intervention	Outcome
ACP PEACE	Older adults with advanced cancer	Advance care planning program	Completed advance care plans, resuscitation preference orders, palliative care consults, hospice enrollment
EMBED	Opioid use disorders	Computerized clinical decision support for ED-initiated BUP, referral for ongoing treatment	Rates of ED-initiated BUP
GGC4H	Parents of early adolescents	Universal evidence-based anticipatory guidance curriculum	Drug use, depression, delinquent behavior
HiLo	Patients with ESRD receiving maintenance hemodialysis	Higher vs lower serum phosphate target	Hospitalization, mortality
ICD-Pieces	Comorbid diabetes, CKD, hypertension	Collaborative primary care program	Hospitalization for 3 conditions

Ongoing Projects (continued)

Project	Population	Intervention	Outcome
LIRE	Low back pain	Insertion of epidemiologic benchmarks in lumbar spine imaging reports	RVU for spine-related interventions
Nudge	Chronic cardiovascular conditions	Text message reminders and AI-based interactive chat	Medication adherence
PRIM-ER	Older adults in EDs with serious, life-limiting illness	Primary palliative care program in EDs	ICU and hospital admissions; inpatient days; discharge to home and palliative care service; use of home health and hospice; survival
PROVEN	Nursing home patients	Advance care planning video (behavioral program)	Hospitalization, presence of advance directive
SPOT	Suicidal ideation or depression	Collaborative care behavioral program (care management and skills training)	Suicide attempts
TSOS	Traumatic injury	Collaborative care management program	PTSD checklist, PHQ-9, alcohol use disorders, SF-12/-36

PRISM Demonstration Projects

Project	Population	Intervention	Outcome
AcuOA	Older adults with low back pain	Standard and enhanced 12-week courses of acupuncture	Back-related function at 26 week, cost-effectiveness
NOHARM	Postoperative pain	EHR-embedded tools to aid shared decision making about pain management	Postoperative opioid use, pain, function
OPTIMUM	Chronic low back pain	Group-based mindfulness in outpatient clinical settings	Pain, physical and psychological function, opioid prescriptions for chronic low back pain
TIPS	Fibromyalgia	Addition of transcutaneous electrical nerve stimulation to physical therapy	Fibromyalgia symptoms, adherence to therapy, meeting therapeutic goals, medication use

