CTSI Strategy Within an Evolving Learning Health Care System

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“I’m looking for a strategy to leverage our core competencies with big data across multiple synergized paradigms. Or something that rhymes. Either way.”
Thinking Strategically

COMPETING TO BE THE BEST → COMPETING TO BE UNIQUE

The worst error in strategy is to compete with rivals on the **same dimensions**.
What Do We Mean by a Strategy?

- Strategy is different than *aspirations*
  - “Our strategy is to be #1 or #2…”
  - “Our strategy is to grow…”

- Strategy is more than *particular actions*
  - “Our strategy is to merge…”
  - “… internationalize…”

- Strategy is not the same as *mission / values*
  - “Our strategy is to serve our customers and communities while meeting the highest standards of integrity…”

- Strategy defines the company’s *distinctive approach to competing and the competitive advantages* on which it will be based
Our competitive advantage is that we are an INTEGRATED ACADEMIC MEDICAL CENTER.

What is our DISTINCTIVE APPROACH based on our competitive advantage?
American health care is falling short on basic dimensions of quality, outcomes, costs, and equity. Available knowledge is too rarely applied to improve the care experience, and information generated by the care experience is too rarely gathered to improve the knowledge available. The traditional systems for transmitting new knowledge—the ways clinicians are educated, deployed, rewarded, and updated—can no longer keep pace with scientific advances.” (IOM, 2012)
Problem Statement

• We are not leveraging our scientific base well enough to benefit our patients.

• We are not training our students and providers well enough to provide value based care.

• We are not deriving our knowledge well enough from our patient care experience.

• We are not engaging our patients, their family, other care givers and other community members well enough in the care and learning cycle.
“...achieving a learning health care system—one in which science and informatics, patient-clinician partnerships, incentives, and culture are aligned to promote and enable continuous and real-time improvement in both the effectiveness and efficiency of care—is both necessary and possible for the nation.” (IOM, 2012)
Virtuous Cycle in Academic Medical Centers

Informatics -> Clinical Practice Network -> Implementation

Science -> Physicians -> Clinicians -> Communities

Evidence -> Trainees -> Educators

Analytics -> Patients

VALUE
Value – Multiple Perspectives in Academic Medical Centers

- Population Health
  - Quality/Cost (Quality – Consumerism, Safety, Outcomes, etc.)
  - Scientific Impact – may or may not directly impact population health in a measurable way but can produce halo effect
  - Competence of workforce and trainees
  - Monetization of discoveries and services

↑ Value  →  ↑ Sustainability
Learning System

• Continuous improvement

• Translate “what we know” into “what we do”
What is the Clinical and Translational Science Awards (CTSA) Program?

• The CTSA Program is a NIH funded program designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public.
Clinical and Translational Science Awards (CTSA) Program

The CTSA Program is designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. Learn more.

About the CTSA Program

Learn more about the CTSA Program and clinical and translational research across the country.

CTSA Program Funding Information

Find CTSA Program funding opportunities and frequently asked questions.

Training & Career Development

Discover resources and training opportunities available through the CTSA Program.

Communities & Research

Learn how the CTSA Program supports a broad range of activities that engage patients and communities in health
Why is this important?

- Aligns with, continues to define, and supports institutional focus on becoming a **Learning Healthcare System**.

- **Money**
  - $15.6M grant funding over 4-year period

- **Access**
  - A number of funding opportunities and projects are only available to institutions with funded CTSAs
  - Resources available through the CTSA network

- **Prestige**
  - With only ~60 CTSAs nationwide, we want to be recognized as a leader in clinical and translational science
## Clinical and Translational Science Institute

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**Central**

**Operations**

**Clinical Trials Office**

**Clinical Research Unit**

**Center & Core Admin**

**Grant Writing**

**Participant & Clinical Interactions**

**Recruitment of Research Participants**

**Multi-Site Study Support**

**Special Populations**

**Services**

**Academic Programs**

- Mentored Career Development
- Mentor Academy
- Translational Workforce Development
- Biostatistics, Epidemiology & Research Design
- Translation Imaging
- Biomedical Informatics
- Community Engagement
- NonHuman Primate Program
- Translational Pilot Program
- Collaboration & Team Science
- Evaluation & Continuous Improvement
# Leadership & Programs

