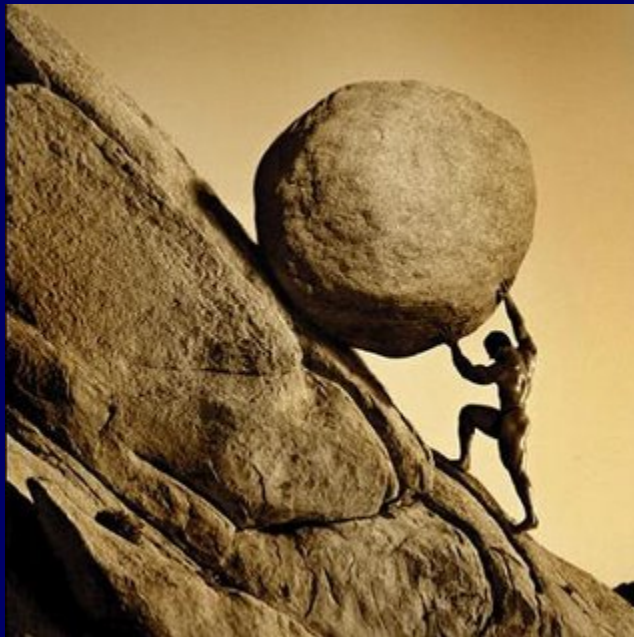


Research funding in the US: la fatica di Sisifo?

Roberto Salvatori, M.D.

Associate Professor of Medicine



You are
hired...congratulations...

*“...But remember: Johns Hopkins is like
McDonald’s, it is a franchise...we give you the
name,...*

AND YOU COME UP WITH THE MONEY!”



JOHNS HOPKINS
M E D I C I N E

=



Universities in the US are structured differently than in Italy

- Every Department/Division is a separate financial entity, with its own budget, which must include the salaries of all the employees
- Each faculty member is his/her own manager, and has to bring in money for his/her salary from a variety of activities (sponsored research, clinical practice, teaching etc.)
- Some senior faculty have an “endowed chair”
- Most teaching is not compensated, so...

How is research initiated?

- 1) Investigator-initiated

The investigator has an idea and seeks funding for it

- 2) Sponsor-initiated

The sponsor (generally a pharmaceutical or biomedical device company) wants to test a drug or device and seeks collaboration from an academic center (often multi-center trials)

- No clinical study can be started without the approval of the IRB (Institutional Review Board) (ethics committee)
- No animal study can be started without the approval of the ACC (Animal Care Committee)

Investigator-initiated

- To federal agencies: National Institutes of Health (NIH) , National Science Foundation (NSF), Food and Drug Administration (FDA), Department of Defense (DOD) etc.
- To Private Foundations: Cystic Fibrosis Foundation, Juvenile Diabetes Association, American Cancer Society, Leukemia Foundation, American Heart Association, Borroughs Welcome Trust, Howard Hughes Foundation, etc...
- To pharmaceutical companies
- To Private donors (“Development office”)

Investigator-initiated

- The investigator looks for an announcement
- S/he studies carefully the requirements specified in the announcement (sometimes very narrow)
- Then s/he writes an application
- The budget and finance part must be approved by the Department (Medicine, Surgery, Pathology, Psychiatry etc.)
- A percentage of the salary of the P.I. (Principal Investigator) **MUST** be included in the budget
- The application must be approved by the O.R A. (Office of Research Administration) BEFORE it is submitted
- The O.R A. is particularly interested in the *INDIRECT COST*

What is the *Indirect Cost*?

- It is the money that the University charges to the funding agencies to run the study
- In most Foundations and Pharmaceutical companies is part of the budget (not always accepted by the University)
- For the NIH, it is **ADDED** to the budget (if you receive a \$1 million grant, the NIH will pay \$1.6 million)
- It pays for the cost of the facilities (buildings, electricity, maintenance etc.) and for the administrative costs (secretaries, computer etc.)

IDC at JHU in 2008

Sponsor	Location	%IDC
NIH	On campus	64%
NIH	Off campus	26%
Commercial contracts	On campus	46.2%
Commercial contracts	Off campus	26%
Foundation	On campus	32.2%
Foundation	Off-campus	18.8%

Sponsor-initiated

- The Pharmaceutical company looks for investigators
- S/he has to have a patient population that fits the needs of the company
- The company writes the protocol
- The budget and finance part must be approved by the Department (Medicine, Surgery, Pathology etc.)
- A percentage of the salary of the P.I. (principal Investigator) **MUST** be included in the budget
- The application must be approved by the O.R.A. (Office of Research Administration) BEFORE it is submitted
- The O.R.A. works on a contract with the company, which specifies the economical aspects (INDIRECT COST) and the issues of intellectual property and patenting

