

Overcoming the T2 Translational Block

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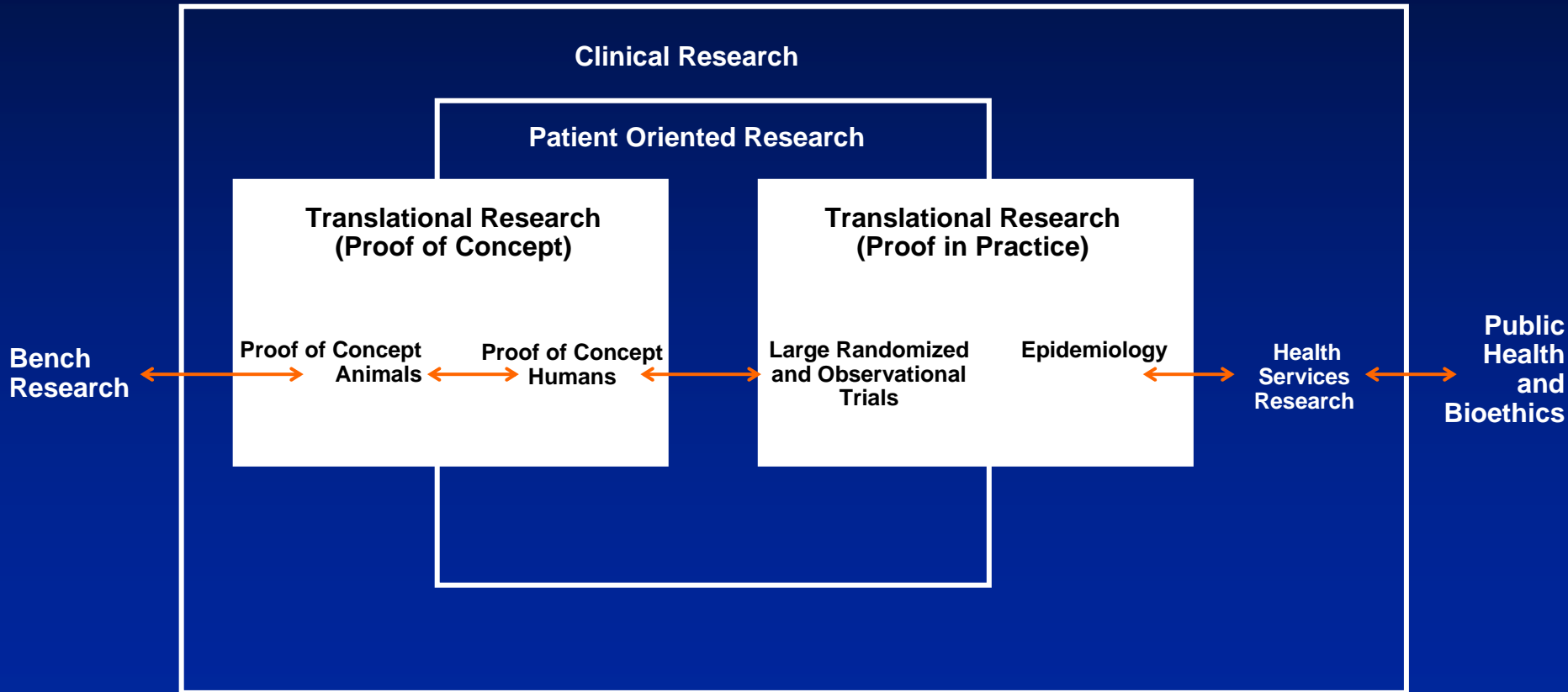
Clinical Research Training at the University of Pennsylvania

- The problem
- Current approach
- New programs initiated



Spectrum of Clinical Research

The diagram below is designed to demonstrate visually the different approaches available in clinical research, relationships among the different approaches, and the relationships among clinical research approaches, bench research, and public health.



This diagram is based on the report written by members of the Clinical Research Roundtable of the Institute of Medicine and published in the March 12, 2003 issue of *JAMA*.