<table>
<thead>
<tr>
<th>King Li, MD, MBA</th>
<th>Lynne Wagenknecht, DrPH</th>
<th>Stephen Kritchevsky, PhD</th>
<th>Donald McClain, MD, PhD</th>
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<tr>
<td>Akiva Mintz, MD, PhD</td>
<td>Emily Gower, PhD</td>
<td>Kathryn Weaver, PhD</td>
<td>Cheryl Bushnell, MD</td>
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<td>Biomedical Informatics</td>
<td>Collaboration &amp; Team Science</td>
<td>Translational Workforce Development</td>
<td>Clinical Trials Office</td>
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<td>(Zhou/Wells)</td>
<td>(TBD)</td>
<td>(Bushardt)</td>
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<td>Community Engagement (Arcury)</td>
<td>Biostatistics, Epidemiology &amp; Research Design (Ambrosius)</td>
<td>Mentored Career Development</td>
<td>Integrating Special Populations</td>
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<tr>
<td>Translational Pilot Program (McCall)</td>
<td>Regulatory Knowledge &amp; Support (Means)</td>
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<td>Participant &amp; Clinical Interactions</td>
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<tr>
<td>Translational Imaging (Mintz)</td>
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<td>Evaluation &amp; Cont. Improvement (Easterling)</td>
<td>Bridge Funding (Means)</td>
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<td>Recruitment of Research Participants</td>
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<td>Nonhuman Primate Program (Kaplan)</td>
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<td>Clinical Research Unit (Woodside)</td>
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Wake Forest Baptist Health (WFBH)

• Formed from the merger of the Medical School and the Health System in 2009.

• Explicit goal of aligning educational, clinical and research missions.

• One of the few truly integrated academic medical centers in the country.
Clinical Integrated Network

- WFBH is the only academic medical center within the 12-county Piedmont Triad region of central North Carolina (1.65 million population, 15% over age 65, 28% underserved minorities).

- Referral area includes North Carolina, Eastern Tennessee, South Carolina, Virginia and West Virginia (8,000,000 population).

- 1,004 acute care, rehab and psychiatric care beds.

- 21 subsidiary or affiliate hospitals with 120 outreach activities including satellite clinics.

- Affiliated with the W.G. Hefner VA Medical Center (over 87,000 veterans).

- Partners with Cornerstone Health Care, Vidant Health and WakeMed to build a Clinically Integrated Network (close to 2,000 providers).
CTSA Services to Support the Learning Healthcare System

- KL2 Scholars: 75% salary support and $35,000 in Research Development Funds for 2 years. Two in Year 1; One in Year 2; Two in Year 3; One in Year 4
- Pilot Awards to produce and test novel tools and methods to bridge translational gaps and overcome barriers inhibiting pace of translation (8/year @ $40,000)
- Ignition funds: Small, rapid-access awards to help teams maintain momentum on feasibility projects with high probability of traversing gaps (12/year @ $5,000)
- Stakeholder Enterprise Portal
- Expanded data sets accessible through the TDW
- Clinical Informatics Toolbox
- Health Informatics Affinity Group
- Clinical Informatics Training Opportunities
- Team Science Training
- Research Studios
- Expansion of Existing Community Engagement Programs
- New Community Engagement Programs: Faculty Preceptors, Internships, Provider Network; Dissemination and Implementation; Citizen Science
- Education/training opportunities for all levels
- Mentor Academy
- STEP Into Research Program
- Biostatistics, Epidemiology, & Research Design support, particularly for early-career faculty
- Research Design education/training opportunities
- Novel (NEAT) Consent Form formulation
- Post-approval monitoring for clinical research
- IND/IDE Facilitation
- Video database of commonly performed procedures
- Special Populations Research Navigator
- Special Populations Voucher Program
- Special Populations Education/Training
- Support for regionally affiliated sites to conduct research
- Research Subject Advocacy
- Research Participants’ Perception Survey
- Central phone line for participant questions/concerns
- Clinical trial enrollment tracking and study intervention
- Access to existing WF databanks and sample repositories
- Improved efficiency in clinical trial initiation
- Use of TDW to identify potential research participants
- Clearinghouse for advertising and recruitment efforts
- Participant Recruitment Tools and Services
- Facilitated use of nonhuman primate models
- Nonhuman Primate funds to underwrite proof-of-principle CTSA Network studies ($40,000/year)
- Translational Research Academy
Virtuous Cycle in Academic Medical Centers

Clinical Practice Network

Informatics

Implementation

Scientists

Patients

Communities

Clinicians

Trainees

Educators

Analytics

Science

Evidence

VALUE
Affinity Groups

Intended to focus on critical methodologies that currently have no departmental home and which address gaps in translation to extend the reach and capabilities of individual investigators.

