

National Cancer Institute

NCI Director's Update

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Director, National Cancer Institute

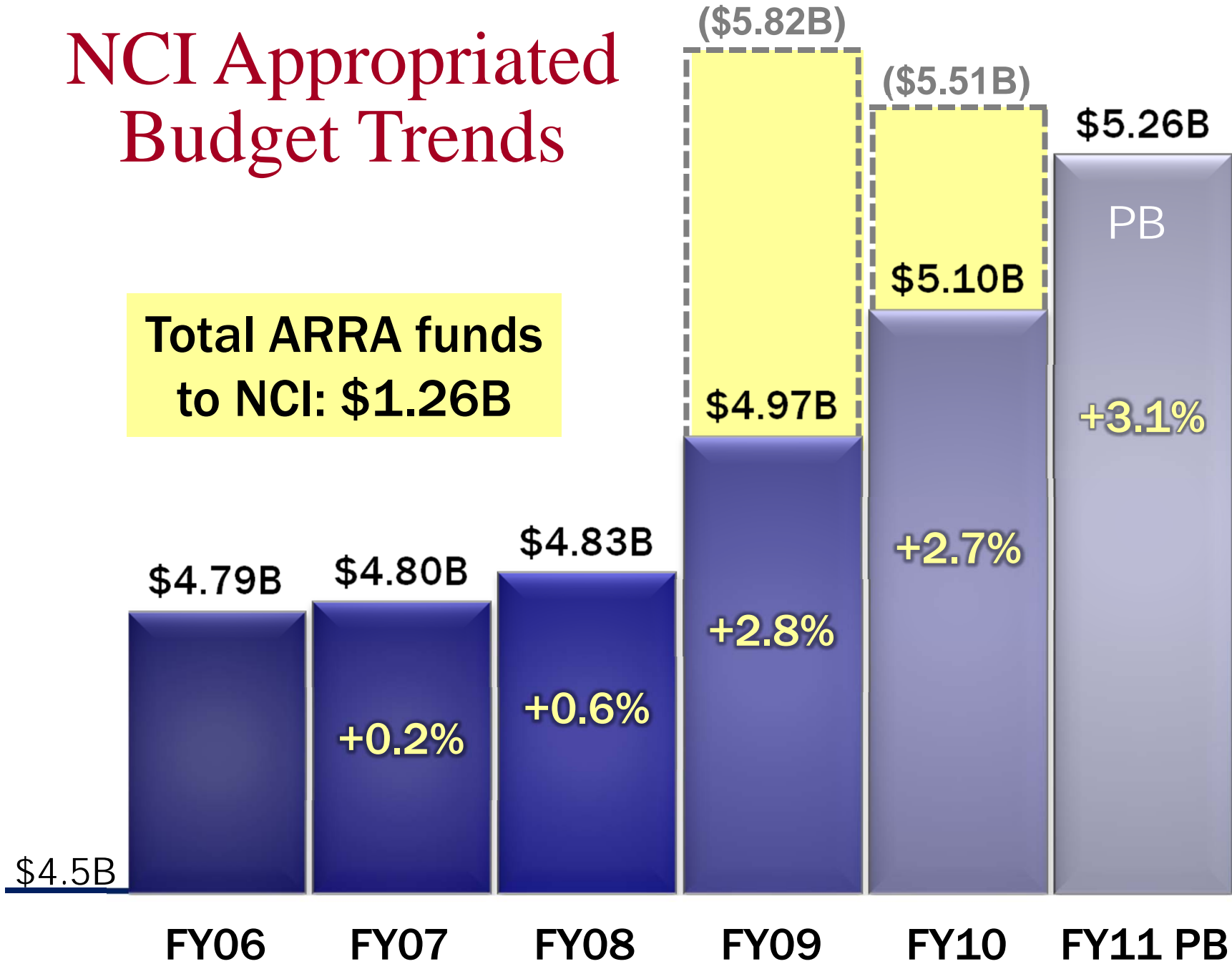
National Cancer Advisory Board
June 22, 2010

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

National Institutes
of Health

NCI Appropriated Budget Trends

Total ARRA funds to NCI: \$1.26B



Applications for 2011

- FY11 President's Budget estimate (without ARRA bump)
 - 1,220 competing RPG awards
 - 7,278 estimated applications
 - 16.8% success rate
- ARRA bump in applications
 - 400 GO and Challenge Grants unfunded
 - 106 ARRA 2-year R01s
 - 7,784 possible applications (↑ ~500)
 - 15.7 % success rate

Preparing for the Fourth Quarter of FY 2010

- **FY 2010 is on track to close out, as expected — without major issues**
 - Approaching the fourth quarter, about 60 percent of the NCI research budget has been obligated
 - This is slightly ahead of where we were at this time last year

Preparing for the Fourth Quarter of FY 2010

- **FY 2010 is on track to close out, as expected**
 - **Approach about research obligations**
 - **This were**
 - **NCI's Executive Committee continues to prioritize funding decisions within budget constraints**
 - **Weekly budget meetings track spending and keep NCI on track for a balanced budget at year's end**
 - **EC traditionally holds a summer budget retreat; holding dates for new director**

Preparing for the Fourth Quarter of FY 2010

- Current estimate for FY 2010 competing RPGs is \$496 million
 - Nearly \$40 million more than FY 2009 and almost 10 percent of the budget
 - Payline = 15th percentile
- We have set aside \$203 million for RFAs, which is \$70 million more than last year

Preparing for the Fourth Quarter of FY 2010

- **\$317 million of ARRA funds still to be obligated, or about 25 percent**
 - **\$164 million in grants**
 - **\$148 million in contracts**