Challenges in clinical Research

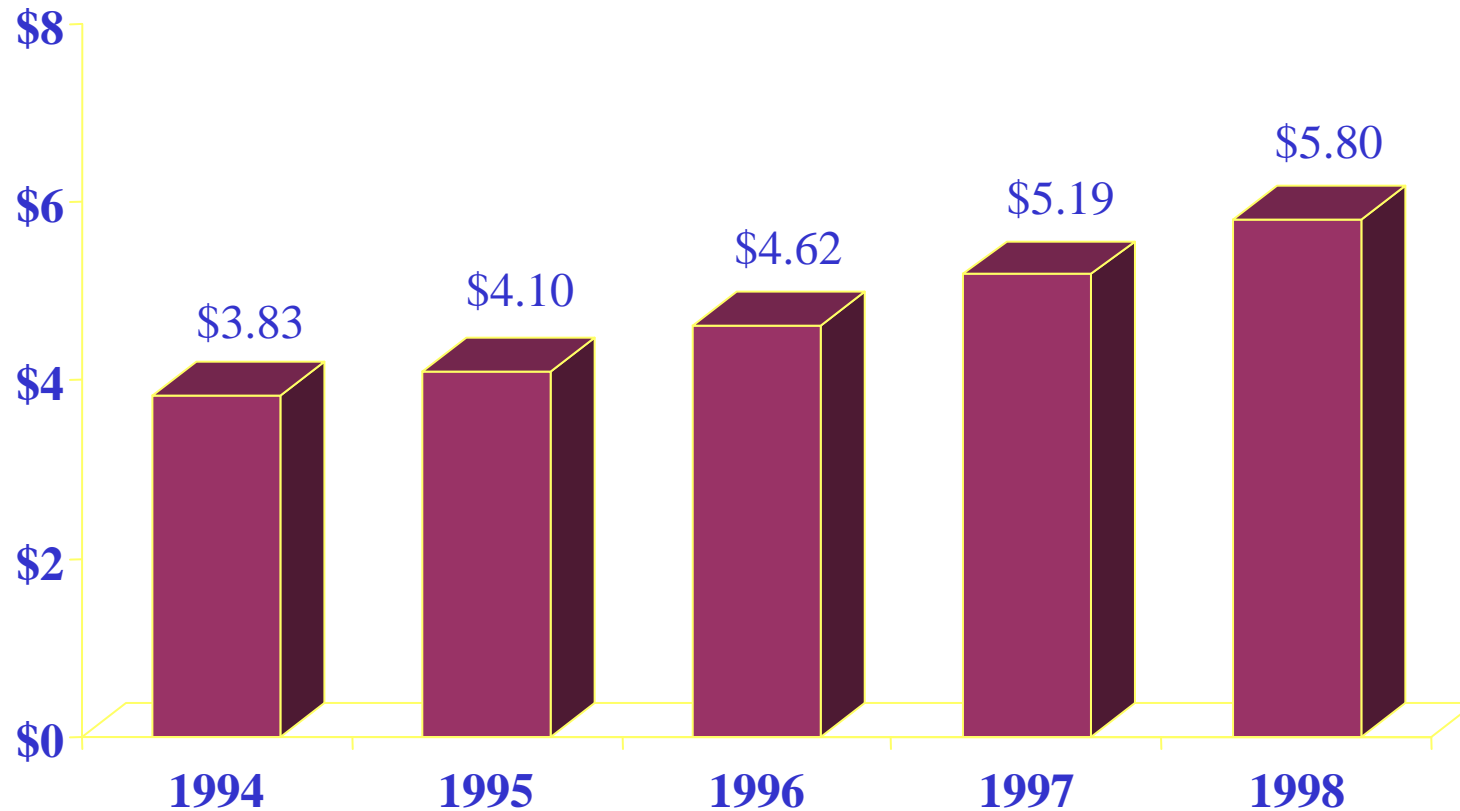
Outline

- Trends in clinical research within Academic Health Systems
- Problems faced by institutions
- New initiatives being developed in to advance the clinical research enterprise
- Challenges

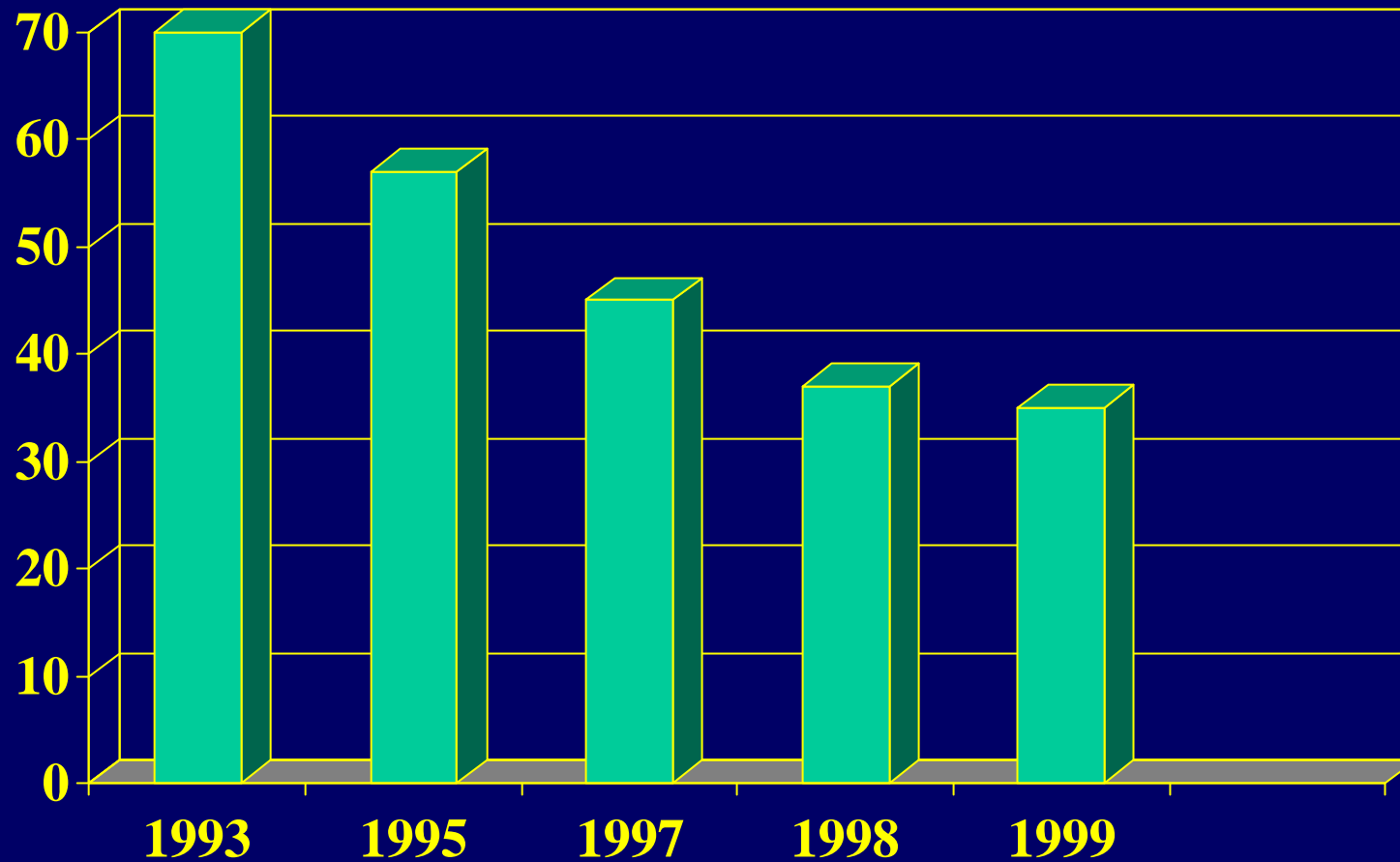
Worldwide Clinical Grants Market



Total Phase I-IV Clinical Spending
\$ in Billions



Percentage of Clinical Research Being Done in Academic Medical Centers (CenterWatch)



