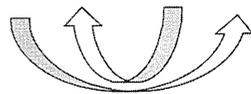


# 革新的医薬品を創出するために 求められる医師主導治験

審査承認体制の進化

創薬シーズ探索  
非臨床試験



双方向の情報交換  
(できれば近距離で)

## アカデミア発のシーズ

早期・探索的  
医師主導治験

企業による後期相臨床試験

# Translation of Highly Promising Basic Science Research into Clinical Applications

Contopoulos-Ioannidis DG, et al.  
Am J Med 114:477-84, 2003.

1979-1983

Science  
Nature  
J Clin Invest  
J Biol Chem  
J Exp Med  
Cell

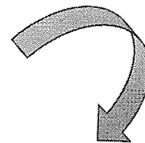
Future clinical therapeutic  
or preventive applications  
in humans for the studied  
technologies



101 articles

25,190 articles

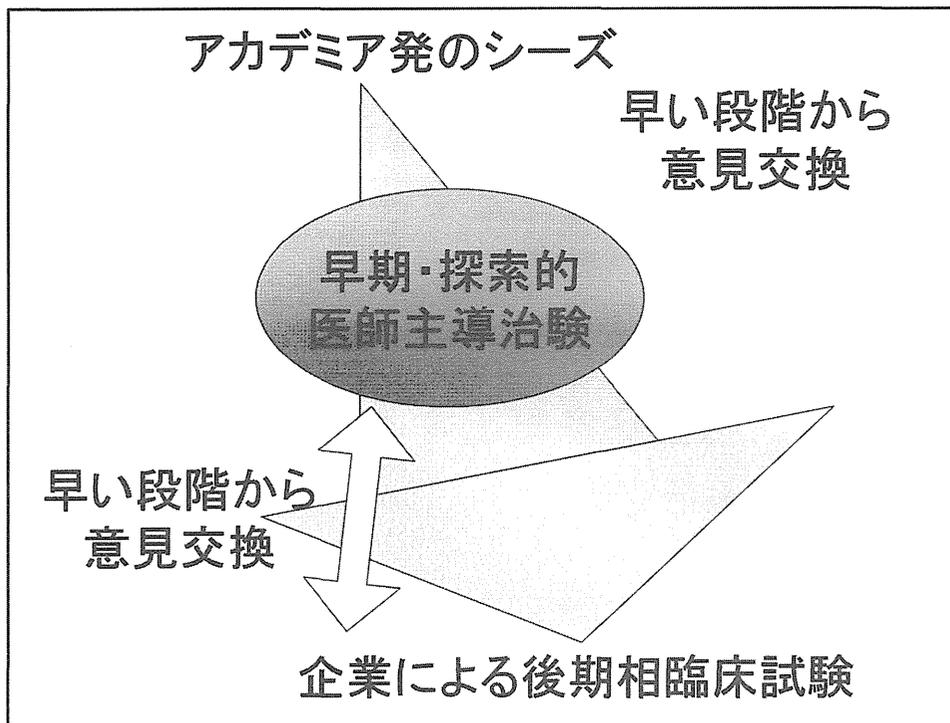
27 promising technologies  
had resulted in at least  
one published trial



Only five are licensed  
for clinical use

## Factors Associated with Publication

Having an author affiliated with the  
pharmaceutical or biotechnology industry  
was associated with an 8- to 10-fold  
accelerated process



## Life Cycle of Translational Research for Medical Interventions

Contopoulos-Ioannidis DG, et al.  
Science 321:1298-99, 2008.

- △ Discovery of new substances and interventions remains essential, but proper credit and incentives should be given to accelerate the testing of these applications in high-quality, unbiased clinical research and the replication of claims for effectiveness.
- △ Multidisciplinary collaboration with focused targets and involving both basic and clinical sciences should be encouraged.

