

The University of Rochester Clinical and Translational Science Institute

Thomas A. Pearson, MD, MPH, PhD
Senior Associate Dean for Clinical Research
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

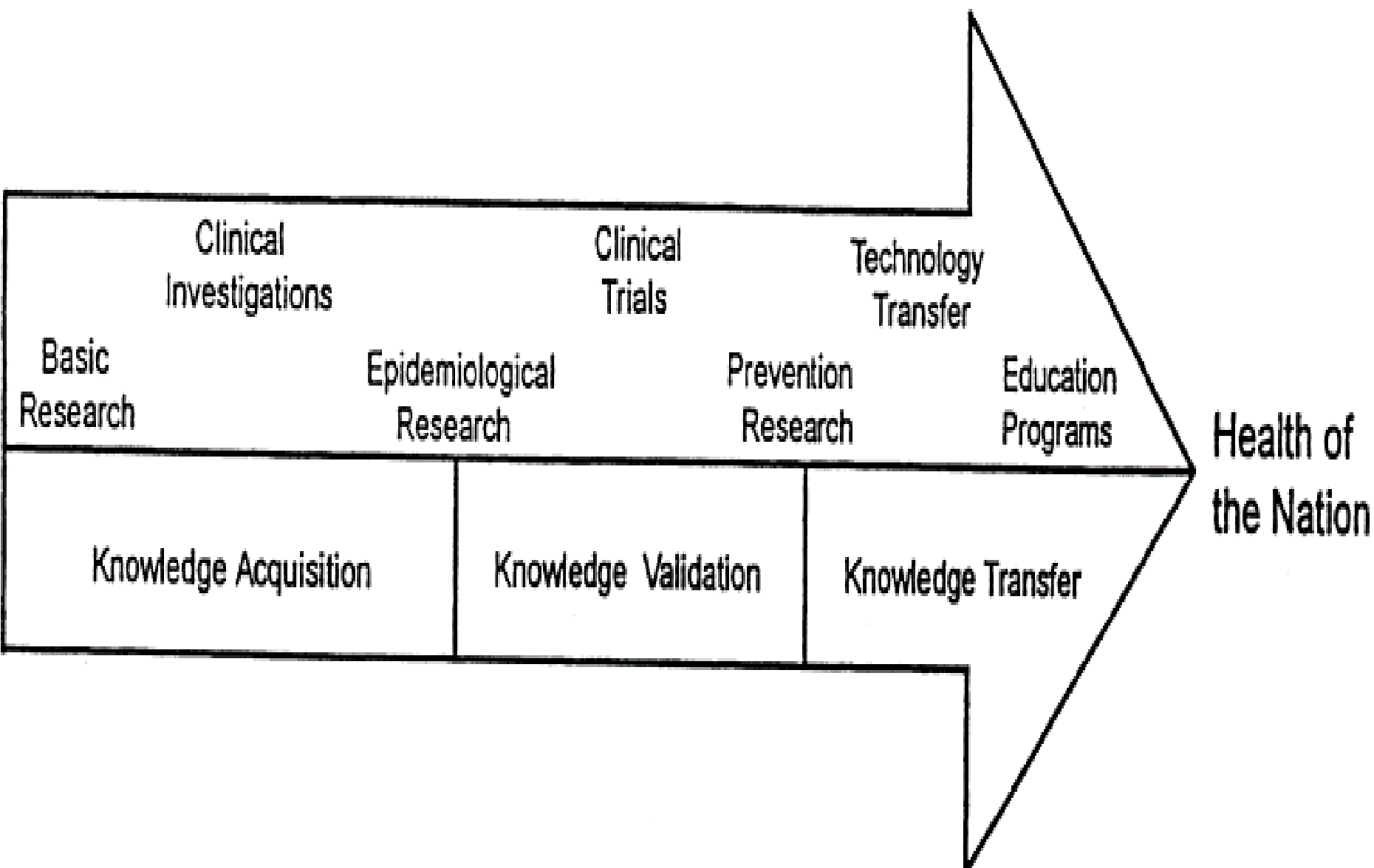
Original Role of National Institutes of Health:

