

# Then, Now, and the Future...

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**NIH PRAGMATIC TRIALS  
COLLABORATORY**

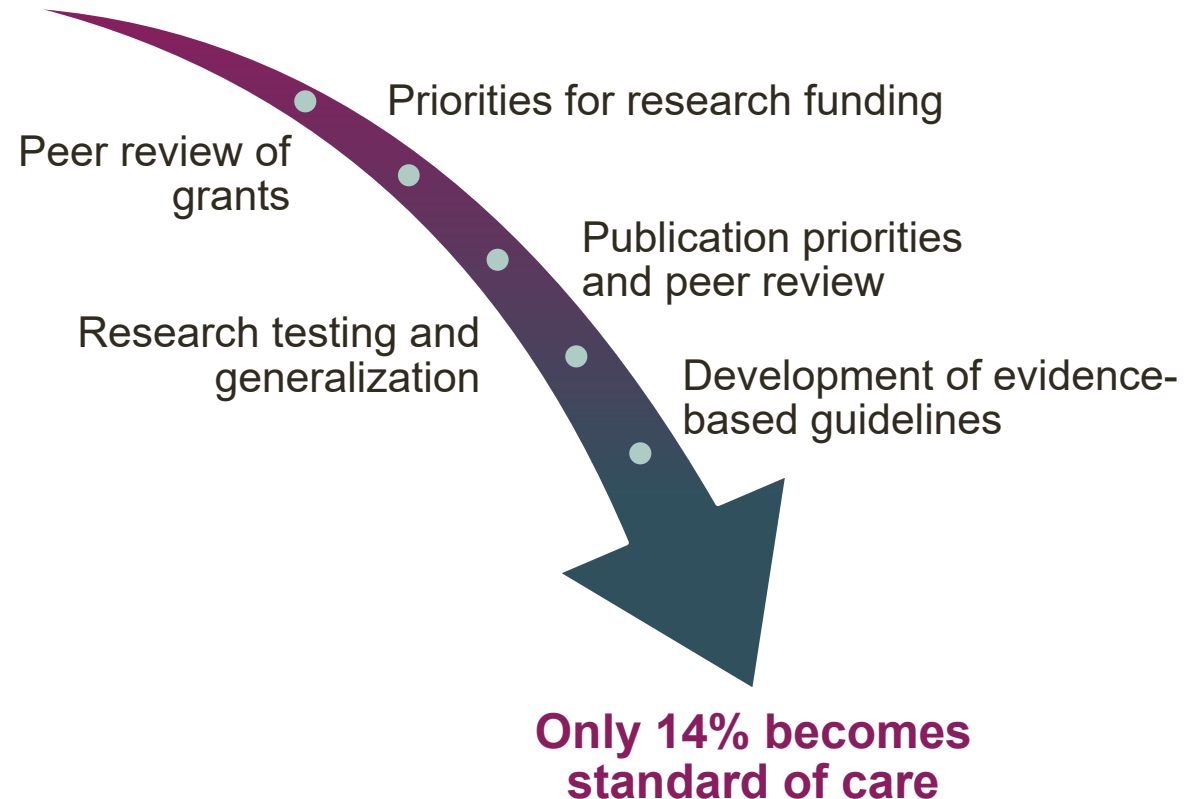
Rethinking Clinical Trials®

# The Problem

- Clinical research was not keeping pace with needs
- Clinical practice was not supported by evidence

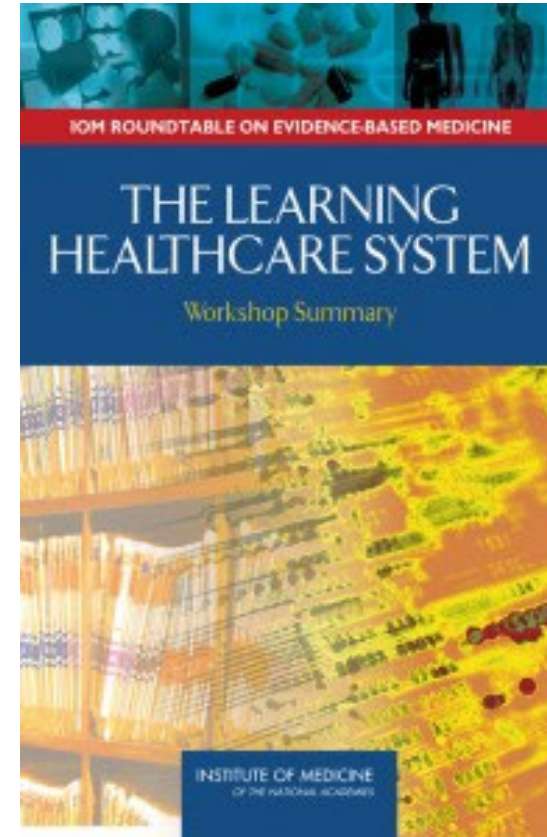
## The Long and Winding Road

(average **17 years** for research to become standard practice)