## 革新的医薬品を創出するために 求められる医師主導治験とは

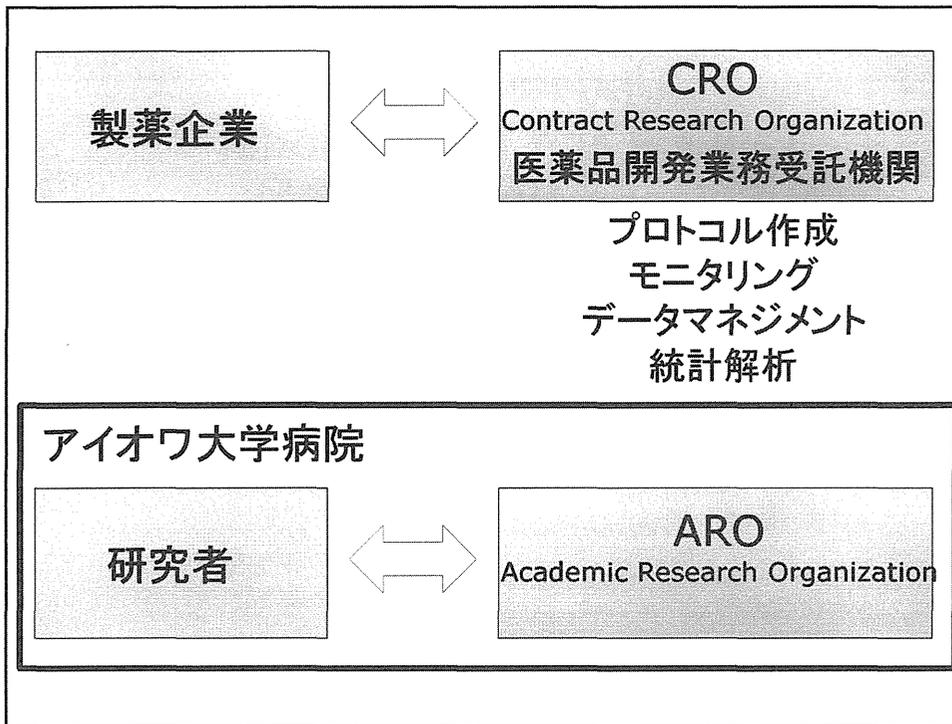
- ✓ 班研究活動の紹介
- ✓ 医師主導治験の現状
- ✓ 革新的医薬品を創出するために
- ✓ 米国の取り組み
- ✓ われわれに医療イノベーション  
を目指す覚悟はあるのか



アイオワ大学病院

シンシナチ小児病院





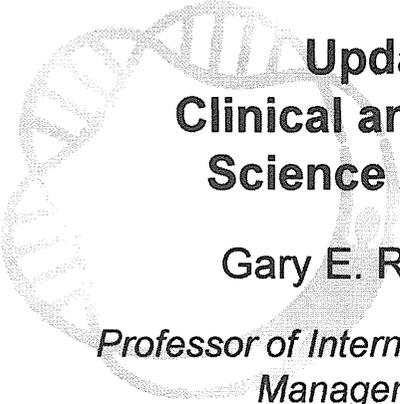
## 学内の優れたARO機能

**Clinical Research Services** supports the development and conduct of clinical trials for investigator authored studies, industry sponsored studies, cooperative group studies, and translational research.

The **Protocol Development and Monitoring** office supports activities for protocol writing, scientific review, and data and safety monitoring.

**The Clinical Trials Support Core (CTSC)** provides overall regulatory support for clinical trials, coordinates the opening of study protocols, and assists with study management from study submission to closure.

**Clinical Trials Management Systems (CTMS)** support is provided through use of OnCore, an online suite of services for protocol management, accrual monitoring, reporting, and data quality assurance.



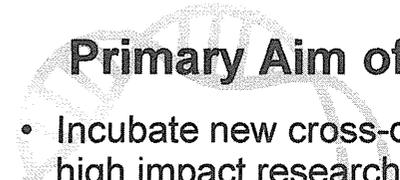
## Update on the Clinical and Translational Science Award (CTSA)

Gary E. Rosenthal, MD

*Professor of Internal Medicine and Health  
Management and Policy*

*Director, Institute for Clinical and  
Translational Science*

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TRANSLATIONAL SCIENCE  
AT THE UNIVERSITY OF IOWA



## Primary Aim of NIH CTSA Initiative

- Incubate new cross-disciplinary collaborations and high impact research across the spectrum of translational science