“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



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

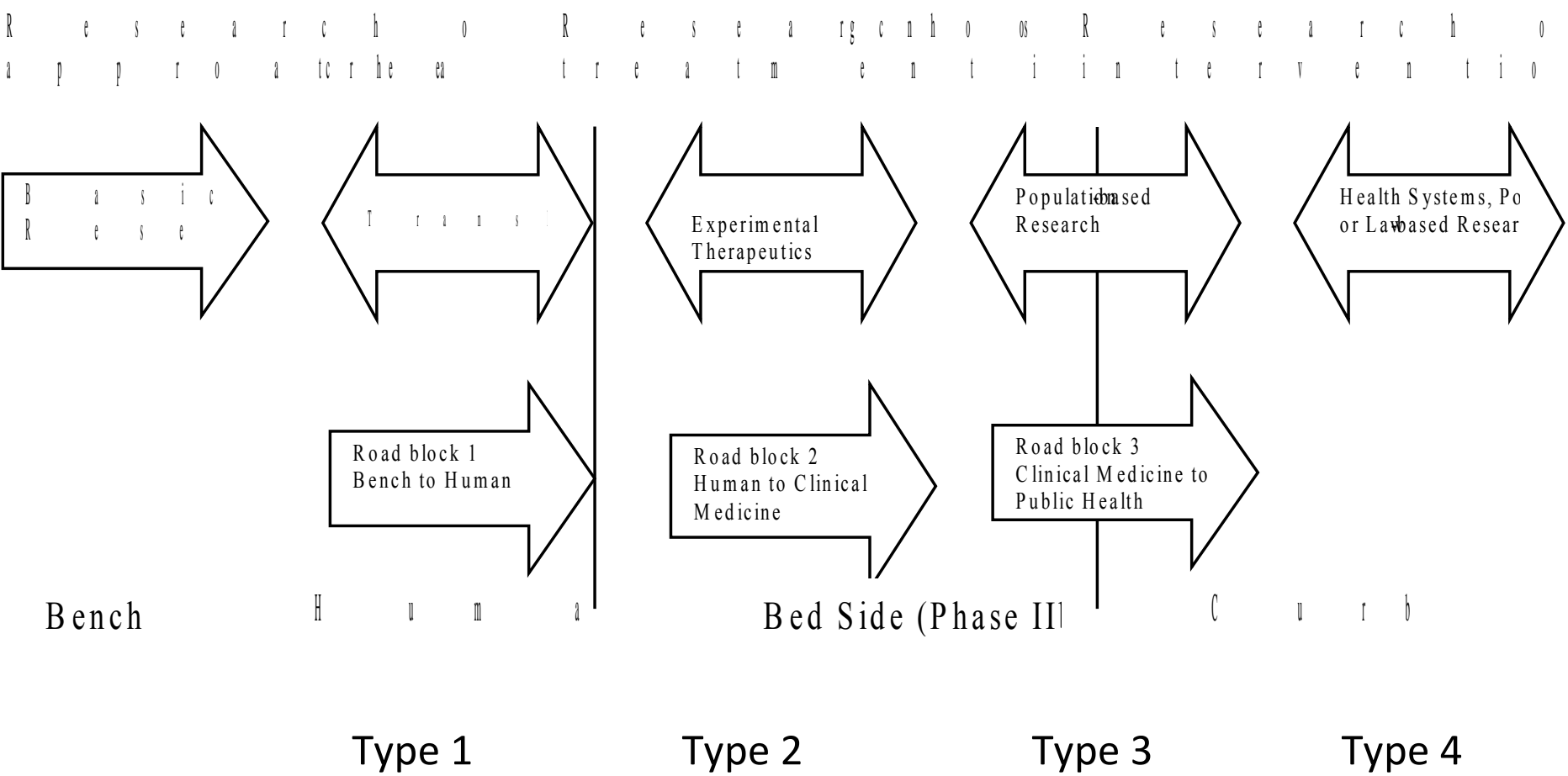
- For historical reasons, clinical research has evolved haphazardly
 - Started as cottage industry and select centers
 - Now has more complex requirements: regulation, technology, speed, efficiency
 - Greater links to basic science
- Need transformation to move into the 21st Century
 - Individual apprenticeship → 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.