- Community Engagement
- Implementation Science
- Clinical Informatics
The Diabetes IPU

Care Team
- Nurse Practitioner
- Primary Physician
- Diabetes Educators
- Consulting Endocrinologist
- Physician Specialists (Ophthalmology, Podiatry, Cardiology, Nephrology)
- Solutions Coordinator
- Bon Ami
- Home Health
- Palliative Care
- Group Facilitator
- Psychologist/Social Worker
- Exercise Physiologist

Patients/Participants

Scientists

Educators
Clinical Informatics Affinity Group
Clinical Informatics Toolbox
Clinical Informatics Consults & 1:1 Data Requests
CTSA & Local Tools (e.g. REDCap, Be Involved)
Education (Online, Seminars, Short Course)
Translational Data Warehouse
Bioinformatics Consultations & Grant Develop
Bioinformatics Service (FFS)

Disparate Data Sources:
- Tonic/Haiku for Mobile Data Collection & Viewing
- Unified Medical Language System
- R-Based Program Library
- Researcher-Defined Phenotypes (e.g. Co-Morbidity)
- NLP Software (e.g. QGIS, Ctakes, Metamap)
- Geocoding Software & Pre-Defined Variables (e.g. Median Income)
- Map Available Human Imaging Data
- Map Genomic Available Genomic Data (TCGA/BRCA)
- Map Basic Nonhuman Primate Data
- Map North Carolina Death Index Data
- Map North Carolina Central Cancer Registry Data
- Map Basic Clinically Integrated Network Data (If Possible)
- Index/Validate Human Clinical Notes (NLP)
- Index/Validate Available Human Omics Data
- Index/Validate Human Imaging Data
- Index/Validate Nonhuman Primate Omics Data
- Index/Validate Nonhuman Primate Imaging Data
- Index/Validate Nonhuman Primate Clinical Notes
- Index/Validate Clinically Integrated Network Data (If Possible)

Prepare & Load/Make Accessible

Customers:
CTSA & Local Tools (e.g. REDCap, Be Involved)
Recent Examples

• **Heart Pathway (PI: Mahler)**
  - Clinical decision support tool that calculates a risk score based on clinical factors for patients who present to the ED with chest pain. Success will result in reduction of unnecessary admissions and excessive cardiac testing.

  **CTSI Biomedical Informatics Role:**
  - Improved calculation of length-of-stay
  - Linkage of patients presenting to Lexington/Davie that are transferred to WFBMC
  - Linkage of patients with mortality status from NC State Center for Health Statistics
  - Improved coordination of data extraction, analysis, and claims data acquisition
  - Provided content knowledge to improve ascertainment of coronary revascularization procedures

• **Internal Medicine Readmissions (PI: Atkinson)**
  - Assessing the possible association between resident workload and risk of readmission.

  **CTSI Biomedical Informatics Role:**
  - Modeling continuous variables using restricted cubic splines to account for non-linear associations between independent and dependent variables
  - Geocoding of patient addresses to estimate household income
  - Generalized estimating equations to account for clustering due to multiple admissions from patients
  - Calculation of variance inflation factor to ensure a lack of multicollinearity between independent variables
  - Creation of a new variable, turnover, that is a sum of admissions and discharges during each 24-hour period for the A&D internal medicine services
  - Imputation of missing data to reduce the potential bias created by conducting a complete case analysis
  - Calculation of the Modified Deyo comorbidity score based on ICD9 coding
Educational and Training Programs
Scope of CTSI Education and Training Programs

- KL2 Scholars
  - Individual K/Career Development awardees
  - Scholar Pipeline (pending K awards and early career faculty with >50% protected research time)

- Translational Workforce Development
  - MD and PhD Fellows
  - Graduate Students/Residents
  - Undergraduate/Medical Students
  - Research Staff
  - Practitioners
  - Community Partners
  - Patients & Families

- Pipeline Education Programs
  - UL1 Education Programs
  - Existing Degree Programs

- The Academy
  - 75% Protected Time
  - Development Funds
  - Individual Development Plan
  - Team-Based Mentoring

- KL2s
  - Academy Forum
  - Priority Access to TSI Resources
Special Elements of the KL2 Program

Preparation for Team Science
1. Team Mentoring
3. Formal Team Training
4. IPU / Research Studio Internship
5. Visiting Scholar Program

