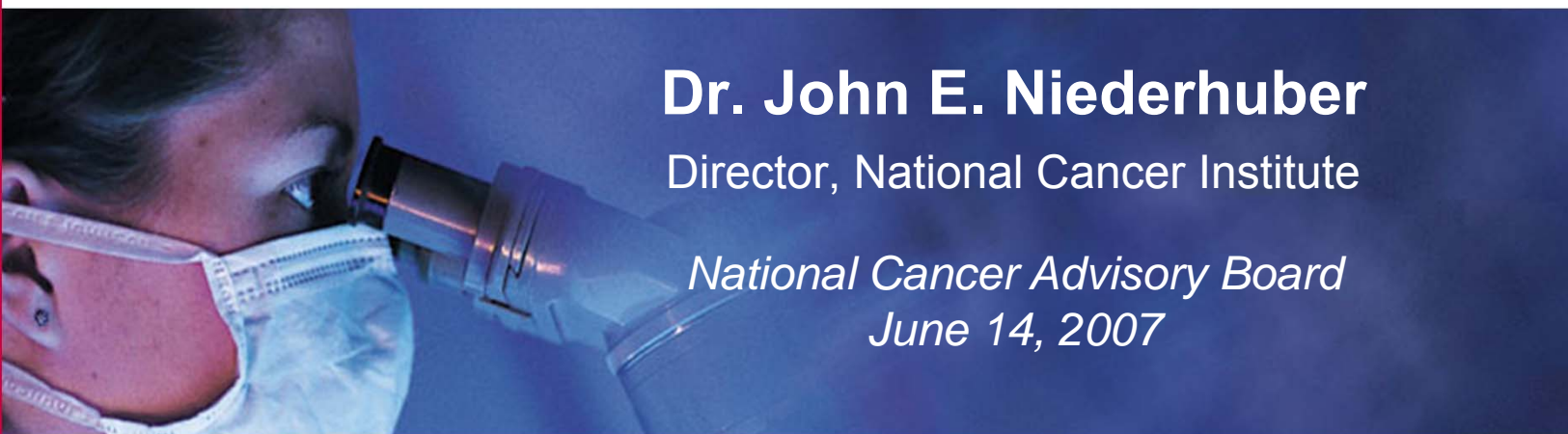


# NCI Director's Update

**Dr. John E. Niederhuber**  
Director, National Cancer Institute

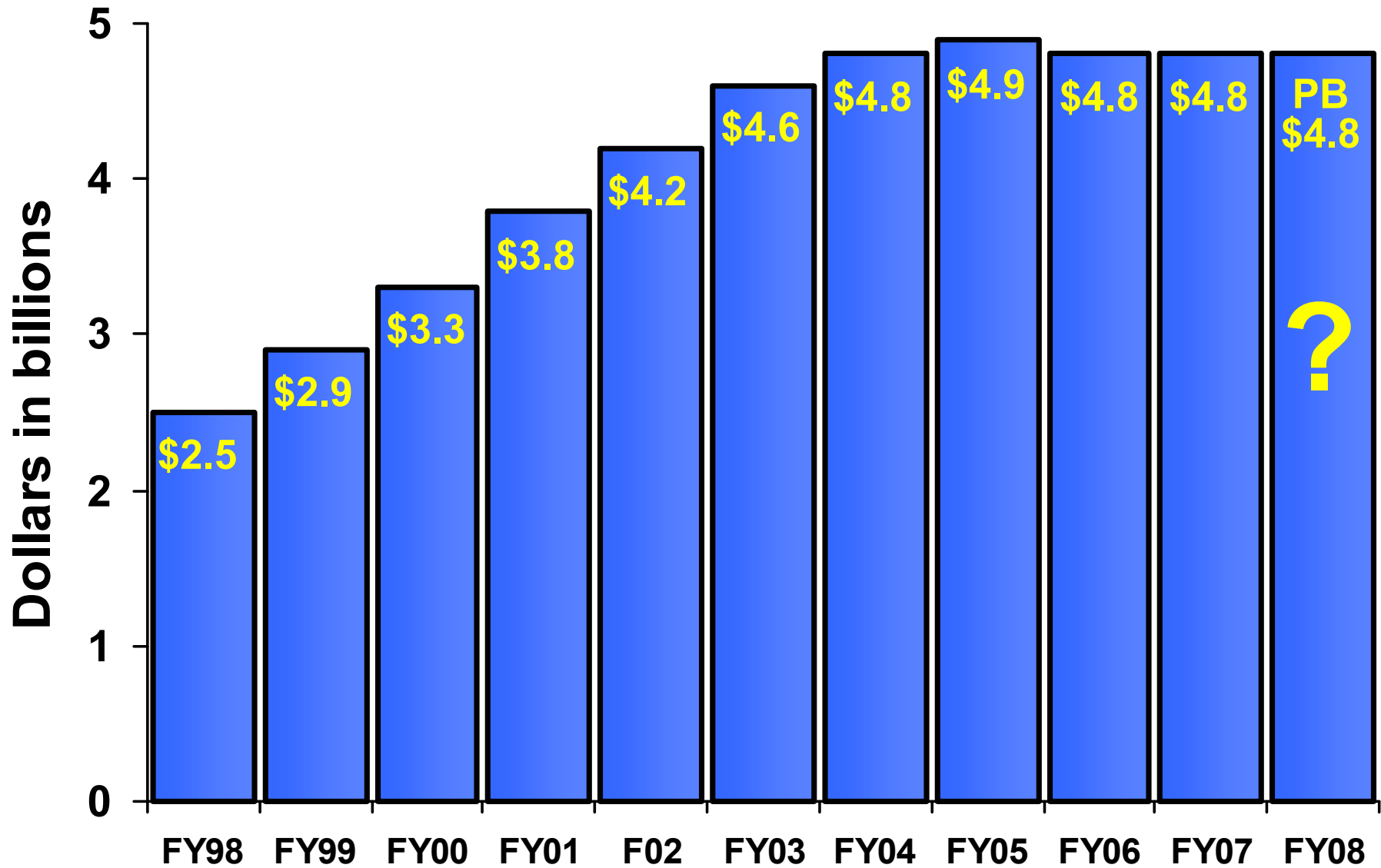
*National Cancer Advisory Board  
June 14, 2007*



# **NCI Director's Update**

- **Status report on FY07 actuals**
- **FY2008 Labor/HHS bill**
- **NCI Community Cancer Centers Program pilot**
- **Some personal thoughts**

# NCI's Congressional Appropriations



# **FY 2007 Operating Budget Development**

- **Inflation is ~3% to 4%  
(BRDPI)**
- **Develop reallocation  
pool = ~\$60M**
- **JR effective Feb. 15**

# Revised Continuing Appropriations Resolution, 2007

- Type 5s (noncompeting) reduced by 2.9%
- NIH-wide target of 1,500 awards to new investigators
  - (FY05 = 1,458; FY06 = 1,363)
- **ICs required to use half of the money they retain from Roadmap to fund additional competing RPGs**
  - NIH to fund 500 more RPGs (average cost \$324K)

# New Cancer Centers

**Dan L. Duncan Cancer Center, Baylor College of Medicine, Houston**



**C. Kent Osborne, M.D.  
Director**



**Irving Weissman, M.D.  
Director**



**Stanford  
Comprehensive  
Cancer Center,  
Stanford, Calif.**

# 2007 – Final Quarter

- JR not finalized until Feb. 15th
- End-of-year R01 payline: ~13th percentile (est.)
- End-of year \*RO1 payline: ~19th percentile (est.)