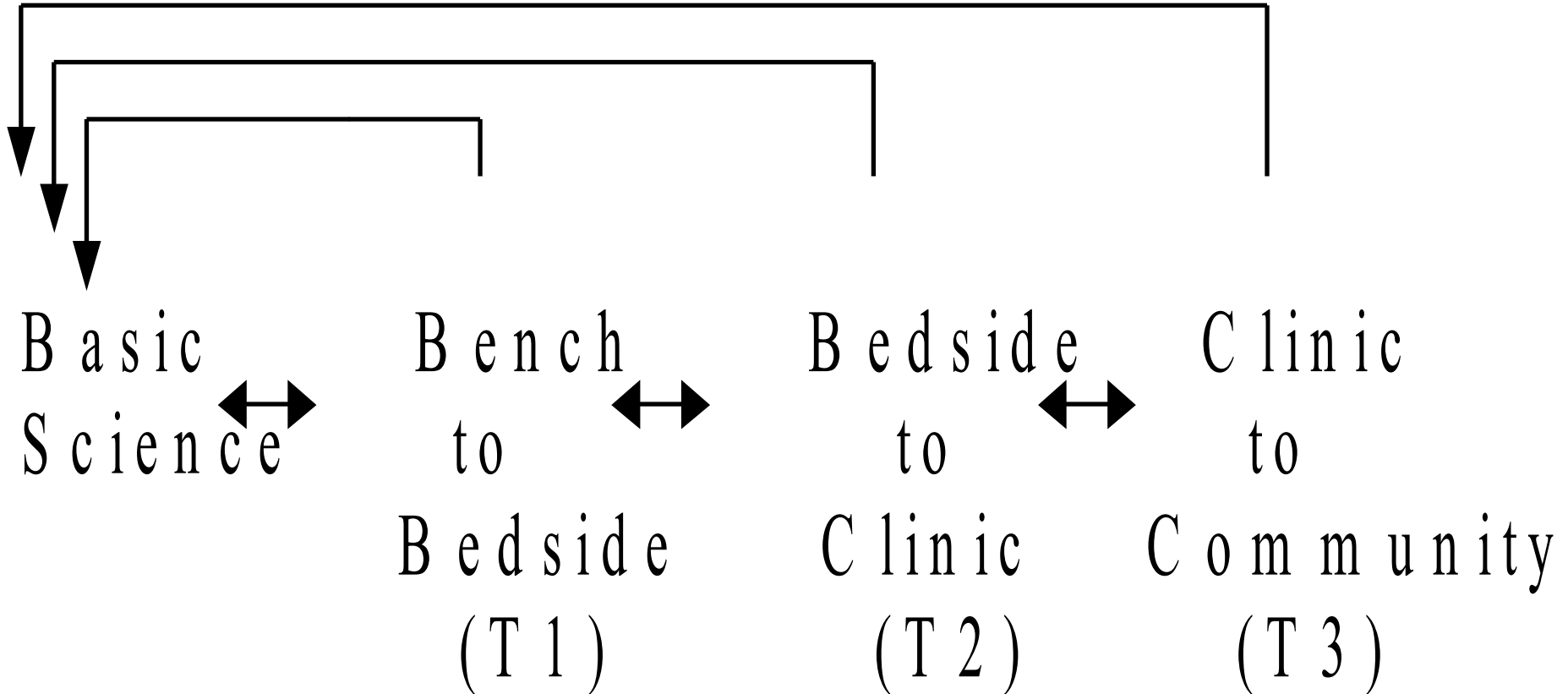
Conceptual Rationale for Development of Programs in Translational Research



Translational Research

Reverse Translation

Reverse Translation



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 CTSA's 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

	Number of Investigators		
Characterization	<u>2005</u>	<u>2007</u>	<u>2009</u>
# of Investigators	536	531	600
# of Active Sponsored Projects	1219	1175	1243
Total Research \$	\$192.4 M	\$217.6 M	\$245.6 M

Total and NIH Research Funds Classified as Clinical or Basic Research by UPMC Principal Investigators for Years 2005 (PreCTSA), 2007, and 2009 from the CTSI Research Resource Inventory

Category	Research Funding in \$ Millions		
	2005	2007	2009
Total Research	192.4	217.5	245.6
Clinical Research	81.0	98.5	110.8
Basic Research	89.5	90.2	108.7
NIH-Funded Research	118.9	126.3	159.5
Clinical Research	42.9	53.4	67.7
Basic Research	76.0	73.0	91.8