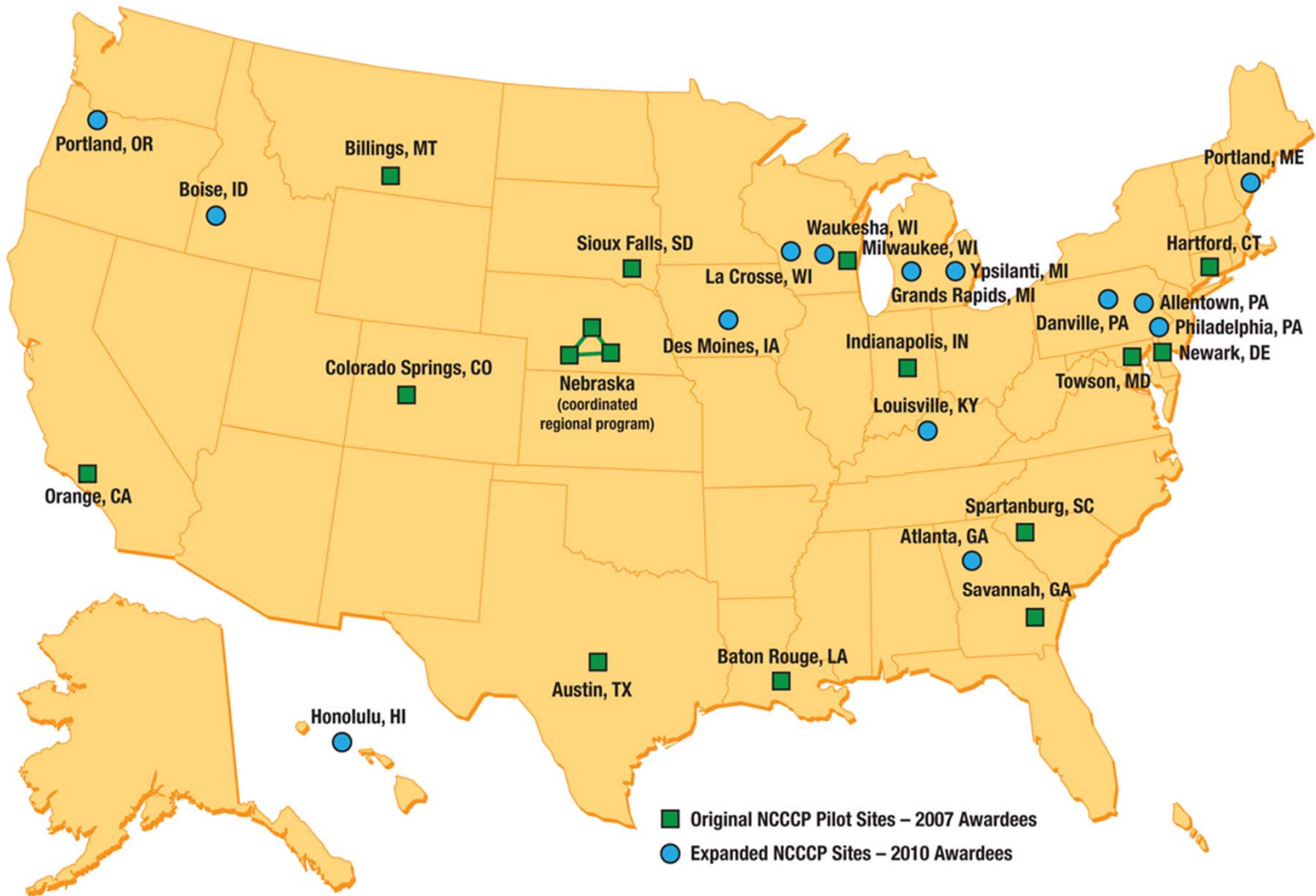


NCI's Investments

Despite below-inflation budgets, NCI has launched a number of important initiatives

- **Chemical Biology Consortium**
- **Functional Biology Consortium**
- **Physical Sciences-Oncology Centers**
- **Coordinating Center for Clinical Trials**
- **BIG Health Consortium**
- **Target Discovery and Development Network**
- **Advanced Technology Partnership Initiative**
- **Cancer Human Biobank (caHUB)**
- **NCI Community Cancer Centers Program**

NCCCP Sites



Notable NCCCP Achievements, 2008-2009

- NCCCP sites are regularly convening surgeons, medical oncologists, and radiologists to discuss cases and arrive at consensus on the best possible courses of treatment
- Easier access to NCI-sponsored treatment trials
- All sites are using a clinical trials screening accrual log
- Each site has developed an individual informatics strategy; many are adopting NCI's caBIG tools and resources for clinical trials and electronic cancer health records
- All NCCCP hospitals now have patient navigators
- All sites are assessing how to adopt NCI's Best Practices for Biospecimen Resources

NCI Programs with NCCCP Involvement

- NCI Cancer Centers Program
- Community Clinical Oncology Program
- Community Network Program
- Minority-Based Community Clinical Oncology Program
- Cancer Trials Support Unit
- Cancer Disparities Research Partnership
- Patient Navigation Research Program
- Cancer Information Service
- NCI Best Practices for Biospecimen Resources
- Cancer Biomedical Informatics Grid
- Centers of Excellence in Cancer Communications Research
- The Cancer Genome Atlas (caHUB)