Outline

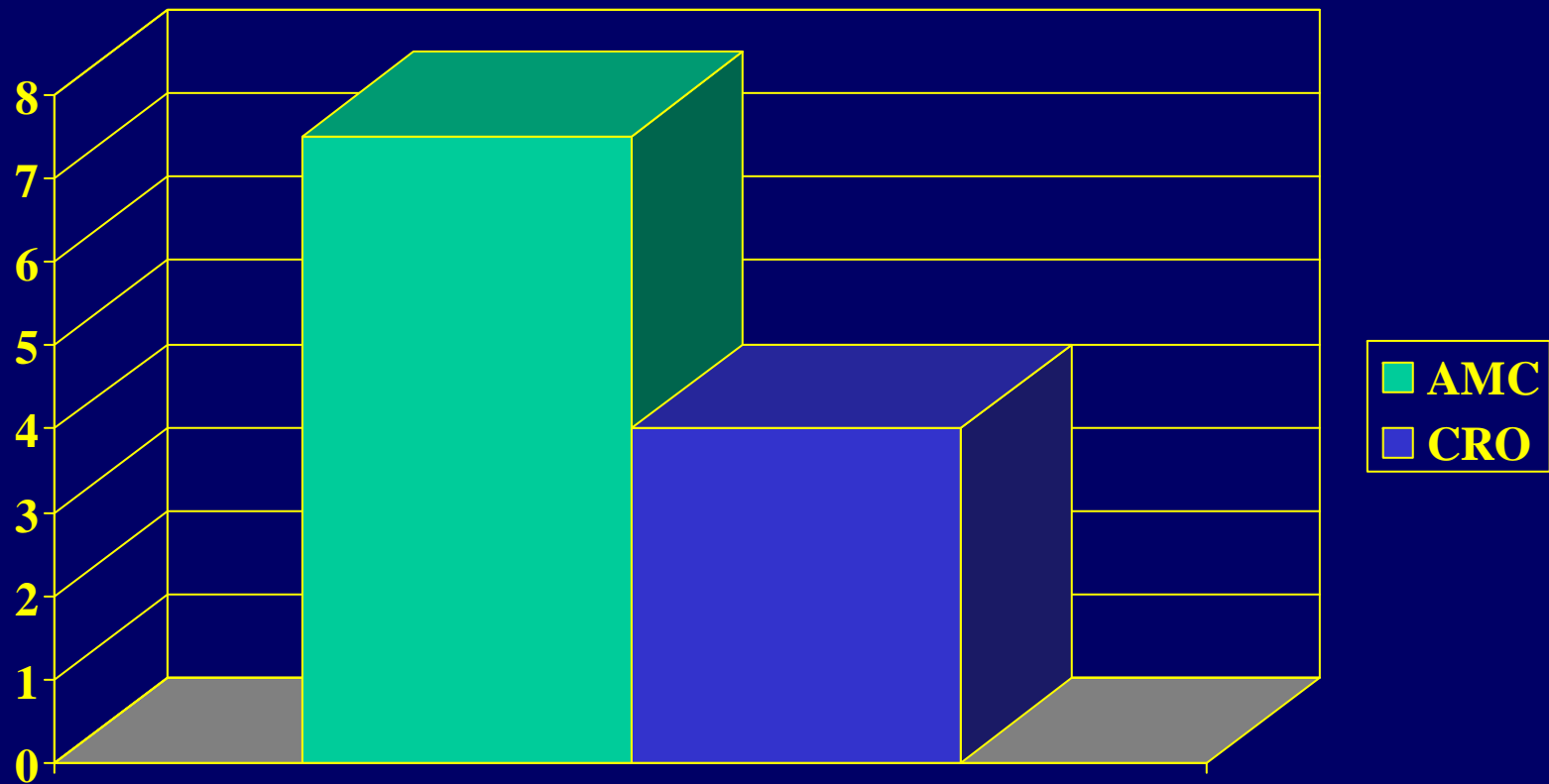
- Trends in clinical research
- Specific problems
 - Overall status at academic health centers
- Training of faculty
- New Initiatives being developed in Academic Health Center
- Challengers

Hopkins Task Force on Faculty Impediments to Clinical Research

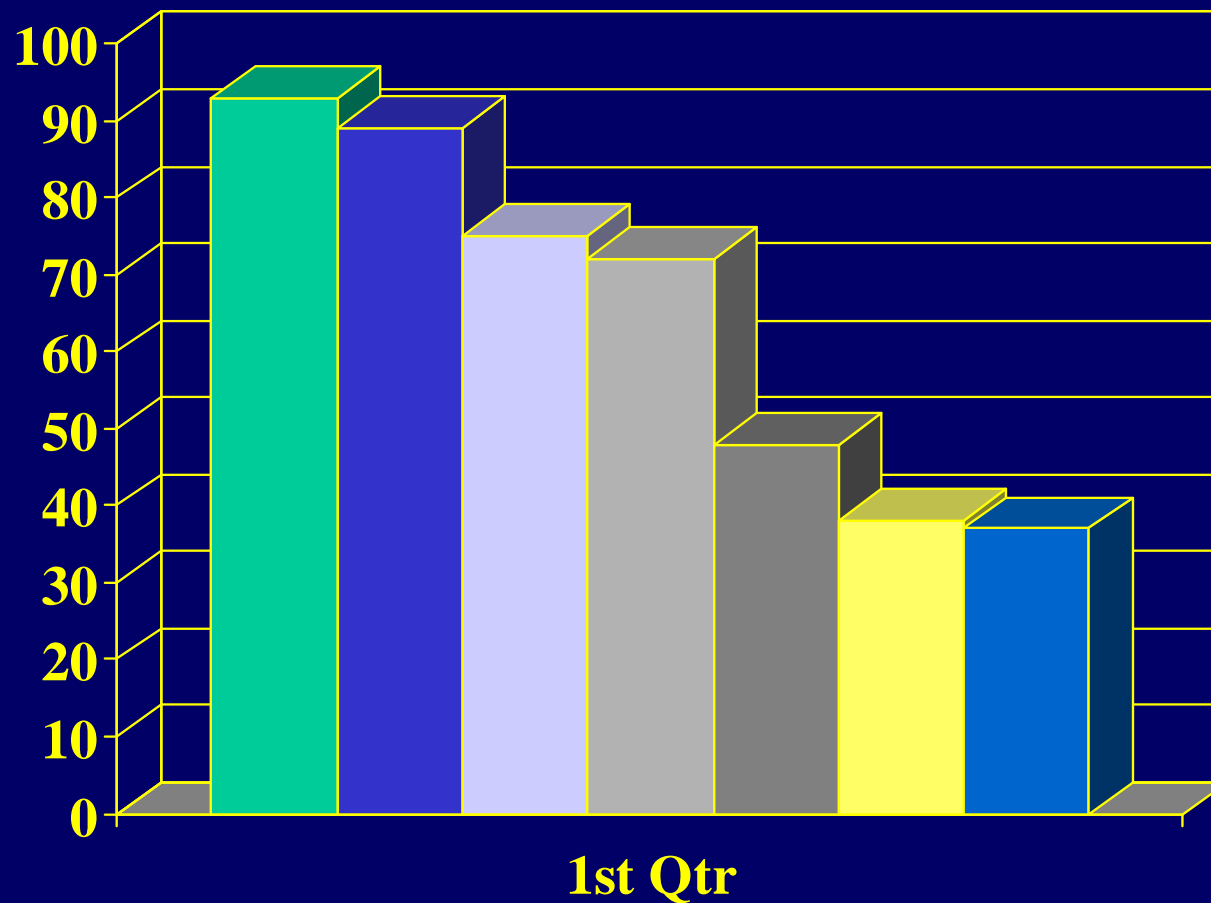
(n=291)

- Lack of time
- Difficulty in identifying funding
- Inadequate research personnel and space
- High institutional costs
- Difficulty in recruiting patients
- Cumbersome regulatory process
- Lack of support for biostatistics
- Inadequate skills for clinical research
- Clinical research not as valued for promotions

Protocol Approval Rates (months) of AMC vs. CRO (Contract Research Organization) (Lilly Experience)