Table-Figure F1.12. Characteristics of URMC-Sponsored Projects in 2007 and 2009

Classification of Project	Number of Research Projects (%)			
	2007		2009	
Type of Research Translation	<u>N</u>	<u>%</u>	<u>N</u>	<u>%</u>
T1	479	41.5	482	38.8
T2	376	32.6	374	30.1
T3	219	19.0	240	19.3
T1, T2, or T3	714	61.9	731	58.9
International Collaboration	147	12.7	200	16.0
Community-Based Participation	249	21.1	261	21.0

URMC Strategic Plan: Innovative Scientific Programs

<u>Basic</u>	<u>Clinical/Translational</u>
Stem Cells & Regenerative Medicine	Experimental Therapeutics (CHET, T1 KF)
Biomedical Imaging and Biomarkers	Patient-oriented Research (CRC, CRRF KF)
Nanomedicine	Comparative Effectiveness Research (CRIT, CER KF)
Genomics and Systems Biology	Community-based Participatory Research (CCH, CE KF)

Integrated Disease Programs: Projects Classified as Basic or Clinical Research

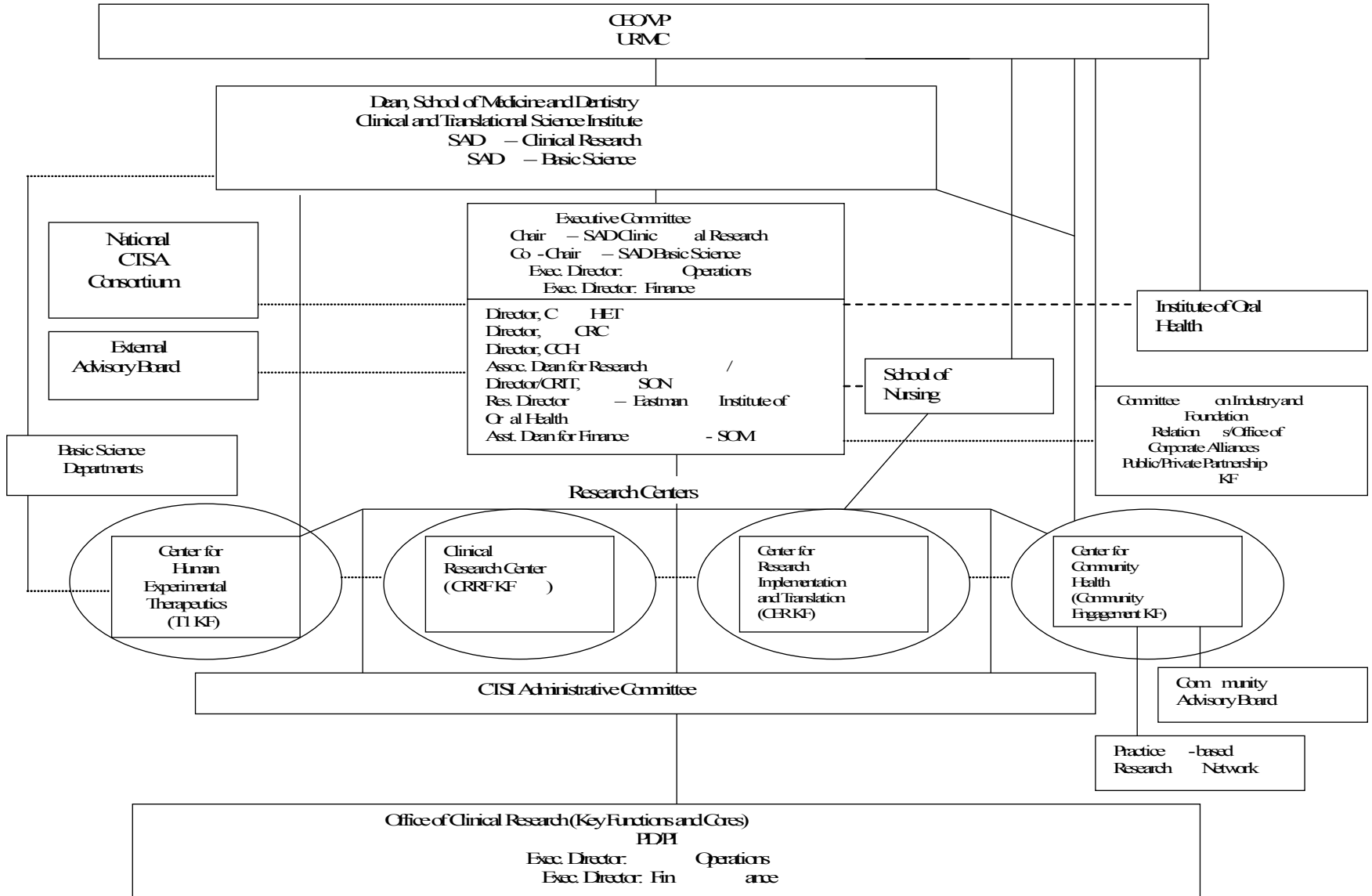
IDP	Basic Science		Clinical Research		Total
	N	%	N	%	N
Cancer	98	42%	134	58%	232
Cardiovascular	60	31%	136	69%	196
Immunology /Infectious Disease	175	48%	192	52%	367
Musculoskeletal	88	49%	91	51%	179
Neuromedicine	135	41%	195	59%	330

