# AHC PRIVATE SECTOR RESEARCH SERVICES PROGRAM

The development of new biomedical therapies and technologies has been and remains one of the strengths of the Academic Health Center. In today's competitive environment, collaborating with private industry to develop new medical products is a notably complex, time sensitive, and highly regulated process. When a company decides to pursue a basic science discovery in hopes of practical application and commercial value, they face a very long development cycle, large risky investments, and high rates of scientific and commercial failure. Particularly at the point when the invention is ready for clinical trials, firms are understandably eager to know the outcome. If they bring such studies to a University, they want good science, lucid results, and an efficient administrative process.

For these reasons, many large biomedical firms have begun to enter into large, long term relationships with particular Academic Health Centers for clinical and developmental research. By doing so, they wish to secure the value of top researchers, but also to minimize administrative delays and procedural inertia. For Academic Health Centers to attract these research relationships, they must be competitive not only in the quality of their science, but also in the efficiency of their procedures and support processes. In essence, the relationship must become "service driven."

Approximately two years ago, a task force within the AHC began to evaluate the processes by which our faculty interact with industry. Since that time, it has become abundantly clear that there are many areas of serious difficulty. One major area was access to patient populations for clinical trials. (Appendix I) While this has been addressed to a significant degree through our new relationship with the Fairview System and linkages with other large health care provider organizations, problems still remain. There is as yet no overarching mechanism that can scan proposed studies and assure adequate coordination between patient populations, potentially competing studies, and the proposal's needs. Because of the sale of UMHC to Fairview there are now also the added complexities of establishing efficient, effective clinical research across public-private boundaries.

In addition, the task force analysis revealed many major impediments to completing project agreements between firms and the AHC. (Appendix II) Unless we move quickly to make our own internal procedures much faster and more user friendly (for both firms and faculty) we can expect to see a serious decline in sponsored research from the private sector. The window of opportunity to be one of the preferred providers of clinical and biomedical research is probably closing quickly. Companies are insisting on performance that can be backed by concrete measures of throughput and completion, measures for which we often lack baseline data and in which we are often deficient.

It is for these reasons that the AHC intends to create a Private Sector Research Services Program (PSRSP), to be operational on September 1, 1997. The PSRSP will serve the faculty of the AHC by providing a specific point of access to faculty expertise for private industry, by streamlining process and procedural performance, and by providing a variety of services in support of research for faculty who choose to use the PSRSP. This program does not duplicate existing services provided by ORTTA. Rather, it was developed with ORTTA to accommodate some of the unique features of clinical research in the health sciences. With the recruitment of a new Vice President of Research for the University and as on-going infrastructure improvements in research processes occur, it will probably be possible to fold in the program.

# AHC Private Sector Research Services Program

## GOALS

- to improve access between faculty and industry
- to improve internal process cycle time
- to facilitate access to experimental subjects
- to improve the performance of clinical and developmental trials
- to reduce the risk of error in compliance and regulatory oversight
- to increase research funding and cost recovery from private industry
- to promote the growth of relationships between industry and the University
- to promote the academic missions of research and education in the AHC

## OPERATING ASSUMPTIONS

- we can substantially improve our internal processes so that they perform as well as our national competitors
- the amount of private sector funding can be increased 2 or 3 times in the next few years
- the primary focus will be on private industry sponsored research
- faculty will choose whether to use the services of the PSRSP
- the intent is not to duplicate existing services in the University, rather to coordinate and streamline the process
- any costs incurred in the improvement process can be more than offset
- over time in better performance, efficiency, and the "capture" of increased funding and cost recovery
- the PSRSP must operate from a customer-oriented, market driven base, both in its relationship to the outside and to the faculty