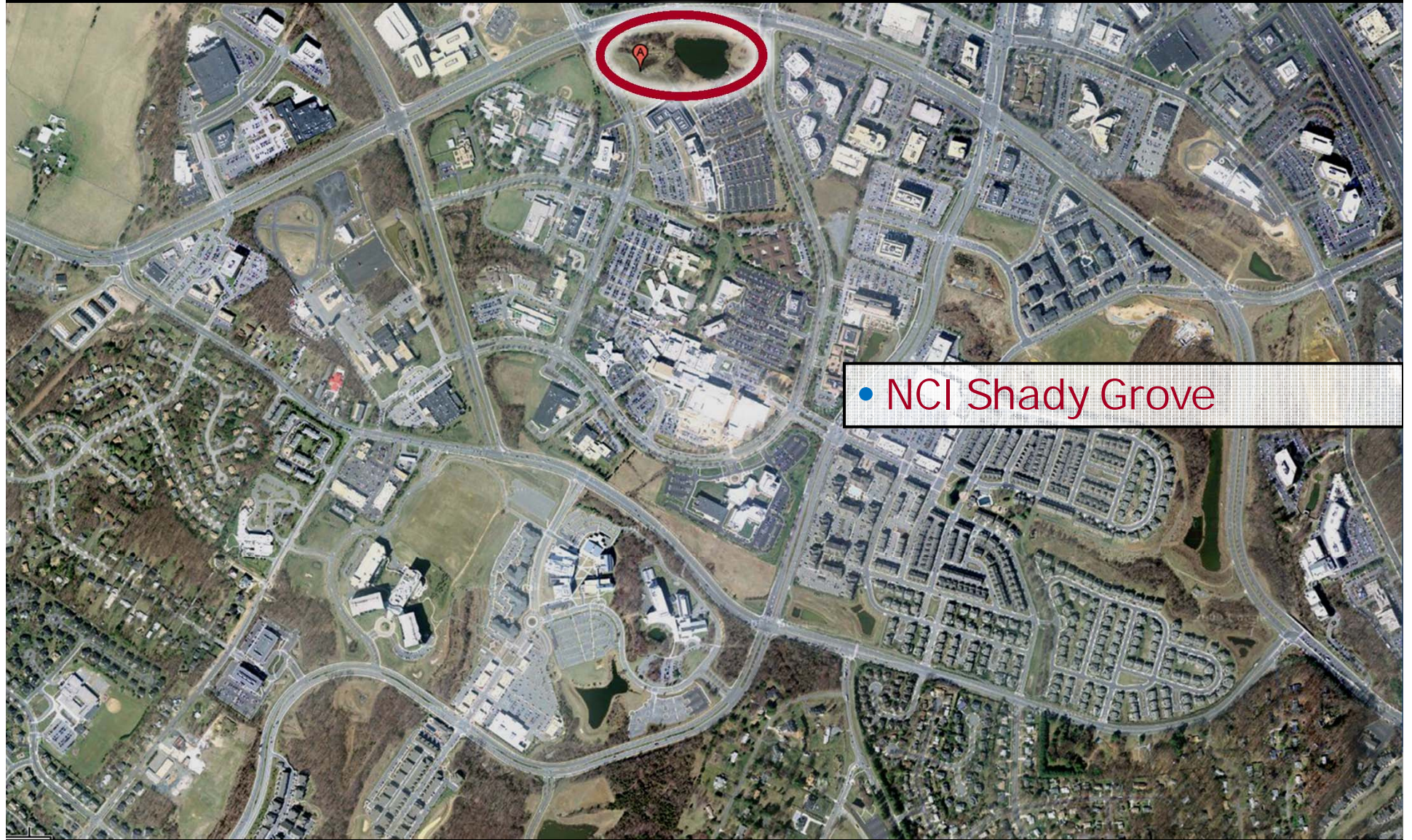
**Planning NCI's space
needs for the years
ahead.**