# 2010 IOM: Learning Health System

- By 2020
- “90% of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence”





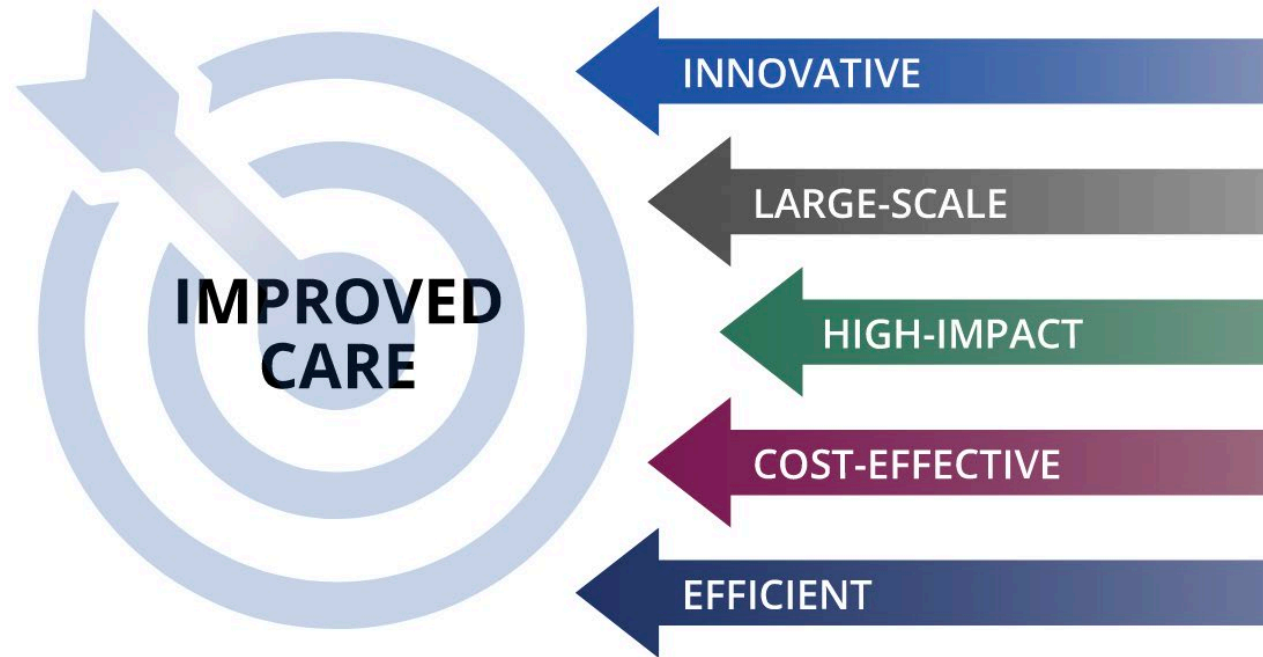
What if...

- We partnered with healthcare systems
- Embedded research into care
- Used routinely collected data to inform care
- Could we make research **faster, better, and more efficient?**