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

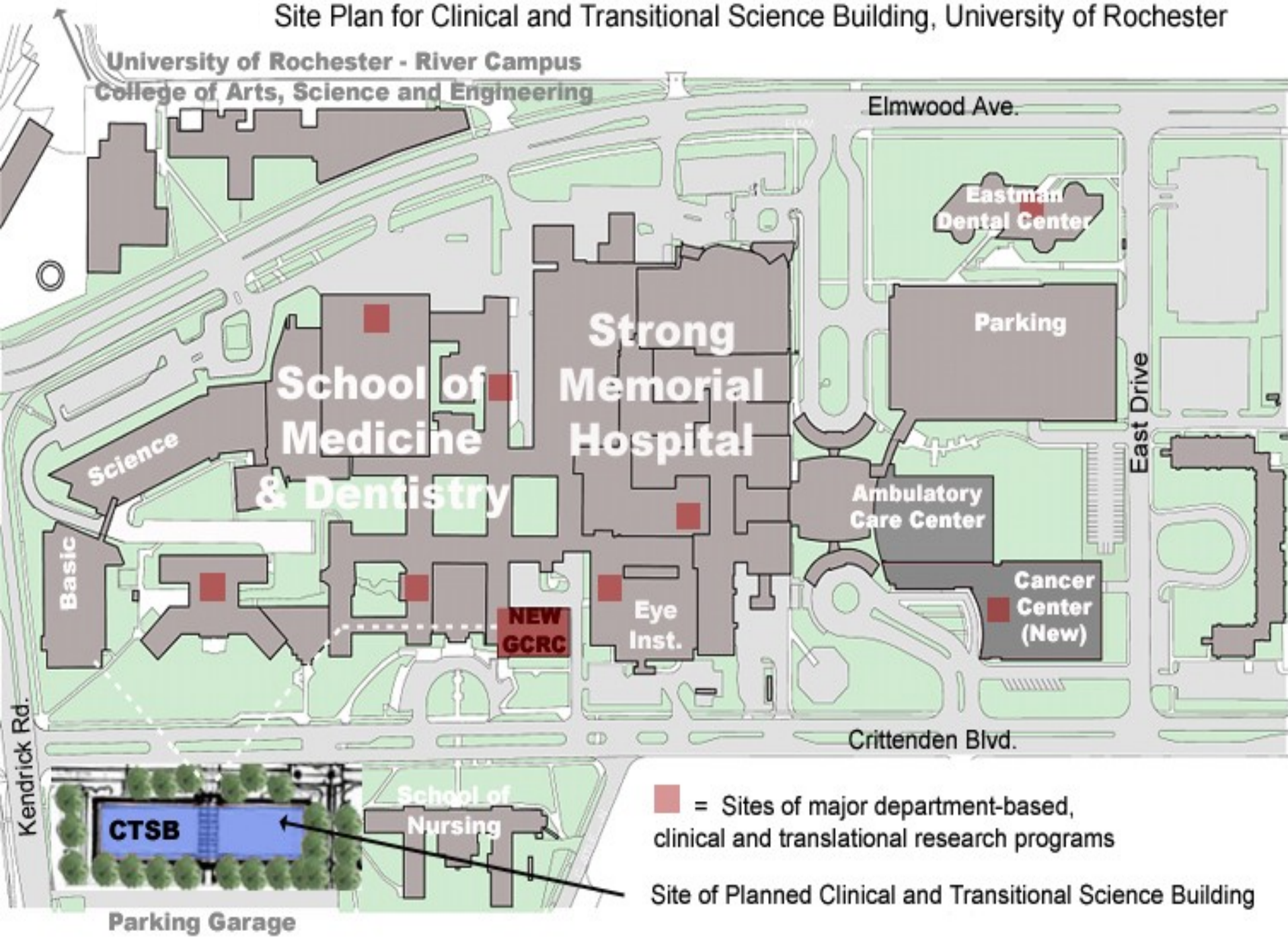


University of Rochester Medical Center Clinical and Translational Science Building