Problems for Clinical Research

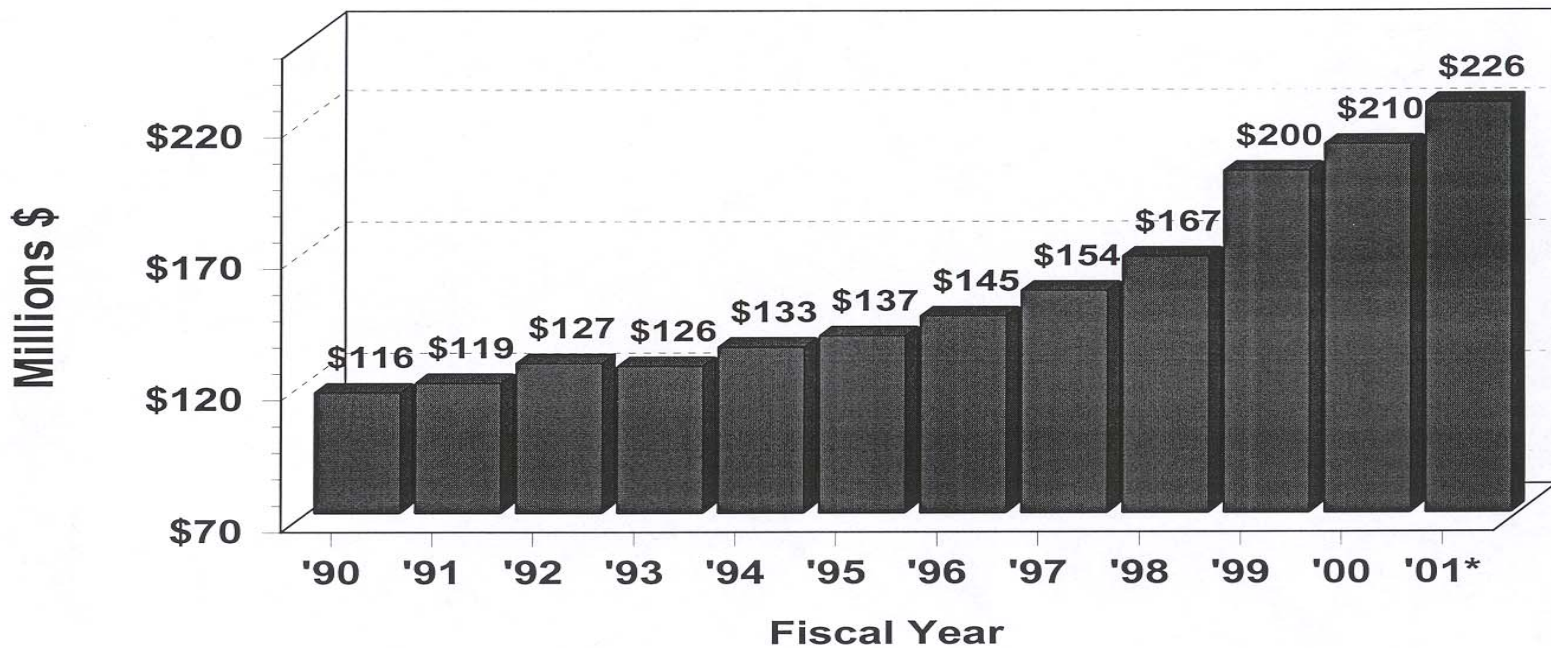


- Pressure to see patients
- Insufficient clinical revenues
- Quality researchers
- External support
- Competition from CROs
- IRB process
- Finding subjects