Translation through Commercial Channels
1. Wake Forest Innovation Associate “embedded” with the Academy Scholars
2. “Innovation Boot Camp”
3. Engagement with Entrepreneurs
Other Educational Opportunities

- **Translational Research Academy**
  - Available to KL2 scholars & 12-15 other research-focused early-career faculty
  - Meets twice monthly for 1.5 Years & enrolls new class each year
  - Education & training in Research Process; Leadership/Personal Development; & Scholarly Communication (e.g. grant/manuscript writing & presentations)
  - Expanded training in Team Science; Translation through Commercial Channels; & Clinical Informatics

- **Online & live seminars, short courses, & experiential learning** for faculty, staff, residents, fellows, and students. Visit CTSI website for full list
Team Mentoring . . .

- Provides a multi-disciplinary and translational perspective that extends the value of traditional dyadic mentoring;
- Increases Scholar accountability;
- Broadens the Scholar’s collaborative network through the mentor team;
- Enhances the translational impact of each Scholar’s project;
- Mitigates weaknesses of individual mentors;
- Promotes the development of new mentors.
Developing Better Mentors

- Mentor Academy to Train 15-20 faculty / year
  - Salary support for participation
  - Curriculum adapted from the National Research Mentoring Network
- Annual invited lectureship and mentoring panel discussion
- Team mentoring approach allows the participation of emerging mentors.
CTSI PROGRAMS

Ask not what I can do for CTSI but what CTSI can do for me!!! (Anonymous)
Clinical Informatics Program

**Translational Data Warehouse:** Access clinical data for cohort identification and/or pull detailed data for approved research projects.

**REDCap:** Secure, web-based application for building and managing online surveys and databases

**Programming:** Experienced programmers are available to build custom tools or provide data management solutions

**Clinical Informatics Short Course:** 16-hour course to introduce participants to the core content of clinical informatics and encourage ongoing learning in this rapidly evolving field
The CTSI provides four categories of support:

- **Pre-Award**: Proposal development assistance at no cost as long as post-award support will be included in the grant budget.

- **Post-Award**: Data entry and management, data analysis, interpretation, and preparation of results for publications and presentations are provided on a fee-for-service basis.

- **Statistical Consultations**: Open consultation hours are available to any faculty member seeking assistance.

- **Early-Career**: Investigators classified as ‘early-career’ can now receive support for research studies at no cost.
Translational Pilot Program

Funds pilot projects designed to produce & test novel tools & methods to bridge translational gaps and overcome barriers inhibiting the pace of translation

- **Open Pilot Awards**
  - 4/year at $40,000
  - Open to any field of study focusing on generalizable solutions to problems of translation

- **Targeted Pilot Awards**
  - 4/year at $40,000
  - Focused on areas of significant local, regional, or national need as identified by CTSI Leadership.

- **Ignition Funds**
  - 1/month at $5,000
  - Small, rapid-access awards to help teams maintain momentum on feasibility projects with high probability of traversing a translational gap and/or to obtain pilot data that will allow for the submission of a subsequent, larger extramural grant application
  - These can be for traditional, hypothesis-driven research projects
## Program in Community Engagement

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<td>Local Community</td>
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<td>Citizen Science</td>
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Clinical Research Unit

**Dedicated Research Space:** 14 exam rooms, procedure room, metabolic kitchen, and CLIA-certified specimen processing laboratories

**Patient Care:** Research nurses and techs conduct procedures for studies with pediatric, adult, and geriatric patients

**Bionutrition:** Research dietitians and techs provide food service, nutrition assessments, and nutrition education

**Specimen Processing:** Techs provide specimen processing with a focus on eliminating pre-analytical variation

**Dry Ice:** Available for research study needs. Dry ice can be used within our outside the CRU.

- The majority of CRU services are provided at no cost to early-career faculty and subsidized fee-for-service for experienced faculty
Study Coordinator Pool

Offers reliable, experienced research staff to assist in the day-to-day management of clinical research studies. Coordinators are available to:

- Prepare & submit IRB applications and consent forms, prepare and maintain regulatory binders, develop study documents, and assist in negotiation and preparation of budgets

- Recruit and Screen participants, conduct study visits, collect data, draw and process specimens, and track finances

- Act as a liaison between study teams and sponsors

- Study Coordinator Pool services are provided at no cost to early-career faculty and fee-for-service for experienced faculty
Other Services

**Research Studios:** CTSI faculty and staff will assist in developing a multi-disciplinary panel of experts to participate in a guided roundtable discussion focused on your needs and goals.