NCI Shady Grove

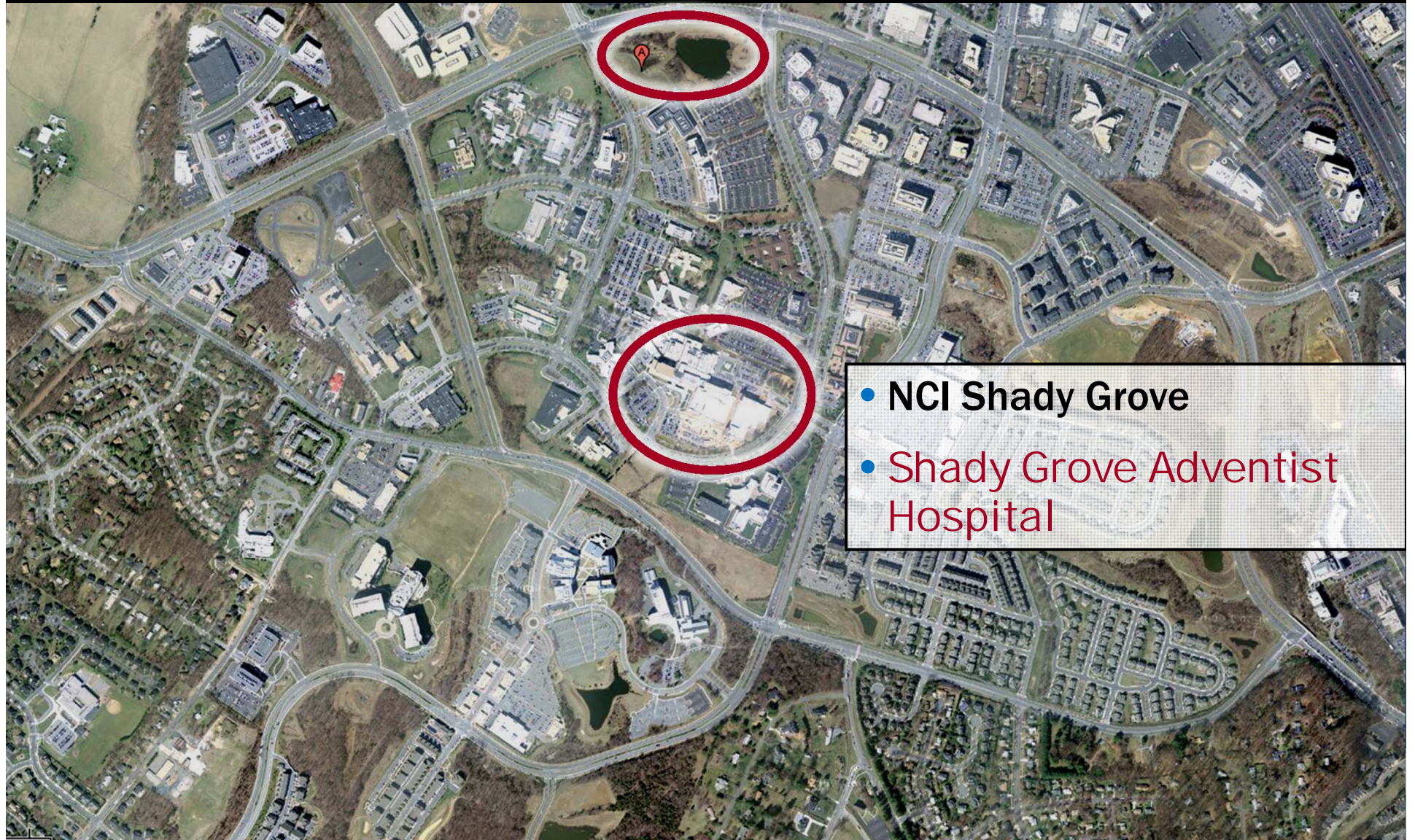


Selected after a rigorous, year long competitive bidding process conducted by the General Services Administration, in consultation with NIH and NCI

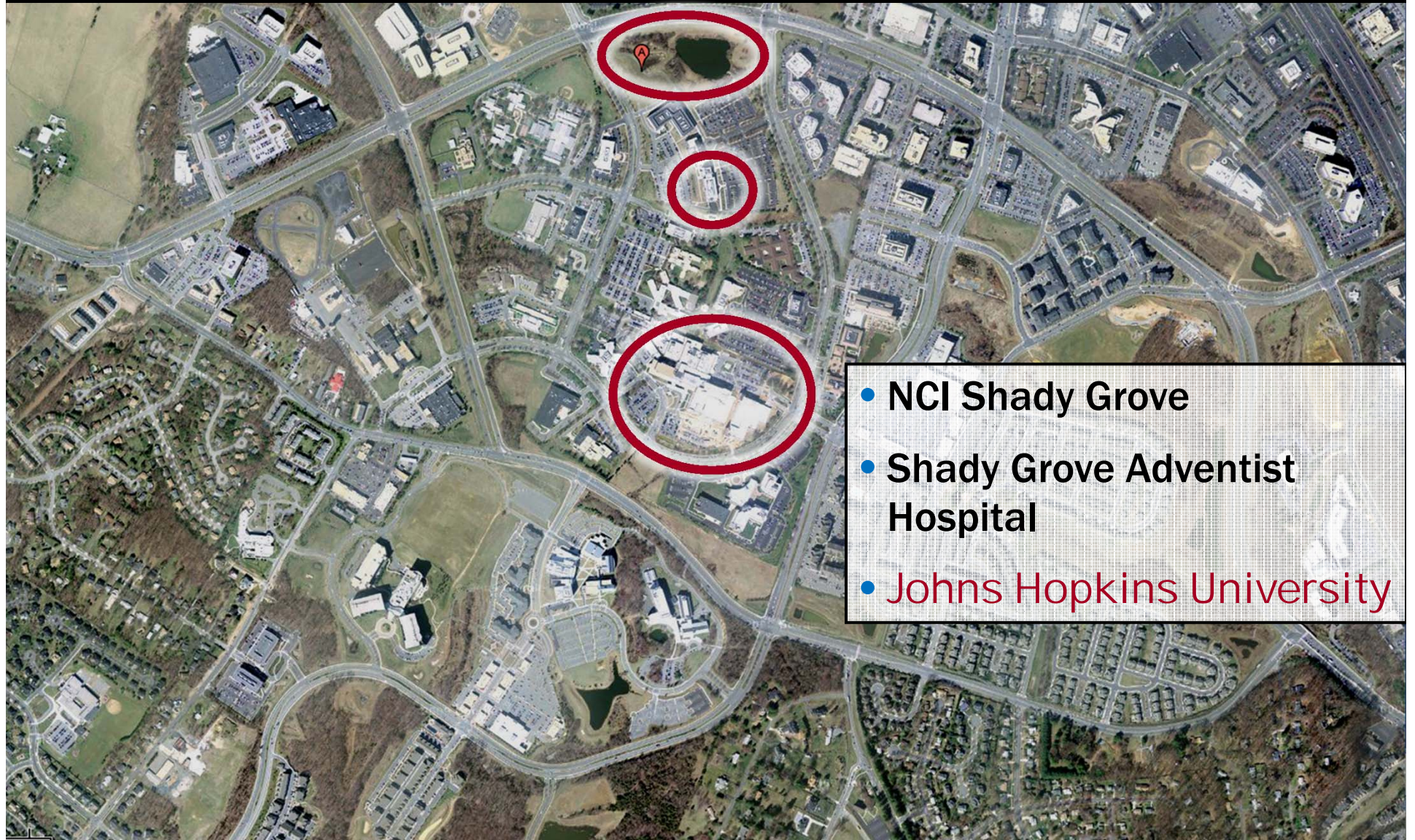
- **2 new custom-built, state-of-the-art buildings with 490,000 net square feet of usable space**
- **Able to accommodate ~2,400 staff members**
- **Leadership in Energy & Environmental Design (LEED) Silver Rating**
- **Move will take place in 2013, over a six-month period**