## IMPLEMENTATION OBJECTIVES

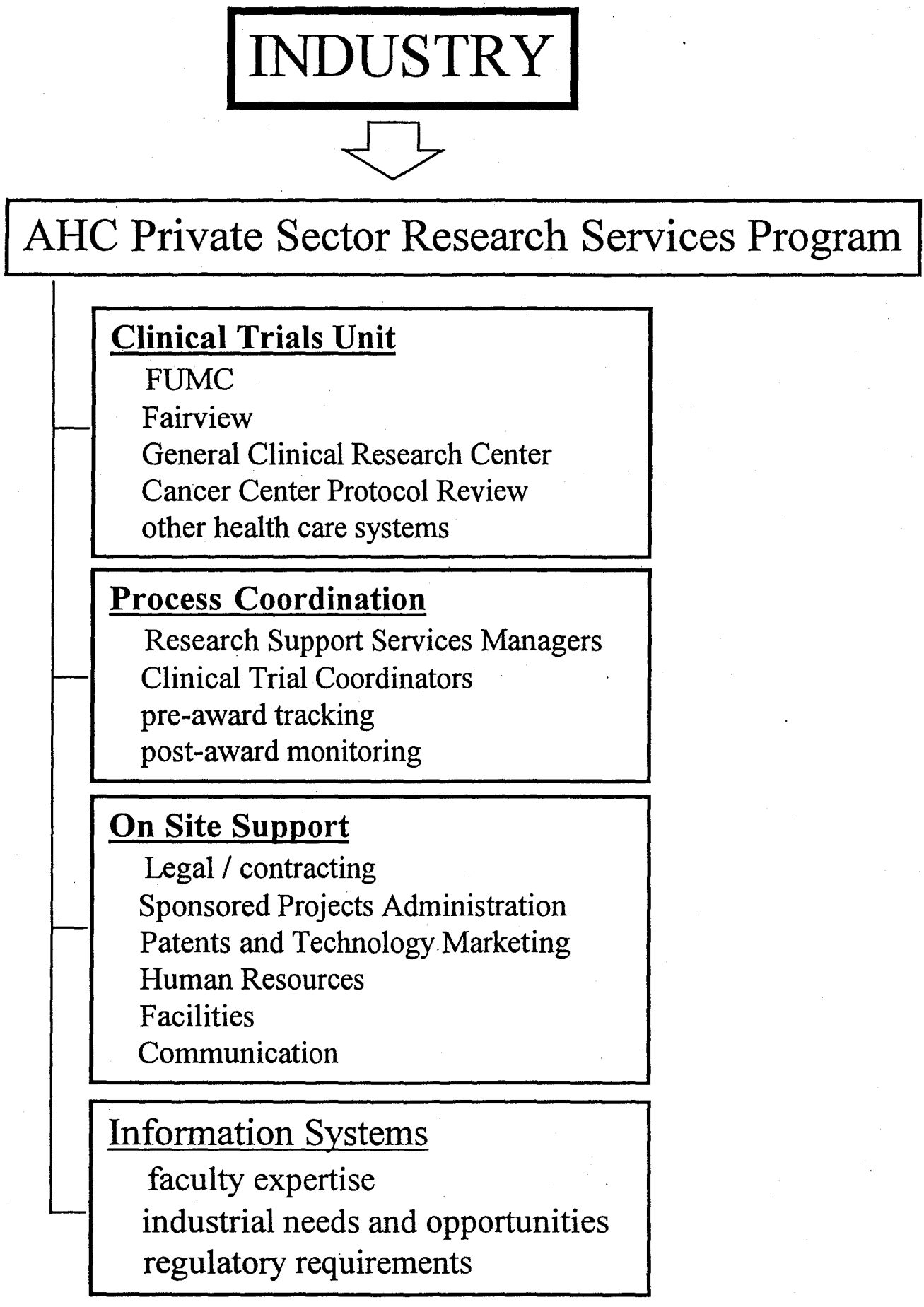
- establish a "preferred portal of entry" for industry into the AHC
  - success based on quality of service, not by forcing faculty or industry to use it
  - ORTTA staffing on site for access and coordination (Sponsored Projects Administration and Patents and Technology Marketing)
  - consistent electronic access to AHC (phone, e-mail, web) and pro-active marketing posture
  - links to databases of potential faculty collaborators, potential corporate sponsors of research
  - on site services: financial / budget preparation, legal / contracting, study support, communication access, facilities, human resources coordination, etc.

- develop a Clinical Trials Unit that connects all clinical trials in the AHC for efficiency and coordination
    - General Clinical Research Center
    - Cancer Center Protocol Review Committee
    - Fairview - University Medical Center
    - Fairview System affiliates
    - other health care systems and provider networks

- initiate internal process improvements
    - shift from a serial process of proposal approval to a parallel process (Appendix III)
    - use Research Support Service Managers (RSSMs) to assist faculty in the approval process
    - implement a approval tracking and process benchmarking system to identify and reduce bottlenecks
    - institute new processes with the Institutional Review Board (IRB) and the Conflict of Interest review process within the AHC
    - develop generic templates for contracts, applications, and reporting formats consistent with University needs and policies so that faculty can more efficiently select and complete project agreements

- establish information systems that
    - do not duplicate, but build on the new grants management systems
    - interface with ORTTA, the IRB, human and animal use review, and other necessary University services
    - interface with necessary external entities, e.g. FUMC, Fairview, industry, regulatory agencies

- develop and implement measures of performance to assure quality of work and responsiveness to market expectations (see Appendix IV)
    - customer satisfaction (industry and faculty)
    - process performance
    - concrete outcomes (contracts, dollars, academic productivity, licenses)


INDUSTRY
AHC Private Sector Research Services Program
Clinical Trials Unit
FUMC
Fairview
General Clinical Research Center
Cancer Center Protocol Review
other health care systems
Process Coordination
Research Support Services Managers
Clinical Trial Coordinators
pre-award tracking
post-award monitoring
On Site Support
Legal / contracting
Sponsored Projects Administration
Patents and Technology Marketing
Human Resources
Facilities
Communication
Information Systems
faculty expertise
industrial needs and opportunities
regulatory requirements