**T1**



**Translation to  
Humans**

- *Animal models of human disease*
- *Phase 1 & 2 clinical trials*

**T2**



**Translation to  
Patients**

- *Phase 3 clinical trials*
- *Uncontrolled observational studies*

**T3**



**Translation to  
Practice**

- *Phase 4 clinical trials*
- *Comparative effectiveness studies*

**T4**



**Translation to  
Populations**

- *Health policy analyses*
- *Social determinants of health*

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## Key Accomplishments: New Services & Training Programs

- Expanded and increased access to consultative services that span the research continuum:
  - *study planning and design;*
  - *regulatory approval;*
  - *study coordination;*
  - *data management and statistical analysis;*
  - *bioinformatics and genomics support;*
  - *dissemination of research findings;*
- Created new education and training programs for graduate students, fellows, junior faculty, & research personnel

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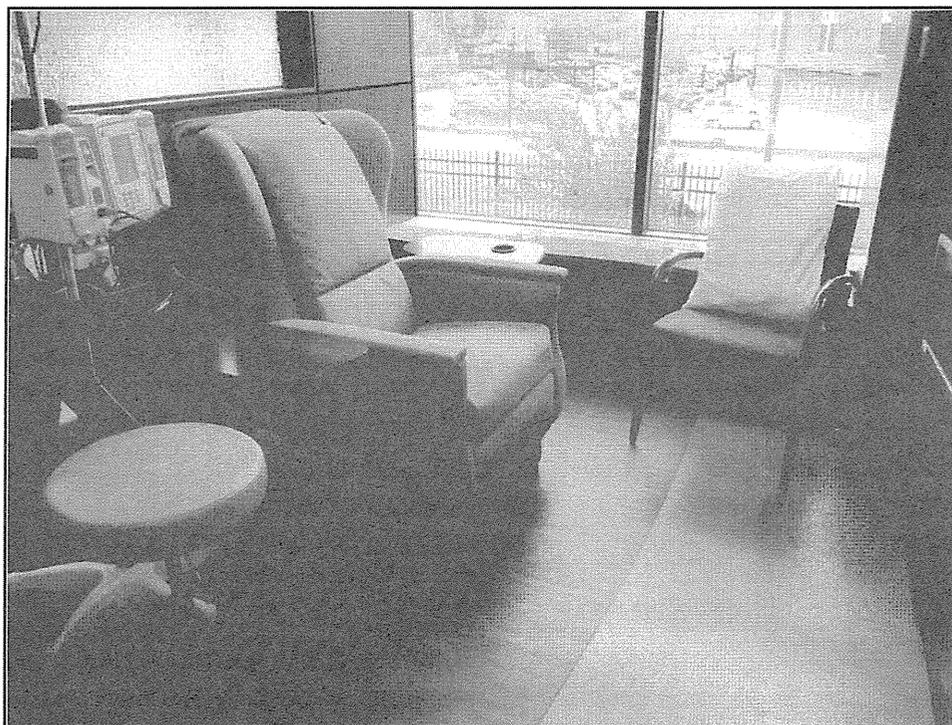
## Translational Research and Clinical Pharmacology Trials in Iowa