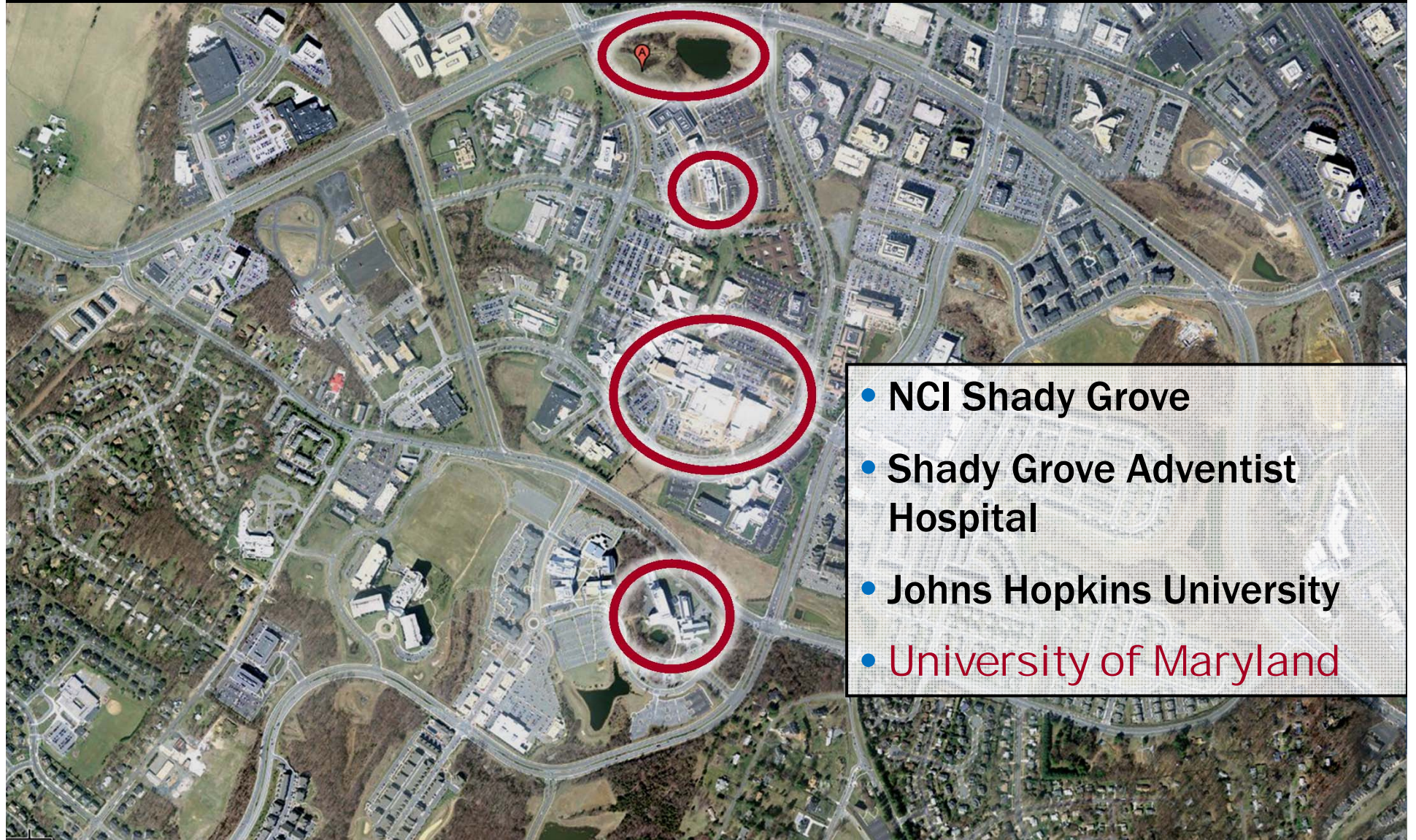
• NCI Shady Grove



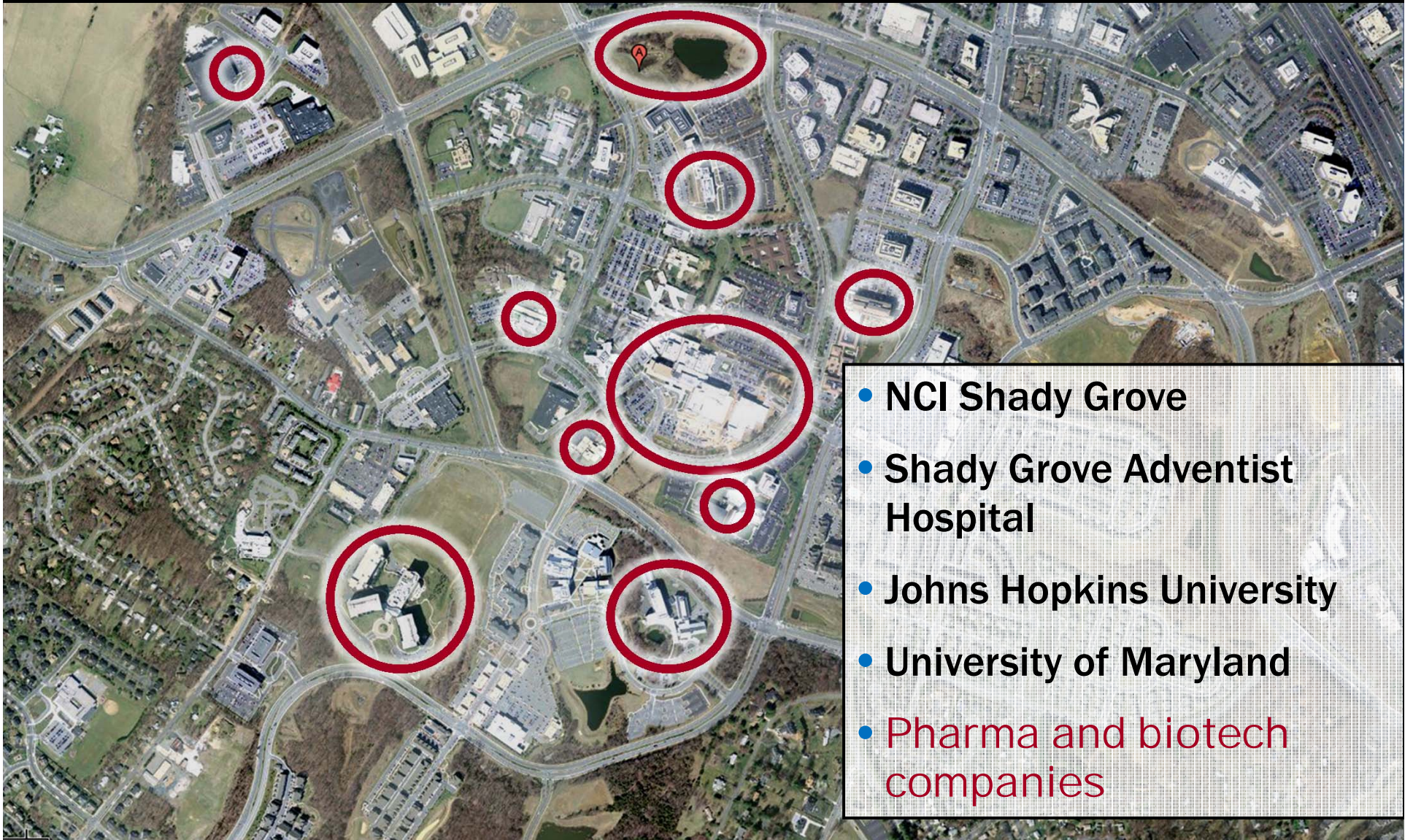
- NCI Shady Grove
- Shady Grove Adventist Hospital



