

# The NCI-Frederick Advanced Technology Partnership Initiative (ATPI) and Advanced Technology Research Facility (ATRF)

A Briefing for:  
The National Cancer Advisory Board  
February 18, 2010



# Advanced Technology Partnerships Initiative (ATPI)

## Purpose:

To accelerate the delivery of **new products** to cancer patients - through the strategic application of **advanced technologies** and effective translational research **partnerships**



# The ATPI Justification

## **2004 – NCI Roundtable “*Leveraging Multi-sector Technology Development Resources and Capabilities to Accelerate Progress Against Cancer*” - Recommendations**

- Build cross-disciplinary collaborations and teams
- Institute standards to improve technology transfer and development of novel agents
- Develop cross-cutting technology platforms (bioinformatics, proteomics, nanotechnology, etc.)

## **2004 – FDA Report “Innovation or Stagnation; Challenges and Opportunity on the Critical Path to New Medical Products”**

- Cited an urgent need to improve the drug development process by enhancing collaboration between government, industry and academia

# The ATPI Justification (cont.)

## **2006 – GAO Report “*Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*”**

- Findings – the number of new drugs developed is not commensurate with level of research and development investment
- Some Major barriers cited -
  - Shortage of investigators trained in translational research resulting in a lack of understanding of how to translate discoveries into safe and effective drugs
  - Inability of drug sponsors to effectively utilize new technologies
- Solution – development of more effective collaboration between government, industry, and academic institutions

# The ATPI Justification (cont.)

**2006 NCI Strategic Plan** – *The NCI's success will depend on our ability to; 1) integrate our activities across a seamless continuum of discovery, development, and delivery and 2) partner with others to leverage resources and build synergy*

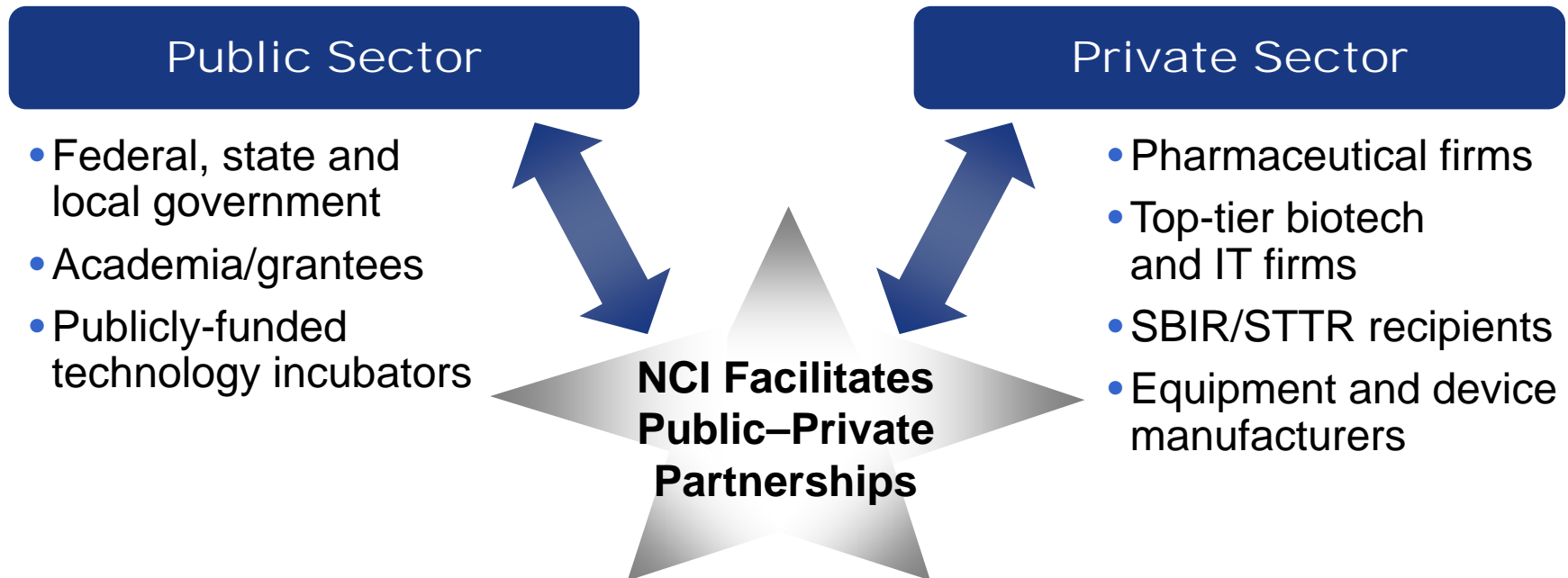
- Strategy 1.6 – Develop and utilize emerging technologies to expand our knowledge of the risk factors and biological mechanisms of cancer
- Strategy 3.1 – Actively move research advances forward by bridging gaps across the translational spectrum
- Strategy 3.2 – Promote collaborative multidisciplinary research - including the development of public-private partnerships to create access to advanced technologies and other resources
- Strategy 4.3 – Accelerate identification, development, and validation of potential targets and strategies for cancer treatment – including leveraging NCI resources to establish public-private partnerships to expedite the selection of agents for movement into the clinical setting