Campbell, JAMA 286, 800-6, 2001

Funds to NIH-funded GCRC

General Clinical Research Centers Program Appropriations



* President's Budget Request

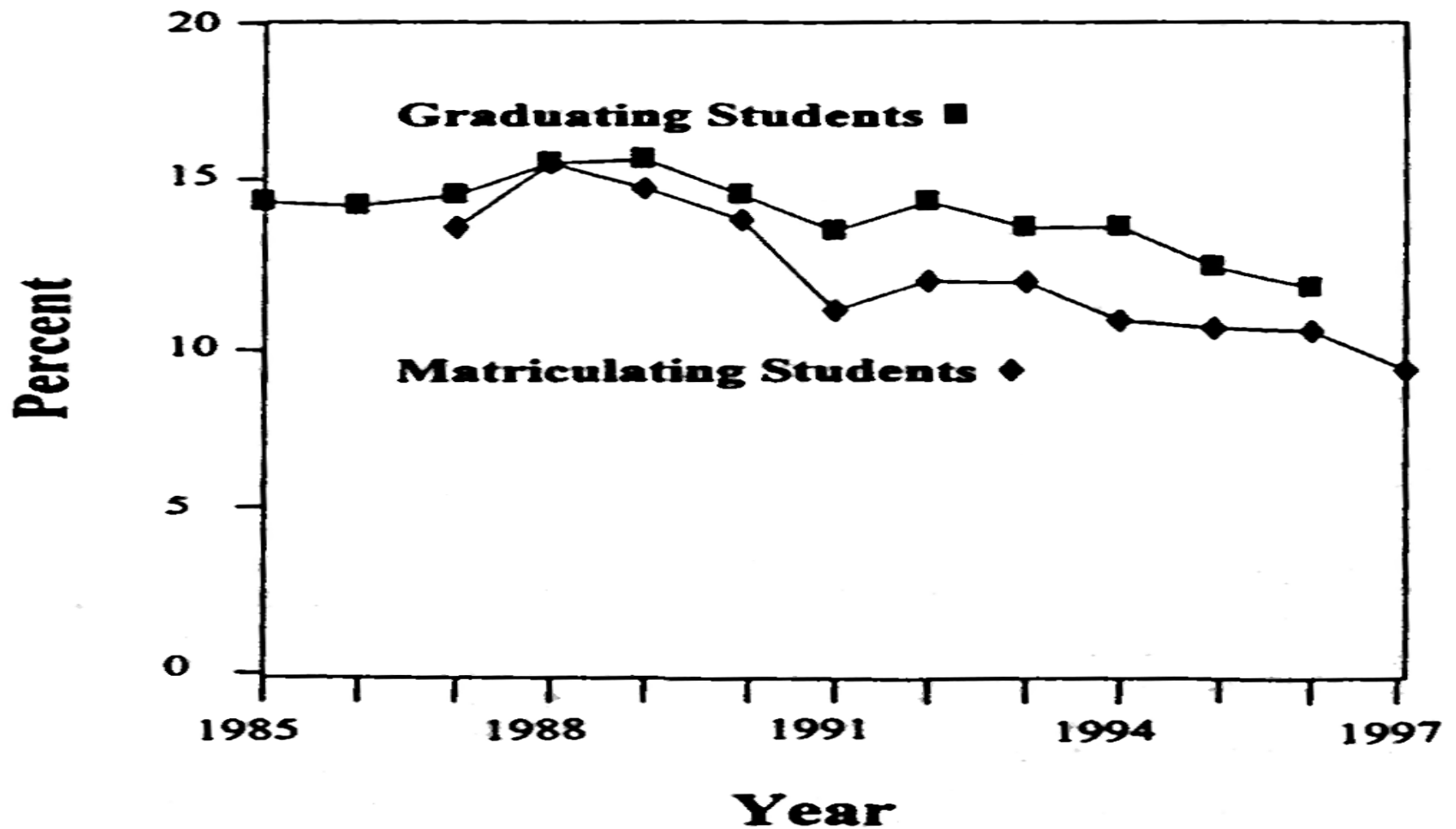
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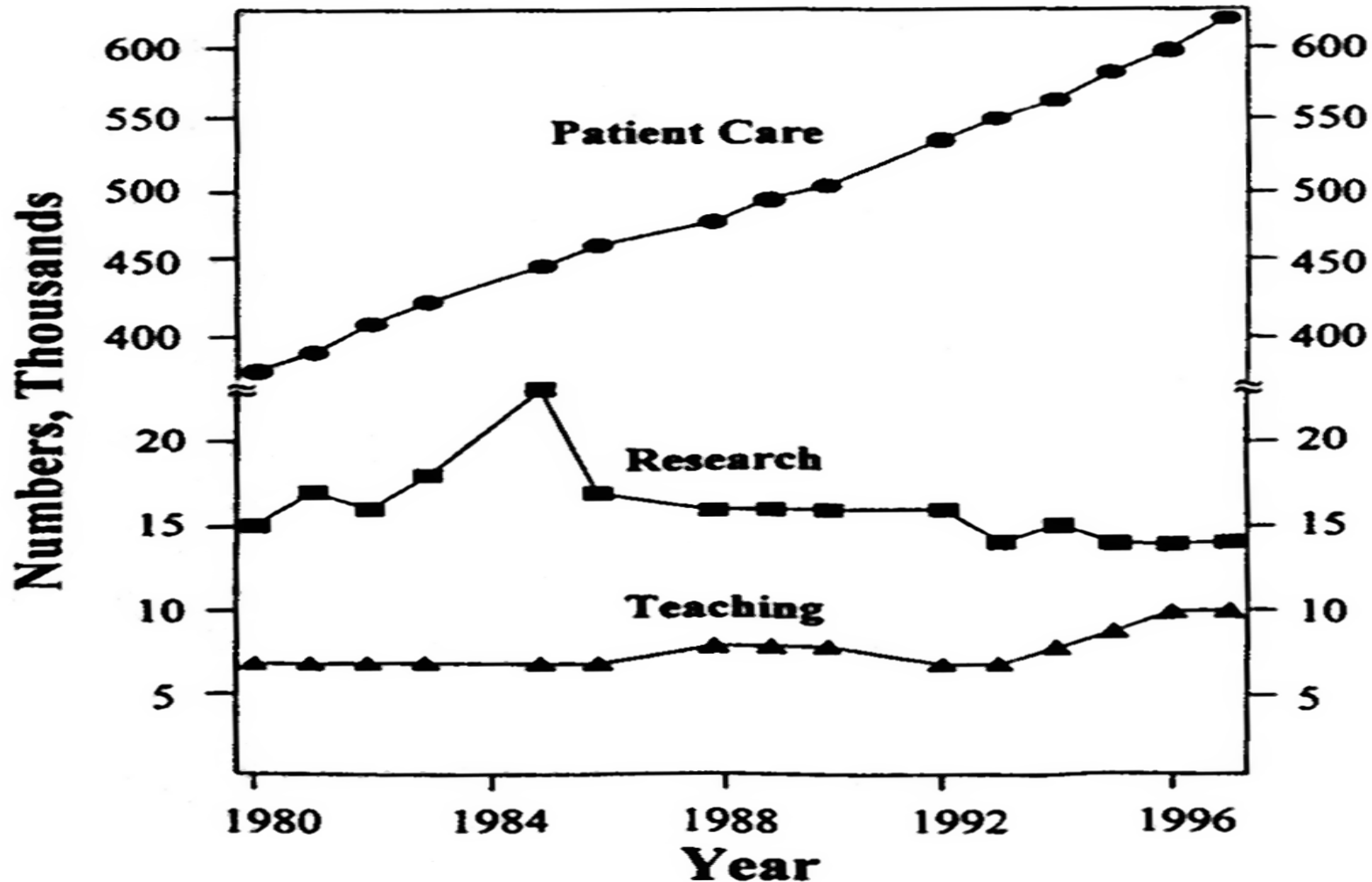
Training of Clinical Investigators

- Decreased numbers entering the field
- Poor training
- Pressure for clinical revenues
- Poor mentorship
- Lack of recognition for promotion
- 75% of institutions report difficult recruitment – compensation package

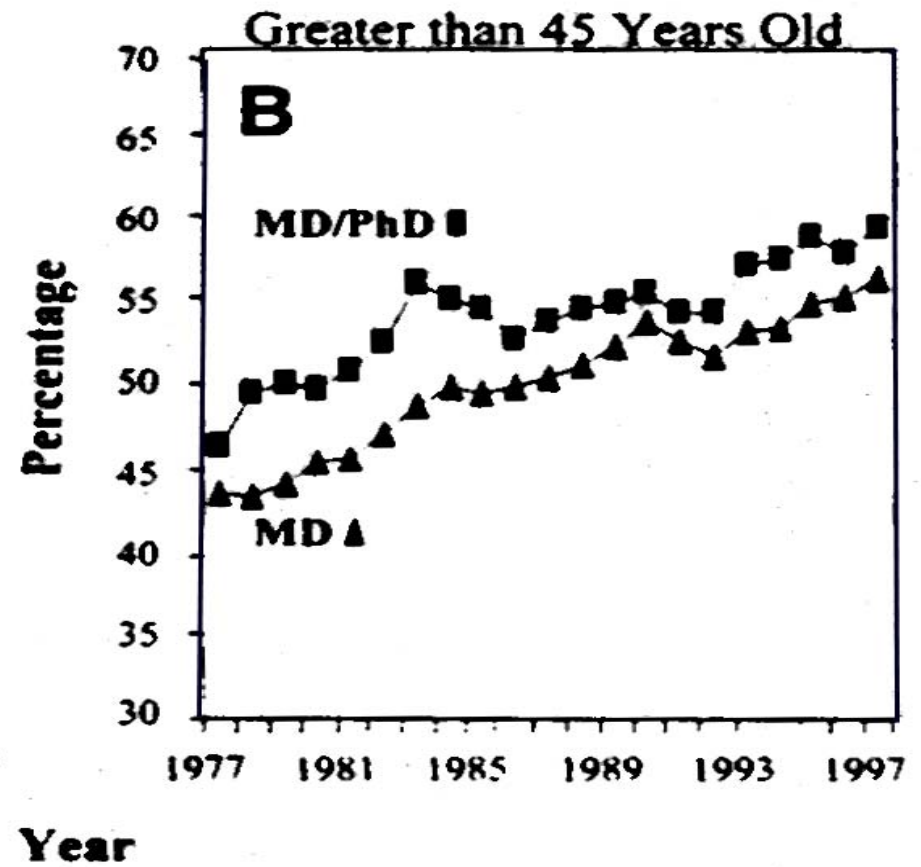
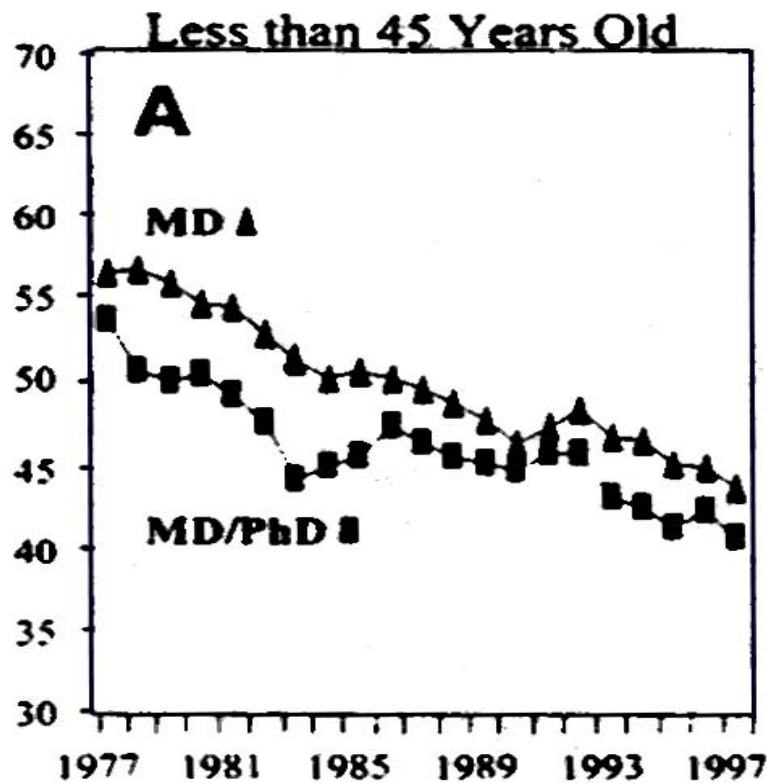
Students Participating in Research