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- Johns Hopkins University



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- Johns Hopkins University
- University of Maryland



- NCI Shady Grove
- Shady Grove Adventist Hospital
- Johns Hopkins University
- University of Maryland
- Pharma and biotech companies

**Meeting the increasing
need for public-private
partnerships.**

Advanced Technology Research Facility

- 330,000 square foot facility will contain:
 - NCI's Biopharmaceutical Development Program manufacturing facility
 - **NCI's Advanced Technology Program**
 - **Administrative offices**

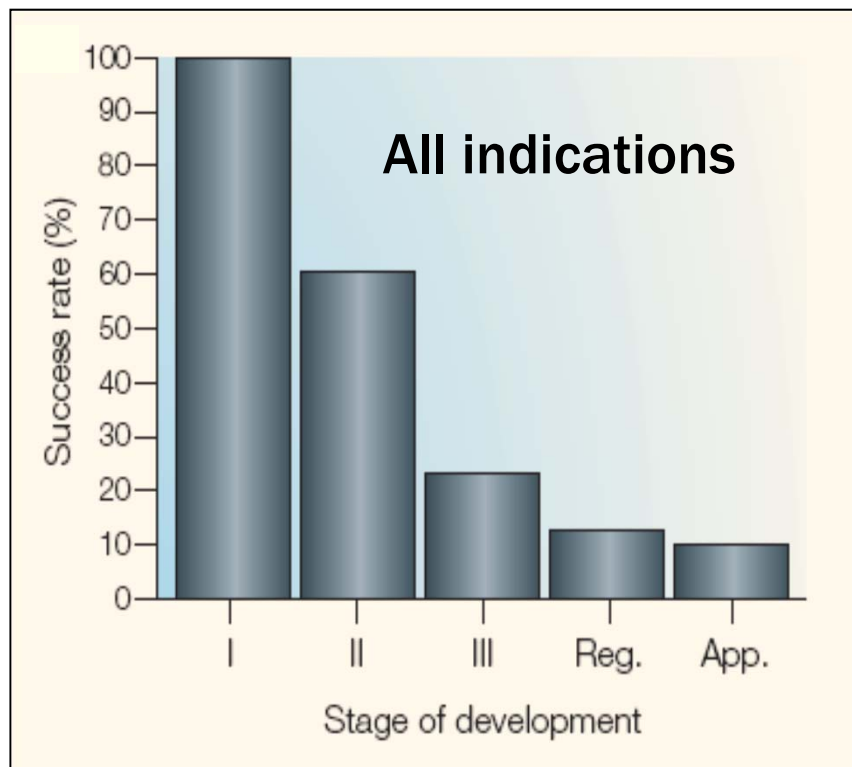


Advanced Technology Research Facility



**Presented the 2010
Economic Development
Award by the Maryland
Economic Development
Association**

Most Drugs Fail in Late Stages of Development, Particularly in Oncology



Rates of success for compounds entering first-in-man that progress to subsequent phase trials

- 70% of oncology drugs that enter Phase 2 fail to enter Phase 3
- 59% of oncology drugs that enter Phase 3 fail
- Late stage failure leads to enormous risk
- Failure is more often due to lack of efficacy than to toxicity

IOM Report

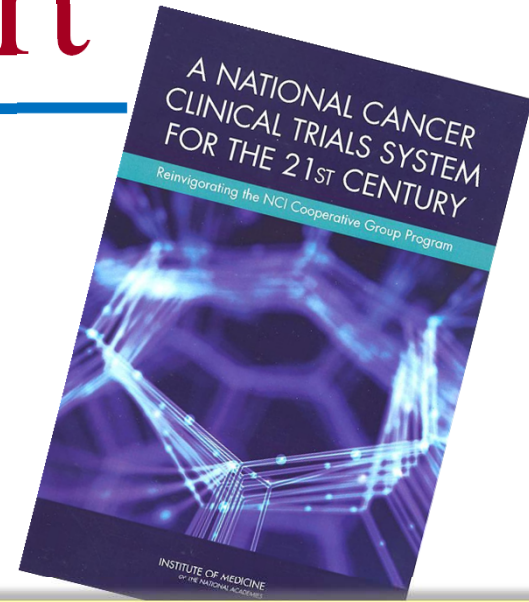
- “A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program”

- **Co-chairs: John Mendelsohn and Harold L....**

- “With many la... trials system... cumbersome... needs to be r... and improve... move beyond... academic, go...

