Building a Translational Biology Team

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Overview

• Clinical vs. Translational Research
• “Translational” Research
• TEAM
• Challenges
• Opportunities
NIH definition of Clinical Research (PHS 398)

• **Patient-oriented research.** Research conducted with human subjects (or of human origin - tissues, specimens and cognitive phenomena) for which an investigator (or colleague) **directly interacts with human subjects:**
  - (a) mechanisms of human disease,
  - (b) therapeutic interventions,
  - (c) clinical trials, or
  - (d) development of new technologies.

• Epidemiologic and behavioral studies.

• Outcomes and health services research.
What is Translational Research?

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Model for translational research, as proposed by the Evaluation Committee of the Association for Clinical Research Training.
The Meaning of Translational Research and Why It Matters

Steven H. Woolf, MD, MPH

TRANSLATIONAL RESEARCH MEANS DIFFERENT THINGS to different people, but it seems important to almost everyone. The National Institutes of Health (NIH) has made translational research a priority, forming centers of translational research at its institutes and launching the Clinical and Translational Science Award (CTSA) program in 2006. With 24 CTSA-funded academic centers already established, other universities are transforming themselves to compete for upcoming CTSA grants. By 2012, the NIH expects to fund 60 such centers with a budget of $500 million per year.\(^1\) Besides academic centers, foundations, industry, disease-related organizations, and individual hospitals and health systems have also established translational research programs and at least 2 journals (Translational Medicine and the Journal of Translational Medicine) are devoted to the topic. By some accounts, translational research has become a centerpiece of the European Commission’s €6 billion budget for health-related research, and the United Kingdom has invested £450 million over 5 years to establish translational research centers.\(^2\)
The Challenges for Clinical and Translational Research

17 years

Basic Science Discovery \[\rightarrow\] Clinical Research Translation \[\rightarrow\] Community Translation Best Practices

T1 \[\rightarrow\] T2

Increase research efficiency
Faster adoption of new findings to patient care
Translational Research Infrastructure

Database management system to centralize information

- Biostatistical Analysis
- Biomedical Informatics
- Biospecimen Repository
- Specialized cores

Community Dissemination Results

Design and Team Development

Regulatory Project Management Recruitment

Clinical Research Center, Data management

Community Partners
Basic scientists are the foundation of the biomedical research enterprise. Their work is key to understanding fundamental biological processes and mechanisms of disease pathogenesis, and it has been critical to preventing, diagnosing, and treating diseases and conditions that afflict millions of people. Yet despite major advances in fundamental biology, there is widespread concern about the slow pace at which these discoveries are translated into safe and effective clinical interventions. The National Institutes of Health (NIH) estimates that 80 percent to 90 percent of potential therapeutics in preclinical testing run into problems that preclude them from advancing to the clinical trial phase. Numerous initiatives to speed translation are under way at the national and institutional levels, many of which have been aimed at providing clinical scientists with the knowledge and tools needed to translate research discoveries into improved patient care. Less attention, however, has been given to the contributions that basic scientists make to the process of translational research.
How difficult is it to overcome barriers to conducting translational research on a scale of 1 (not at all difficult) through 7 (extremely difficult). Perceived (P), Actual (A)
What don’t we have?

• Centers for Translational Research
  – Current clinical research space inadequate
  – temporary, small,
  – and at many institutions -- nonexistent
• Clinical research training programs
• Clinical research mentor pool still small
• Clinical research processes are not transparent- no one place, no one person knows everything
• Regulatory Processes is Complicated and Inefficient: time to contract and time to final REB approval (benchmark <4-6 weeks), biotechnology licensing, separate REB approval and credentialing of research personnel are time consuming
What don’t we have?

• New collaborations slowed by many factors:
  – faculty #, type, or difficult to find
• Funding structure for Translational Research
• No facilities to manufacture drugs, cells, novel therapeutic agents
• No Biospecimen Repository
• Mixed messages on value of interdisciplinary clinical research: no space assigned for funded clinical research, only PI given ‘credit’ for research performed by investigator teams
• Accountability less than clear: who is “in charge” of Translational research?
Objectives

Create and support new teams, Increase efficiency through integrating research infrastructure and Support innovation
A model for multidisciplinary research teams cycles

- Team formation
- Sustain collaboration
- Team collaboration
- Team growth
- New MDRT cycle
- New translational discoveries

**Initial recruitment to MDRT**
- Prior interactions (40%)
- Introduced by colleagues (25%)

**Factors facilitating team formation**
- Shared interest/vision among agreeable individuals (55%)
- Team members/leader (75%)
- Trust (25%)
- Agreeable personalities (10%)
- Resources Having funds and time from institution (25%)

**Barriers to team formation**
- Lack of members with similar interest (60%)
- Non-agreeable team members/leader (45%)
- Non-social members/personality differences (20%)
- Lack of incentives for working in teams (15%)
- Limited resources (10%)
- Lack of institutional support (10%)
- Time and scheduling demands (40%)

**Facilitators to collaborations in MDRT**
- Agreeable team members/leader (70%)
- Open and frequent communication (70%)
- Building and gaining trust among members (20%)