Thirty-Third Annual Meeting

# *Optimizing Pharmaceutical Development: External Academic Linkages*

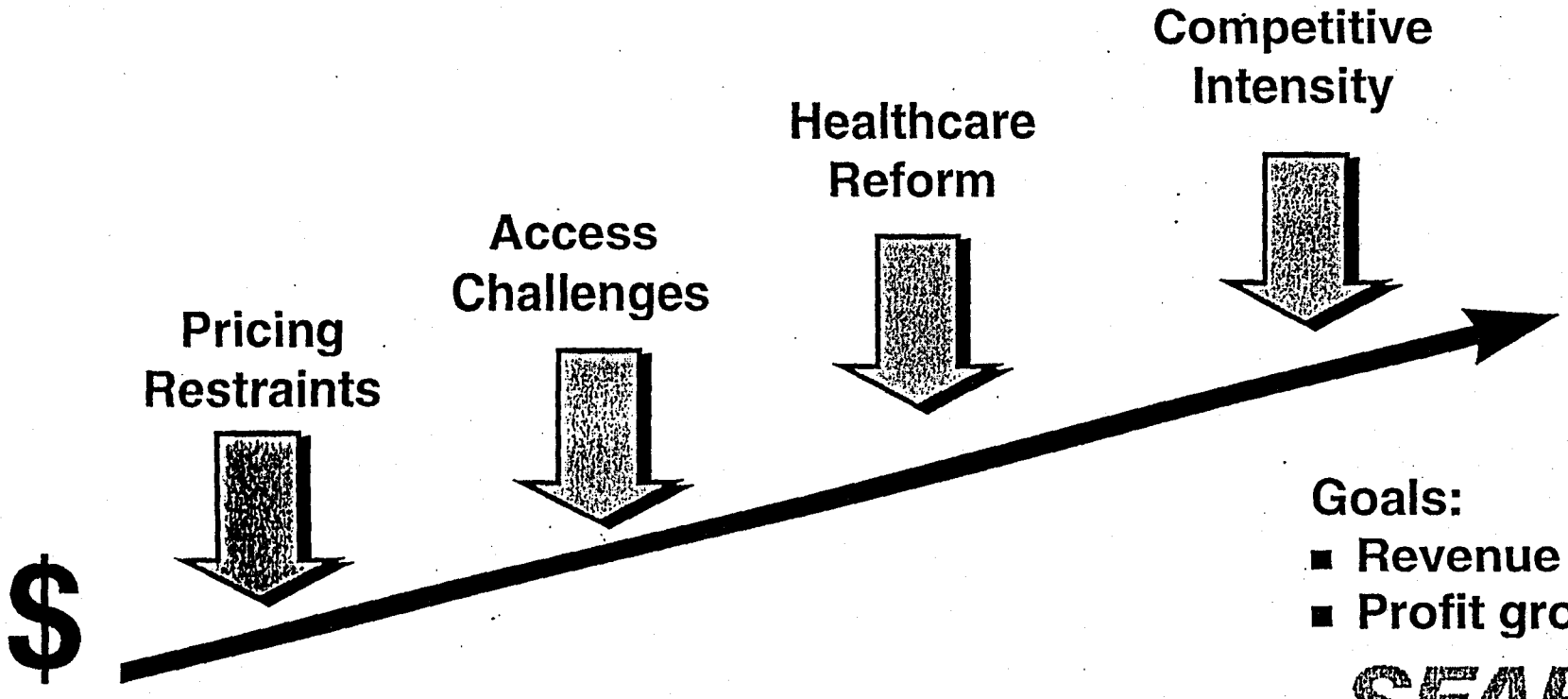
Session Chairperson:

Jeffrey W. Sherman, M.D.
Executive Director, Clinical Research
G.D. Searle & Company

# Optimizing Pharmaceutical Development: External Academic Linkages

*The Situation Today*

## The Pharmaceutical Industry Faces Serious Challenges to Revenue and Profit




**Goals:**

- Revenue growth
- Profit growth

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# Optimizing Pharmaceutical Development: External Academic Linkages

## Industry response to the situation today

- Consolidation
- Increase R&D spending to discover and develop new value-added therapeutic agents
- Enhance the drug development process
  - Decrease cycle times
  - Improve productivity