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007 (est.)</u>
<b>Total RPG</b>	<b>5,070</b>	<b>5,147</b>	<b>5,172</b>	<b>5,175</b>
<b>Competing</b>	<b>1,492</b>	<b>1,292</b>	<b>1,280</b>	<b>1,314</b>
<b>New Invest.</b>	<b>208</b>	<b>235</b>	<b>184</b>	<b>205</b>

# 2007 – Final Quarter

- **~20% competing pool reserved for exceptions**
- **Type 5s targeted at 2.9% below commitment of record, per NIH policy**
- **SPOREs were about 3% below FY2006**
- **Centers were increased 2% from FY2006**
- **Coop. Groups flat with FY2006**
- **Training 2.6% below the FY2006 level**



# FY 2008 President's Budget

- **NIH PB request is \$28.849 billion:**  
\$232 million (0.8%) over the FY 2007  
Annualized CR
- **NCI PB is \$4.782 billion: 0.2% lower**  
(-\$9 million) than the FY 2007  
Annualized CR

# FY2008 Labor/HHS Appropriations Bill

- House subcommittee mark up June 7
- Would appropriate **\$29.650 billion** to NIH
  - \$750M (2.6%) over JR07
  - \$1.029 billion (3.6%) over the FY08 PB
- Provides **\$4.870 billion** to NCI
  - ↑\$73M (1.5%) over JR07 (+\$63.2M Roadmap)
  - ↑\$88M (1.8%) over FY08 PB (+\$63.2M RM)

# FY2008 Labor/HHS Appropriations Bill (cont'd)

Increase to NIH is an investment to:

- “Increase the number of new and competing research grants by approximately 545 over last year” (~10,645)
- “Lift a two-year freeze on the average cost of new research grants”
- “Help train the next generation of researchers”
- “Provide \$110.9 million for the National Children's Study and \$300 million for the global AIDS fund”

Source: Statement by Rep. David Obey, June 7, 2007

# FY2008 Labor/HHS Appropriations Bill (cont'd)

- House would **continue to fund the Common Fund from the NIH OD,** rather than from the ICs
- Bill provides **\$495 million** for the Common Fund
  - **↑ \$12 million (2.5%) over FY 07**

# NCI FY 2008 Operating Budget Development

<b>FY 2007 Appropriation</b>	<b>\$4,797,639</b>
<b>FY 2008 House Subcommittee Mark</b>	<b>\$4,870,382</b>
<b>Difference '07 to '08</b>	<b>\$72,743</b>

**Percent Change '06  
to '07**

**1.5%**

**(dollars in thousands)**

# FY 2008 Operating Budget Development

	<u>Amount (in thousands)</u>	<u>Percent change</u>
<b>Subtotal Available</b>	<b>\$72,743</b>	<b>1.5%</b>
<b>Less:</b>		
• Potential NIH Director's 1% Transfer	?	
• Potential DHHS Secretary's Transfer	?	
	<hr/>	
<b>Subtotal Available</b>	<b>72,743</b>	<b>1.5%</b>
<b>NIH Taps/Assessments Increase (estimated)</b>	<b><u><u>-20,000</u></u></b>	
<b>Subtotal Available</b>	<b>\$52,743</b>	<b>1.1%</b>

# FY 2008 Operating Budget Development

	<u>Amount</u> <u>(in thousands)</u>	<u>Percent</u> <u>change</u>
<b>Subtotal Available</b>	<b>\$52,743</b>	<b>1.1%</b>
<b>NCI-wide Requirements:</b>		
• <b>Competing RPG Increase (est.)</b>	<b>- 38,000</b>	
• <b>Rent/Lease/Utilities Increase</b>	<b>- 10,900</b>	
• <b>Small Business Program Increase</b>	<b>- 2,000</b>	
• <b>Mandated Salary Increases</b>	<b>- 15,500</b>	
	<hr/> <hr/>	
<b>Subtotal Available</b>	<b>-13,657</b>	<b>- 0.3%</b>
<b>NCI Director's Reserve</b>	<b>- 25,000</b>	
	<hr/> <hr/>	
<b>Subtotal Available</b>	<b>- \$38,657</b>	<b>- 0.8%</b>

# FY 2008 Operating Budget Development

	<u>Amount</u> <u>(in thousands)</u>	<u>Percent</u> <u>change</u>
<b>Subtotal Available</b>	<b>- \$38,657</b>	<b>- 0.8%</b>
<b>Potential Recoveries/ Redeployments:</b>		
• Phaseouts/Reductions to ongoing programs	?	
• Noncompeting RPGs	?	
<b>Available for New Initiatives/ Expansions/Restorations</b>	<hr/> <hr/> ?	

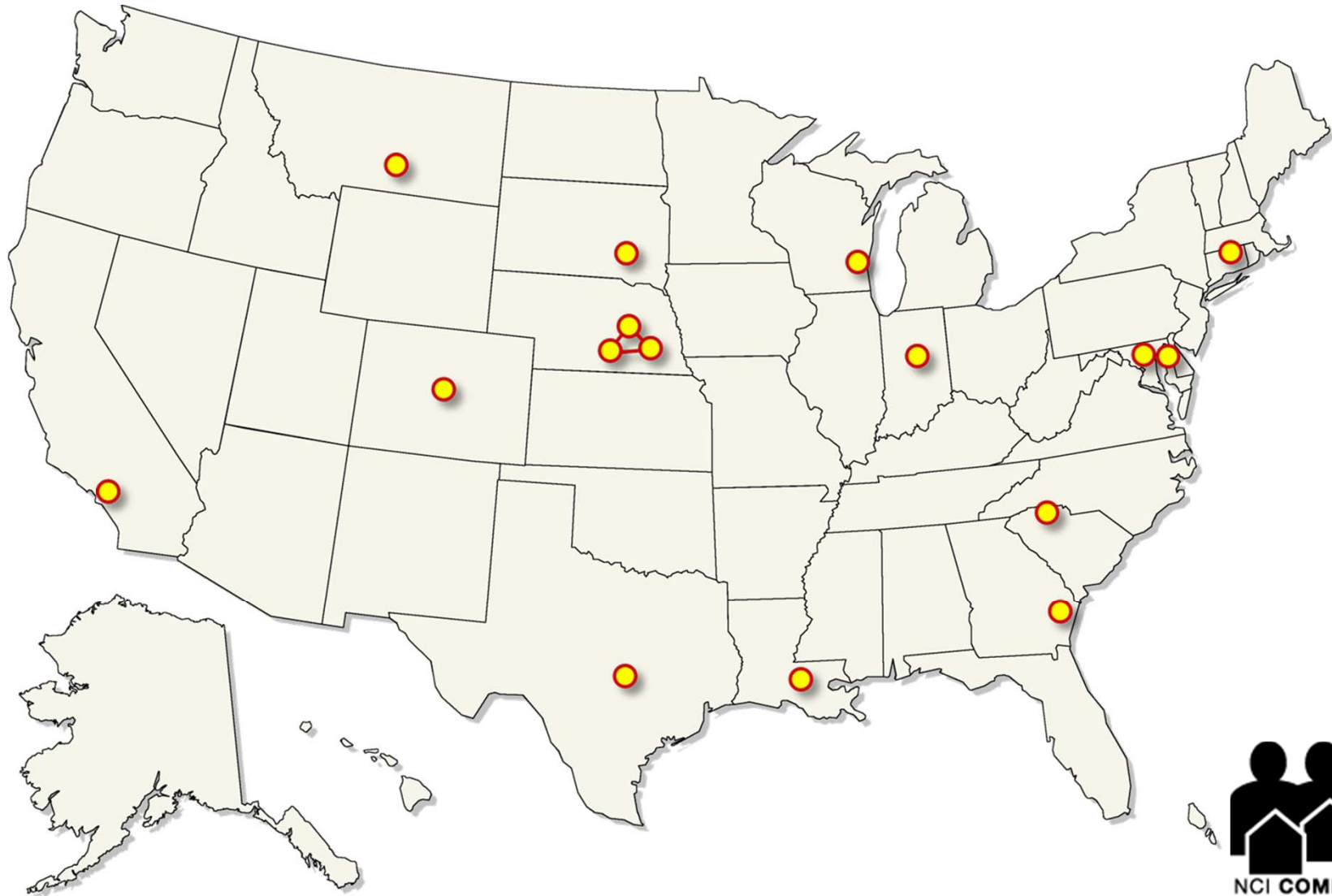
**Goal is to generate ~\$60 million for reallocation to highest-priority items.**