**Conflict resolution**
- Through communication (40%)
- Leader's policy (10%)
- Conflict resolution training (10%)
- Give and take/proper attribution for work (15%)
- Lack of professional respect (20%)
- Lack of resources (10%)
- Perceived value of teamwork
- Lack of institutional support
Translational Research Team Members

- **Sebastien J. Hotte** (Medical Oncologist — Principal Investigator)
- **Anita Bane** (Pathologist — Principal Investigator)
- **Andrew Arnold** (Medical Oncologist — Head Clinical Trials)
- **Jonathan Bramson** (Vaccines and Biotherapeutics)
- **Sheila Chou** (Interventional Radiology)
- **Bindi Dhesy-Third** (Medical Oncologist)
- **Karen Gulenchyn** (Nuclear Medicine Physician)
- **Hal Hirte** (Medical Oncologist)
- **Rosalyn Juergens** (Medical Oncologist)
- **Peter Kavask** (Biochemist)
- **Brenda Kowaleski** (Clinical Trials Manager)
- **Brian Leher** (Hematologist)
- **Mark Levine** (Medical Oncologist — Chair Department of Oncology)
- **Som Mulherjee** (Medical Oncologist)
- **Nicole Hodgson** (Surgical Oncology)
- **Mike Noseworthy** (Functional Imaging)
- **Greg Pond** (Biostatistics)
- **Leyo Ruo** (Surgical Oncology)
- **Sheila Singh** (Pediatric Neurosurgeon)
- **Anne Snider** (Director — Department of Oncology)
- **John Valiante** (Functional Imaging)
- **Tim Whelan** (Radiation Oncology)
- **Kevin Zbuk** (Medical Oncologist)
- **Martin Butcher** (Research Coordinator)
How can transformation be achieved on a larger scale?

Create an integrated environment for the clinical and translational researcher that can provide:

1. An academic home for **Translational Research** (a Center, Department, or Institute)
2. Support for protocol preparation, regulatory compliance, data and biospecimen management
3. Support for participant recruitment, human subject safety monitoring
4. Specialized cores and services for translational research
5. Education leading to advanced degrees in clinical research
TREST: Translational Research Support Team

Principal Investigator

[Your name here]

Research Facilitators

- Completion of protocol documents for the approval process (IRB, IACUC, and the Translational Research Advisory Committee/CTSC application)
- Coordinate ancillary team members, i.e. research nurses, research pharmacists, and research aides
- Obtain necessary cores, staff, equipment, and facilities to achieve aims specific to each study
- Introduce research team to Web-based research systems and biomedical informatics

Research Aides

- Recruitment and retention of research subject participants
- Coordinating visits with research subject participants and staff
- Pre-screening research subject participants
- Organizing and maintaining study forms and applications for regulatory purposes
- Completing regulatory paperwork with research team facilitator
- Serving as liaison for research teams cross-institutionally
- Assistance with data collection and maintenance of study databases
Translational Funding

Bridging the Gap

Research Labs

Basic Science

Proof of Concept

Clinical Trials

Clinical Practice

Diagnostic Labs
NIH CTSA Awards: A Home for Clinical and Translational Science
Securing an NIH CTSA

• A physical and administrative “home” for **Translational** research
• Mentored **interdisciplinary** clinical research training
• New ways of organizing our research enterprise to speed up translation from bench <=> bedside <=> community:
  – better access to available data,
  – Better access to biospecimens
  – new and innovative ways to gather new data,
  – teams to address health issues,
  – minority and rural community engagement
• This work can only be accomplished by a **team** of individuals who have been given **institutional authority** and dedicated funding support
What Does the CCTS Have Available To Support My Career?

- **Everyone**
  - Education, training and career development
    - Seminars
    - Special focus groups
    - TL1 (pre and post-doctoral) and KL2 (clinician scientist) trainee support
    - MPH in clinical and translational science
    - Formal mentoring programs *(and mentor training)*
    - Graduate interdisciplinary specialization in biomedical, clinical and translational science (IBGP)*
  - Research networking tools*
  - Informatics tool kits

- **T1 Investigators**
  - MS and PhD in Translational Science
  - Biostatistics study design for grant submission
  - Integration with clinical research teams
  - New drug discovery and comparative animal cores
  - Pilot funding initiatives
    - Linking basic science with clinical research
    - Methodologic research
  - Support creation of biorepository and further development of tools for deep phenotyping within IW*

- **Clinical Research Investigators**
  - Biostatistics and ethics study design
  - Regulatory expertise and assistance
  - Recruitment Office
  - Access to research nurses and study implementation through CRC or PBRN
  - Specialized cores for laboratory processing, nutrition analyses and body (musculoskeletal) composition
  - Pilot funding initiatives
    - Development of imaging core next year*
    - Development of training opportunities for research staff*

- **T2 Investigators**
  - PhD in Implementation Science*
  - Toolkit supporting community-based participatory research
    - Community partners and sites
  - Community engagement pilot funding

* Under development
Challenges and Opportunities

We are all faced with a series of great opportunities brilliantly disguised as impossible situations.
Charles R. Swindoll

We are continually faced by great opportunities brilliantly disguised as insoluble problems.
Lee Iacocca

We are all faced with a series of great opportunities - brilliantly disguised as insoluble problems.
John W. Gardner
Thank you for your attention

Questions?