**Recruitment/Feasibility:** Unit available to help determine the feasibility of your research project, identify qualifying patients, and provide consultations and support to reach participants.

**Grant & Manuscript Editing:** Professional medical editing and writing service available to assist with grants, manuscripts, resubmissions, letters of support, biosketches, and other supporting documents.

**Grant Management Core:** Finance staff available to provide post-award support to manage all aspects of grant account activity and maintain fiscal compliance. Fee-for-service.
Other Services (Cont.)

**IND/IDE Navigation:** A full-time navigator is available to facilitate IND/IDE applications by offering in-depth advisory consultations to improve investigators’ ability to met FDA requirements.

**Clinical Trials Office:** Facilitates all stages of clinical trial development, including budget development, study initiation and protocol implementation, and data and regulatory management.

**Integrating Special Populations:** Faculty and staff will work with you to better understand the needs of older adults, children, and underrepresented minorities and assist with recruitment and enrollment.

**Nonhuman Primate Program:** Extends the value of this institutional resource to the CTSA Network and facilitates investigation by researchers new to nonhuman primate models.
Macro-level:

Teams of teams.

How can we leverage teams of teams to deal with issues at the population level?

WF is ready to be part of the CTSA network to really impact population health at the macro-level.
What WF can offer to the CTSA Network:

• Expertise in coordinating large multi-center trials
• Provides access to large, de-identified, longitudinal study data bases for research
• Nonhuman primate center facilities and expertise
• Coordinates and participates in “Common IRB”,
• Coordinates and participates in developing streamlined consent with goal to add video
• Coordinates and participates in training teams in more than “soft” skills (both research and clinical teams)
• Coordinates and participates in developing educational materials for Translational Workforce Development
Experience in coordinating large multi-institutional trials

- ACCORD Study
  - compared intensive glycemic control to usual care in persons with type 2 diabetes. (~10,000 subjects)
- Look AHEAD Study
  - compared intensive lifestyle intervention to education/support to prevent cardiovascular disease in persons with type 2 diabetes. (5,145 subjects)
- LIFE Trial
  - first-ever randomized trial demonstration that age-related mobility disability can be prevented. (1,600 subjects)
- SPRINT
  - Studies intensive blood pressure management in patients with hypertension. (9,361 subjects)
- PCORI-Falls
  - Randomized trial of a multi-factorial fall injury prevention pathway. (ongoing)
- PCORI Clinical Data Research Network (PRDN)
  - WF part of the Harvard led network (SCILHS)
**WHAT IS IT?**

*Precision medicine* is an emerging approach for disease prevention and treatment that takes into account people’s individual variations in genes, environment, and lifestyle.

The Precision Medicine Initiative® will generate the scientific evidence needed to move the concept of precision medicine into clinical practice.
### 11. DESCRIPTIVE TITLE OF APPLICANT’S PROJECT*
PRECISE: PREcision medicine Cohort In the SouthEast

### 12. PROPOSED PROJECT

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<th>Ending Date*</th>
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<tbody>
<tr>
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### 15. ESTIMATED PROJECT FUNDING

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<th>Description</th>
<th>Amount</th>
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<tbody>
<tr>
<td>a. Total Federal Funds Requested*</td>
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<tr>
<td>b. Total Non-Federal Funds*</td>
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<tr>
<td>c. Total Federal &amp; Non-Federal Funds*</td>
<td>$45,989,991.04</td>
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<tr>
<td>d. Estimated Program Income*</td>
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Existing Infrastructure – Supporting the Mission

• Pathology and imaging research support services
• Surgical expertise and facilities
• Research technical support
• Neonatal care/nursery, operates 24/7
• Diet Laboratory > 1500 purpose made diet formulas
• Importation and quarantine from countries of origin
• Pedigreed and genomically sequenced breeding colony of African green monkeys (N = 325)
• Approximately 50 middle age and older cynomolgus monkeys, many obese and prediabetic
TEAMWORK
○ Agree on goals / milestones
○ Establish tasks to be completed
○ Communicate / monitor progress
○ Solve problems
○ Interpret results
○ Agree completion of project

INDIVIDUAL WORK
○ Work on tasks
○ Work on new / revised tasks
○ Research / development
○ Networking
Thank you
Questions?