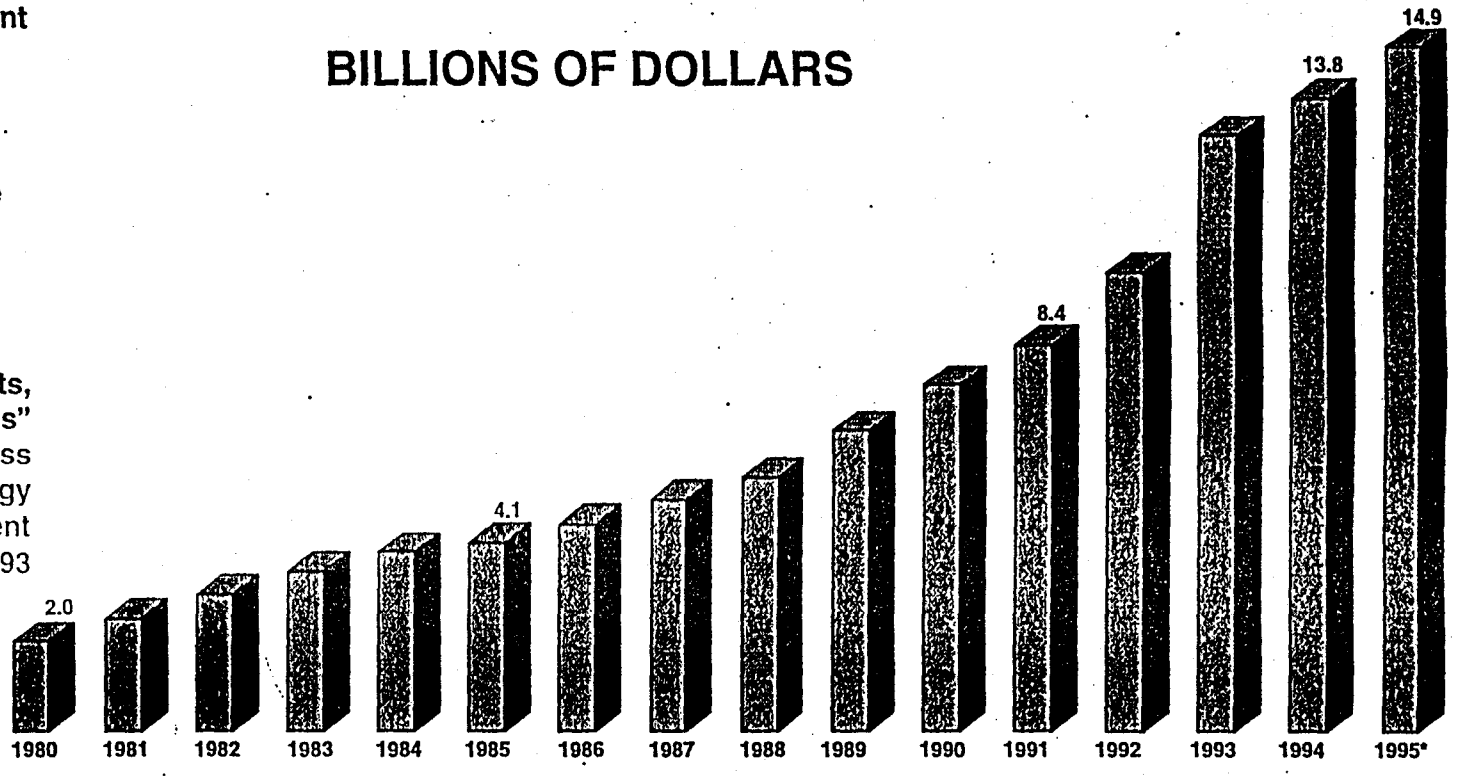
SEARLE

# Optimizing Pharmaceutical Development:
## External Academic Linkages

## PHARMACEUTICAL R&D

**"R&D...expenditures in constant dollars have risen at an astonishing rate of roughly 10 percent per year. Since 1980, pharmaceutical firms in the United States and abroad have devoted an increasing proportion of total sales to R&D."**

**–"Pharmaceutical R&D: Costs, Risks and Rewards"**
The United States Congress
Office of Technology
Assessment
February 1993




***Estimated**
**Source: PhRMA Annual Survey**

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# Optimizing Pharmaceutical Development: External Academic Linkages

## *Domestic U.S. R&D Spending by Functional Areas*

- Nearly 44 percent of Domestic U.S. R&D expenditures are allocated to pre-clinical functions.
- Clinical evaluation phases I through IV comprise about 30 percent of R&D. Over the past 10 years, the percent of R&D allocated to clinical evaluation phases I, II, and III has increased.

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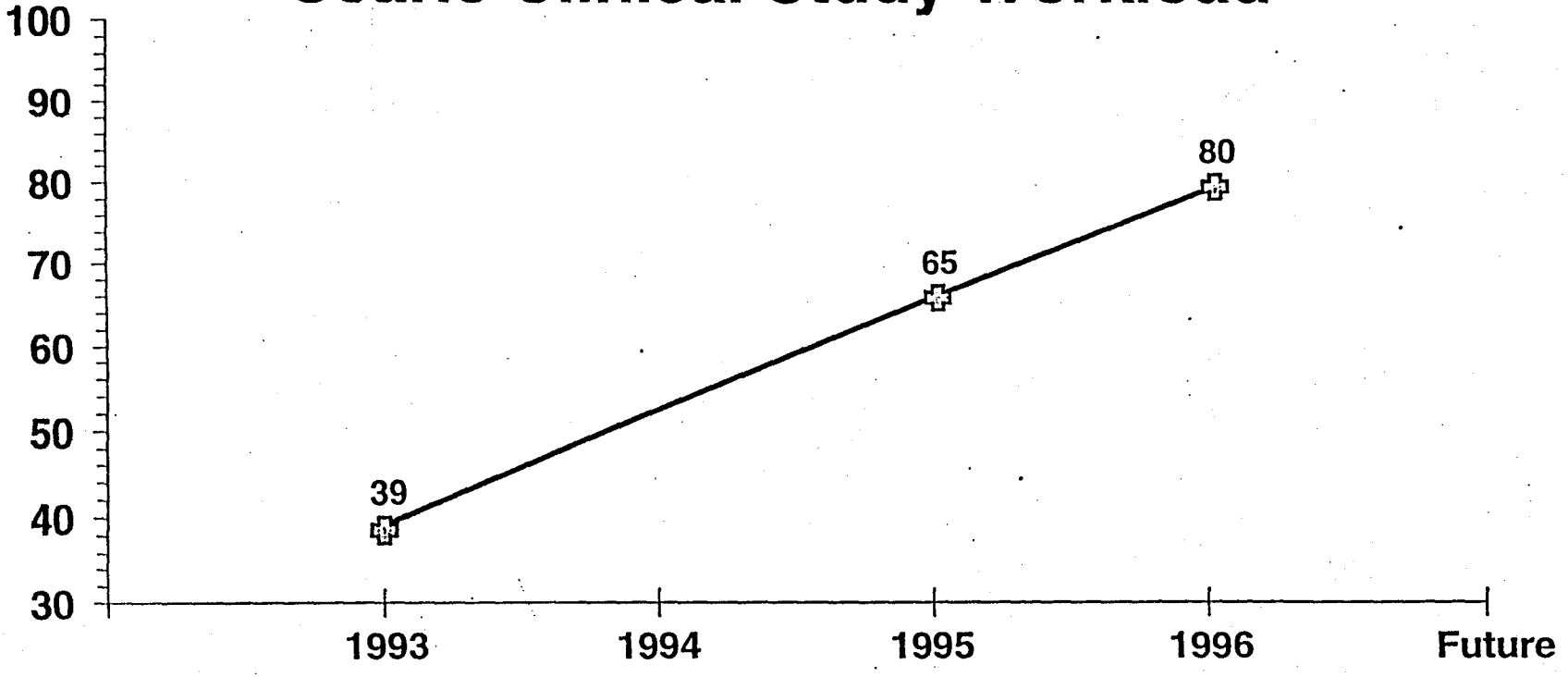
# Optimizing Pharmaceutical Development: External Academic Linkages

