Advancing Your Research with CTSI Expertise

An AHC Faculty Conversation with
Dr. Bruce Blazar, CTSI Director
and
Dr. David Ingbar, CTSI-Ed Director

Helping researchers bring discoveries into practice
CTSI Director Dr. Bruce Blazar provides an overview of CTSI (10 minutes)

CTSI-Ed Director Dr. David Ingbar provides an overview of CTSI’s education and career development programs (5 minutes)

Scholars Alexa Pragman, Siobhan McMahon and Mark Osborn highlight CTSI’s KL2 program (10 minutes)

Dr. Blazar charts CTSI’s future direction (10 minutes)

Q&A from the live and web audience (10 minutes)
OVERVIEW OF CTSI
Dr. Bruce Blazar, CTSI Director and CTSA Principal Investigator
CTSI helps researchers be more successful in bringing discoveries into practice – to ultimately improve human health.

Here’s one example:
CTSI’s Office of Discovery and Translation (ODAT) is helping Dr. Valerie Pierre convert her idea into a real-world bacterial infection diagnostic tool through funding and support.

“Our expertise enhanced the quality of my translational project, and is maximizing its chance for success.”
CTSI helps researchers be more successful in bringing discoveries into practice – to ultimately improve human health.

Here’s one example:
CTSI’s Education group helped Dr. Youssef Roman launch his career and expand upon his research.

“Their career development programing went beyond scientific theories and statistics by teaching me how to convey complex scientific topics in a way that’s clear and compelling.”
Supporting your research

Through:

– Consultations
– Services, staff and space to facilitate studies
– Education and career development
– Tools, resources and support
– Funding
Specific support

- Build out a study plan and budget
- Statistical and data management support
- Develop research protocols
- Attain regulatory and IRB approvals
- Access de-identified data
- Identify patient cohorts
- Recruit participants for studies
- Manage a study throughout its lifecycle
- Connect you with research resources and expertise
Comprehensive support

- CTSI supports all stages of translation

- CTSI’s resources, funding and consultations are available pre- and post-award

- CTSI provides multi-site study support through MARCH, a Midwest research consortium, and PCORI-supported Greater Plains Collaborative
Who we support

- University of Minnesota faculty across all campuses
- Research professionals and study teams
- Community-based researchers
- Undergrad, pre-doctoral and post-doctoral students via career development programs
Clinical and Translational Science Institute

Funding programs

- Early-stage, clinical research, and later-stage award programs
- Six pilot award programs
- Current opportunities:
  - Community Health Collaborative Grants Program
  - Committee for Pharmaceutical Development
  - Community Research Van
231 scholars have been trained through 7 unique programs and
4,200 attendees at 312 seminars

Provided services to 650+ investigators across 12 UMN schools and
colleges and supported 465 research projects since 2012
Network of 160+ University and industry experts and matched 50+ research teams

Awarded more than $22 million in research funds and supported 325+ researchers
Clinical and Translational Science Institute

Focus areas

- Child health research
  - Child Health Collaborative Grant program
  - Pediatric Medical Device Translational Grant program
  - CTSA network’s Child Health Research Acceleration through Multi-Site Planning grant

- Driven to Discover research at the State Fair
  - D2D Community Health Research Grant program

- Biomedical informatics
  - Clinical data repository
Focus areas

- Participant recruitment
  - Integration of clinical care and research visits
  - StudyFinder

- Multisite study support
  - MARCH consortium
  - Greater Plain Collaborative through PCORI

StudyFinder.umn.edu
Dean Brooks Jackson highlights the Clinics and Surgery Center and its unique mission of integrating clinical care with research.
Five core offices located at 717 Delaware St.
- Office of Discovery and Translation (ODAT)
- CTSI-Ed
- Community Engagement to Advance Research and Community Health (CEARCH)
- Biomedical Informatics in Diehl Hall
- Clinical Translational Research Services (CTRS)

And the Center for Health Equity

CTSI operates three clinical research units on campus
CTSI’S EDUCATION AND CAREER DEVELOPMENT PROGRAMS

Dr. David Ingbar, CTSI-Ed Director
Clinical and Translational Science Institute

Education & Training Programs

- **Faculty Scholar Programs:**
  - Pre-K Program
  - KL2 Program (Nancy Raymond)
  - K to R01 Program (Kola Okuyemi)

- **Trainee Programs**
  - Summer Research Programs (Kelvin Lim)
    - Undergrad Pathways to Research Program (PReP)
    - Predoctoral Advanced Research Pathways to Research Program (A-PReP) – for MD, MPH, PharmD students
  - Pre & Postdoctoral Translational Research Development Program (Yoji Shimizu)

- Mentor Training (Anne Marie Weber Main & Esam el Fakahany)
- Online Training Courses – for faculty, trainees & staff
- Career Development Seminars
CTSI-Ed Career Development Continuum

[Diagram showing a career development continuum with stages including:
- Advanced PReP (professional students)
- PReP (undergraduates)
- Foundational CTS research training (TRDP / TL1)
- CDA preparation (Pre-K)
- Career development in CTS research
- Research leadership (K-R01, Individual K, KL2)
- MAJOR GRANTS]