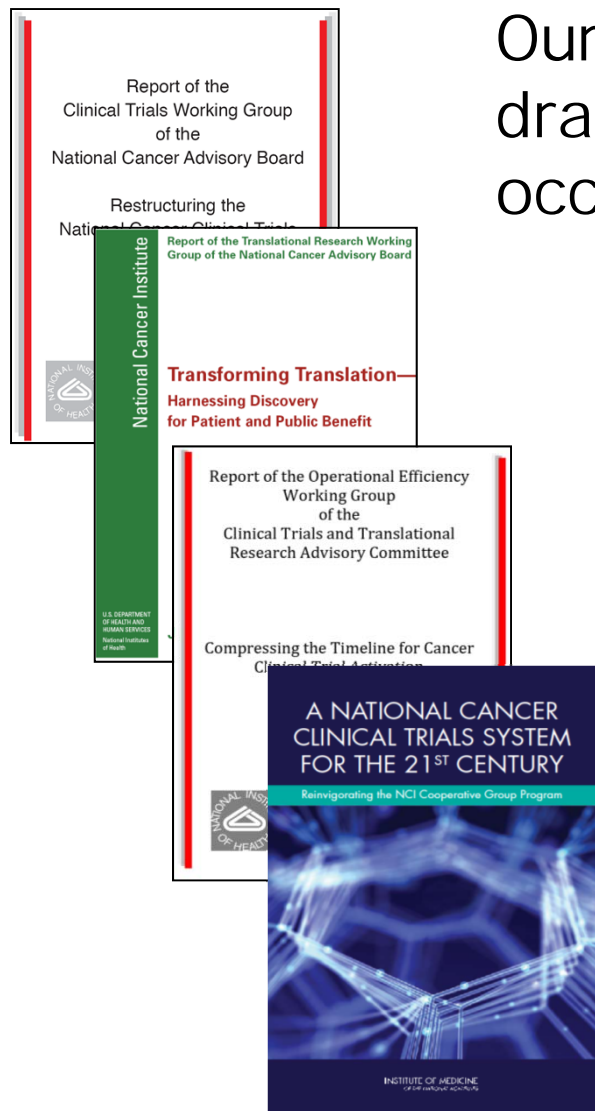
Four goals:

- **Promote consolidation and efficiency**
- **Incorporate innovation in science and trial design**
- **Provide adequate funding and support**
- **Incentivize participation by patients and physicians**



Changing the NCI's Clinical Trials System to Meet the Needs of the 21st Century

Our clinical trials system must reflect dramatic changes in cancer biology that occurred over the past 15-20 years



What do we need to change?

- Improve the speed and efficiency of the development and conduct of trials
- Incorporate innovative science and trial design into our studies
- Improve prioritization, support, and completion of trials
- Incentivize the participation of patients and physicians in clinical investigations

What have we changed?

- Resources for the development of predictive biomarkers
- Clinical trial prioritization
- Operational efficiency standards for trial development
- Regulatory & administrative support
- Modernized clinical trial IT infrastructure

Where do we go from here?

Mission of the NCI Experimental Therapeutics (NExT) Program

“To advance clinical practice and bring improved therapies to patients with cancer by supporting the most promising new drug discovery and development projects.”

“The NCI will partner with successful applicants to facilitate the milestone-driven progression of new anti-cancer drugs (small molecules, biologics) and imaging agents towards clinical evaluation and registration.”