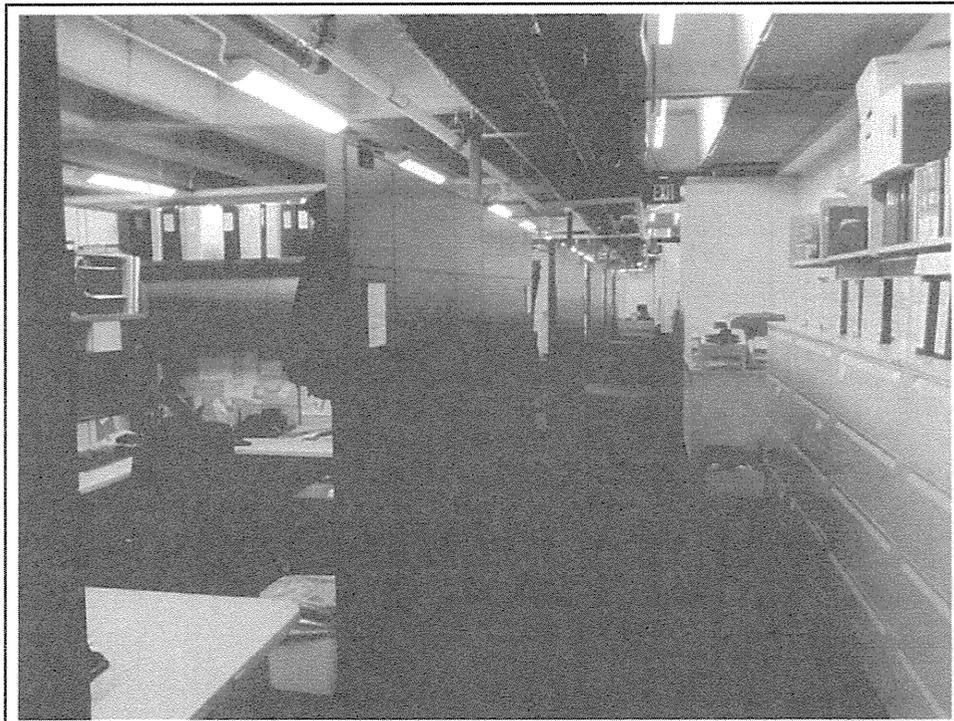
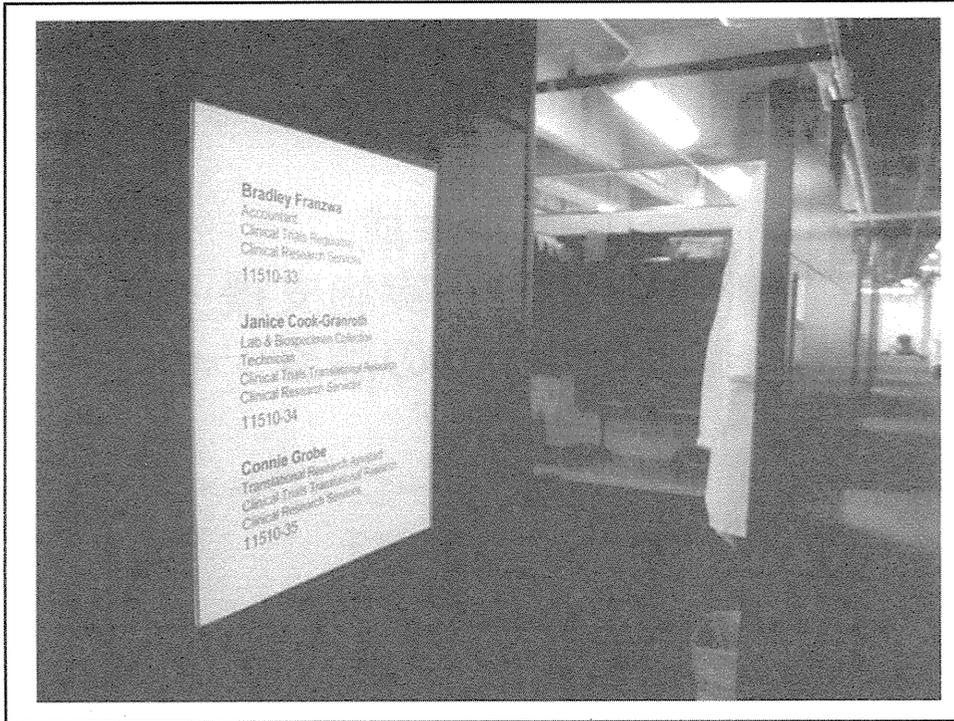
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## Core Facilities

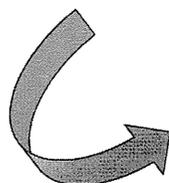
- Clinical Research Unit
- High Throughput Screening Facility
- University of Iowa Pharmaceutics
- Biocatalysis Center
- Holden Comprehensive Cancer Center Cores
- Pharmacology Analytical Core