Introduction and exposure to CTS research
Faculty

Students
Post-docs (MD, PhD)
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<th>Year</th>
<th>Designation</th>
<th>Funding source</th>
<th>Time protection</th>
<th>Education</th>
<th>CTSI-Ed support</th>
<th>Progress reports and monitoring</th>
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<tr>
<td>1</td>
<td>KL2</td>
<td>NIH CTSI</td>
<td>75%</td>
<td>Required KL2 seminar, individual coursework, +/- MS degree</td>
<td>Presubmission grant reviews, mock study session, grant writing assistance</td>
<td>6-month progress reports, mentor teams, Multidisciplinary Advisory Committee (MAC) reviews</td>
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Career Development Activities

- Grant writing:
  - Annual grant writing seminar
  - Co-sponsor grant writing course (3x/year)
- Monthly career development seminars (open)
- Mentor training – Online & META
- Translational Research Bootcamp 3 day event for CTSI faculty and trainee scholars
- Online modules: GCP & others
- Developing Practice-Oriented Research Training (PORT) program (Univ Michigan) – for clinicians with little formal training in clinical research
Evaluation of the Lung Microbiota and Inflammation in the Progression of Chronic Obstructive Pulmonary Disease

Alexa Pragman, MD, PhD, Assistant Professor, Medical School, Department of Medicine, Division of Infectious Diseases
CTSI F&T and KL2 Scholar | VA Career Development Award
**Significance**

- COPD is the 3\textsuperscript{rd}-leading cause of death worldwide
- The mechanisms of progression are poorly understood
- Inflammation due to a disrupted lung microbiota is a potential mechanism
  - COPD progression
  - Frequent exacerbations of COPD

**KL2 project: A cross-sectional study comparing the lung microbiota of frequent and infrequent COPD exacerbators**

- Oral wash and induced sputum samples to define the lung microbiota of both frequent and infrequent exacerbators
- Evaluation of systemic and lung inflammation
- Associate lung microbiota factors with inflammation

**Research Question:** Is the lung microbiota associated with COPD exacerbation phenotype or inflammation?
What CTSI has meant for my career

- Financial and social support
- Networking
- Developing skills I didn’t know I needed
- External grant reviews!
- Formalizing mentorship skills and optimizing my mentoring relationships
- Offering a continuum of funding opportunities
Next steps in my career

- 5-year independent Career Development Award at the Minneapolis VA
- Transition my research and clinical duties to the VA
- Roll my KL2 study patients into my CDA-2 study
- Continue my F&T project
- Grow my lab, look for mentoring opportunities
- Develop interventional and mechanistic studies of the lung microbiota
ENHANCING MOTIVATION FOR PHYSICAL ACTIVITY TO REDUCE THE RISK OF FALLS AMONG COMMUNITY-DWELLING OLDER ADULTS
A WELLNESS INTERVENTION

Siobhan McMahon, PhD, MPH, GNP-BC, Assistant Professor, School of Nursing
CTSI KL2 Scholar | PCORI Site Co-PI

Interdisciplinary Mentorship Team
Alexander J Rothman, PhD, Psychology
Jean Wyman, PhD, RN, GNP-BC, Nursing
J Michael Oakes, PhD, Public Health
Beth Lewis, PhD, Kinesiology
Weihua Guan, PhD, Public Health
Significance, objective, and approach

Significance
- **Evidence**: Leg-strengthening, balance training, and walking programs reduce falls in older adults
- **Limited Translation of Findings to Behavior**: Physical activity levels remain low & falls are increasing
- **Improve Translation**: Research examining strategies that motivate older adults to engage in physical activity is scarce and inconclusive

Objective
Assess the relative influence of two unique sets of behavioral change strategies - each representing different ways of motivating people to take action: *inter-personal* and *intra-personal* when combined with an evidence-based fall-reducing physical activity protocol

Approach
Community-Based Factorial Experiment. 102 adults > 70 years old randomized to 1 of 4 conditions
1) Physical activity only (n = 25)
2) Physical activity + interpersonal component (n = 25)
3) Physical activity + intrapersonal component (n = 25)
4) Physical activity + interpersonal + intrapersonal components (n = 27)

Primary Outcome: Physical Activity
1) Measured directly: Accelerometers built in to Fitbit Ones™
2) Self-report: CHAMPS physical activity questionnaire

Comparable Attention
- Fitbit Ones™
- 8 week program
  - 90 minute per week
  - Small groups (4-6)

• Immediately post-intervention
• 6 months post-intervention
Impact on my career

**Leadership**
- Mentor
  - CTSI PReP
  - SoN Honor students
  - UMN UROP
- Lead/ Direct
  - KL2 research project team
- Award
  - John A. Hartford Award *(Midwest Nursing Research Society)*

**Collaborative Team Science**
- Interdisciplinary Mentorship Team
  - PCORI/ NIA Multi-site Fall Prevention Grant *(Site Co-PI, Essentia Health)*
  - SoN, Adult/ Gero Coop *(Co-I)*
  - MN Board on Aging, Fall Prevention Project *(Consultant)*

