T3/T4 Research: Where does your research fit in?

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Presentation Outline

1. What is T3/T4 research?
2. Why is it an exciting time for T3/T4 research?
3. CCTSI resources for you
“… the stark reality [is] that we invest billions in research to find appropriate treatments, we spend more than $1 trillion on health care annually, we have extraordinary knowledge and capacity to deliver the best care in the world, but we repeatedly fail to translate that knowledge and capacity into clinical practice.”

-- Institute of Medicine (2003)
“Scientific knowledge about best care is not applied systematically or expeditiously to clinical practice. It now takes an average of 17 years for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then application is highly uneven.”

-- Institute of Medicine (2001)
Clinical Translation Stages

- **T0**: Basic science and animal research
- **T1**: Translation to humans
- **T2**: Translation to patients
- **T3**: Translation to practice
- **T4**: Translation to population health
Institute of Medicine. The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research (2103). Figure adapted with permission from Macmillan Publishers Ltd: *Nature Medicine* (Blumberg et al., 2012), copyright (2012).
T3: Translation to practice

Evidence in Real-World Settings
• Phase 3b and Phase 4 drug trials
• Dissemination & implementation research
• Pragmatic trials
• Comparative effectiveness research
• Community Participatory Based Research
• Demonstration projects
• Quality improvement
• Meta-analyses and systematic reviews
T4: Translation to population health

True Benefit to Society

• ‘Scale Up’ and ‘Diffusion’ research
• Systems research, e.g., social network analysis
• Policy analysis, ‘natural experiments’
• Epidemiology and outcomes research studies
• Performance management measurement
• Cost effectiveness
Institute of Medicine. The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research (2103). Figure adapted with permission from Macmillan Publishers Ltd: *Nature Medicine* (Blumberg et al., 2012), copyright (2012).
Technology enthusiasts and visionaries are the first to embrace a new technology or process, followed by a frustrating period of time before the pragmatists (early majority) start to utilize the technology.

Source: *Crossing the Chasm*, Geoffrey Moore
Why it is an exciting time for T3/T4 research

• ARRA investment in CER
• Patient-Centered Outcomes Research (PCORI)
• ‘Big Data’ and ‘Pragmatic Trials’
Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, appropriated $1.1 billion to jump-start the nation’s efforts to accelerate CER.

The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

-- Institute of Medicine (2009)
Nearly 90% of the funding was spent on developing and synthesizing evidence and improving research capacity.

[P]riorities for the new funding should include greater emphasis on ... dissemination of results.

Benner J S et al. Health Aff 2010;29:1768-1776

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Research That Helps the Healthcare Community Make Informed Decisions

• Patient-centeredness
• Potential to improve health care and outcomes -- quickly
• Patient and stakeholder engagement
• Dissemination plan
The Patient-Centered Outcomes Research Trust Fund will invest $3.5 billion over its 10-year authorization.
PCORnet Coverage Map
This map depicts the number of PCORI funded Patient-Powered or Clinical-Data Research Networks who have coverage in each state.

PPRN = Patient Powered Research Network  CDRN = Clinical Data Research Network
Mission: Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners.
Your Medical Records May Unlock Disease Secrets for All

Electronic health data, long touted as a way to inject new life into patient recruitment, will finally be put to the test with clinical trials.
CTSA National Consortium, Collaborative Innovation Awards
CCTSI Pragmatic Trials and Dissemination/Implementation Research Program

1. To **foster a learning community** and serve as a conduit for active dissemination of resources from NIH and other national organizations engaged in implementation science and pragmatic research.

2. To **catalyze and centrally support** the CCTSI community in the development of pragmatic trials, comparative effectiveness research methods, and implementation science to achieve increased efficiency and economies of scale.
Pragmatic Trials & Dissemination/Implementation Research

Catalyzing and supporting the development of pragmatic trials, comparative effectiveness research methods, and implementation science to achieve increased efficiency and economies of scale. We aim to foster a learning community and serve as a conduit for active dissemination of resources from NIH and other national organizations.

We are partnered with the Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS), funded by the University of Colorado School of Medicine and Children’s Hospital Colorado.

Educational and Best-Practice Resources

Colorado Research in Implementation Science Program (CRISP)
- Seminar series and training workshops on implementation science, pragmatic clinical trials, and mHealth applications
- Learning E-books on Implementation Science

NIH Health Care Systems Research Collaboratory
- Rethinking Clinical Trials: a Living Textbook of Pragmatic Clinical Trials

Patient-Centered Outcomes Research Institute (PCORI)
- Rubric for Patient Engagement in Comparative Effectiveness Research
- Methodology Standards
- Dissemination and Implementation Framework & Toolkit
Colorado Research in Implementation Science Program (CRISP) Educational Seminars

How to Successfully Obtain Patient-Centered Outcomes Research Institute (PCORI) Funding

- “Nuts and Bolts of PCORI”
- “Insights from the Annual PCORI Meeting”
- “What is Patient-Centeredness?”
- “Community Engagement Pipeline Awards”
- “Who are key stakeholders and how do you write them into a grant?”
- “Data Networks: PCORNet”
- “Implementation Science Methods”
- “Obtaining a PCORI grant: Lessons learned from successful PCORI grantees”
www.CRISPeBooks.org
Designing for T3/T4 Translation: Tips for T1/T2 Researchers

The diagram illustrates the Technology Adoption Lifecycle with different adopter categories: Innovators, Early Adopters, Early Majority, Late Majority, and Laggards. The area under the curve represents the number of customers.
Questions?

Feel free to contact me at:

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