

# Exploring the Generative Investment of an ePCT for Catalyzing Research

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**NIH PRAGMATIC TRIALS  
COLLABORATORY**

Rethinking Clinical Trials®

# Panelists

- Susan Huang, MD
  - Active Bathing to Eliminate (ABATE) Infection
  - INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients (INSPIRE)
- Natalia Morone, MD
  - Group-based Mindfulness for Patients with Chronic Low Back Pain in the Primary Care Setting (OPTIMUM)
- Jon Tilburt, MD
  - Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management (NOHARM)

# Session Goals

- Discuss elements of research platforms in NIH Collaboratory Trials most at risk of dissipating and needing to be rebuilt for future research
- Describe which elements could be reused (e.g., relationships, teams, interventions, EHR/IT systems)



# Exploring the Generative Investment: ABATE & INSPIRE Trials

Susan Huang, MD MPH

Chancellor's Professor, Division of Infectious Diseases  
Medical Director, Epidemiology & Infection Prevention

University of California Irvine School of Medicine

*On behalf of Harvard-HCA-UCI Trials Team*



Active **B**athing to **E**liminate Infection Project



# Reusable Investments

- Intangibles
- Tangibles
- Limitations

# Intangibles: Rapport

## *Efficiencies*

- Engagement discussions
- Communication
- Recruitment
- Access to key leaders, steering committees
  - ✓ Prioritization
  - ✓ Troubleshooting
  - ✓ Requests for operational support and speed

# Intangibles: Experience

## *Efficiencies*

- IRB
- DUAs, legal clearance for data access
- Framework and templates
  - ✓ Roadmap
  - ✓ IT specifications
  - ✓ Coaching call templates
  - ✓ Toolkits

# Tangibles: Computer Programs

## *Infrastructure*

- Research computing enclave (VPN, server, software)

## *Efficiencies*

- Variables and data streams
- EHR functions (e.g., screens, prompts)
- Data cleaning programs
- Analytic programs

## Limitations

- Operational priorities change
- Funding for maintaining ready infrastructure
- Experience with select variables or outcomes not always translatable
- Team turnover: health system partners, investigators, staff

# Exploring the Generative investment of an ePCT for Catalyzing Research

**Natalia Morone, MD**  
Boston Medical Center



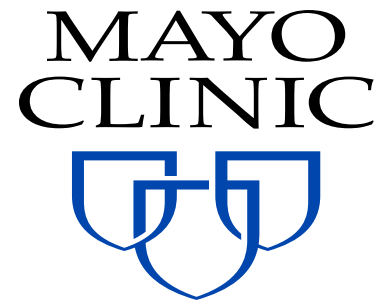
## Platforms at risk of dissipating: OPTIMUM experience

- Community Advisory Board dissolves after trial end (significant time spent training board members and staff)
- Team skilled in facilitating an electronic intervention and team may not continue after trial end (working with participants' training needs to use technology effectively)
- Operating procedures customized to the ePCT (text/email communications, content and context of the communications, training and participants, involvement of clinical staff, etc.)  
dissipation

## “Re-using” infrastructure

- Collaboratory Community Advisory Board available to ePCTs.
- Trained staff available to Collaboratory trials to expedite training staff involved in ePCTs.

Cost/resources: likely involve some FTE effort and website maintenance



# NOHARM

MAYO CLINIC ROBERT D. AND PATRICIA E. KERN  
**CENTER FOR THE SCIENCE OF  
HEALTH CARE DELIVERY**



**NOHARM**=*Non-Pharmacological Options in post-Hospital and Rehabilitation pain Management*

Andrea Cheville, MD, MSCE & Jon Tilburt, MD  
May 2024

# Reusable infrastructure

- running start
- Repurposing content and methods
  - (NOHARM to ASCENT)
  - (E2C2 to ASCENT)

# Maintaining infrastructure btwn studies

- Organizational Culture (“trust & good will”)
- Institutional memory
- IRB Know How
- Staff continuity
  - Epic programmer
  - Practice data scientists
  - Project management

## Same partners for new studies ?

- Old protocols/patterns vs. Fresh perspective

# Reframing Goals

- from ... “faster & more efficient”
- to ...”meaningful, sustainable, practice changing”



# Thank You!

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# Questions