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## 研究代表者: Principle Investigator



プロトコル作成  
CRCによる実施支援  
規制当局との調整  
モニタリング  
データマネージメント  
生物統計・解析  
論文作成

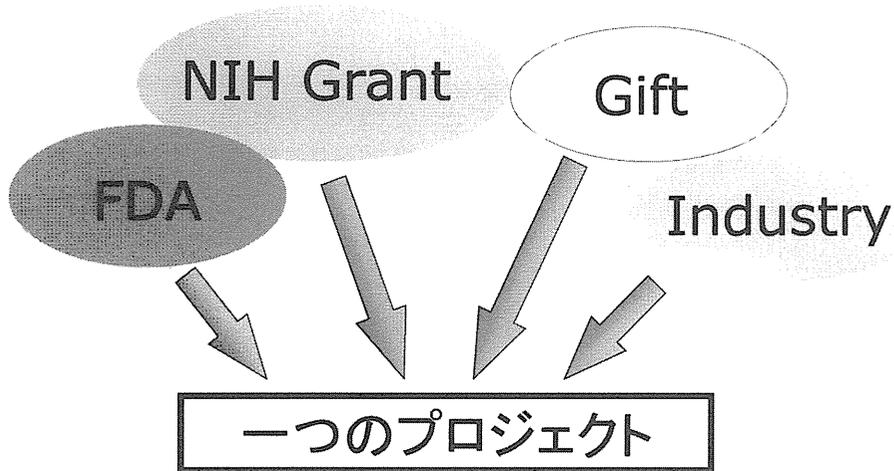
### 日本の研究者

プロトコル作成  
規制当局との調整  
データマネージメント  
生物統計・解析  
論文作成

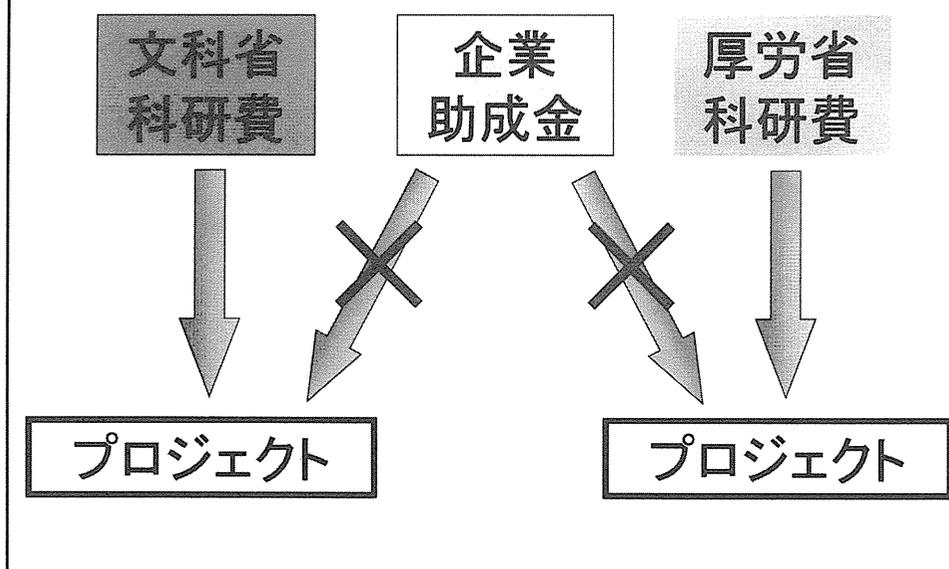


CRCによる実施支援  
モニタリング

## 研究資金源の多様性

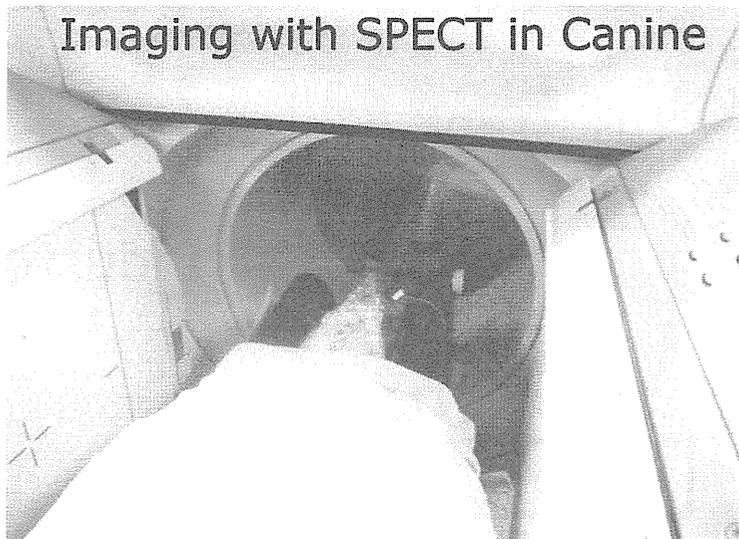


## 日本の研究資金源の硬直性



## Mayo Clinic における SPECT活用

Imaging with SPECT in Canine



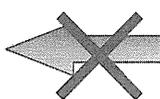
大阪大学 循環器内科 大谷朋仁先生より提供

## 公的研究費の硬直性

厚労省  
科研費  
(治験推進目的)