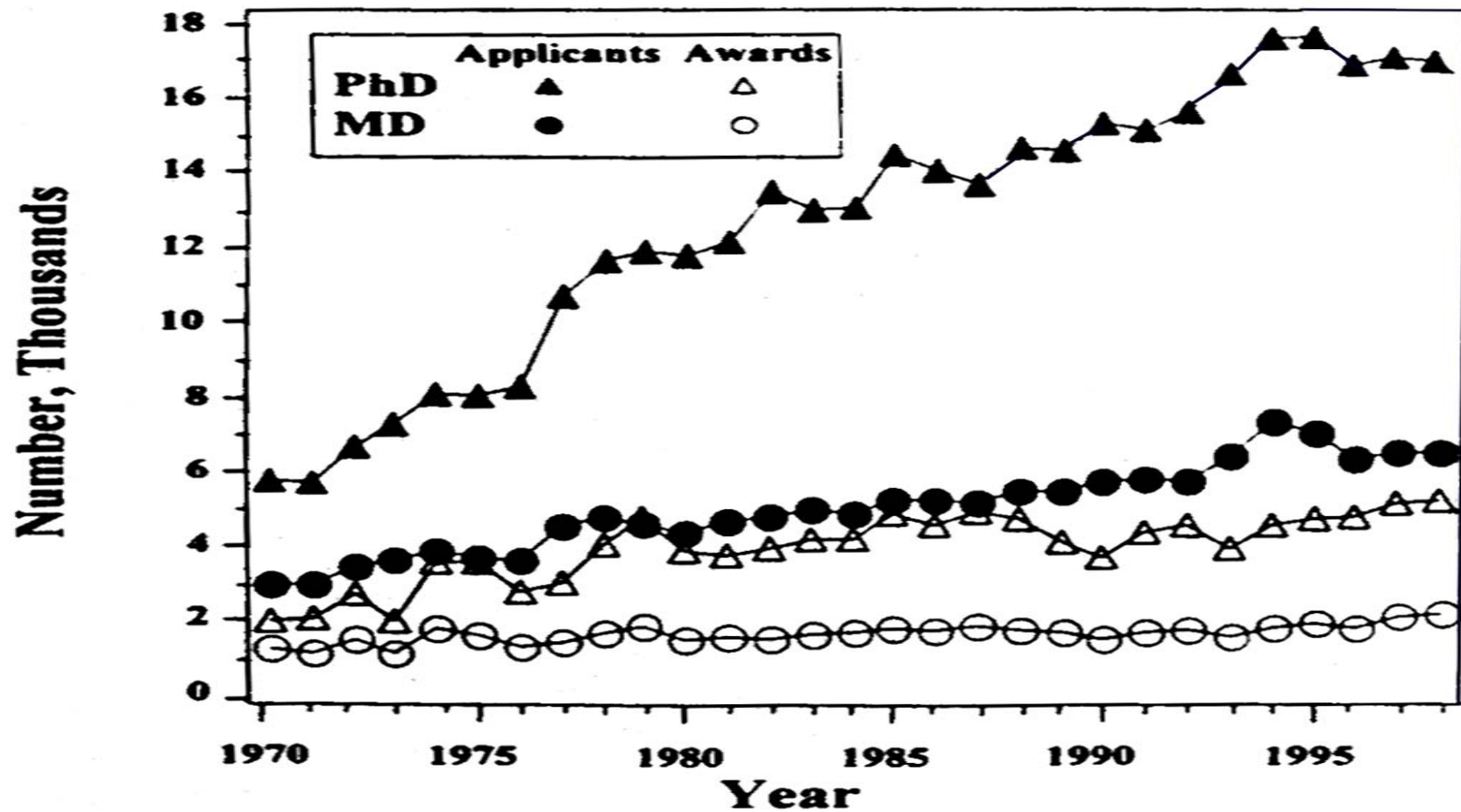
Career Paths of Graduating Medical Students



Age of NIH Investigators



Degree of NIH Investigators



Outline

- Trends in clinical research
- Specific problems
 - Perceptions of quality
 - Workforce
- **New Initiatives being developed in Academic Health Center**
- Challenges

Initiatives Developed to Address Problems in Clinical Research

	Initiatives
Identify funding	69%
Identify collaborators	48%
Write grants	45%
Review grants	45%
Recruit subjects	34%

