

Highlights of the NIH Pragmatic Trials Collaboratory

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Since 2012, program has worked with diverse range of pragmatic trials to:

1. Optimize their capacity to complete their trials
2. Help them contribute generalizable knowledge



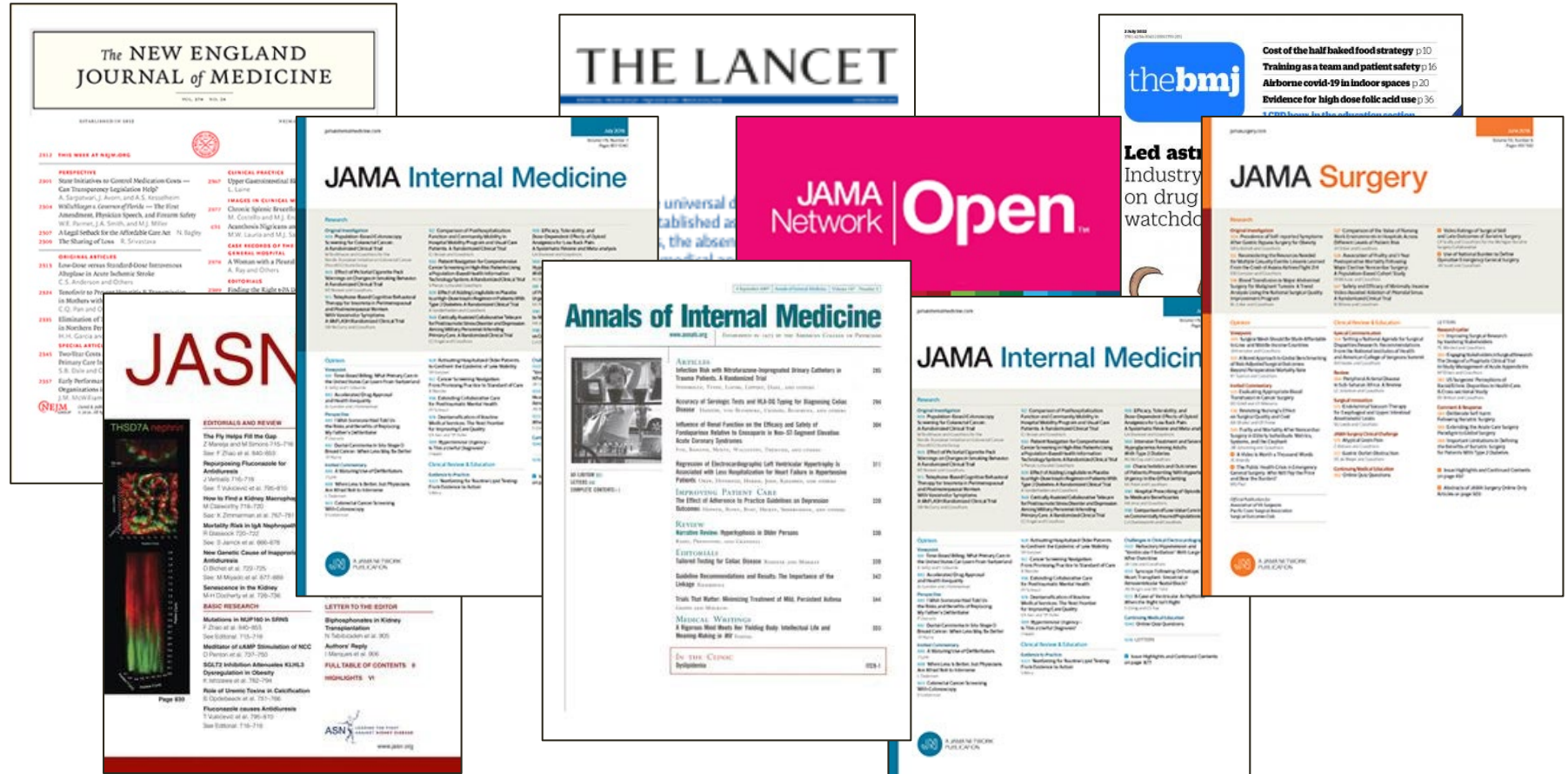
NIH Collaboratory Trials

- ePCTs addressing questions of major public health importance
 - Wide variety of therapeutic areas
 - Many have phased funding
 - Planning/Startup phase
- ↓
- Implementation phase



Nine Trials Completed and Published

- STOP CRC
- TIME
- ABATE Infection
- PROVEN
- LIRE
- TSOS
- PPACT
- SPOT
- EMBED
- ICD-Pieces



Question:

Does an EHR-based outreach program with mailed stool tests improve rates of colorectal cancer screening?