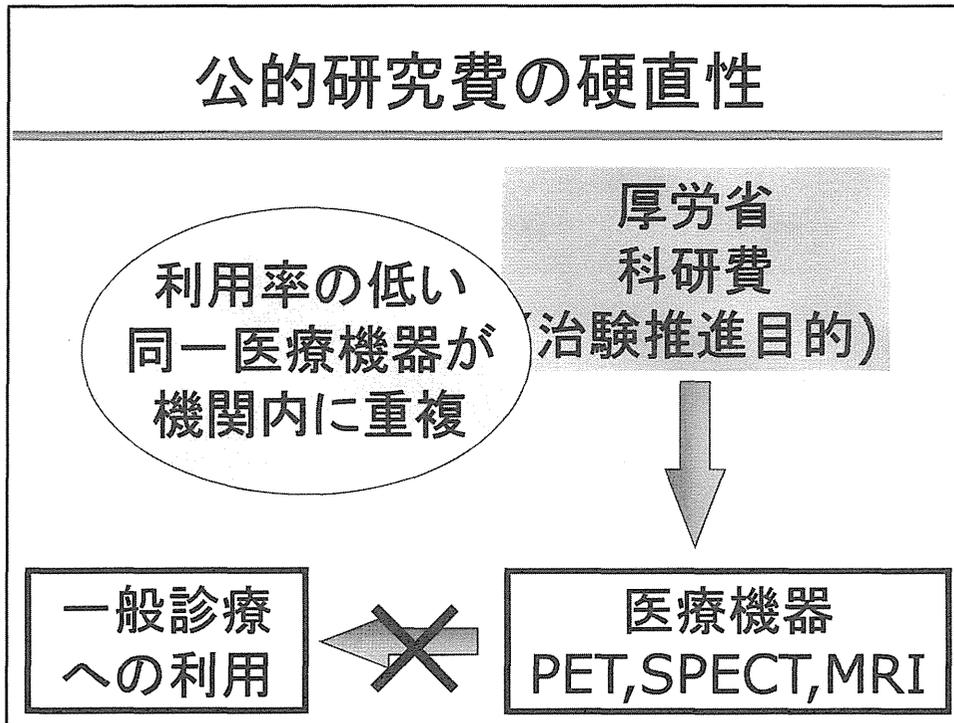


一般診療  
への利用

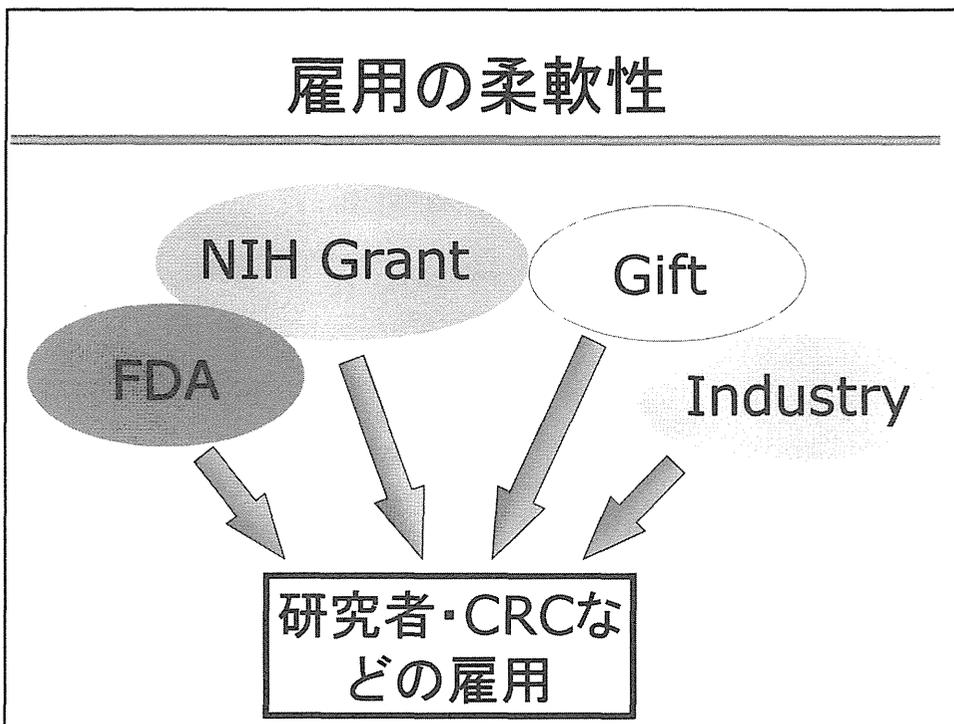


医療機器  
PET,SPECT,MRI

## 公的研究費の硬直性



## 雇用の柔軟性





## Cincinnati Children's Today

---

- 520-539 beds
- Operations of \$1.8 billion annually
- Endowment of \$1.6 billion
- 12,932 employees
- 2012 Data Outpatient visits 1,058,947
- Emergency Department visits 124,274
- Surgical procedures 33,459
- Admissions 30,604

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CRCの人数は？

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CRCの人数は  
600人

## Cincinnati Children's Today

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臨床試験が  