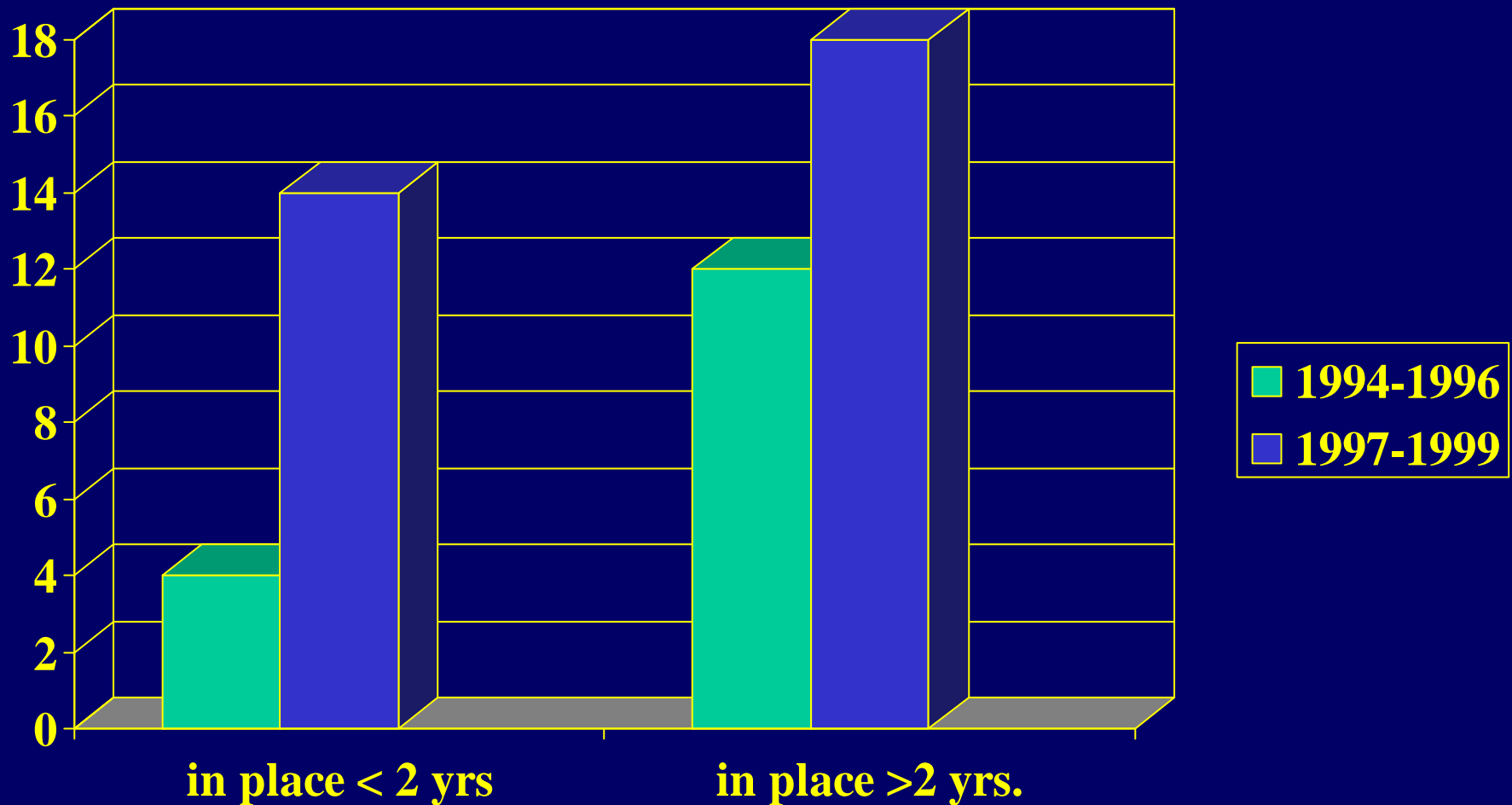
Initiatives at Academic Medical Centers to Foster Clinical Research

- Clinical Trials Offices
- Statistical Services
- Specific assistance – IRB, grant writing
- Training programs

Benefits of a Centralized Clinical Trials Office

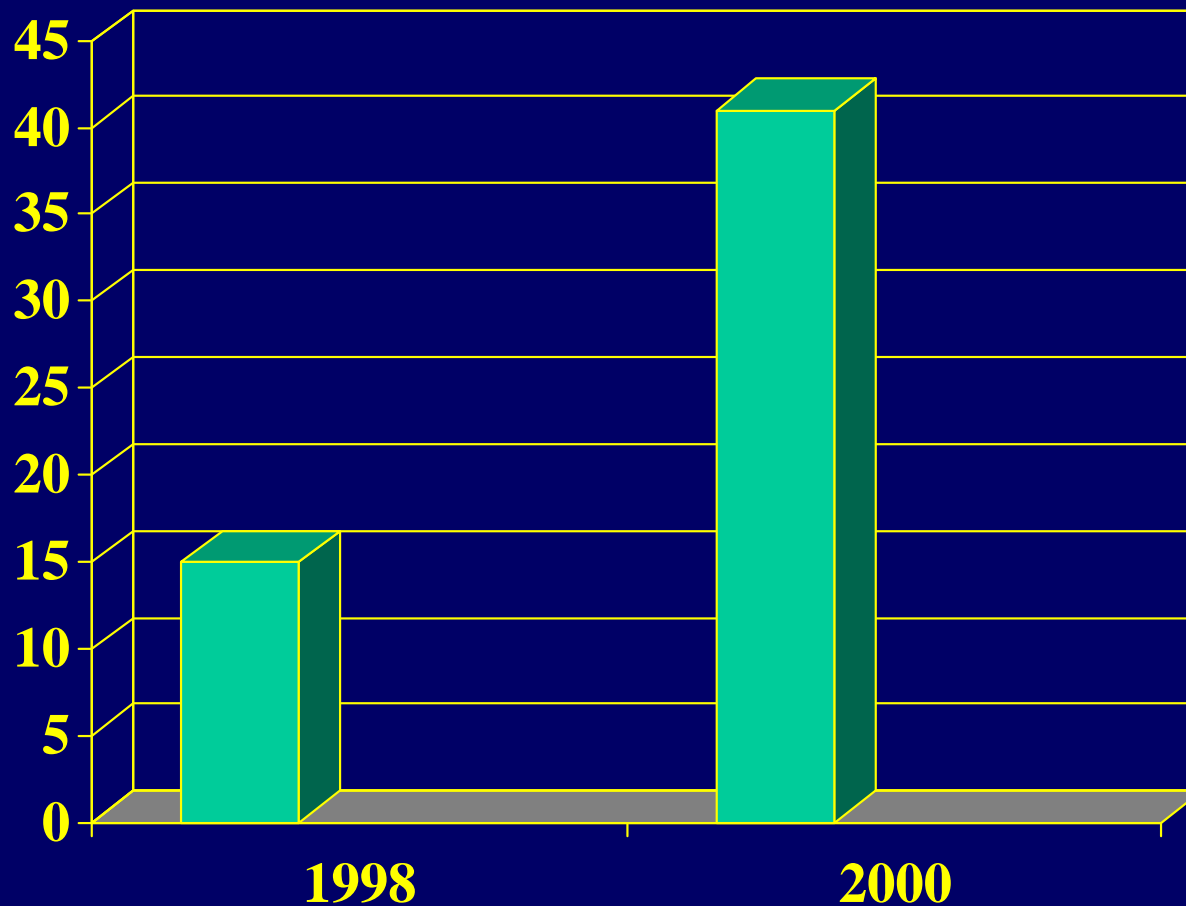
- For sponsors: access to superb institutions, portal to investigators, dedicated team as point of contact for budgets/contracts
- For faculty: assist busy faculty in all aspects of study administration, salary support
- For institution – salary and IDC support, patient accessibility to new therapies

