The University of Rochester
Clinical and Translational Science Institute

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Director, Rochester CTSI
The Rochester CTSI: An Overview

• The Clinical and Translational Science Award Program at the National Center for Research Resources (National Institutes of Health)

• Clinical and translational research at the University of Rochester Medical Center

• Programs within the Rochester CTSI
The Crisis in Clinical and Translational Research

Original Role of National Institutes of Health:
“The ultimate purpose is to help provide the practicing physicians of this nation – and of the world – with better means of alleviating physical suffering and emotional imbalance, for prolonging human life, and for making all the years of that span more useful both to the individual and to society.”
Questions from the U.S. Congress

• How have the American people benefitted from the taxpayer monies spent on medical research?
• Can we expect discoveries to be translated into diagnostic tests or therapeutic drugs or devices more rapidly?
Emphasis Areas

Basic Research
Knowledge Acquisition
Epidemiological Research
Knowledge Validation
Clinical Investigations
Prevention Research
Clinical Trials
Knowledge Transfer
Technology Transfer
Education Programs
Health of the Nation
Multi- and Interdisciplinary Research will be Required to Solve the “Puzzle” of Complex Diseases and Conditions

- Genes
- Behavior
- Diet/Nutrition
- Infectious agents
- Environment
- Society
- ???
Translational Research

• For historical reasons, clinical research has evolved haphazardly
  – Started as cottage industry and select centers
  – Now has more complex requirements: regulation, technology, speed, efficiency
  – Greater links to basic science

• Need transformation to move into the 21st Century
  – Individual apprenticeship → discipline of clinical research
  – Uniform gauge → harmonize rules, build infrastructure and create networks
  – Focus on mentoring → multidisciplinary teams

• The key value is access to well characterized cohorts of patients and biological samples
Definition of Translational Research?

That body of scientific inquiry which:
1) Seeks to ultimately describe variations in human physiology and disease, 2) Employs studies of molecular and cellular mechanisms of human disease, 3) Potentially produces knowledge and tools that can be applied in clinical and population settings to the prevention, diagnosis, or treatment of human disease.
Conceptual Rationale for Development of Programs in Translational Research

Type 1  Type 2  Type 3  Type 4

Basic Research  Experimental Therapeutics  Population-based Research  Health Systems, Policy, or Law-based Research

Road block 1: Bench to Human  Road block 2: Human to Clinical Medicine  Road block 3: Clinical Medicine to Public Health

Bench  Clinical Medicine  Public Health
Translational Research
Reverse Translation

Basic Science  Bench to Bedside  Bedside to Clinic to Community
(T1)  (T2)  (T3)
The National Clinical and Translational Science Program

- Initiated in 2006 with the selection of 12 US Universities
- 55 CTSA institutions have been selected as of 2010, with the goal of 60 CTSAs by 2012
- Requires sharing of tools, data, methods.
- Organizing as a National Consortium with educational programs, clinical trials, methods and data repositories, etc.
NIH Goals for the CTSA Program

• Create an “academic home” for clinical and translational research
• Enhance training and career development in clinical and translational sciences
• “Incubate” innovative research tools and technologies
• Reduce translational barriers to stimulate the application of new knowledge to clinical practice
Historical Examples of URMC Translational Research

- Lung surfactant in premature infants with respiratory distress syndrome.
- Haemophilus influenzae vaccine development.
- Human papilloma virus vaccine to prevent cervical cancer.
### Number of Investigators with Sponsored Research Projects at URMC, 2005-2009

<table>
<thead>
<tr>
<th>Characterization</th>
<th>2005</th>
<th>2007</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Investigators</td>
<td>536</td>
<td>531</td>
<td>600</td>
</tr>
<tr>
<td># of Active Sponsored Projects</td>
<td>1219</td>
<td>1175</td>
<td>1243</td>
</tr>
<tr>
<td>Total Research $</td>
<td>$192.4 M</td>
<td>$217.6 M</td>
<td>$245.6 M</td>
</tr>
</tbody>
</table>
## Total and NIH Research Funds Classified as Clinical or Basic Research by URMC Principal Investigators for Years 2005 (PreCTSA), 2007, and 2009 from the CTSI Research Resource Inventory