<http://next.cancer.gov>

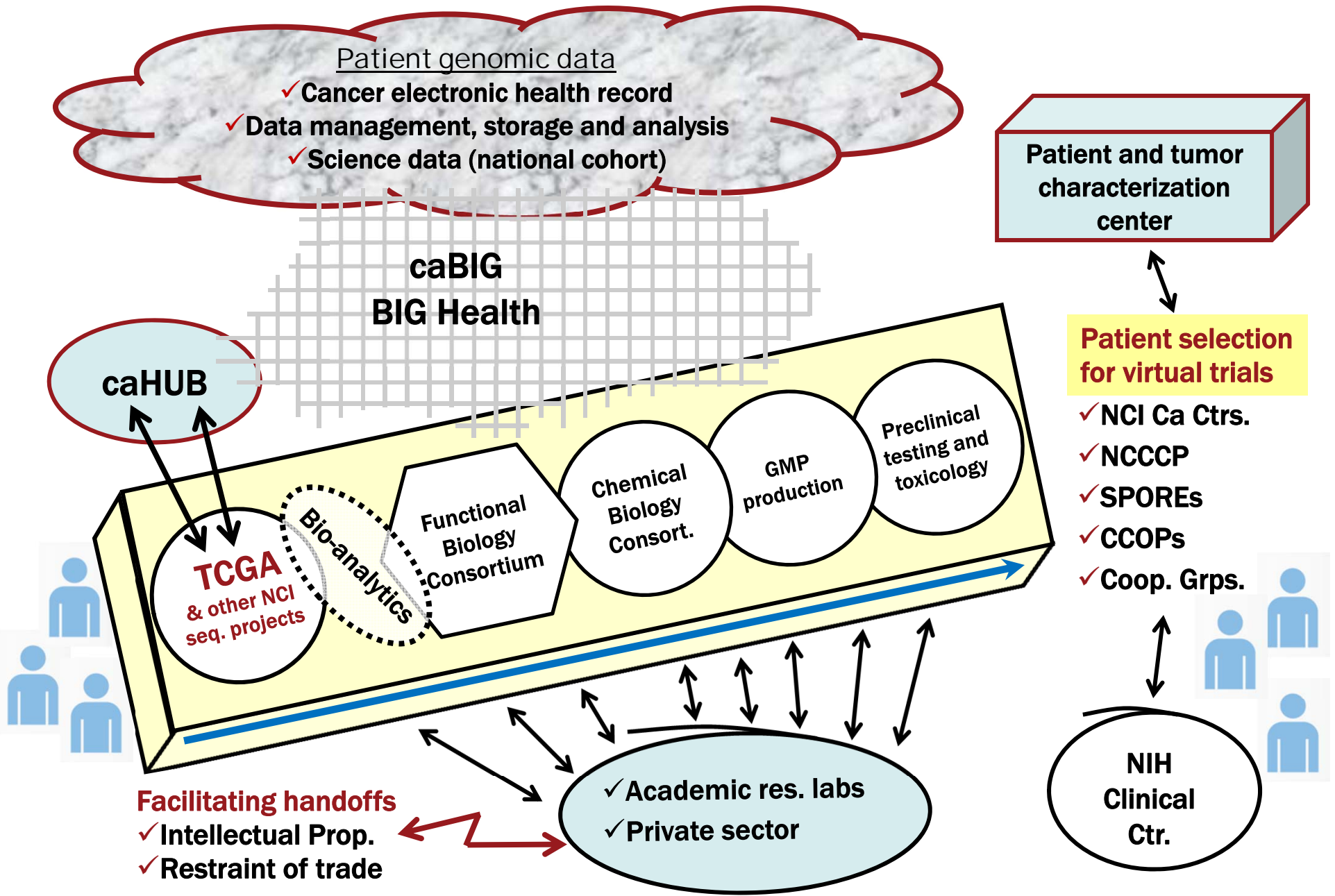
NExT Program

Merger of NCI drug and imaging agent development programs

- **Integration of PD-Biomarkers Program**
- **Creation of Chemical Biology Consortium**
- **Development of Functional Biology Consortium**

NExT Application and Review Process

- 4 rounds annually; completed review of 3 cycles
- Cycle one: 52 applications received
 - Discovery: 44 applications; 8 approved
 - Development: 8 applications; 2 approved
- Cycle two NExT & RAID: 53 applications
 - Discovery: 20 applications, 3 approved
 - Development: 33 applications, 6 approved
- Cycle three NExT: 23 applications
 - Discovery: 11 applications, 3 approved
 - Development: 12 applications, 3 approved



If we ask ourselves...
**“Where is the optimal
integration of molecular
cancer science and
clinical research being
conducted?”**



Single, national Cooperative Group trial structure?

- **NCI Cancer Centers**
 - Translational trials
 - Correlative science
 - SPOREs
- **NCI Clinical Center Cancer Program**
- **Patient Characterization Centers**
- **NCI Community Cancer Centers Program**
- **Community Clinical Oncology Program**
- **National clinical trial patient cohort???**



EC Scientific Retreat

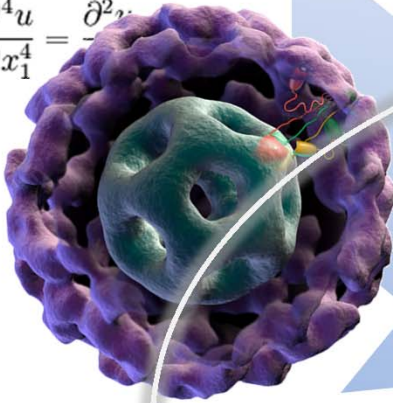
"Making
Personalized
Cancer
Medicine a
Reality What
Will It Take?"

[http://www.cancer.gov/
directorscorner](http://www.cancer.gov/directorscorner)



Computational biology/
subcellular imaging

$$\begin{aligned} \frac{\partial u}{\partial t} &= \frac{\partial u}{\partial x_1} + \frac{\partial u}{\partial x_2} \\ 0 &\Leftrightarrow \frac{\partial^2 u}{\partial x_1^2} + \frac{\partial^2 u}{\partial x_2^2} + \frac{\partial^2 u}{\partial x_3^2} = 0 \\ u &\Leftrightarrow \frac{\partial^4 u}{\partial x_1^4} = \frac{\partial^2 u}{\partial x_1^2} \end{aligned}$$



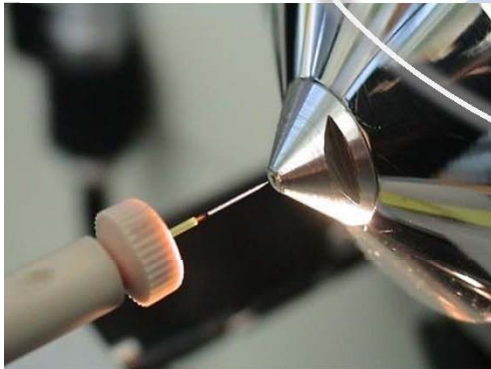
Somatic epi/genomics



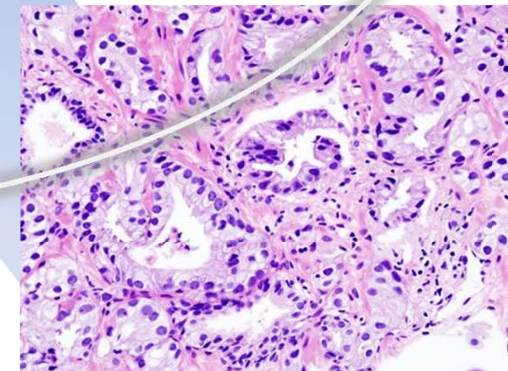
Germline susceptibility
(C-GEMS,
pharmacogenomics)



Integration –
from discovery
to therapy



Proteomics
Functional biology



Phenotypes

Messages from the EC Scientific Retreat

- Cancer must be analyzed as a **network of systems**; not a tissue-specific disease state
- **Multi-dimensional data sets** will be the rule; we need new tools to analyze those data that yields new insights
- **Drug and diagnostic development in an age of personalized medicine requires a new business model**
- **Teamwork is critical** and the barriers that impede teamwork need to be eliminated
- Resistance to change within the clinical and scientific cultures is impeding progress

Messages from the EC Scientific Retreat

- The field must embrace the complexity and heterogeneity of cancer
- Nanotechnology is driving revolutionary advances and will open new avenues of research
- There is a critical need for better incentives for collaboration and tissue collection

Challenges Ahead

- **NCI's ability to form public-private partnerships, particularly around drug development**

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- **Fostering innovative, collaborative scientific initiatives**

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- Reshaping clinical trials
- Increasing the base, to maintain momentum created by ARRA
- Fostering innovative, collaborative scientific initiatives
- **Balance good citizenship vs. leadership on the NIH campus**



www.cancer.gov