# The ATPI Justification (cont.)

## 2007 NCI Translational Research Working Group Report - *“Transforming Translation: Harnessing Discovery for Patient and Public Benefit”* – recommendations;

- Collaboration between NCI-funded researchers, industry, research foundations, academic institutions, and patients is fundamental to the success of translational research
- Such collaborations should be promoted by streamlining legal negotiations and building partnerships that leverage complementary skills and resources
- High-quality, cost effective core services, from molecular imaging to cGMP manufacturing, must be accessible to investigators
- Enhanced coordination across institutions and programs is needed to ensure cost effective services and to avoid duplicative infrastructure

# The ATPI Concept: Public-Private Partnerships



## Specific Areas of Partnership

- **Advanced technologies;** imaging, genomics, nanotechnology, *in silico* modeling, animal models, proteomics, bioinformatics,
- **cGMP capabilities:** product development and pilot-scale manufacturing
- **Clinical trials:** first-in-man or drug combinations
- **Biological and small molecules:** NCI serves as a resource to further develop lead molecules
- **Education:** training of integrated translational research teams
- **Beta testing:** testing and validation of new state-of-the-art equipment

# Timeline of the ATPI Concept

**2005: Presentation of draft concept to NCI Executive Committee (April)**

**2006: Evaluation of Alternatives and Development of Final ATPI Concept**

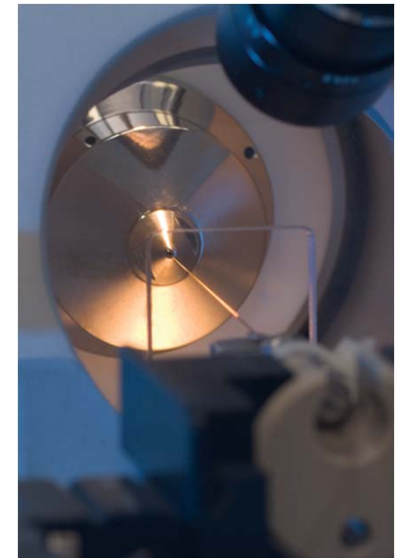
**2007: Formal Presentations to NIH Director (February/April)**

**2007: Briefing to HHS Assistant Secretary (August)**

**2007: Concept presented to the NCAB**

**2007- present:**

- Discussions with industry leaders
- Discussions with SBIR/STTR community
- Discussions with academic investigators