The T2 Translational Research Block

- "The more significant block exists at the level of translating the knowledge that we do have into clinical practice and into actual healthcare settings."

Myron Genel, MD, Professor of Pediatrics and
Associate Dean at Yale School of Medicine



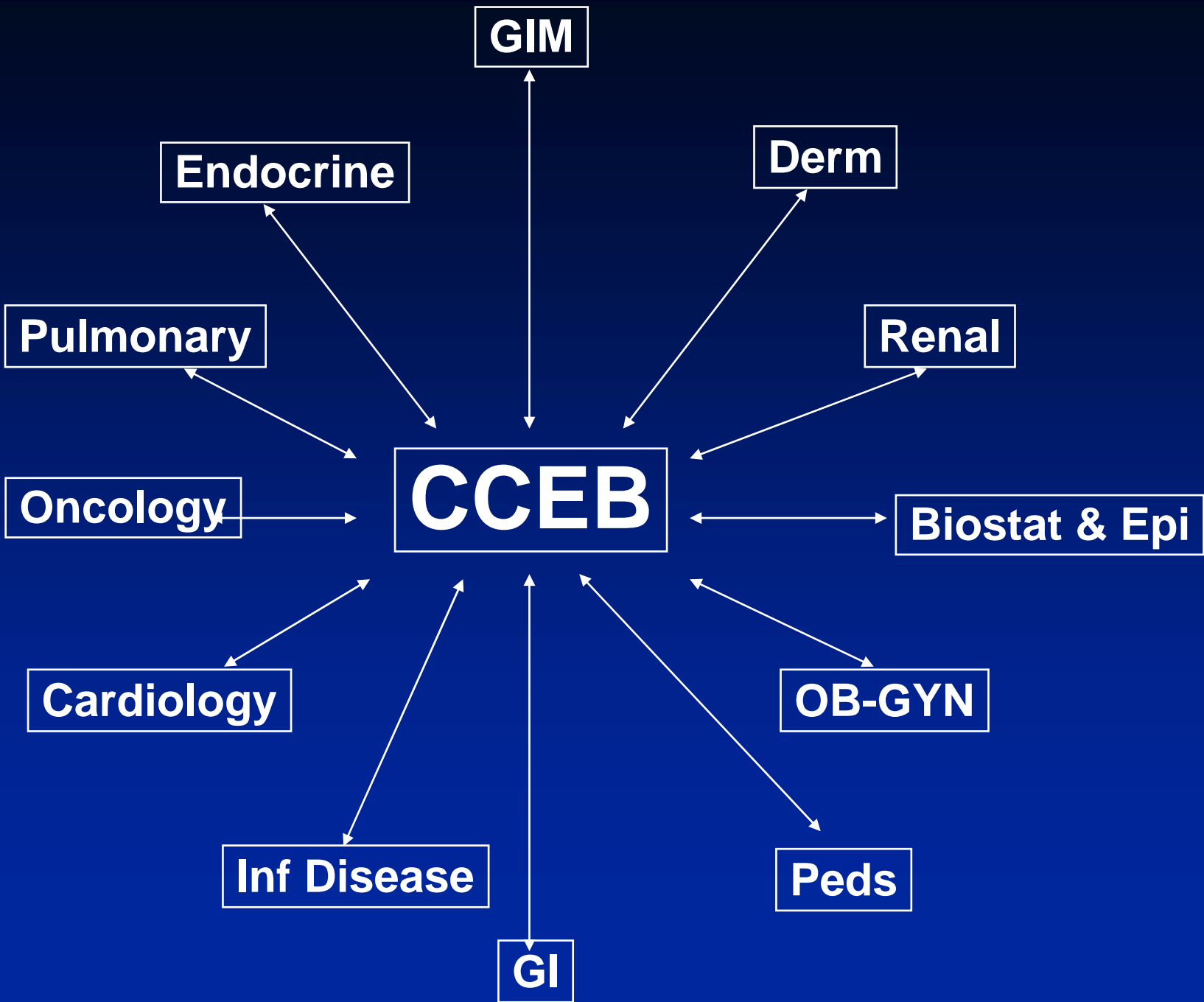
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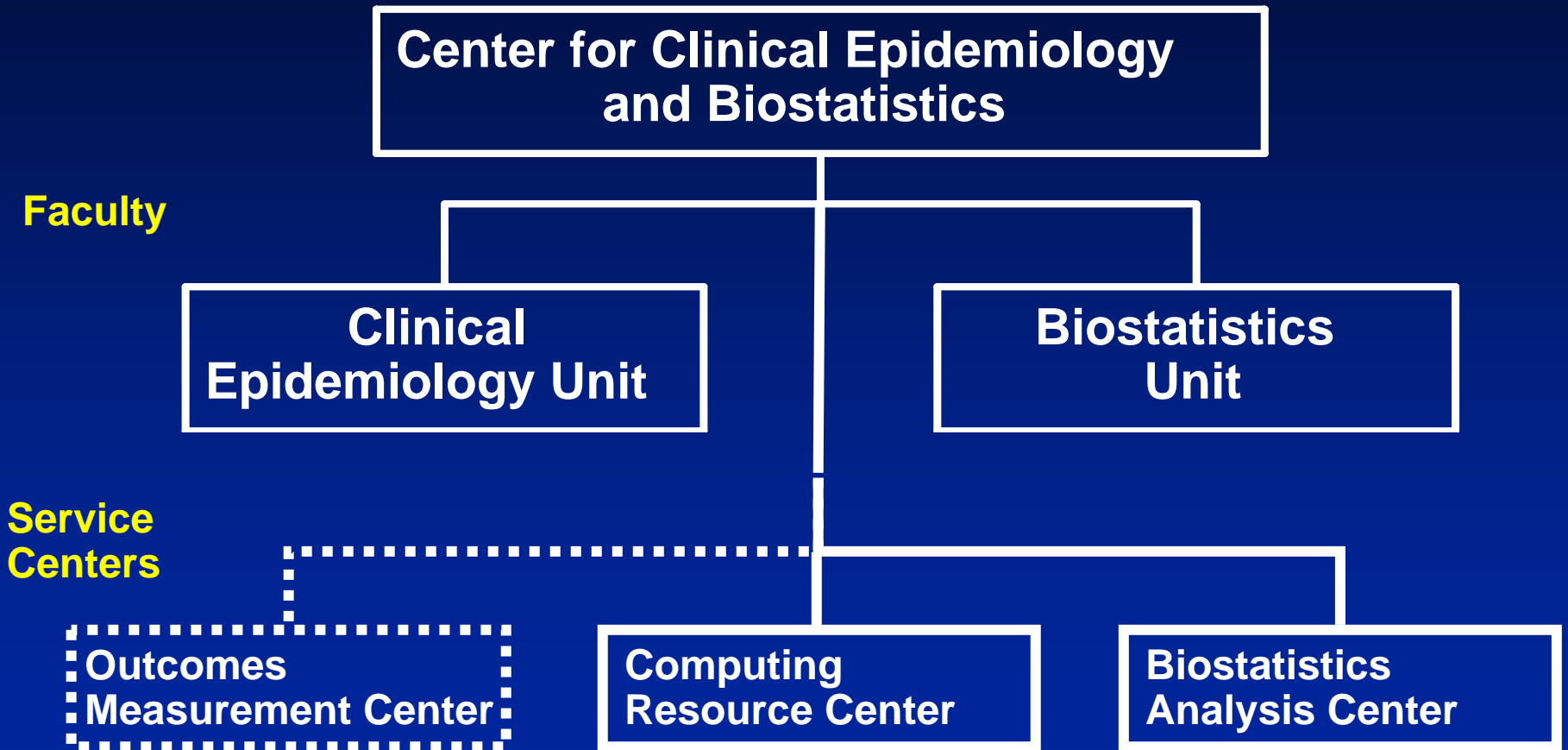
Current Structures at Penn