Pragmatic Trial:

26 FQHC clinics randomized to routine care or intervention



Clinical Impact:

Adopted intervention in at least 150 clinics
Implementation materials published to support uptake



Care

Research

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Evidence

Results:

Significantly improved screening rates

Study Population:

>40,000 patients and ~6,300 mailed stool tests

NIH Collaboratory Support:

- *Biostatistics:* Extensive support to modify analysis, develop secondary analysis
- *Data:* Helped team learn and implement standards and methods for validating EHR code
- *Overall:* Knowledge sharing, troubleshooting

Core Working Groups: Your Contributions Matter

Sharing challenges and lessons promotes success, advances methods

>150
publications &
products



>1,000
Core meetings

Core	Topics Addressed
Biostatistics & Study Design	<ul style="list-style-type: none">▪ Design and analysis of group-randomized trials
Electronic Health Records	<ul style="list-style-type: none">▪ Assessing data quality▪ Integrating real-world data sources▪ EHR-based phenotyping
Ethics and Regulatory	<ul style="list-style-type: none">▪ Consent, waiver, and notification▪ Participant preferences▪ Data monitoring
Health Care Systems Interactions	<ul style="list-style-type: none">▪ Building partnerships▪ Accounting for quality improvement▪ Understanding system perspectives
Health Equity	<ul style="list-style-type: none">▪ Diversifying the research workforce▪ Expanding clinical sites
Implementation Science	<ul style="list-style-type: none">▪ Sustainment vs de-implementation▪ Posttrial responsibilities
Patient-Centered Outcomes	<ul style="list-style-type: none">▪ Selection and collection of PROs▪ Incorporating PROs into the EHR▪ Acceptability and burden of PROs

Impact of Cores



>225 trial consultations



>150

publications & products



>1,000 Core meetings



PI Testimonials

“Take the Biostats Core Working Group advice seriously—get it early and act on it early.”

“The CC helped greatly with the selection of our secondary outcome measures.”

“Have as many key members of your team work closely with Collaboratory Cores.”

“Having adjusted our strategy prior to IRB submission based on input from the Core was likely a major reason the IRB review went so smoothly.”

Dissemination Highlights

LIVING TEXTBOOK

30+ chapters 

 **>75,000**
visitors/year

>100 
contributors

TOTAL PUBLICATIONS

>315

CITATIONS

>8,300



>500

total Grand Rounds

>83,600 total attendees

Sharing Trial Data and Resources

STUDY TOOLS

- Protocols
- Consent forms
- Implementation tools
- Site materials
- Questionnaires
- Toolkits
- Ethics and regulatory documentation



77 study tools

DATASETS AND DOCUMENTATION

- Data dictionaries
- Public use datasets
- Analytic code
- Computable phenotypes
- Data quality manuals
- Data request forms
- Data sharing checklists



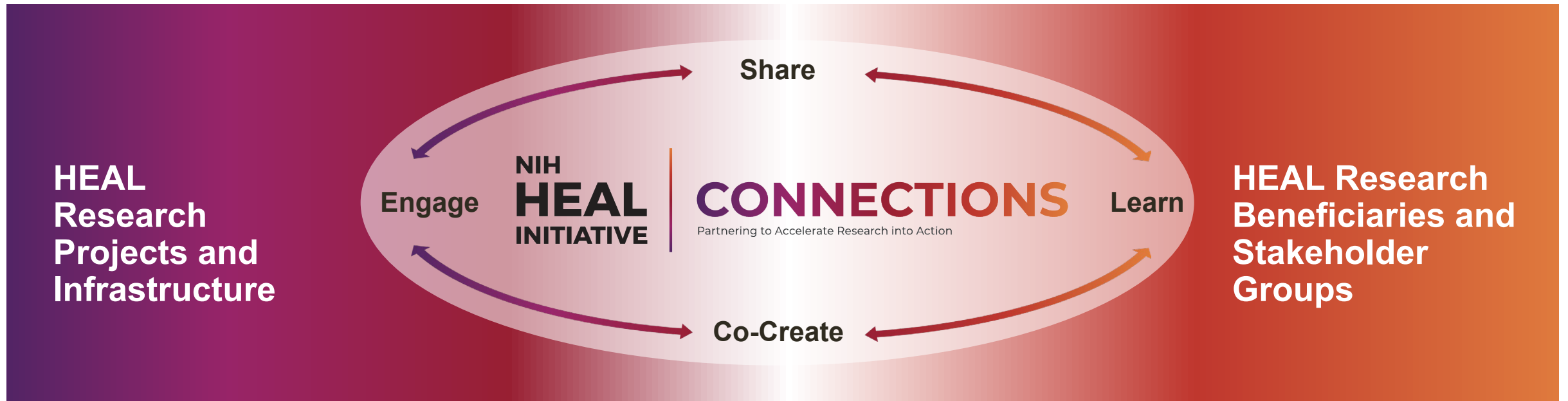
17 datasets and documentation

New: HEAL Connections Services

Creating pathways to **further build and sustain researcher-community partnerships**

Supporting HEAL researchers to **meaningfully share research results**

See handout in meeting eBinder



Latest Cohort of Trials (You!)

- IC-funded trials
 - Addressing health disparities
 - Enhanced implementation science methods
- HEAL-funded trials
 - Rural communities
 - Pain management
 - Requirements for community engagement



- How can we help you?
- What can you contribute?
- Questions for NIH?



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