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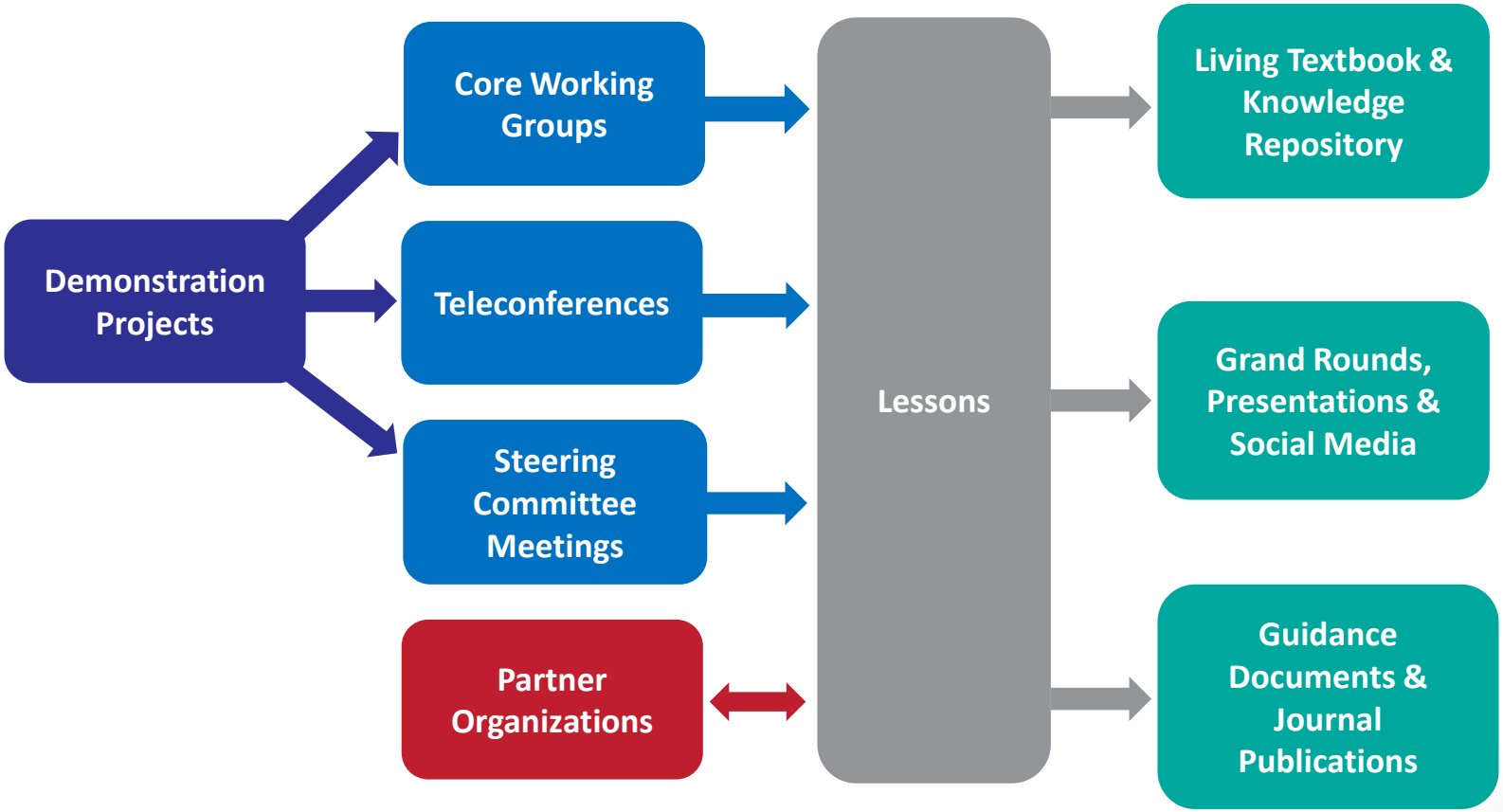
How Are We Doing It?

Process for Identifying and Responding to Issues

Flow of Information



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Issue Tracker

Challenge	Raised by (PI)	Category	Date Reported	Status Updated	Status at Last Check In
Culture: Beginning second set of site visits; culture change is needed around beliefs about infection control.	Huang	Practice norms & workflow	9/12/14	2/25/15	Ongoing – Investigators continuing follow up site visits for facilities struggling with compliance and overuse of CHG.
A radiologist unhappy with the intervention and how it changes the format of radiology reports. This might lead to a site withdrawing.	Jarvik	Engage-ment	4/24/15	4/24/15	New challenge: We're currently doing what we can to work through this issue.