PMT Meeting
July 22, 2008

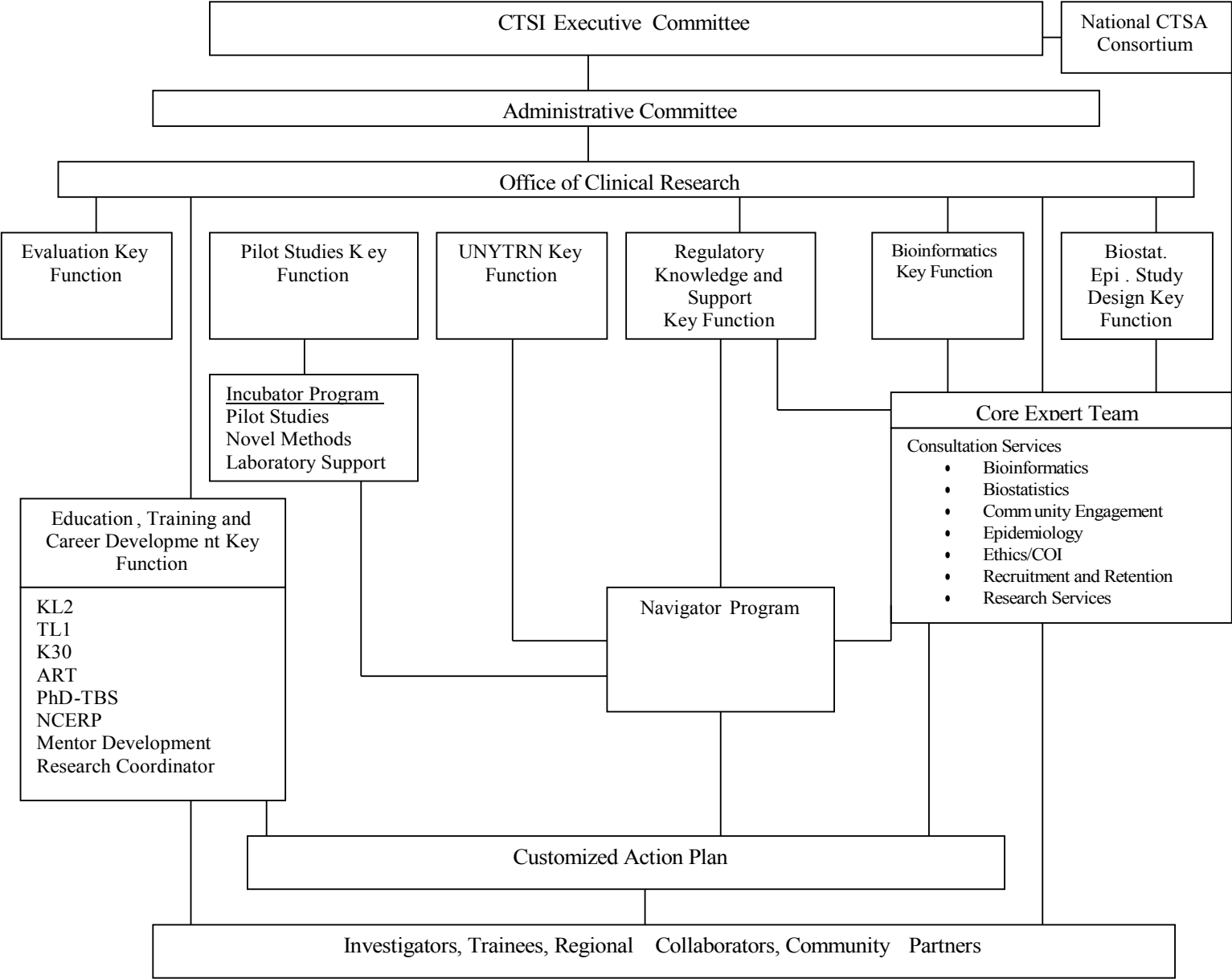
Site Plan for Clinical and Transitional Science Building, University of Rochester