# Enter our fearless trailblazers...

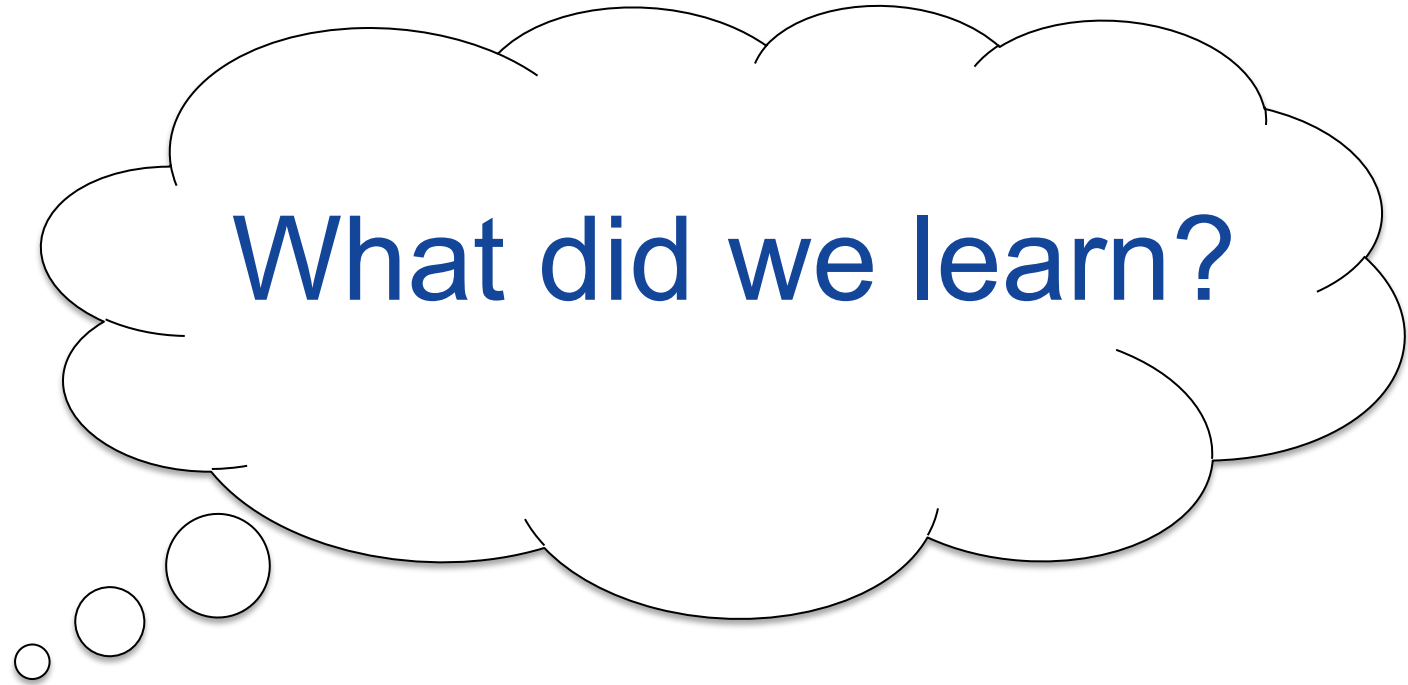


# The NIH Pragmatic Trials Collaboratory

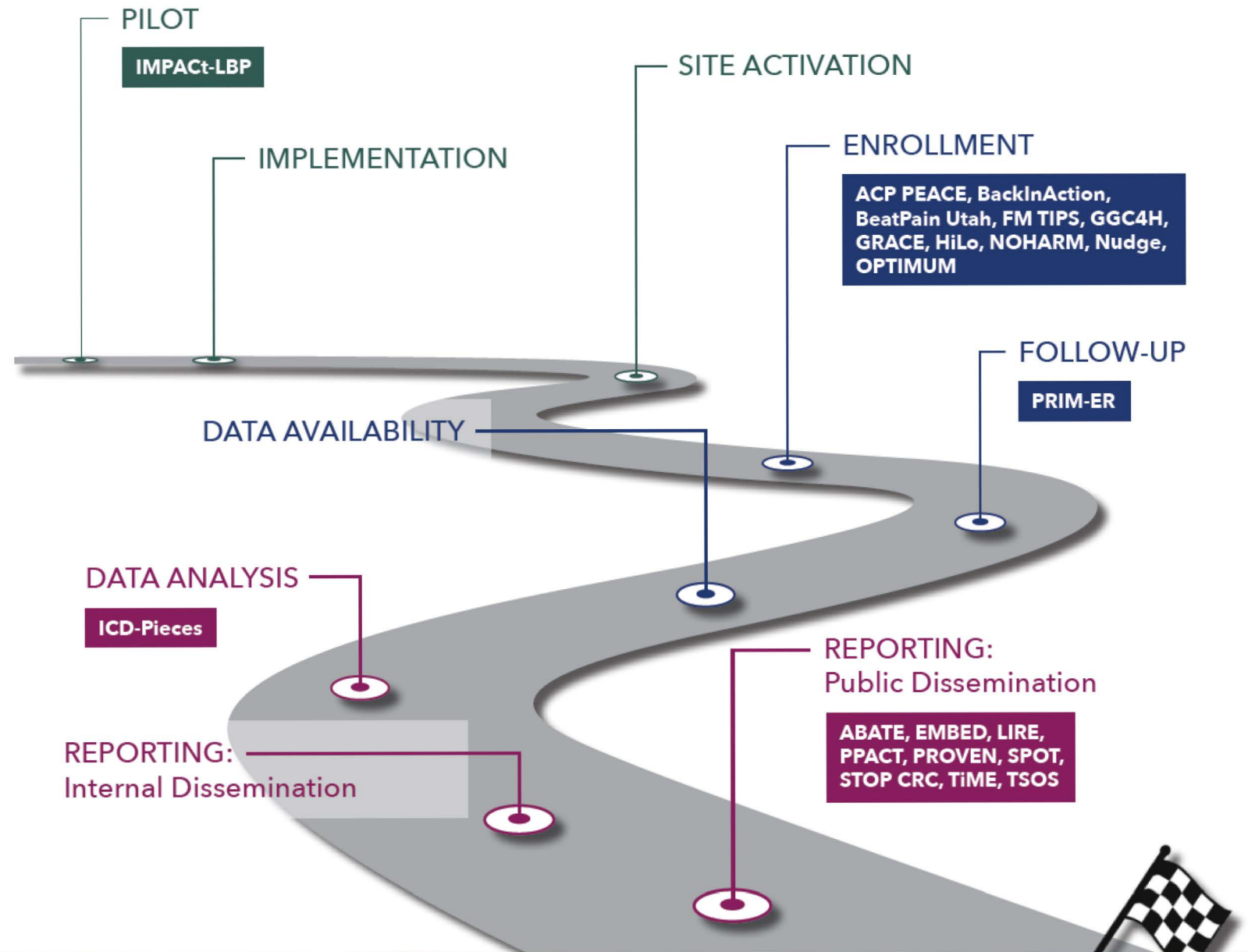


**OUR GOAL:** Improve care by ensuring healthcare providers and patients have the best clinical evidence on which to base care decisions

10 years later...



- 22 trials
  - 9 completed
- Influenced the evolution of clinical trials at NIH and beyond



# Pragmatic trials are hard

- There were many surprises
    - Cultural barriers
    - EHR complexities
    - Intervention fidelity concerns
    - Stability of control issues
    - Stepped-wedge challenges
    - Negative trials
- ...and more



# What did we get right?

- We've solved critical issues with regard to:
  - Ethics and regulatory
  - Biostatistics
  - Partnering with health systems
  - Using the EHR