# Summary

- **NCI budget will continue to be less than inflation**
- **Attempting to find and fund best science and best scientists**
- **Need to manage expectations**
- **Need to continue scientific growth and maintain balance**
- **Need to leverage additional resources**

# NCI Community Cancer Centers Program Pilot Sites

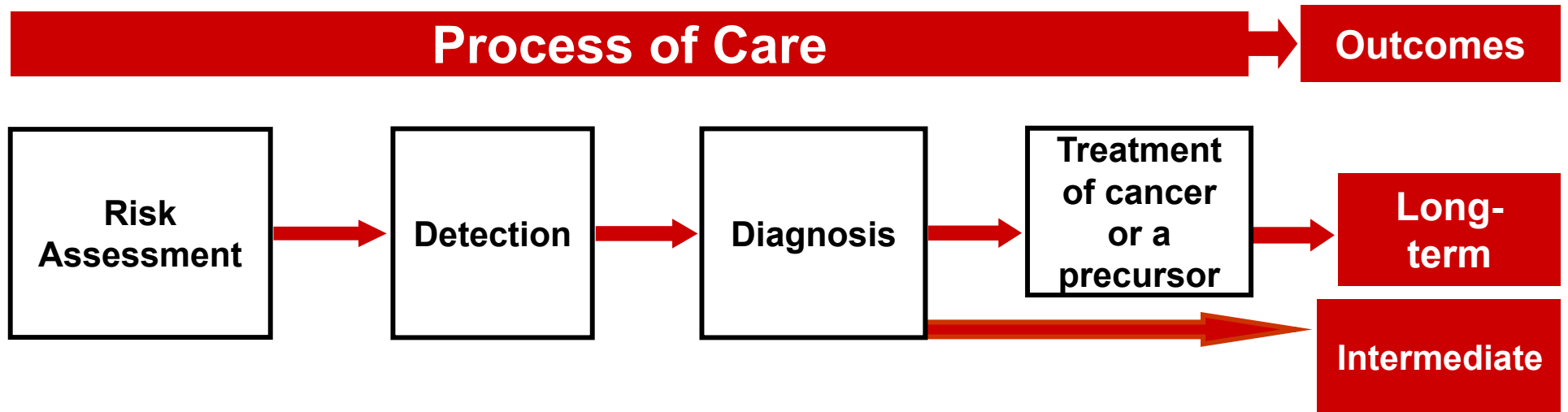


# NCI Community Cancer Centers Program

**Pilot Goal:** Sponsor multiple pilot sites for three years to **identify critical factors that define a state-of-the-art community cancer center** that will be incorporated into a future program.

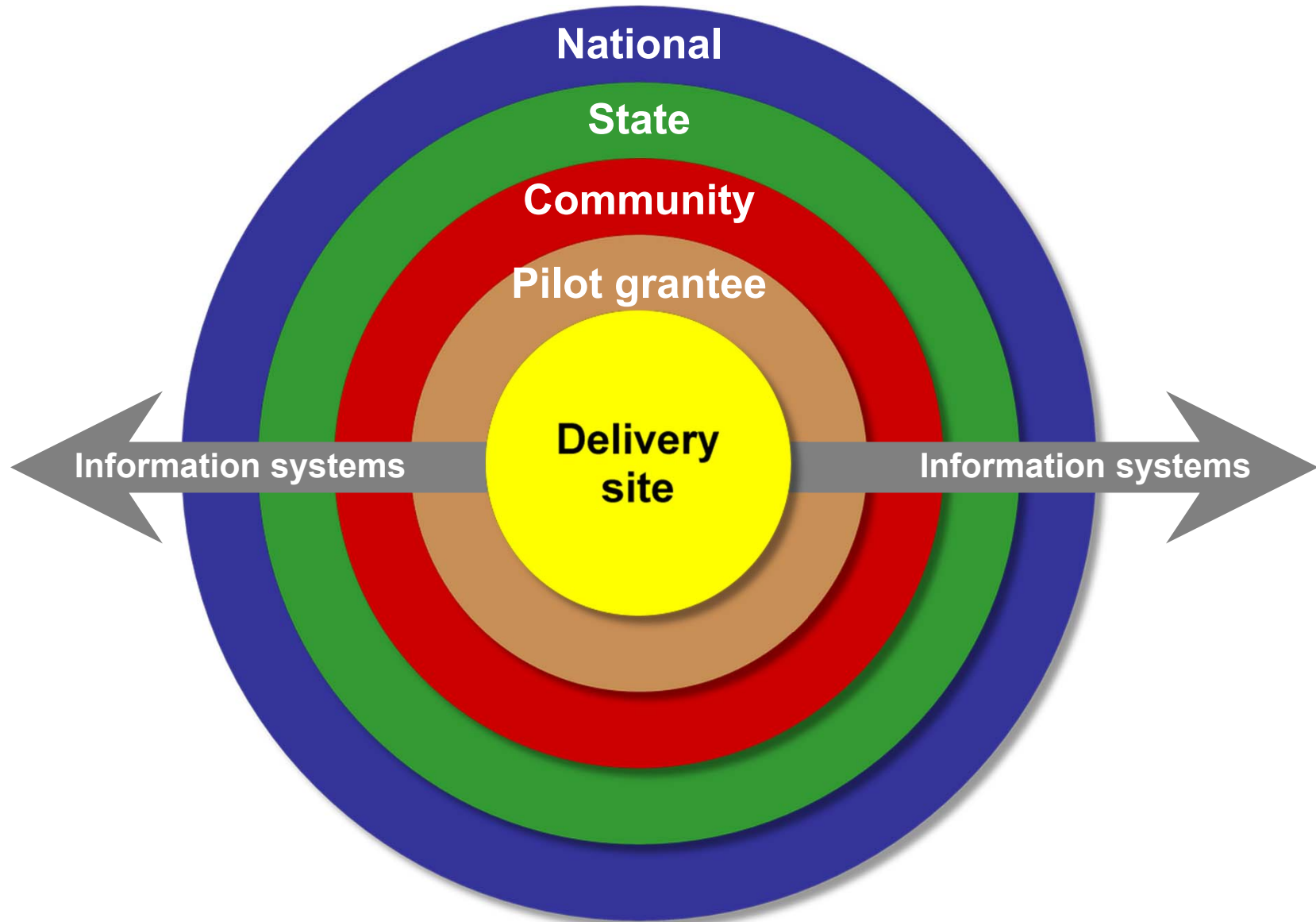


# Cancer care continuum



Potential for improvement at transitions ( → )  
or during types of care delivery ( □ )