雇用創出の場

## Research Statistics

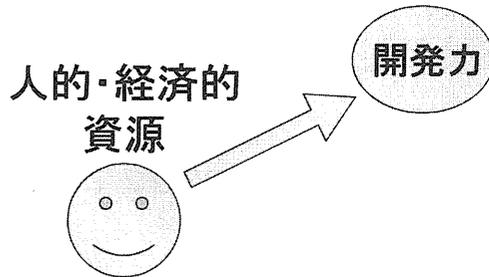
- Research budget of \$259 Million
- 950,000 square feet of research space
- National Institutes of Health Funding of \$111 Million-2nd in the US among all Children's Hospitals or pediatric departments
- Research endowment of ~\$1.6 billion
- ~100 PhD students and 136 post-doctoral research fellows
- 1,938 publications, 1,425 in peer-reviewed journals

## Research Statistics

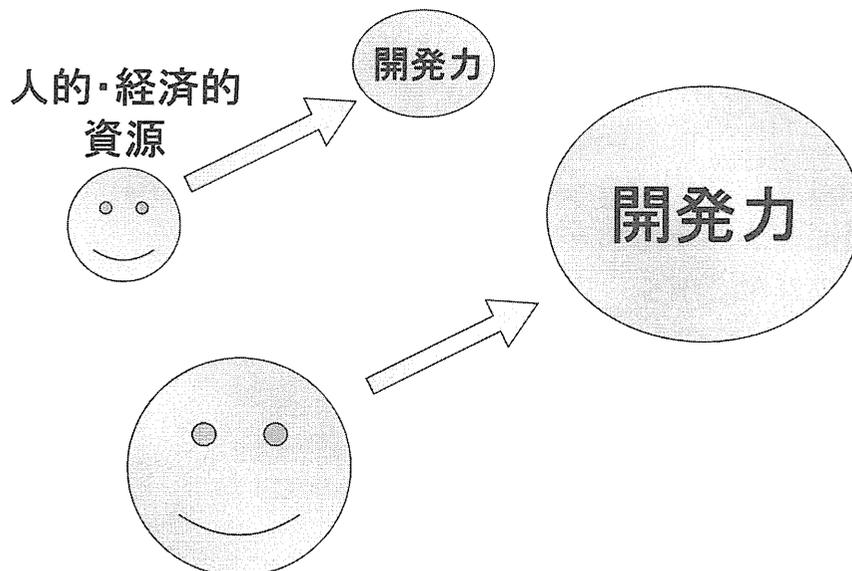
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研究への  
潤沢な資金供給