- **Institute for Translational Medicine and Therapeutics (ITMAT)**
- **Center for Clinical Epidemiology and Biostatistics (CCEB)**
- **Public Health Program (MPH)**
- **Leonard Davis Institute of Health Economics (LDI)**





Center for Clinical Epidemiology and Biostatistics: Organizational Chart



CCEB Faculty Appointments

(As of October 2006)

- 63 Senior Scholars¹ (36 CEU, 27 BU)
 - 65 Associate Scholars² (57 CEU, 8 BU)
 - 42 Adjunct Scholars² (33 CEU, 9 BU)
 - 5 Affiliate Members
- 175 total (126 CEU, 44 BU, 5 Affiliate Members)

¹CCEB usually provides space, infrastructure, and grants management support

²Space, infrastructure, and grants management support provided by home departments



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Staffing

(October 2006)

- 175 faculty (63 Senior Scholars)
 - 1 instructor
 - 190 research staff
 - 25 administrative/professional staff
 - 25 clerical/support staff
 - 4 post-doctoral students
 - 8 MS students in Biostatistics
 - 28 PhD students in Biostatistics
 - 105 MSCE students
 - 6 PhD students in Epidemiology
- 567 total



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Targets of Training in Clinical Epi/Outcomes Research

**Users of Clinical Research
vs.
Do-ers of Clinical Research**



Teaching Programs – Medical School

- Four year integrated medical student curriculum
- First year basic science clinical epidemiology course
- Bridging the Gaps: Community Health Internship Program
- Research electives
- International electives



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Teaching Programs – Advanced Degrees

- 2-year MSCE in Clinical Epidemiology
- 5-year joint MD/MSCE program
- PhD in Epidemiology Program
- MD/PhD Program in Epidemiology
- MS Program in Biostatistics
- PhD Program in Biostatistics
- Certificate Program in Epidemiology



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MSCE Program: Unique Characteristics

- **Focus: performing clinical research**
- **Didactic plus mentor guided research**
- **Students: all clinicians**
 - Medical students
 - Pharmacists, nurses, physical therapists, etc
 - Fellows during or after subspecialty training
 - Junior faculty
 - Faculty on sabbatical



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Curriculum

- **Epidemiology - 1**
- **Biostatistics – 2**
- **Health Measurement – 1**
- **Critical Appraisal – 0.5**
- **Protocol Development – 0.5**
- **Database management – 0.5**
- **Grant review course – 0.5**
- **Meeting with mentor credits - 1**
- **Thesis credits – 4**
- **Track specific courses and/or electives 3**



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MSCE Tracks

- **Epidemiology**
- **Health Services Research**
- **Human Genetics**
- **Bioethics**
- **Clinical Trials**
- **Community Oriented Research**
- **Medical Informatics (?TBD)**



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MSCE Fellows

- Program started in 1981 with 2 fellows
- Admitted 38 fellows 2006-07
- Total number of fellows – 411
- Currently in training – 105
- Hold positions at Penn – 100
- At other academic centers – 168



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CTSA Proposal

- Led by ITMAT
- PI: Garret FitzGerald
- Co-PIs: Peter Adamson, Glen Gaulton, Dan Rader, Brian Strom
- Incorporates HUP and CHOP GCRCs
- Joint proposal from Penn's Schools of Med, Nsg, Dentistry, Edn, Arts & Sciences, Vet, Engineering, Annenberg, and Wharton; plus Children's Hospital of Philadelphia, Wistar Institute, & Univ of the Sciences in Phila