<table>
<thead>
<tr>
<th>Category</th>
<th>2005</th>
<th>2007</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Research</td>
<td>192.4</td>
<td>217.5</td>
<td>245.6</td>
</tr>
<tr>
<td>Clinical Research</td>
<td>81.0</td>
<td>98.5</td>
<td>110.8</td>
</tr>
<tr>
<td>Basic Research</td>
<td>89.5</td>
<td>90.2</td>
<td>108.7</td>
</tr>
<tr>
<td>NIH-Funded Research</td>
<td>118.9</td>
<td>126.3</td>
<td>159.5</td>
</tr>
<tr>
<td>Clinical Research</td>
<td>42.9</td>
<td>53.4</td>
<td>67.7</td>
</tr>
<tr>
<td>Basic Research</td>
<td>76.0</td>
<td>73.0</td>
<td>91.8</td>
</tr>
</tbody>
</table>
# Table-Figure F1.12. Characteristics of URMC-Sponsored Projects in 2007 and 2009

<table>
<thead>
<tr>
<th>Classification of Project</th>
<th>2007</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Research Translation</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>T1</td>
<td>479</td>
<td>41.5</td>
</tr>
<tr>
<td>T2</td>
<td>376</td>
<td>32.6</td>
</tr>
<tr>
<td>T3</td>
<td>219</td>
<td>19.0</td>
</tr>
<tr>
<td>T1, T2, or T3</td>
<td>714</td>
<td>61.9</td>
</tr>
<tr>
<td>International Collaboration</td>
<td>147</td>
<td>12.7</td>
</tr>
<tr>
<td>Community-Based Participation</td>
<td>249</td>
<td>21.1</td>
</tr>
</tbody>
</table>
### URMC Strategic Plan: Innovative Scientific Programs

<table>
<thead>
<tr>
<th>Basic</th>
<th>Clinical/Translational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem Cells &amp; Regenerative Medicine</td>
<td>Experimental Therapeutics (CHET, T1 KF)</td>
</tr>
<tr>
<td>Biomedical Imaging and Biomarkers</td>
<td>Patient-oriented Research (CRC, CRRF KF)</td>
</tr>
<tr>
<td>Nanomedicine</td>
<td>Comparative Effectiveness Research (CRIT, CER KF)</td>
</tr>
<tr>
<td>Genomics and Systems Biology</td>
<td>Community-based Participatory Research (CCH, CE KF)</td>
</tr>
</tbody>
</table>
## Integrated Disease Programs: Projects Classified as Basic or Clinical Research

<table>
<thead>
<tr>
<th>IDP</th>
<th>Basic Science</th>
<th>Clinical Research</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Cancer</td>
<td>98</td>
<td>42%</td>
<td>134</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>60</td>
<td>31%</td>
<td>136</td>
</tr>
<tr>
<td>Immunology / Infectious Disease</td>
<td>175</td>
<td>48%</td>
<td>192</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>88</td>
<td>49%</td>
<td>91</td>
</tr>
<tr>
<td>Neuromedicine</td>
<td>135</td>
<td>41%</td>
<td>195</td>
</tr>
</tbody>
</table>
Four Specific Aims of the UR-CTSI

• Create an academic home for clinical and translational research at the University of Rochester.
• Organize services to better support investigators and their projects.
• Create or reorganize four Centers of Research Excellence across the translational research spectrum.
• Offer a broad range of education and training opportunities in clinical and translational research.
CTSI Organization

Proposed Organizational Chart of Rochester Clinical and Translational Science Institute

CEO/VP
URMC

Dean, School of Medicine and Dentistry
Clinical and Translational Science Institute
SAD — Clinical Research
SAD — Basic Science

Executive Committee
Chair — SAD Clinical Research
Co-Chair — SAD Basic Science
Exec. Director — Operations
Exec. Director — Finance

Director, C HET
Director, CRC
Director, CCH
Assoc. Dean for Research / Director CRIT, SON
Res. Director — Eastman Institute of Or al Health
Asst. Dean for Finance — SOM