# NIH Director's Response to ATPI Briefing

## Dr. Zerhouni's Comments;

- He was supportive of the ATPI concept
- Initiative is “modest in scope” and “reasonable in cost”
- NCI-Frederick resources are unique and of high quality
- The NCI should proceed forward with the initiative by;
  1. further engaging industry to define partnerships that are “core themes” and “mission critical”
  2. evaluating potential expansion sites to facilitate the ATPI

# Industry Response to ATPI Briefing

- The government (NCI) is the logical organization to serve as the facilitator of these collaborations between government, industry, an academia.
- Co-location of partnership activities with NCI would be valuable to industry.
- Strong agreement that the ATPI would enhance both therapeutic and diagnostic agent development.
- There are more drugs in the pipeline than we can reasonably develop. We need to facilitate “go/no-go” decisions using collaborative expertise, advanced technologies, and pooled resources.
- Pre-competitive technology development will foster initiatives that one company alone cannot answer (e.g. biomarker development or development of systems to identify “failures” more quickly and at less cost).
- The ATPI offers the ideal mechanism where specialized teams can work on problems using the unique expertise and resources available through the NCI.
- Only the NCI can easily provide a means for testing combination therapies using agents from competing firms. This is one area where breakthroughs will likely emerge.

# ATPI – Implementation Approach

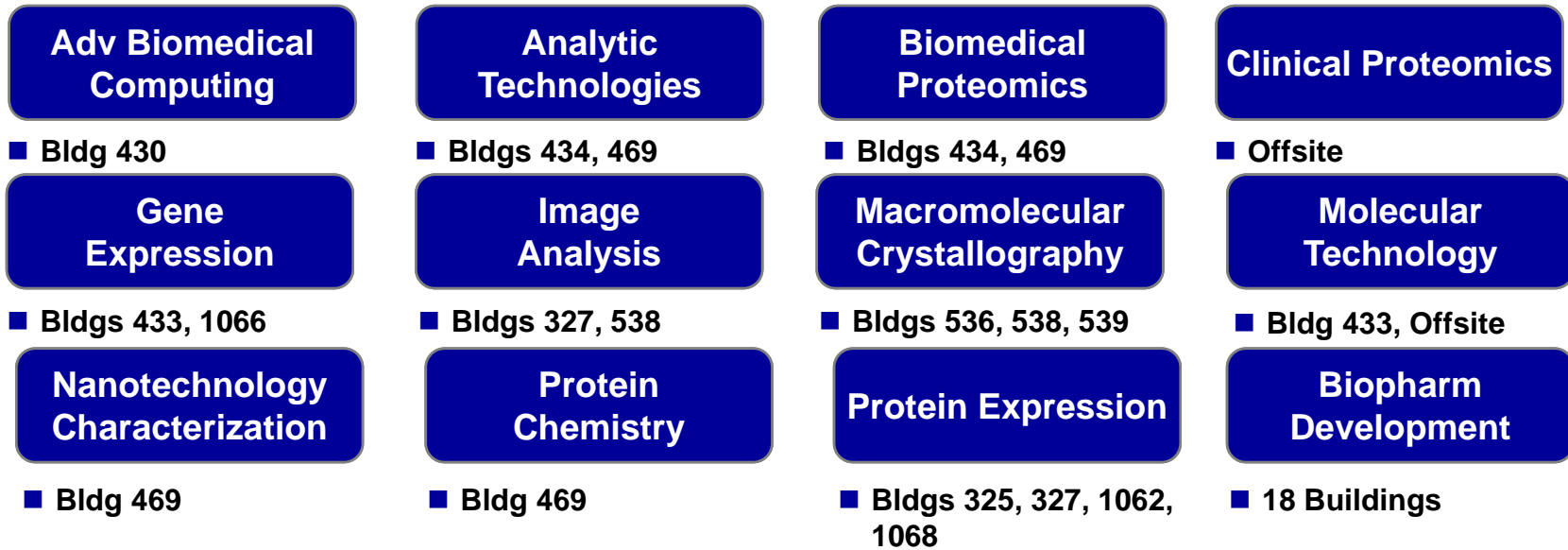
- **NCI takes a leadership role by**
  - Developing approaches to accelerate/facilitate the development of partnerships
  - Developing and dedicating facilities in support of the ATPI
- **Locate majority of ATPI support activities in a research park which would**
  - Encourage collaboration among partners
  - Facilitate shared resources and development of synergistic relationships
  - Facilitate training of a new generation of translational scientists
  - Provide space for a translation research “think tank”
  - Support co-location of a Higher Education Center
  - Support co-location of a Technology Incubator
- **Leverage NCI-Frederick special authorities and resources to facilitate partnerships**