**Scholarship**
- Internal Grants
  - Grant-In-Aid
  - D2D *(State Fair Surveys)*
- External Grants
  - NIA/PCORI Multi-Site Fall Prevention Grant
  - R01 *(pending)*
  - R21 *(pending)*
- Coursework /Learning
  - Grant writing course
  - PH courses
  - Workshops
- Dissemination
  - Conferences
  - Manuscript submission(s)

* MNRS members who have demonstrated the potential for leadership in geriatric nursing science, and who will likely improve the quality of care for older adults in the MNRS region as evidence of their scholarship.
Next steps (12 months)

- Disseminate KL2 results
  - Conferences
    - International Society of Nutrition and Physical Activity
    - Gerontological Society of America
    - Society of Behavioral Medicine
    - National CTSA conference
  - Manuscripts focusing on
    - Primary outcome of the intervention (physical activity)
    - Psychosocial processes of physical activity behavior change among participants in this intervention

- Implement *or* revise
  - R21 ancillary for PCORI/NIA Multisite Fall Prevention Study (Co-PI)
  - R01, *Community-based intervention effects on older adults’ physical activity and falls*
NEXT GENERATION CHIMERIC ANTIGEN RECEPTOR AND ENGINEERED NUCLEASE BASED TUMOR THERAPY...and progression as a CTSI Scholar
Mark J Osborn, PhD, Assistant Professor, Pediatrics, Blood and Marrow Transplantation Stem Cell Institute, Center for Genome Engineering | KL2 Scholar
Significance

- T-cell leukemia affects adults and children with poor outcomes for relapsed disease
- Treatment is with bone marrow transplantation
  - Graft Versus Leukemia & Graft Versus Host
- Chimeric Antigen Receptor

Research Question

- To Engineer an ‘Off the Shelf’ Pool of T-cells with Enhanced Tumor Targeting and no Host Tissue Recognition
Engineered T-cells: Next Generation Therapy for the Current Generation of Patients

- Research Question
- Engineered T-cells: Next Generation Therapy for the Current Generation of Patients

- Precision Molecular Medicine to Prevent Host Tissue Recognition

- Chimeric Antigen Receptor Tumor Recognition
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Opportunities due to CTSI Involvement

Research and Training

• Presentations at Local, National, and International Conferences
  - Keynote speaker: US Oncology Network

• Grant Application Submissions

• Scholarly Reports (primary research and reviews)

• Research Awards
  – Department of Pediatrics Basic Science Paper of the Year Award (2014)
  – Children’s Cancer Research Fund Butterfly Award (2015)

World-Class Mentorship Team

Next Steps: Translational Application of Universal Donor T-cells for Many Malignancies
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CHARTING CTSI’S FUTURE
Dr. Bruce Blazar, CTSI Director and CTSA Principal Investigator
NIH grant proposal submitted in January
  – Anticipate receiving a score in late June-early July
  – Anticipate a funding decision soon after
  – Potential receipt of the award in November

New application responded to new strategic framework from NIH’s National Center for Advancing Translational Science (NCATS)
New NCATS strategic framework calls for a re-allocation of funding for:
- A stronger local, regional, and national CTSA network with more opportunities for multi-site trials, collaboration, and education
- Deeper integration of research and clinical care
- Improved methods and processes of research and clinical care
- More clinical and translational education and training for all members of the “team”
– More community engagement, including more patient advocate engagement
– Expanded informatics
– More diversity in the clinical and translational research community, especially KL2 and TL1 scholars
– Unique programmatic contributions to the national CTSA consortium
CTSI’s overarching goals

- **Train an outstanding multidisciplinary, diverse workforce** across the spectrum of clinical and translational science research

- **Streamline methods and processes** to increase CTSI’s research capacity, locally and nationally

- **Engage communities and stakeholders** to improve the process of translation and the delivery of healthcare across the lifespan

- **Contribute unique resources** to the CTSA network
CTSI’s local goals

- Support the University’s mission of an Integrated Academic Health System
  - Bio-specimen and Laboratory Services (BLS)
  - Responsibilities for research conduct at M Health

- Continue to support the OVPR’s Human Research Protections Program

- Continue to build a single clinical research enterprise
Forge stronger partnerships

- To increase our local, regional and national impact
  - Hennepin County Medical Center (HCMC)
  - Minneapolis Veterans Administration Medical Center (VAMC)
  - Fairview Health Services system
  - Children’s Hospital and Clinics of Minnesota
  - UMN’s Duluth campus
  - Mayo Clinic’s CTSA
Helpful tools & resources

- I2b2 cohort discovery tool – demo available today
- Clinical data repository of more than 2 million patients
- Informatics consultations to request data
- StudyFinder – stop by the kiosk today
- Research Toolkit – a one-stop resource
- Biostat walk-in appointments available
- Community Research Van – tour earlier
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Accessing CTSI resources

- Research Navigator

- Invite CTSI to your departmental meeting or research day

- Sign up to receive CTSI news and information via its monthly newsletter

Melissa Hansen
WHAT QUESTIONS DO YOU HAVE?

ONLINE AUDIENCE: SUBMIT YOUR QUESTIONS NOW