Specific Aim #2: Consolidate and Reorganize Services for Better Support of Investigators

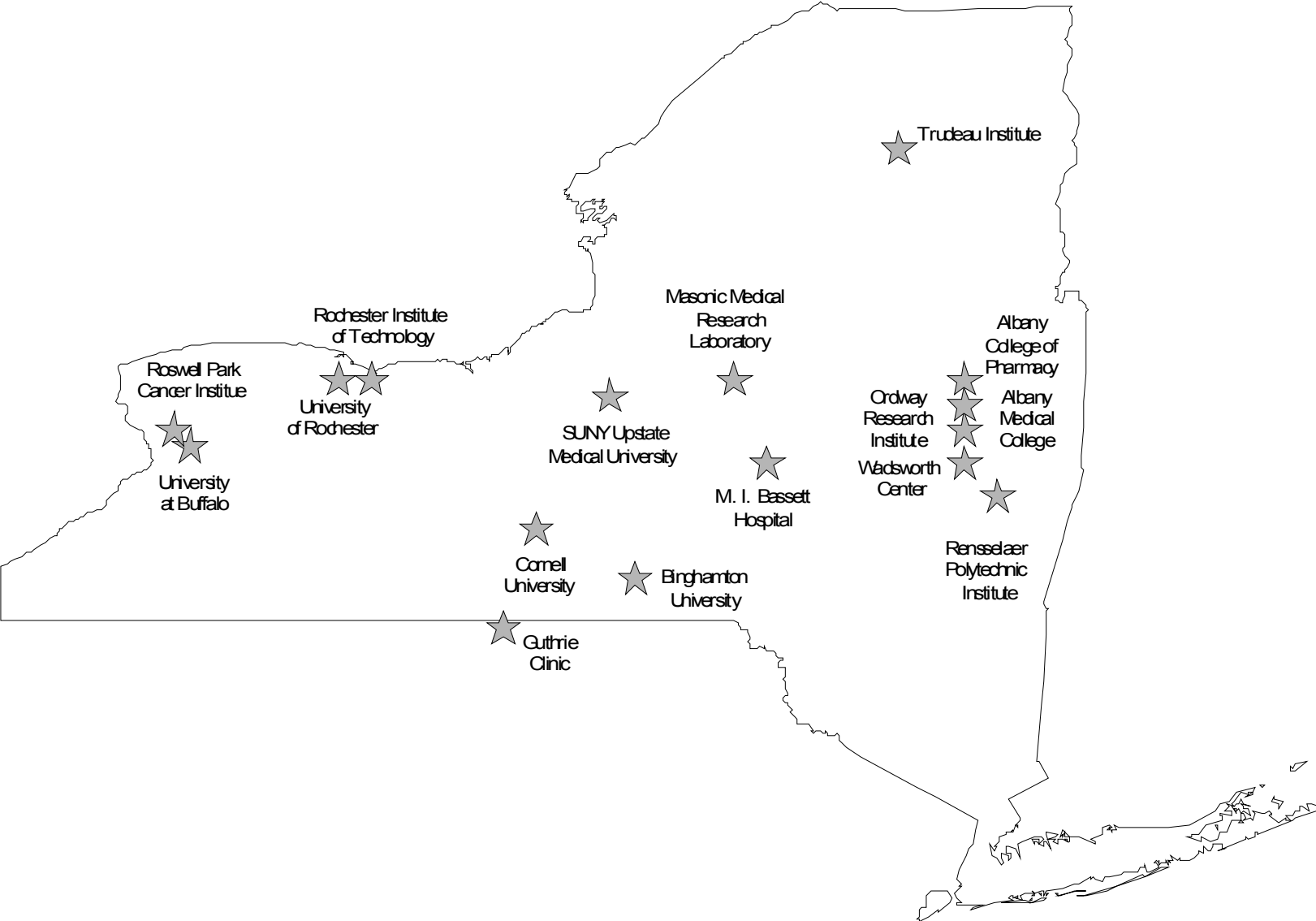
- Incubator Program
- Navigator Program
- Core Expert Team
- Clinical Research Cores
- Consultation Services