## Searle Clinical Study Workload*




* Phase I-III studies with active enrollment;
excludes unreported studies (approximately 80 studies for 1996)

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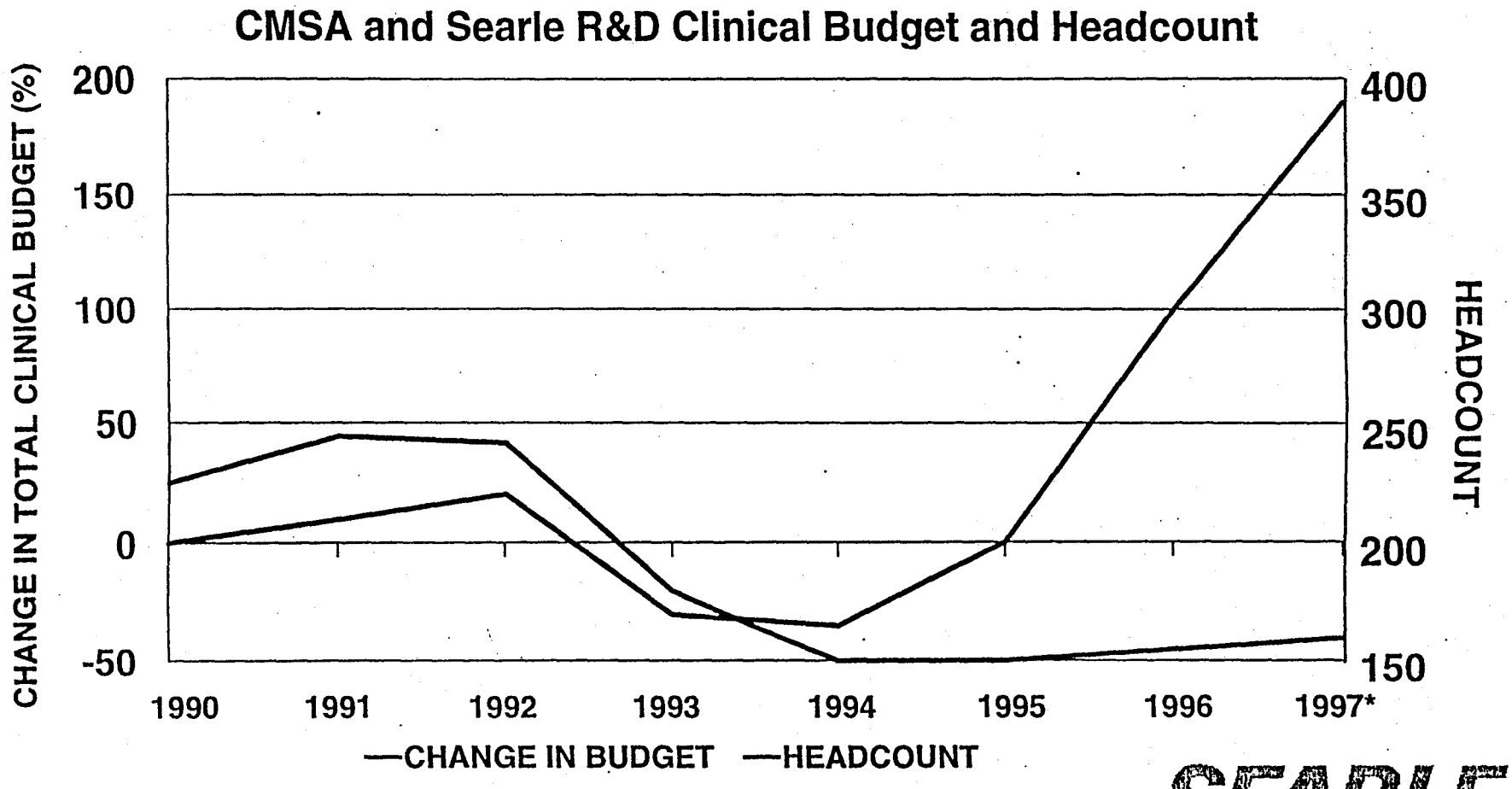
# Optimizing Pharmaceutical Development: External Academic Linkages