# NCCCP quality of care is affected by multiple levels of influence



# Research Focus Areas and Development of Best Practices

- **Clinical Research**

- Increase trial accrual/minority accrual;  
can we do early phase trials?
- Participation in Research Networks

- **Disparities**

- Decrease healthcare disparities
- Increase community outreach
- Increase Patient Navigation



# Research Focus Areas and Development of Best Practices

- **Quality of Care**

- Use of evidence-based guidelines
- Multidisciplinary care

- **Survivorship**

- Survivorship plans
- Palliative care
- Hospice



# Research Focus Areas and Development of Best Practices

- **Biospecimen initiatives**
  - NCI Best Practices for Biospecimens
  - IT related to biospecimens
  - Privacy/data sharing issues
  - Biospecimen Network exploration
- **Information Technology**
  - caBIG™ implementation assessment
  - Privacy/data sharing issues





# Research Focus Areas and Development of Best Practices

- **Overall Program**

- Appropriate program components
- Cancer Medical Staff credentialing
- Academic linkages
- Institutional Commitment
- Knowledge exchange among sites
- Federal and state program linkages



# Evaluation Plan

- **Independent evaluation contractor** throughout the pilot program duration
- **Quantitative and qualitative metrics** across components through the 3 years
- **Evaluate the implementation, operations and performance of NCCCP pilot sites**
  - **Process assessment**
  - **Impact assessment**



# NCI Community Cancer Centers Program Pilot Sites

- Billings Clinic, **Billings, Montana**
- Hartford Hospital, **Hartford, Connecticut**
- St. Joseph's/Candler, **Savannah, Georgia**
- Our Lady of the Lake Regional Medical Center, **Baton Rouge, Louisiana**
- Sanford University of South Dakota Medical Center, **Sioux Falls, South Dakota**
- Spartanburg Regional Hospital, **Spartanburg, South Carolina**
- St. Joseph Hospital, **Orange, California**

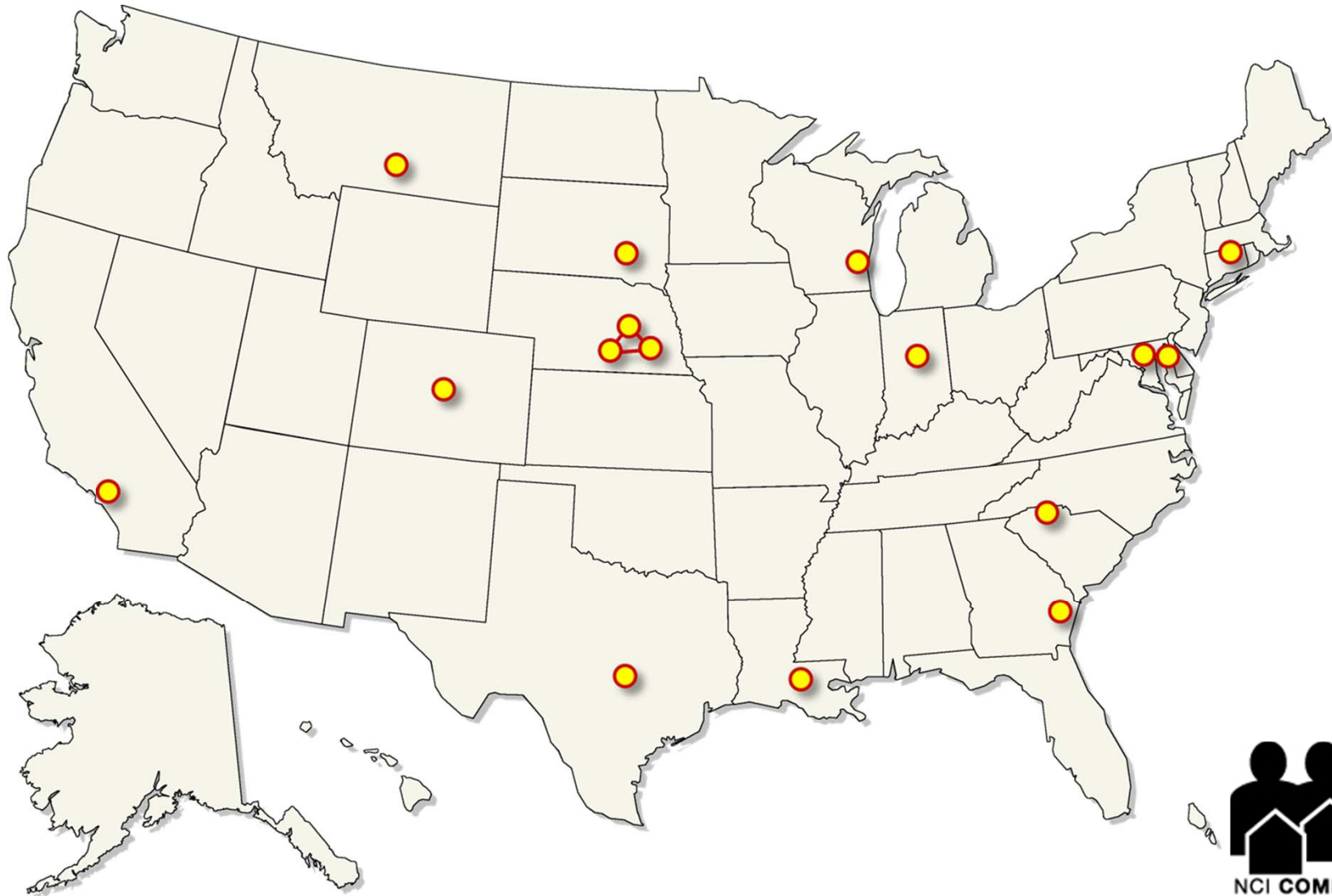


# NCI Community Cancer Centers Program Pilot Sites (cont'd)

- **Christiana Hospital, Newark, Delaware**
- **Ascension Health of St. Louis will operate:**
  - **St. Vincent Indianapolis Hospital, Indianapolis, Indiana**
  - **Columbia St. Mary's, Milwaukee, Wisconsin**
  - **Brackenridge Hospital, Austin, Texas**
- **Catholic Health Initiatives of Denver will operate:**
  - **Penrose-St. Francis Health Services, Colorado Springs, Colorado**
  - **St. Joseph Medical Center, Towson, Maryland**
  - **A coordinated site of three hospitals in Kearney, Lincoln, and Grand Island, Nebraska**



# NCI Community Cancer Centers Program Pilot Sites



# Three Years from Now...

**Through research, we will have determined the best methods to enable the provision of state-of-the-art, multispecialty care and early-phase clinical trials in community-based locations to meet the needs of the people.**