Growth in AMC with Central Clinical Trails Units



Medical Schools with Centralized Clinical Trial Offices (n=125)

(CenterWatch)

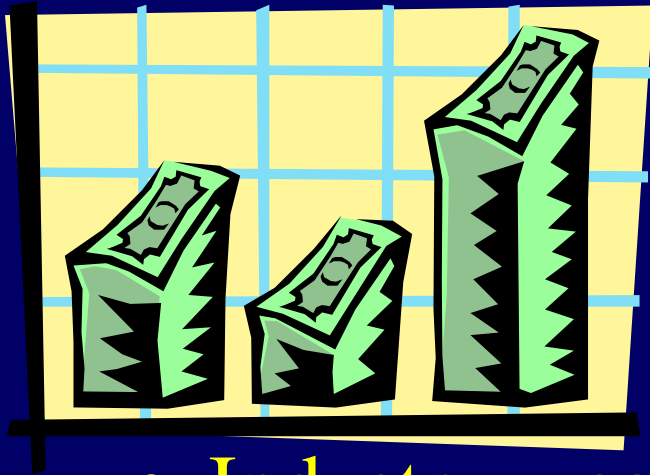


Services Commonly Offered by Centralized Offices

- Contract negotiation – 100%
- Study budget assistance – 100%
- IRB support – 92%
- Study coordinator training – 92%
- Business development – 83%
- Assistance recruiting patients – 75%
- Tracking of patient accrual – 67%

Clinical Support

- Dedicated research space, separate from the GCRC in the hospital and in a suburban location
- Physician support
- Nursing/nurse practitioner
- Coordinator support
- Technical support



Marketing Audience

- Industry – convincing them that AMC provide quality, timely data
- Faculty – convincing them that shared resources will lead to their academic and financial success
- Patient volunteers – convincing them that research improves their life

Outline

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Problems Faced in Developing Clinical Trials Offices

- Limited financial institutional support
- Insufficient dedicated space and high cost of university space
- “Difficult” primary care-oriented studies for tertiary referral centers
- Financial risk balancing between a central Clinical Trials Unit vs. the investigator
- Regulatory environment difficult to involve a broad base of physicians

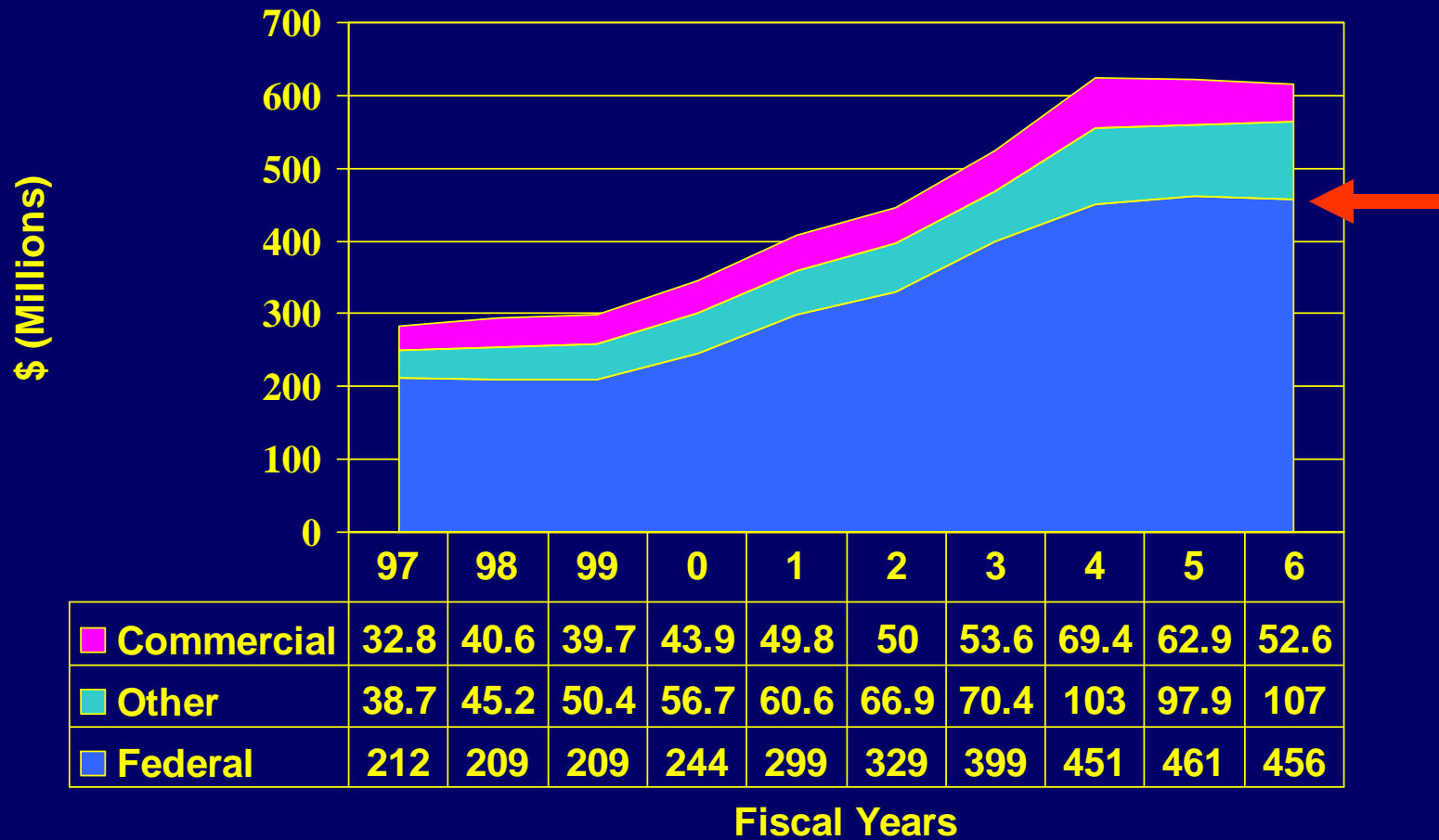
Internal Obstacles to Further Growth

- Cultural resistance to centralized structures
- Resistance to any but the mandated training
- Financial pressure to maintain research staff
- Need to better track clinical research done throughout our institution
- Resources for new initiatives – continued access to investment

What is Success?

- Money – total, direct, indirect
- Publications – impact journals
- NIH grant success
- Investigator initiated research
- Institutional leadership
- Faculty retention
- Faculty promotion
- Community involvement

Sponsored Project Sources Johns Hopkins School of Medicine



Conclusion

- There is no easy way to do research
- No funding=no research
- Supporting administrative and clinical staff on clinical trials alone is tenuous and requires the buy-in from both the institution and the faculty
- McDonald's model may need to be revisited in the future as research funding reduces