Office of Clinical Research



UNYTRN Member Institutions

100 mi

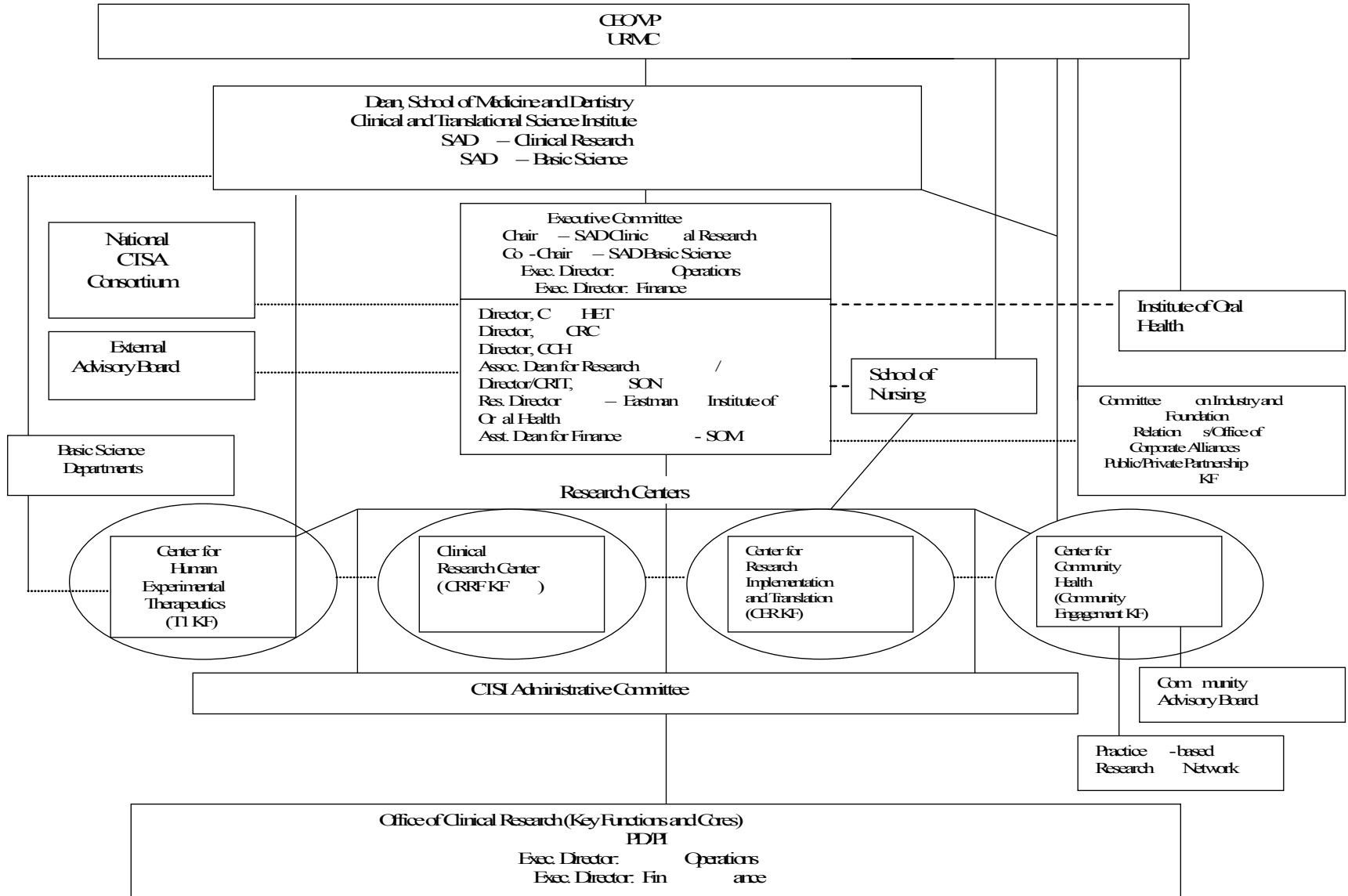


Specific Aim #3: Create or Reorganize Four Centers of Excellence in Translational Science to Foster the Breadth of Translational Research

- 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)

CTSI Organization

Proposed Organizational Chart of Rochester Clinical and Translational Science Institute



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