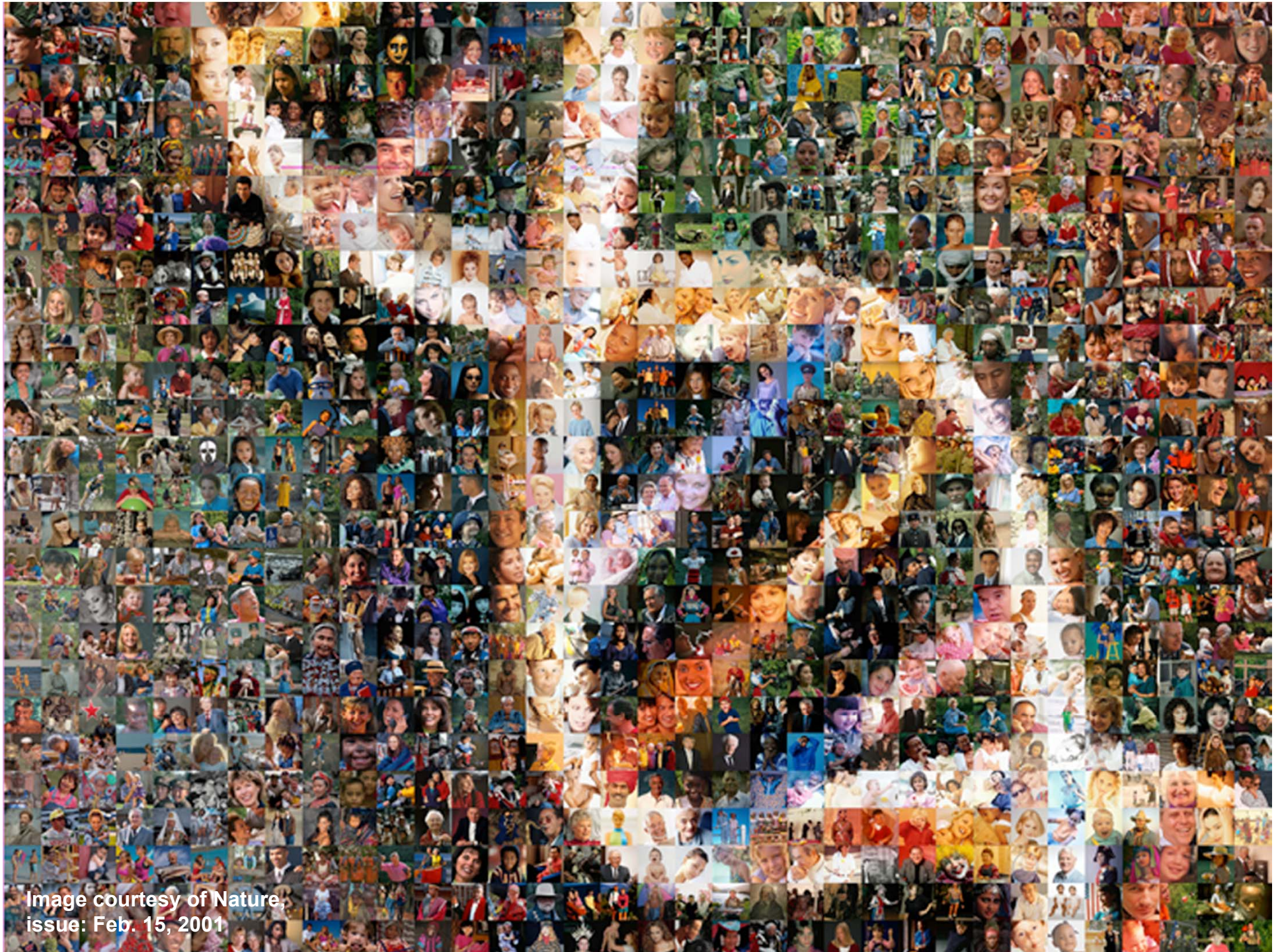


Image courtesy of Nature,  
issue: Feb. 15, 2001

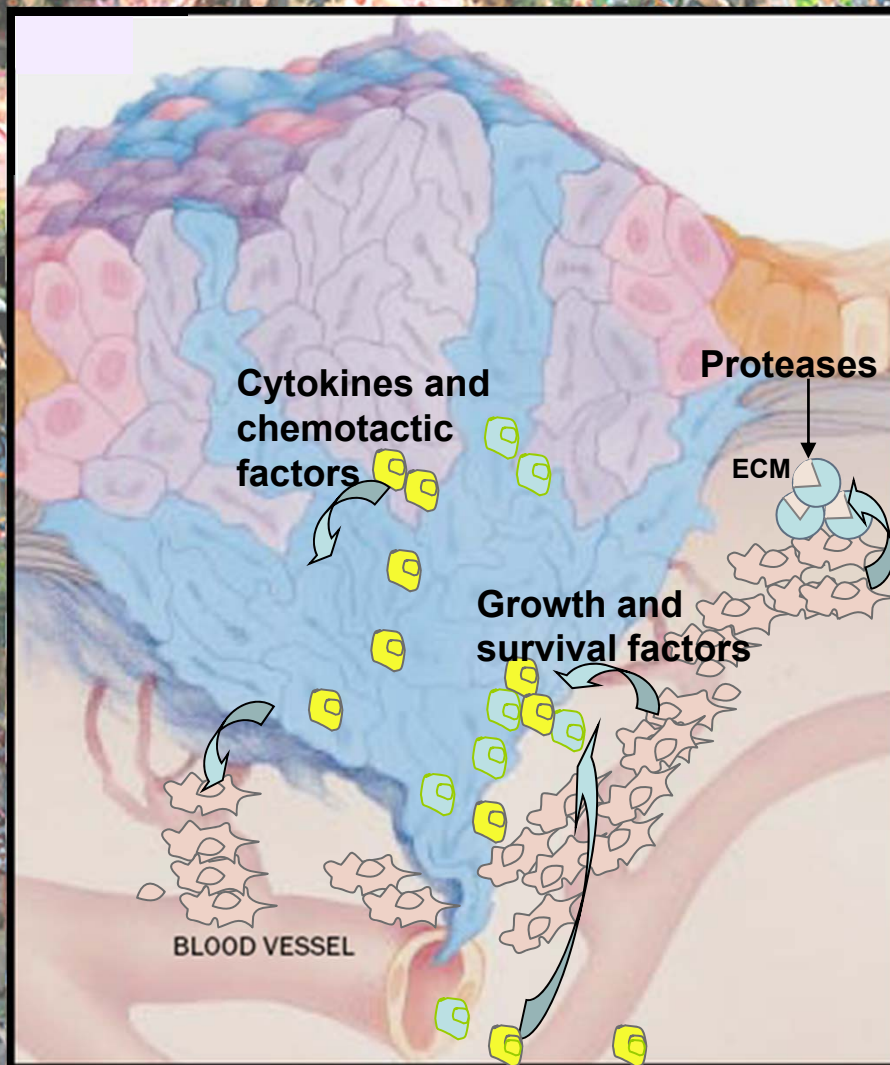


Image courtesy of Nature,  
issue: Feb. 15, 2001



# Cancer is a disease of staggering complexity...

**Integrated Cancer Biology Program**

**Centers for Systems Biology (NIGMS)**

**Centers for Nanobiology**

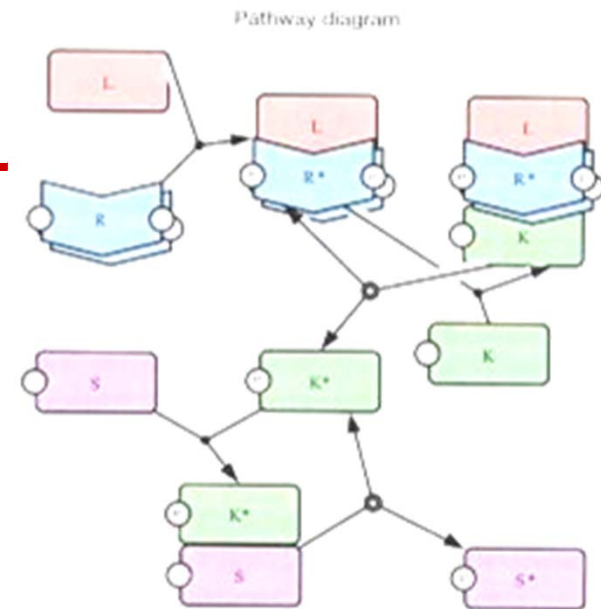
**Cancer genome project; whole genome scanning**