# Where are we now?

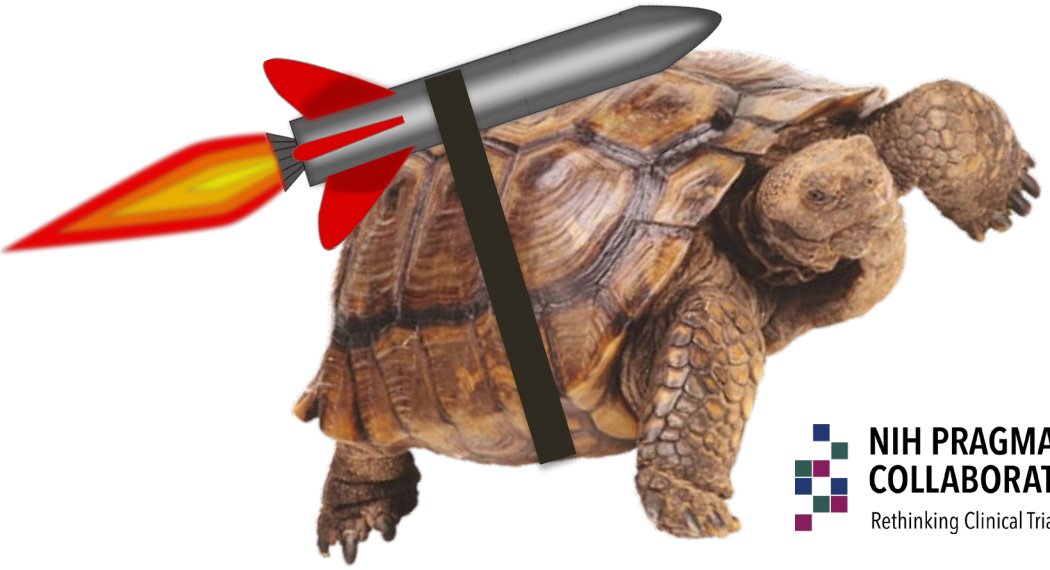
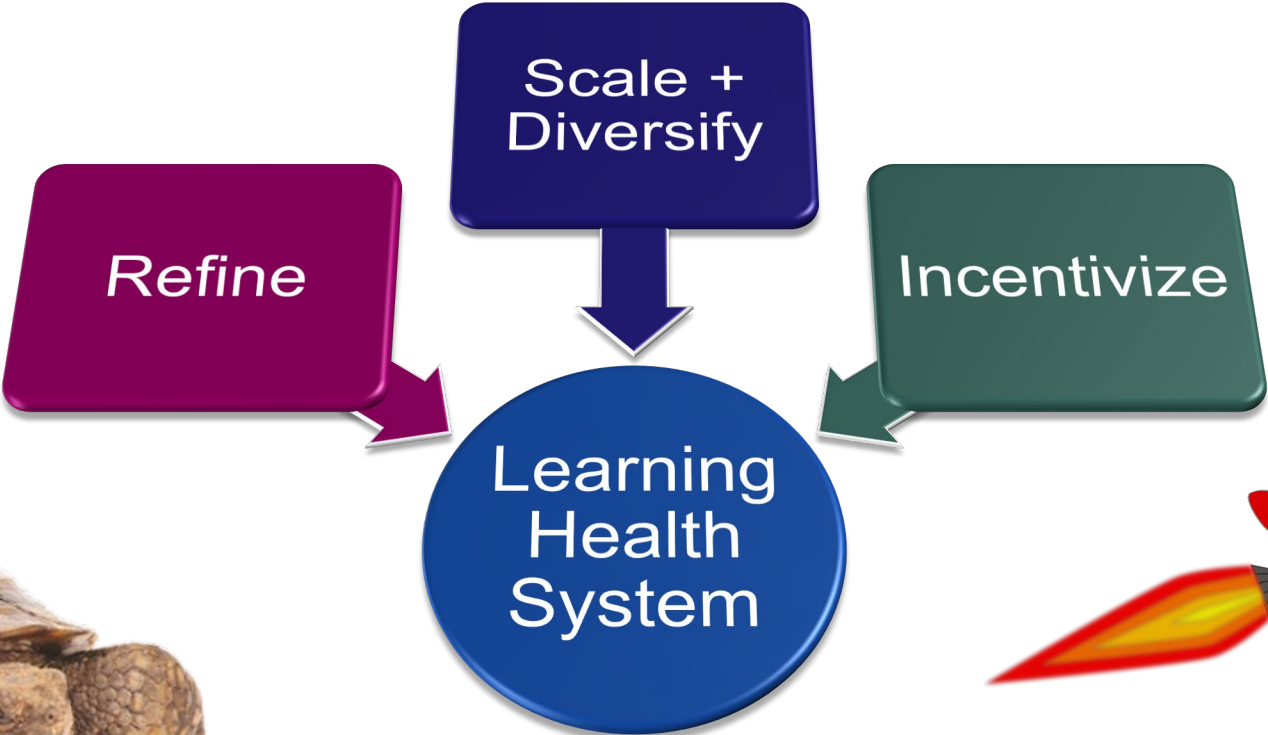
- We got the clinical research system unstuck

But...

We have yet to achieve a continuously learning health system



# Where do we go from here?



# Then, Now, and the Future

- This panel will discuss
  - Where we've been
  - Where we are now
  - What the future of embedded pragmatic trials holds



# Panel: NIH Colleagues

- Helene Langevin, MD from NIH NIDCR
- Richard Hodes, MD from NIA
- Walter Koroshetz, MD from NINDS

# Panel: From the Collaboratory

- Patrick Heagerty, Biostatistics and Study Design Core
- Jeremy Sugarman, Ethics and Regulatory Core
- Greg Simon, PI of SPOT and HCS Interactions Core
- Miguel Vazquez, PI of ICD-Pieces