## 資源の大小と医薬品開発力



## 資源の大小と医薬品開発力

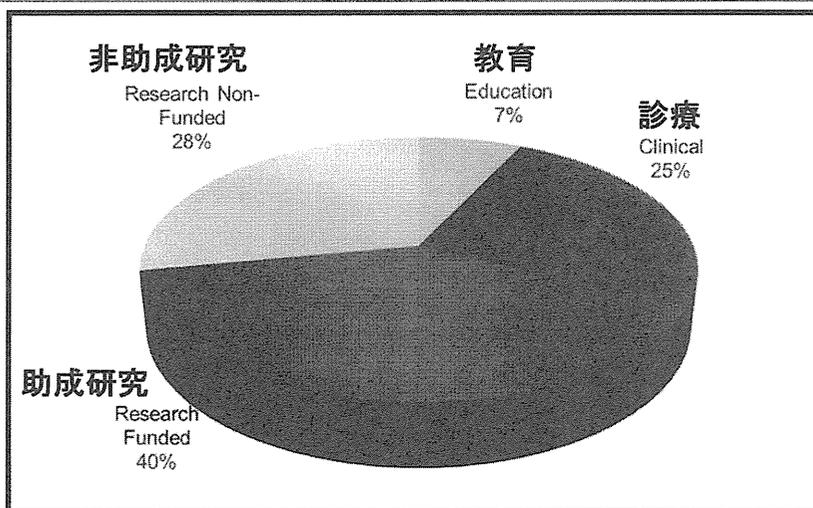


## Our Missions Department of Pediatrics

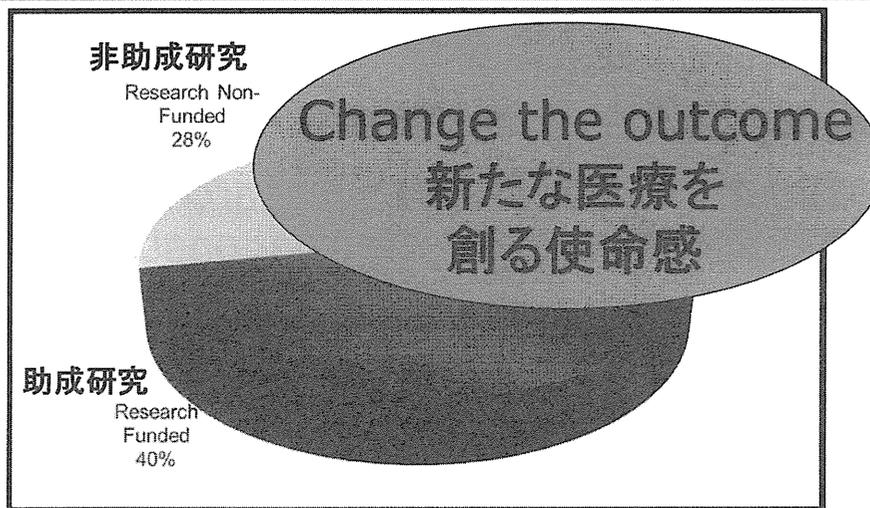
- Education
- Clinical Care
- Foundational or basic research
- Applied or clinical, translational, and outcomes research
- Advocacy and Community Service



## What Do We Do? Pediatric Faculty by Mission



# What Do We Do? Pediatric Faculty by Mission



アイオワ大学病院

シンシナチ小児病院



Change