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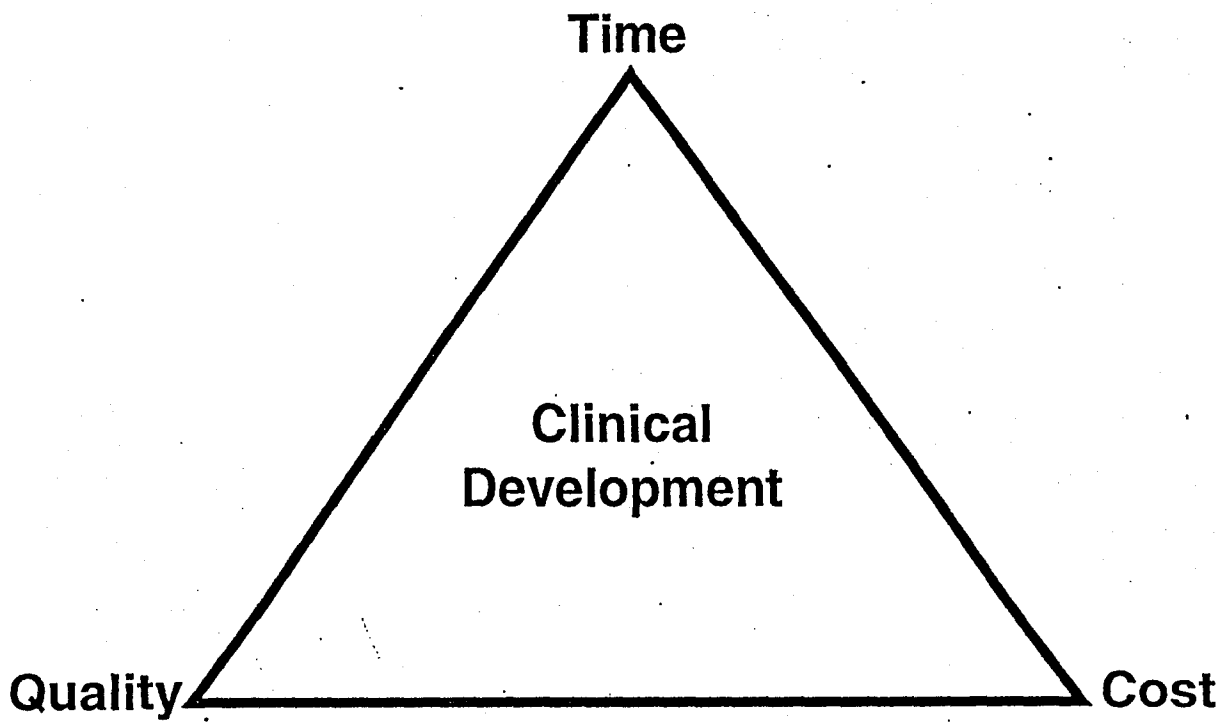
* 1997 data is based on 1996 budget submission

# Optimizing Pharmaceutical Development: External Academic Linkages

## Key Factors in Accelerating Clinical Development

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# Optimizing Pharmaceutical Development: External Academic Linkages

## Key Skill Requirements

- Sufficent expertise in therapeutic areas and in clinical research to devise innovative drug development strategies
- Ability to plan and manage complex projects
- Medical data analysis and interpretation
- Administrative skills to enhance and support all of the above

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# Optimizing Pharmaceutical Development: External Academic Linkages

## Searle Would Like to Have

- Access to leading academic institution to partner drug development
- Umbrella legal agreement to facilitate study initiation while protecting intellectual property
- Agreement to limit overhead and laboratory costs
- One IRB for all participating hospitals
- Research office at the institution to facilitate study initiation and completion

SEARLE

# Optimizing Pharmaceutical Development: External Academic Linkages

## Searle Would Offer

- Guaranteed annual level of clinical trial activity
- Preferential access to all development compounds

SEARLE

# Optimizing Pharmaceutical Development: External Academic Linkages

- The University of Minnesota Perspective
  - Leo T. Furcht, M.D.
    Vice Provost, Academic Health Center
    Allen-Pardee Professor and Head, Laboratory Medicine and Pathology
    Director, Biomedical Engineering Center
    University of Minnesota
- The Evanston Hospital Perspective
  - Antoni A. Piergies, M.D.
    Director, Clinical Pharmacology Unit
    Evanston Hospital
    Associate Professor, Clinical Medicine
    Northwestern University Medical School
- The Washington University School of Medicine Experience
  - Daniel P. Schuster, M.D.
    Professor, Medicine
    Associate Dean, Clinical Studies
    Director, Center for Clinical Studies
    Director, Critical Care Program
    School of Medicine, Washington University in St. Louis

SEARLE

Appendix II

# Research Support Services Task Force

# EXECUTIVE SUMMARY

(draft 6-5-97)

In September 1996, Academic Health Center Frank Cerra created the Research Support Service Task Force to examine the process of applying for, receiving, and reporting on industry-sponsored research. The objectives were to enhance the ability of faculty to market their research capabilities and improving compliance with government regulations.

The task force found

- there are no time performance demands placed on any area, committee or office involved in overall internal processes of grant submission and approval.

- there is much "down" time, when a grant or contract just "sits" in an office or committee.

- there is little regard for how the efforts of each office or committee might make the process more user friendly for faculty and sponsors.

- there has been little attention to "parallel processing", where multiple internal approvals could be completed simultaneously--thereby reducing the time it takes to complete a review.

More specific task force findings dealt with 1) the Conflict Review Committee, 2)principal investigator responsibility, 3) subjects protection programs-human subjects, 4) ORTTA patents and technology marketing, 5) ORTTA sponsored research programs, 6) coordination of clinical trials review processes, 7) the General Clinical Research Center, 8) monitoring compliance with research regulations.

One of the critical observations made by the task force is a pervasive lack of performance criteria for almost every component of a research contract, including submission, approval and execution of the research. Task force members were struck by that fact that there is little or no regard for the value of time.