Research Centers

Center for Human Experimental Therapeutics (HET)
Clinical Research Center (CRRC)
Center for Research Implementation and Translation (CRRIT)

Center for Community Health (Community Engagement KF)

CTSI Administrative Committee

Office of Clinical Research (Key Functions and Cores)
PD/PI
Exec. Director — Operations
Exec. Director — Finance

Institute of Oral Health

National CISA Consortium

External Advisory Board

Basic Science Departments

School of Nursing

Committee on Industry and Foundation Relations/Office of Corporate Alliances
Public/Private Partnerships KF

Committee on Industry and Foundation Relations/Office of Corporate Alliances
Public/Private Partnerships KF

Gum munity Advisory Board

Practice — based Research Network

Center for Community Health (Community Engagement KF)
Table-Figure F1.8. Floor Plan for Ground Floor
Specific Aim #2: Consolidate and Reorganize Services for Better Support of Investigators

- Incubator Program
- Navigator Program
- Core Expert Team
- Clinical Research Cores
- Consultation Services
UNYTRN Member Institutions

- University of Rochester
- SUNY Upstate Medical University
- Ordway Research Institute
- Masonic Medical Research Laboratory
- M.I. Bassett Hospital
- Wadsworth Center
- Guthrie Clinic
- Rensselaer Polytechnic Institute
- University at Buffalo
- Roswell Park Cancer Institute
- Rochester Institute of Technology
- Cornell University
- Binghamton University
- Albany Medical College
- Albany Medical College of Pharmacy
- Trudeau Institute
- Albany College of Pharmacy
Specific Aim #3: Create or Reorganize Four Centers of Excellence in Translational Science to Foster the Breadth of Translational Research

- Center for Human Experimental Therapeutics (T1)
- Clinical Research Center (T1-3)
- Center for Research Implementation and Translation (T2-3) (SON)
- Center for Community Health (T2-4)
Specific Aim #4: Goal of Research Education, Training and Career Development Programs

To develop and integrate a program of research education, training, and career development that has the breadth and flexibility to meet the needs of a new type of investigator:

- committed to careers in clinical and translational science
- requires additional knowledge and skills to contribute to multidisciplinary teams
Aims of the Research Education, Training, and Career Development Programs

1. Organize education and training programs within UR-CTSI

2. Create new curricula leading to:
   • Masters Degree in Clinical Investigation
   • Masters Degree in Translational Research
   • PHD Degree in Translational Biomedical Sciences
   • Certificate/Masters in Clinical Research Coordination
   • Certificate in Comparative Effectiveness Research

3. Expand a mentor development program
Aims of the Research Education, Training, and Career Development Programs (Cont’d)

4. Develop a predoctoral (T32) program using new curricula, skill-building workshops, seminars, and mentored research experiences leading to MD-MS, DNP-MS, PhD, or MD-PhD Degrees.

5. Initiate a Clinical/Translational Research Career Development (K12) Program for junior faculty.

6. Evaluate the performance of the Education and Training Programs.
Opportunities for Biomedical Engineers in the Rochester CTSI

Education, Training, and Career Development
  Masters Programs (MSTR, MSCI, MPH)
  PhD in Translational Biomedical Science
  MD-PhD Program
  Certificate in Clinical/Translational Research

Incubator Program (Pilot Studies, Novel Methods, Laboratory Support)

Navigator Program (Consultations in Bioinformatics, Biostatistics, Epidemiology, Research Services)

Regulatory Support

Upstate NY Translational Research Network
Center for Governmental Research: Economic Impact of the CTSA

- **Direct funds**: $8M/yr
- **Indirect funds for research**: $29.26 million/yr.
- **Direct and spillover impacts**:
  - **Labor income**: $42.6 M/year
  - **New positions created**: 556
Summary: The CTSA as a Transformational Agent

- Creation of a Home for CT Science
- National presence in planning
- Publicity of URMC research
- Support for new research resources
- Support for pilot studies, technology development
- Renewal of GCRC
- Creation of novel training programs
- Organization of Upstate Consortium