

Exploring the Generative Investment of an ePCT for Catalyzing Research

Greg Simon, MD, MPH
Kaiser Permanente Washington Health
Research Institute



**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

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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 clinicians)
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!

tilburt.jon@mayo.edu

cheville.andrea@mayo.edu

Questions