Overall, the task force recommended the following actions:

- **Establish very rigorous performance criteria for each office, unit, or committee that is involved in initiation, approval, performance, and closing of research projects sponsored by outside corporations.** Assume that professionals in these offices have the authority they need and hold them accountable. There is a need to adopt more of a service mentality on the part of the staff.

- **Establish a parallel review and approval process for all internal approvals.** In negotiations, no 24-hour period should expire without the appropriate university official contacting both the corporation's representative and the university faculty member. It is the expressed goal of the task force to have the internal process

completed in 10 working days without sacrificing the current highly quality of the review.

- **Establish a process in which an activity sheet will be placed on the front of each contract or grant that tracks time in and time out with a uniform office stamp.** Professionals in the office would initial the grant as it moves along. This would establish a log of all actions and time taken to accomplish the work. Once this became routine, it would not be intrusive.

The task force also offered specific recommendations to address the issues that emerged from the principal findings:

- **Disband the Conflict Review Committee** and establish a new AHC committee, the Conflict Review and Management Committee, to review conflict of interest issues.

- **Establish a Research Support Services Office** and director reporting to the provost to provide research support to investigators seeking assistance with industry-sponsored research.

- **Establish a Business Development Office** within the RSSO to identify technology and services that could be protected by licensing, patents, or trademarks, to advise faculty about intellectual property, to market faculty research and services, and to establish a Technology Research Pool to invest in promising projects.

- **Enhance performance of subjects protection programs--human subjects review process** to provide sufficient staff to train, consult and provide information services to the research community on an on-going basis, to use video-conferencing, e-mail, courier and fax services to improve the IRB review process, and to establish a web site to post IRB results.

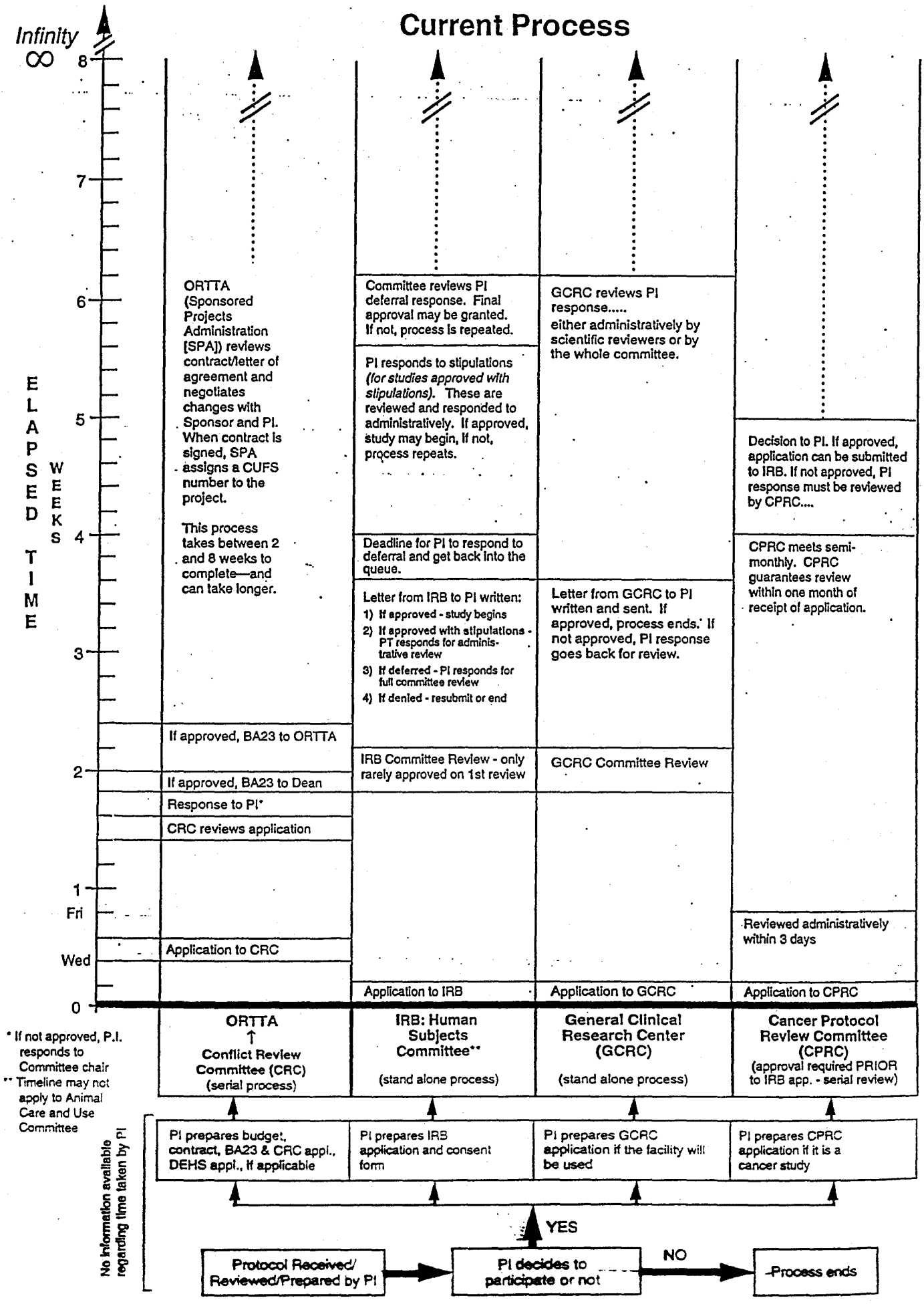
- **Improve and expedite contract review and negotiation** by allowing the AHC to have an on-site representative from the Sponsored Projects Administration and by developing a standard AHC/SPA research agreement for industry-sponsored research.