Sharing Challenges & Solutions

Teleconferences, SC Meetings,
Collaboratory Videos & Interviews

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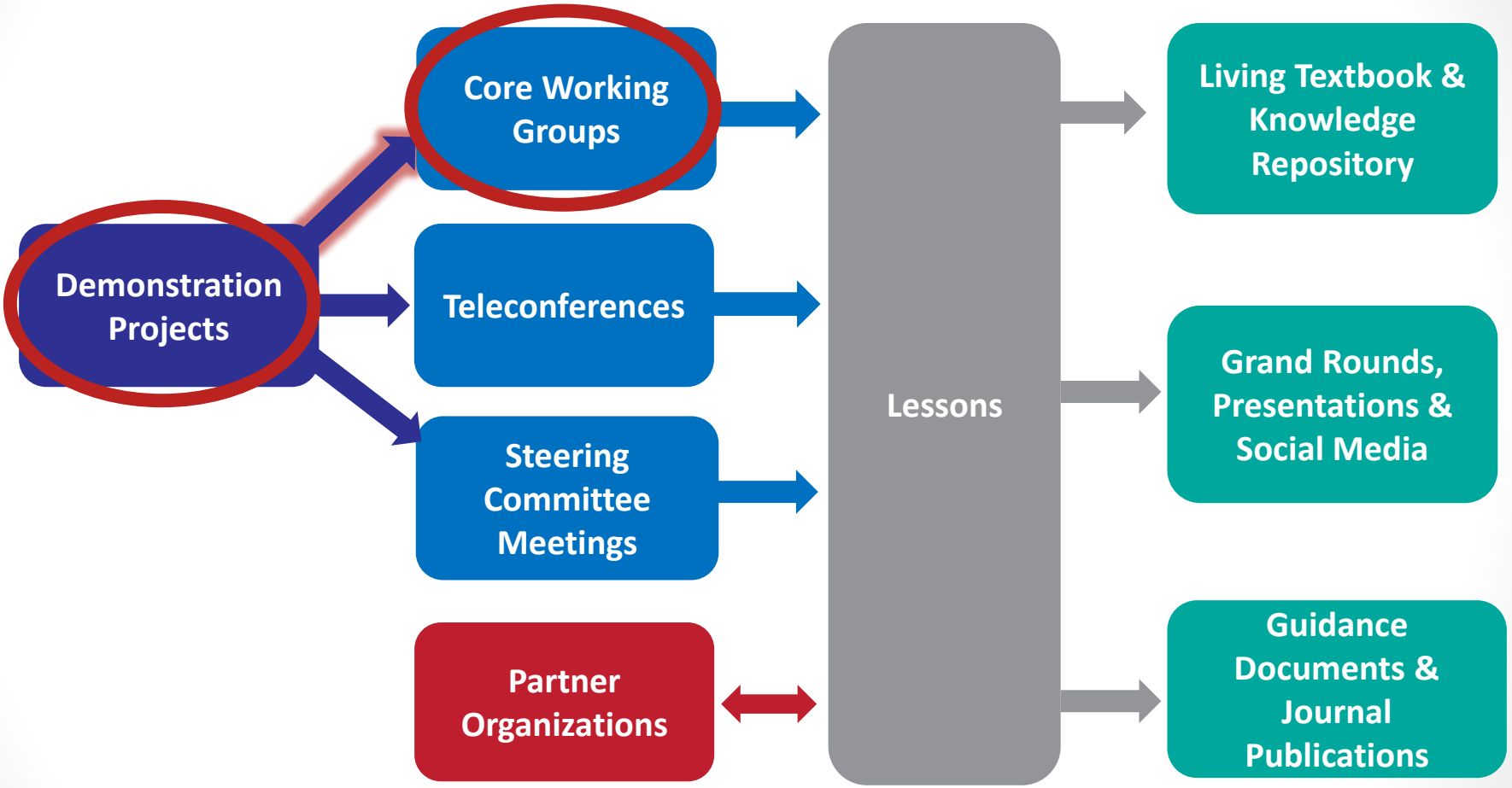
How Do We Share What We Learn?

Process for Dissemination

Flow of Information



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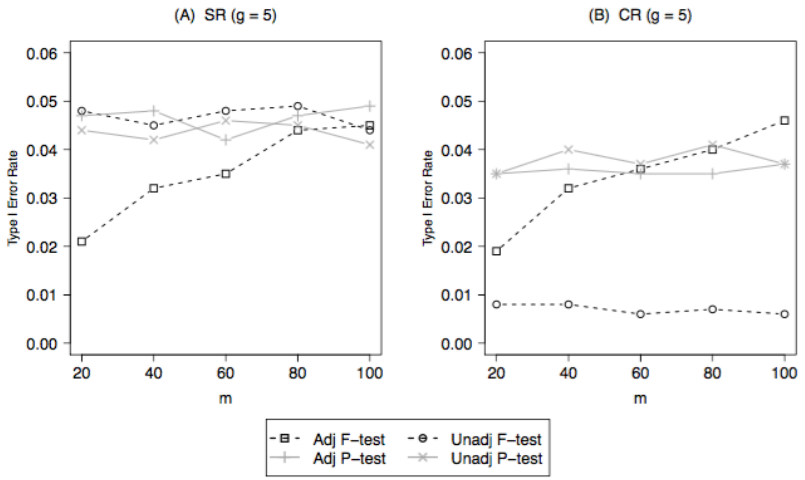
Simulation Studies