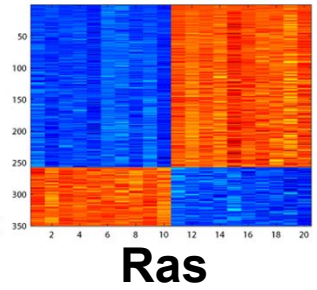
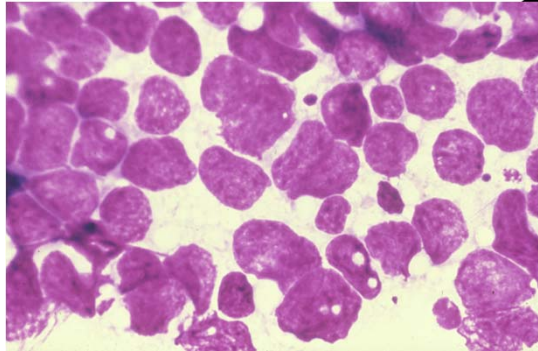
**Centers for proteomics**

**Network centric biomedicine**

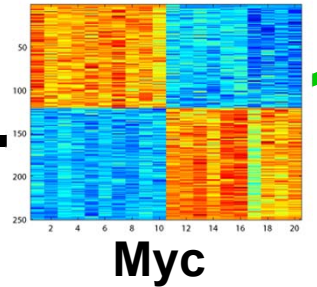
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- Sub-cellular imaging • protein
- capture • physics • energy •
- gradients • dimension of time •
- technology development •
- reciprocal signaling •

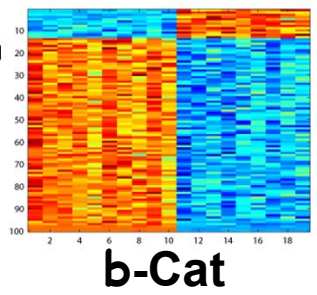




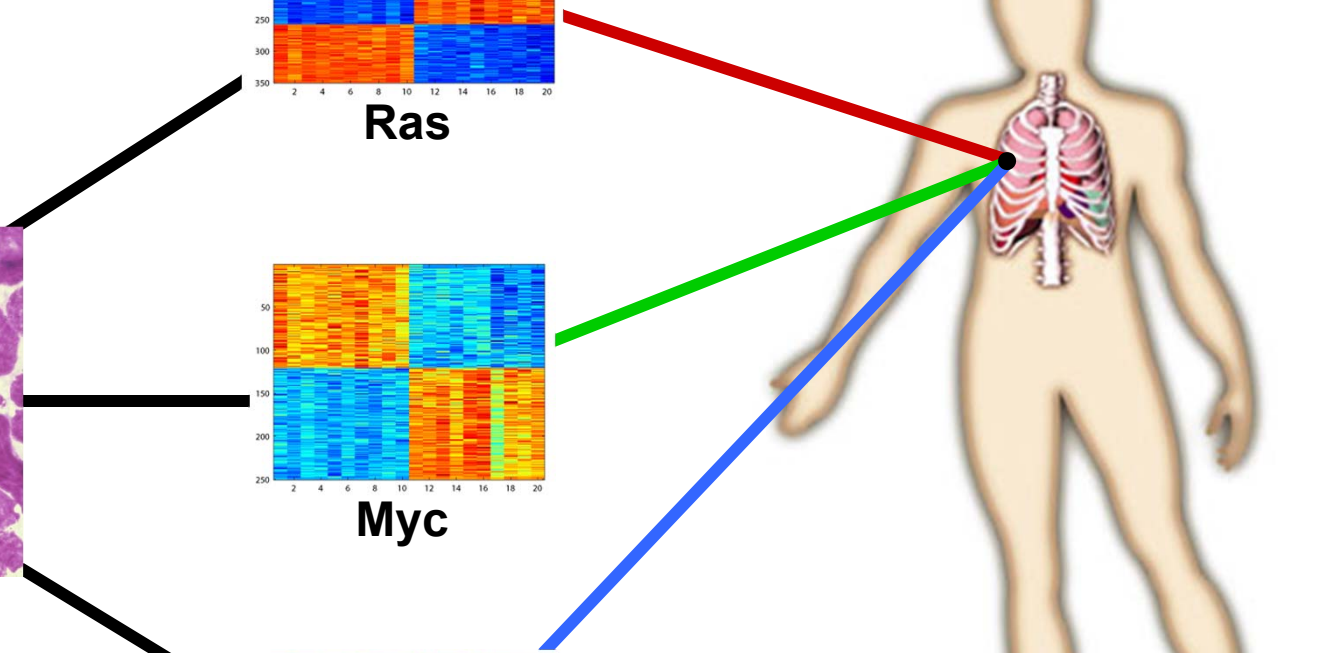
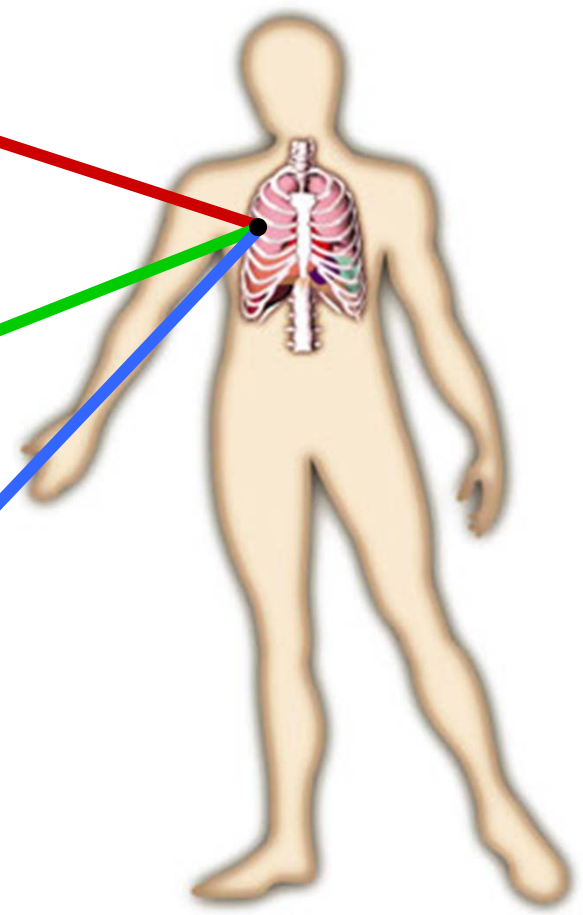
**Ras**