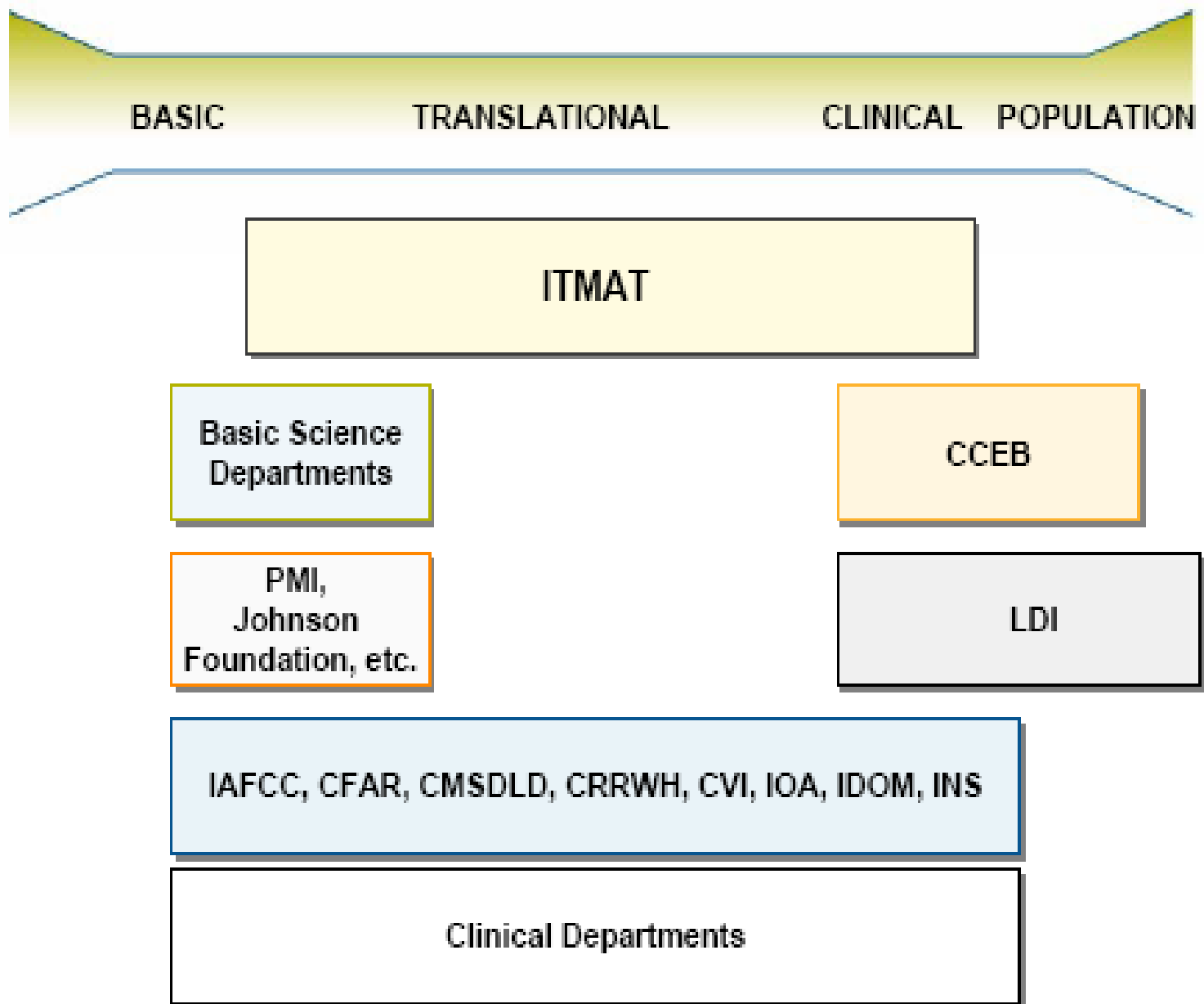


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The Spectrum of Biomedical Research

Research
Continuum:



Range of Educational Programs

- Master of Translational Research
- Master of Science in Clinical Epi
- Masters of Science in Health Services Research
- MSCE/PhD in Health Care Systems
- MBA/PhD in Epi
- Expanded med school class with slots for MSCE/MTR
- Etc.



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Central Challenges to Clinical Research

- **Enhancing public participation**
- **Developing information systems**
- **An adequately trained workforce**
- **Funding**
 - Federal government
 - Private industry



Sung NS, Crowley WF, Genel M, et al. Central Challenges Facing the National Clinical Research Enterprise, JAMA, 2003, 289(10) 1278-87



Conclusions

- **Clinical and translational research is possible with the right support**
- **Teaching programs should be appropriate for educational needs**
- **Insist on evidence based medicine and questioning of medical dogma**
- **Target and cultivate public opinion in support of the effort**



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