Lessons re: Design & Analysis



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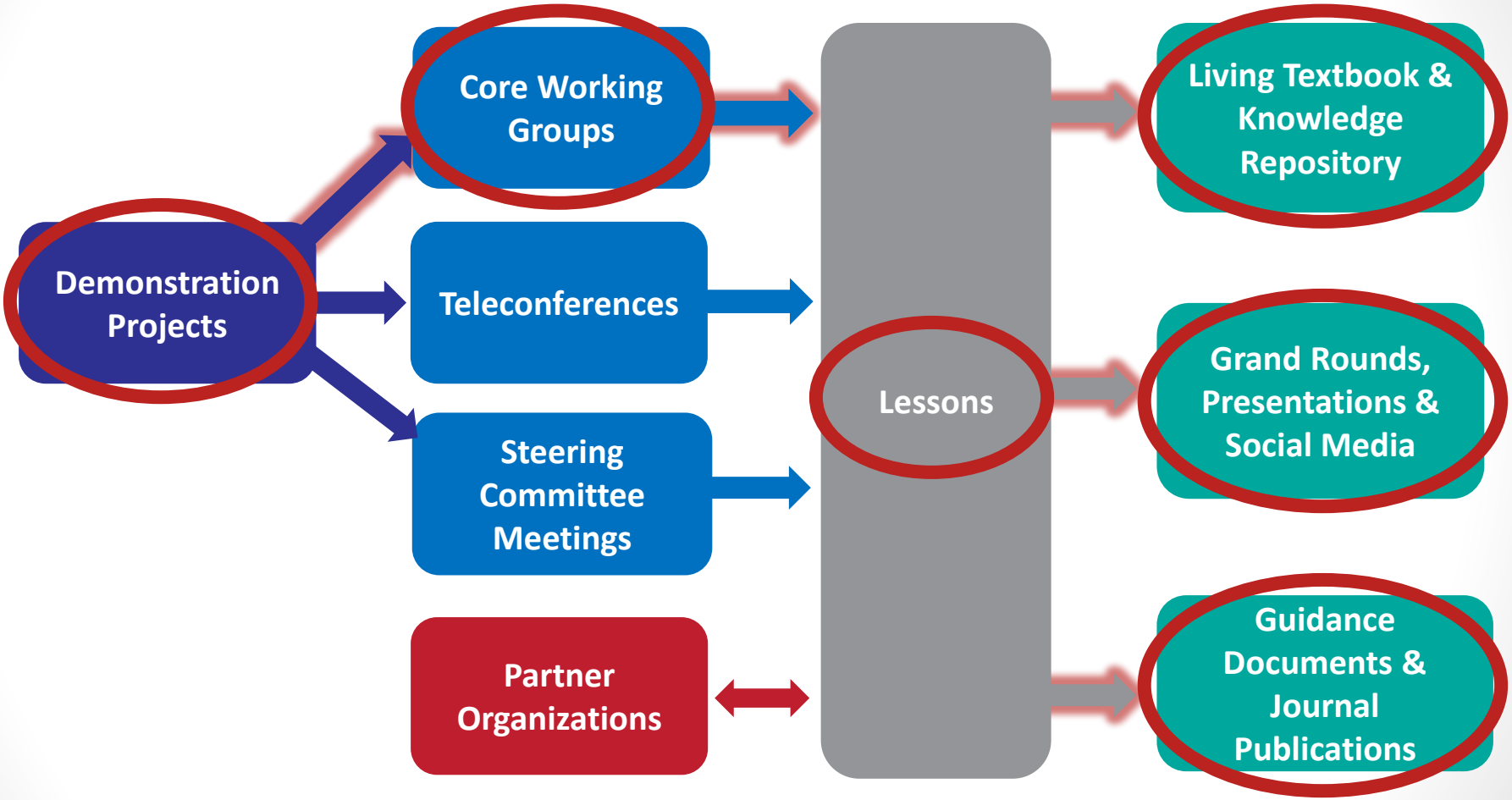
Flow of Information