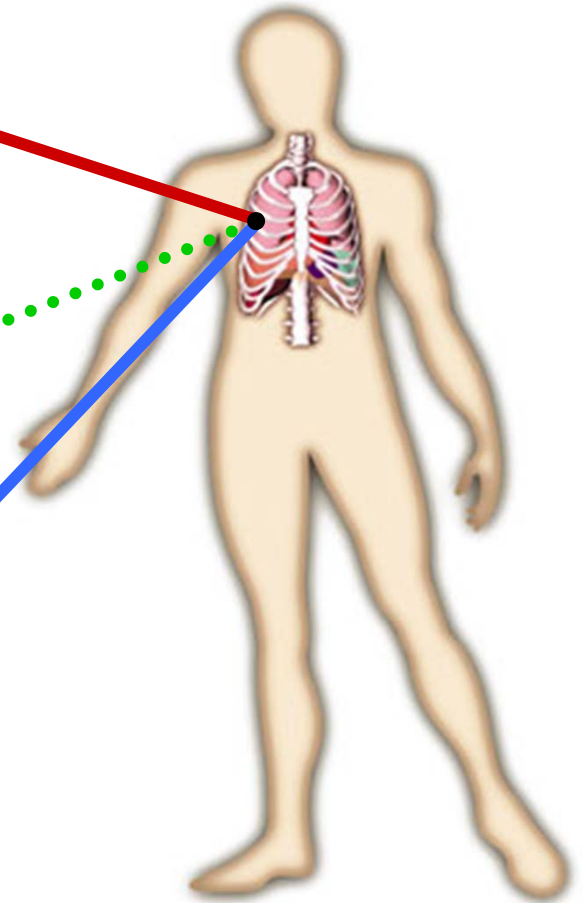
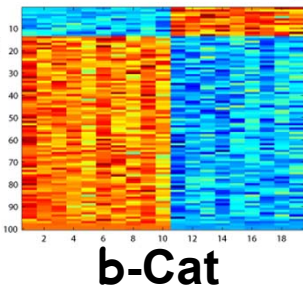
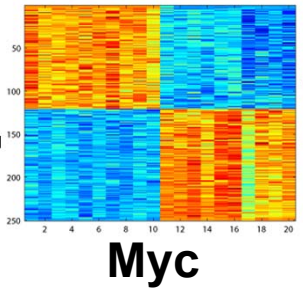
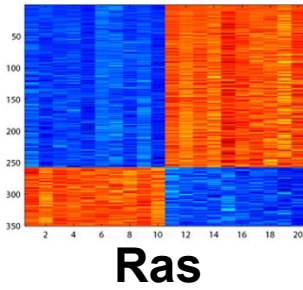
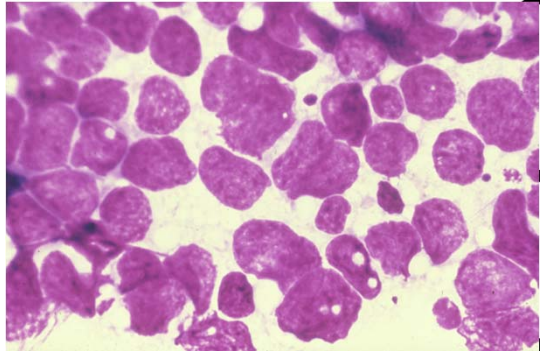


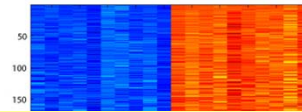
**Myc**



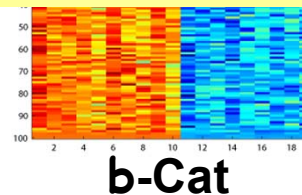
**b-Cat**

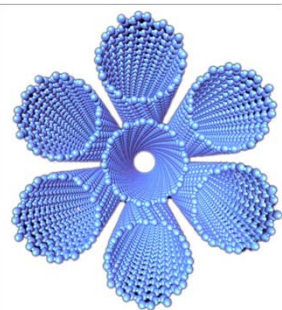




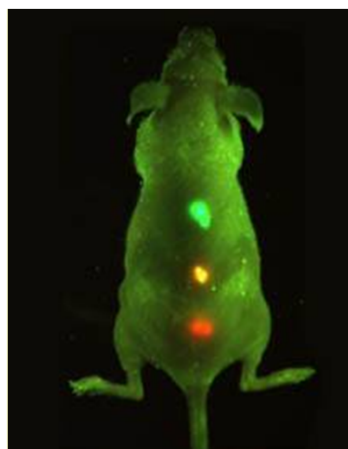
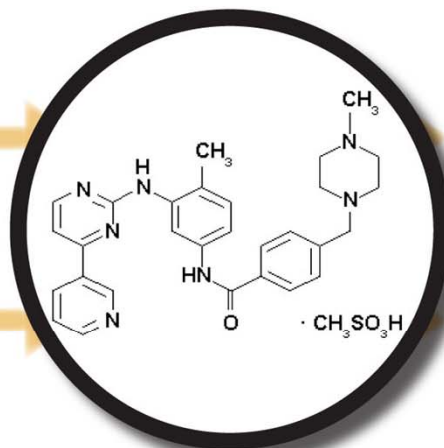
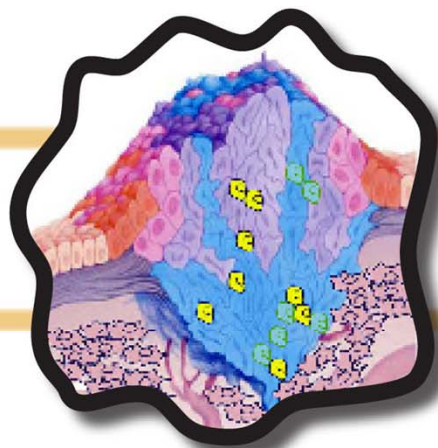
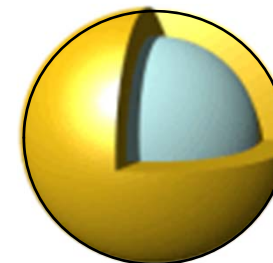


- The discovery process is too long and too costly**
- No longer test one drug at a time**
- Regimens rather than single agents**

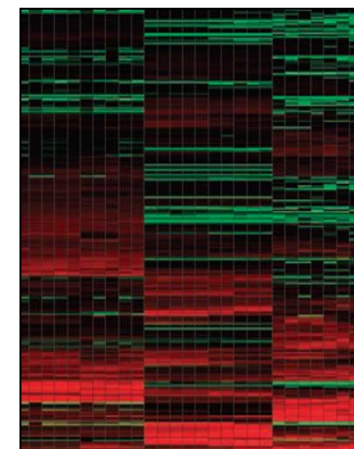




# A Continuum of Science



**NCI is an honest broker  
between government,  
academia, and the  
private sector**











# Evaluation Oversight Committee

- **Mary Fennell, PhD (Chair)**, Brown Univ.: applications of organizational theory to healthcare organizations; extensive community-based cancer program evaluation experience
- **Steven Clauser, PhD**, NCI: healthcare outcomes research and applied research
- **Thomas Gribbin, MD**, Medical Director Lacks Cancer Center of St. Mary's Healthcare-Grand Rapids, Mich.: models of cancer care; survivorship issues
- **Mark Hornbrook, PhD**, Kaiser Permanente Center for Health Research: healthcare cost and utilization analysis; economic evaluation methods, patient classification methods, health status measurement, predictive modeling, and health-based payment systems