- **Establish a Clinical Trials Coordinating Center** to coordinate all clinical trials efforts in humans and animals.

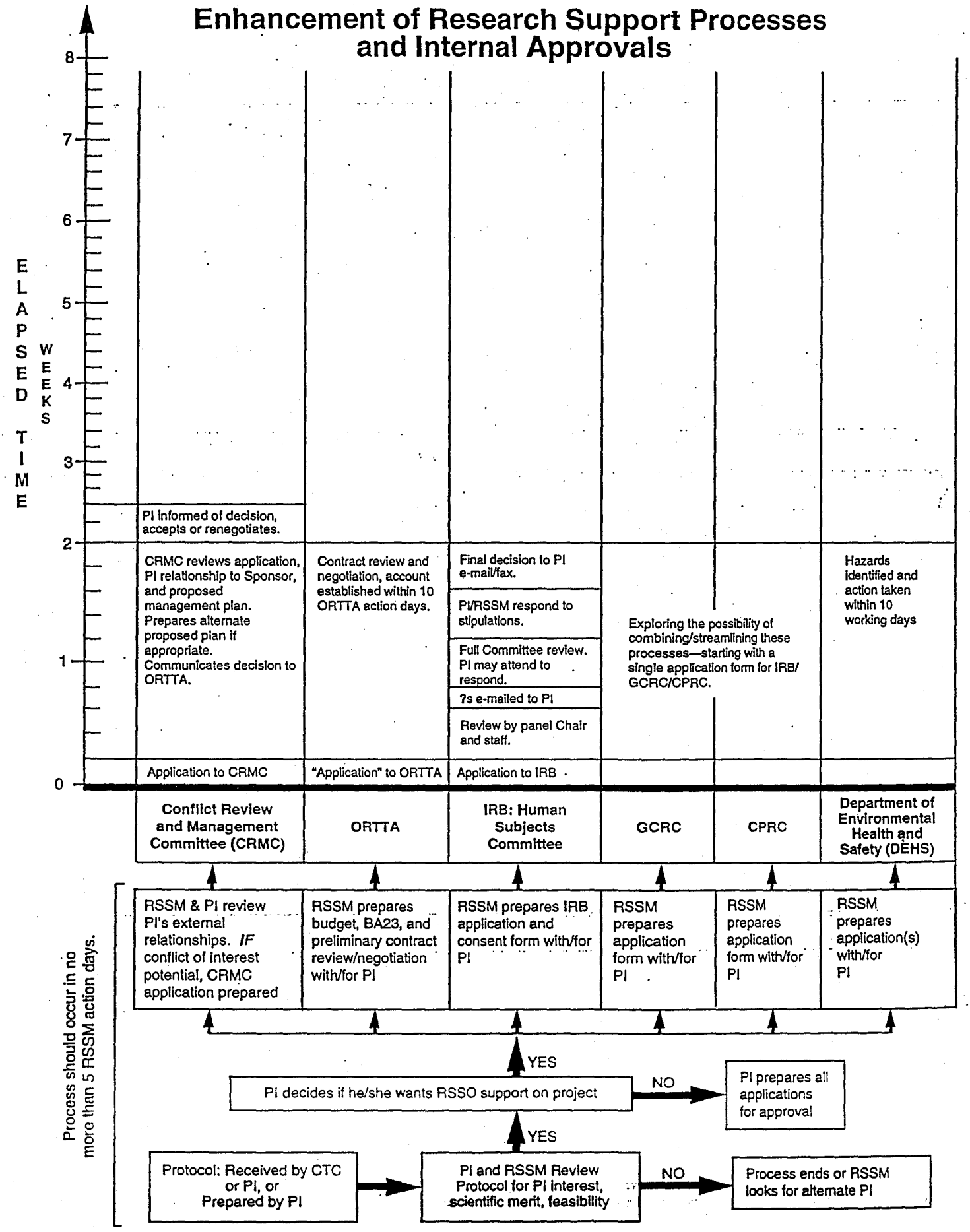
- **Provide support for regulatory compliance monitoring** and to expand educational opportunities and information about good scientific practices.

The task force's work indicates that any plan to help faculty be more competitive in attracting industry-sponsored research much include the seamless coordination of all institutional and regulatory policies, procedures and approvals that affect corporate research. The plan must also include more responsive administrative, oversight, approval, and compliance monitoring services throughout the Academic Health Center.

# Current Process



# Enhancement of Research Support Processes and Internal Approvals



Appendix IV

## Measures of Performance of the Private Sector Research Services Program

1) AHC - PSRSP Performance

   a) number of awards/amount of awards
   b) number faculty/companies participating
   c) $ projects finished on time
   d) $ projects finished on budget
   e) number patent applications/awards
   f) faculty publications and presentations

2) Approval Process

   a) time from PI contact to all approvals
   b) subsets of cycle time, e.g., IRB, ORTTA contract, etc.

3) Study Performance

   a) time from all approvals to first patient enrolled
   b) time from test article presence to first patient enrolled
   c) time from test article presence to completion of study
   d) CRF completion, inquiries, corrections