The Living Textbook *of Pragmatic Clinical Trials*

www.rethinkingclinicaltrials.org

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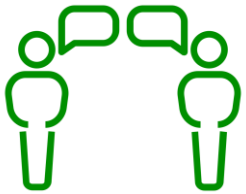
PCT Training Workshops

- What are Embedded PCTs?
- Engaging All Stakeholders & Aligning With HCS Partners
- Designing With Implementation in Mind
- Design & Analytic Considerations
- Regulatory & Ethical Challenges
- Measuring Outcomes
- Pilot & Feasibility Testing
- Dissemination
- ePCT Team Composition
- Developing a Compelling Application

Case Studies

Interactive Exercises



Living Textbook Content

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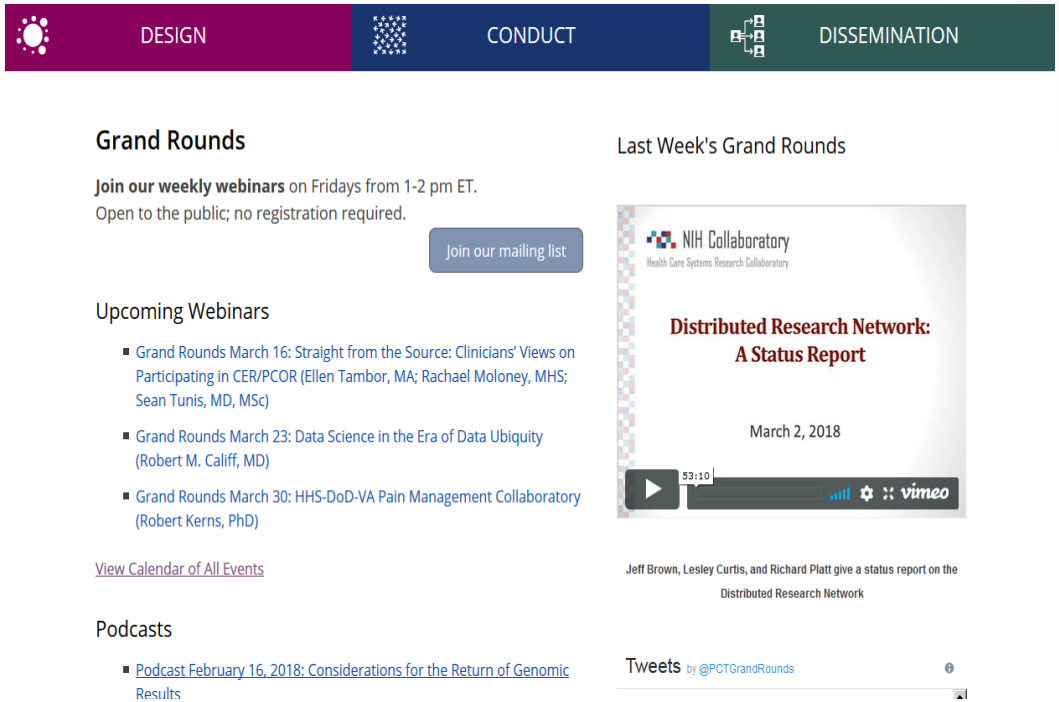
PCT Grand Rounds Presentations

- Weekly webinars on a wide range of research topics
- >300 presentations since inception
- Podcasts of expert interviews available on iTunes and Soundcloud



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For More Information

Living Textbook

- Comprehensive, searchable information on design, conduct, and dissemination of embedded PCTs
- rethinkingclinicaltrials.org

Monthly Newsletter

- Convenient monthly wrap-up of NIH Collaboratory news, Demonstration Project spotlights, and new Living Textbook content
- rethinkingclinicaltrials.org/newsletter-subscribe

Twitter

- @Collaboratory1

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Conclusions

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

What's Next: Expanded Knowledge

- Develop and disseminate guidelines and lessons learned from the PRISM projects
- Promote synergies with newer Collaboratory programs
  - NIA Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory
  - NIH-DoD-VA Pain Management Collaboratory
- Advance the quality and impact of patient-centered outcome measures
  - Using patient engagement activities
  - By understanding and disseminating best practices for assessing pain and related constructs in the context of ePCTs
- Study innovative dissemination and implementation science approaches

What will you contribute…

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

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