# Evaluation Oversight Committee

- **Timothy Johnson, PhD, U. Ill, Chicago:** survey methodology and health behaviors in disadvantaged populations
- **Maureen Johnson, PhD, NCI NCCCP Project Officer**
- **Bryan Weiner, PhD, UNC Chapel Hill;** the adoption, implementation and sustainability of innovations in healthcare organizations; conducted CCOPs evaluation
- **Jane Zapka, ScD, U. South Carolina;** qualitative and quantitative research, program evaluation, quality improvement, managed care, and other health services research, including the continuum of cancer care
- **Joy Beveridge, MS, Ad Hoc Member, SAIC Project Manager**



# Evaluation Oversight Committee

## Consultants to Committee

- **Arnie Kaluzny, PhD**, UNC Chapel Hill; organizational factors affecting program implementation and change in a variety of health care organizations, with specific emphasis given to cancer treatment, prevention and control; continuous quality improvement initiatives in both organizational and primary care settings; and the study of alliances within health care
- **Donna O'Brien, MHA**, Healthcare Consultant: Expertise in the design, formation, and management of health systems, networks, and partnerships. NCI-designated Cancer Center management experience



# 2006 – Final Quarter

- Mid-year increase in taps for utility costs of almost \$4 million
- End-of-year R01 payline: 12th percentile;  
\*RO1 payline: 18th percentile
- 15% of competing pool reserved for exceptions
- Type 5s generally 2.35% below commitment of record
- SPOREs were about 6.1% below FY2005
- Centers were increased 3.9% from FY05
- Training 1% above the FY05 level

# Summary: NCI Myths and Facts

- **1,280 competing RPGs** in 2006 (↓ from 1,492 in 2004)
- **5,172 total RPGs** in 2006 (↑ from 5,070 in 2004)
- **\$324,000 average \$ per competing grant** in 2006 (↓ from \$346,000 in 2003)
- **7% of the competing pool** went to RFAs in 2006 (↓ from 9% in 2004)
- **5,679 individual investigators supported** in 2006 (↑ from 5,636 in 2004)
- **\$42.8M to Roadmap** in 2006 (↑ from \$16.2M in 2004)
- **\$60M in flexible dollars** (↓ from \$108M in 2005)

# Baseline pilot program components

- **Community cancer center**
- **Clinical trials experience**
- **Disparities & community outreach**
- **Hospice and palliative care**
- **Information technology**
- **Biospecimen initiatives**



# Quality of Care Relates to Several Other NCCCP Components



# Evaluation Plan

- Independent evaluation contractor throughout the pilot program duration
- Quantitative and qualitative metrics across components through the 3 years
- Evaluate the implementation, operations and performance of NCCCP pilot sites
- Process Assessment
  - Implementation experience of the pilot sites
  - Assess feasibility, best practices, relationships to NCI-designated Cancer Centers and other Federal, state and community resources
  - Replicability potential of the NCCCP model components
    - Role of hospital executive level support/institutional commitment
    - Role of the medical staff to determine which factors support an effective NCCCP Program
    - Implementation of effective models to address healthcare disparities
    - Assessment of operational costs necessary to support an effective NCCCP program
- Impact Assessment
  - enhancing delivery of evidence-based cancer screening and therapies through multidisciplinary care
  - Improve physician participation and accrual rates in clinical trials, especially among minority individuals





# **FY 2007 Operating Budget Development Cancer Centers Program**

## **T-2s on a sliding scale FY 2007**

- **Outstanding to low Excellent Peer Review Scores will receive some increase over current level**
- **Mid Excellent Peer Review Scores will be funded at current funding level**
- **High Excellent Peer Review Scores will receive a percentage below their current funding level**
- **Peer Review Scores 200 and above receive more significant decreases and a shorter award period**

**Measuring whether we  
can deliver care in the  
community setting—or  
what needs to be  
changed.**

# **FY 2007 Operating Budget Development**

## **Cancer Centers Program**

	<b>Amount (in thousands)</b>
<b>FY 2006 Obligations P30 (excludes Minority)</b>	<b>\$254,518</b>
<b>Program Reduction Exercise (↓10%)</b>	<b>-22,000</b>
<b>EC Approved Restoration</b>	<b>26,081</b>
<b>Subtotal Available</b>	<b>258,599</b>
<b>Noncompeting @ 2.9% reduction from Commitment of Record</b>	<b>-178,020</b>
<b>Subtotal Available</b>	<b>80,579</b>
<b>Recycled Extensions with 2.9% Reduction</b>	<b>-28,233</b>
<b>Planning Grants – most in final year in FY 2007</b>	<b>-3,503</b>
<b>Subtotal Available</b>	<b>48,843</b>

# FY 2007 Operating Budget Development

## Cancer Centers Program

Amount  
(in thousands)

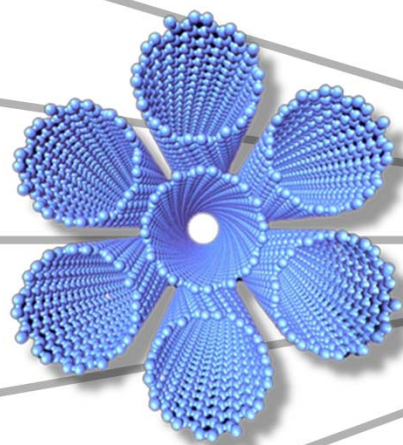
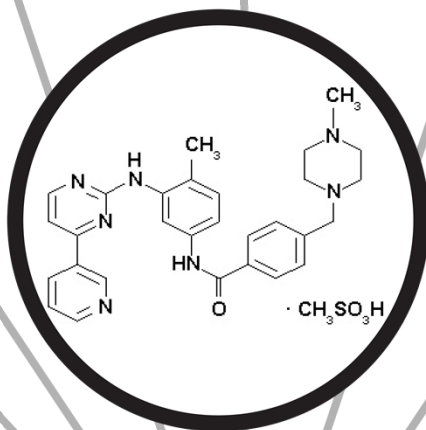
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<b>Subtotal Available</b>	<b>48,843</b>
<b>AVON</b>	<b>-1,609</b>
<b>Other Supplements</b>	<b>-1,861</b>
	<hr/>
<b>Subtotal Available</b>	<b>45,373</b>
<b>Two New Centers @ \$1.5 each</b>	<b>-3,000</b>
	<hr/>
<b>Subtotal Available</b>	<b>42,373</b>
<b>Keep FY 2006 One-Shots in Place (requires supplements)</b>	<b>-5,600</b>
<b>T2s on Sliding Scale</b>	<b>-38,588</b>
	<hr/>
<b>Subtotal Available</b>	<b>-1,815</b>

# FY 2007 SPORE Budget

	<u>No.</u>	<u>Amount</u> in thousands
Non-competing grants w/ 2.9% reduction	40	\$83,848
Competing grants	11	24,304
Extensions partially funded (A1, A2)	10	8,937
AVON Supplements		403
Admin. Supplements (Clinical Trials)		2,217
Minority Branch Supplements		1,000
<b>Total FY 2007 SPORE Budget</b>	<u>61</u>	<u>\$120,709</u>

**FY 2006 obligations (including Minority Branch) = \$125,019 (↓ 0.4%)**



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