# Why Not Use Existing NCI-Frederick Space?

- Of the 110 buildings at the NCI-Frederick 56% are more than 45 years old
- Only 6% are less than 10 years old
- 15% are trailers or leased buildings
- The space on the NCI-Frederick campus is already fully utilized meeting other NCI efforts
- Access by partners to shared space is restricted by the NCI-Frederick location at Fort Detrick
- Most research programs that would support the ATPI are spread out over multiple buildings



# Consolidating Advanced Technology Programs



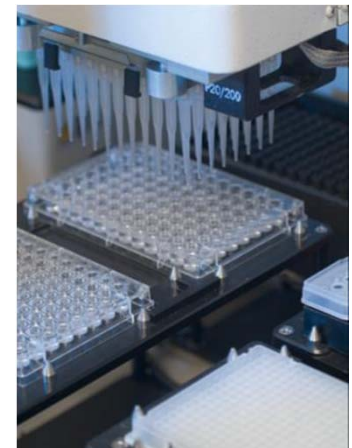
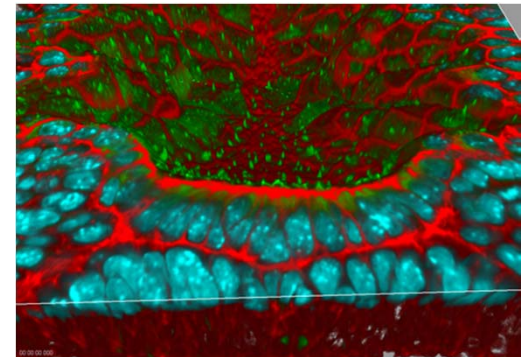
## *The Advanced Technology Research Facility (ATRF)*

- **Confluence of technologies from 34 buildings to a centralized location will promote efficiency, synergism, and collaboration**

# Programs and Technologies at the ATRF

**ATRF lab spaces designed to enable collaborative work with partners in the following areas;**

- **Genomics**
- **HTP screening and G3 sequencing**
- **Protein chemistry & proteomics**
- **Imaging (molecular/cellular/small animal)**
- **Nanotechnology**
- **High-performance computing and bioinformatics**
- **Biopharmaceutical development**
- **cGMP manufacturing**
- **QC/QA/ regulatory affairs programs**



# Advanced Technology Research Facility (ATRF)

- Lease 330,000-square-foot building with office and lab space
- 230,000 sf for existing science programs
- 100,000 sf for synergistic partnerships, training, conference space, beta test
- Maintain existing campus at NCI-Frederick
- Move ~370 existing employees to ATRF
- Hire ~200 additional employees during next 5 years
- FFRDC contractor leases building shell, builds out shell, acquires special-purpose equipment
- Government retains the right to purchase the building at any time

## Operating Budget Estimate

Landlord investment	~\$ 80M
SAIC-Frederick fit out	~\$130M
Annual operating budget: lease, utilities	~\$12M

# Status of the ATRF Project

- **Site Location**

- Riverside Research Park (RRP) in Frederick, MD has been chosen
- RRP total capacity – 177 acres – 1.5M GSF
- NCI Campus – 62 acres and up to 800,000 GSF

- **Lease**

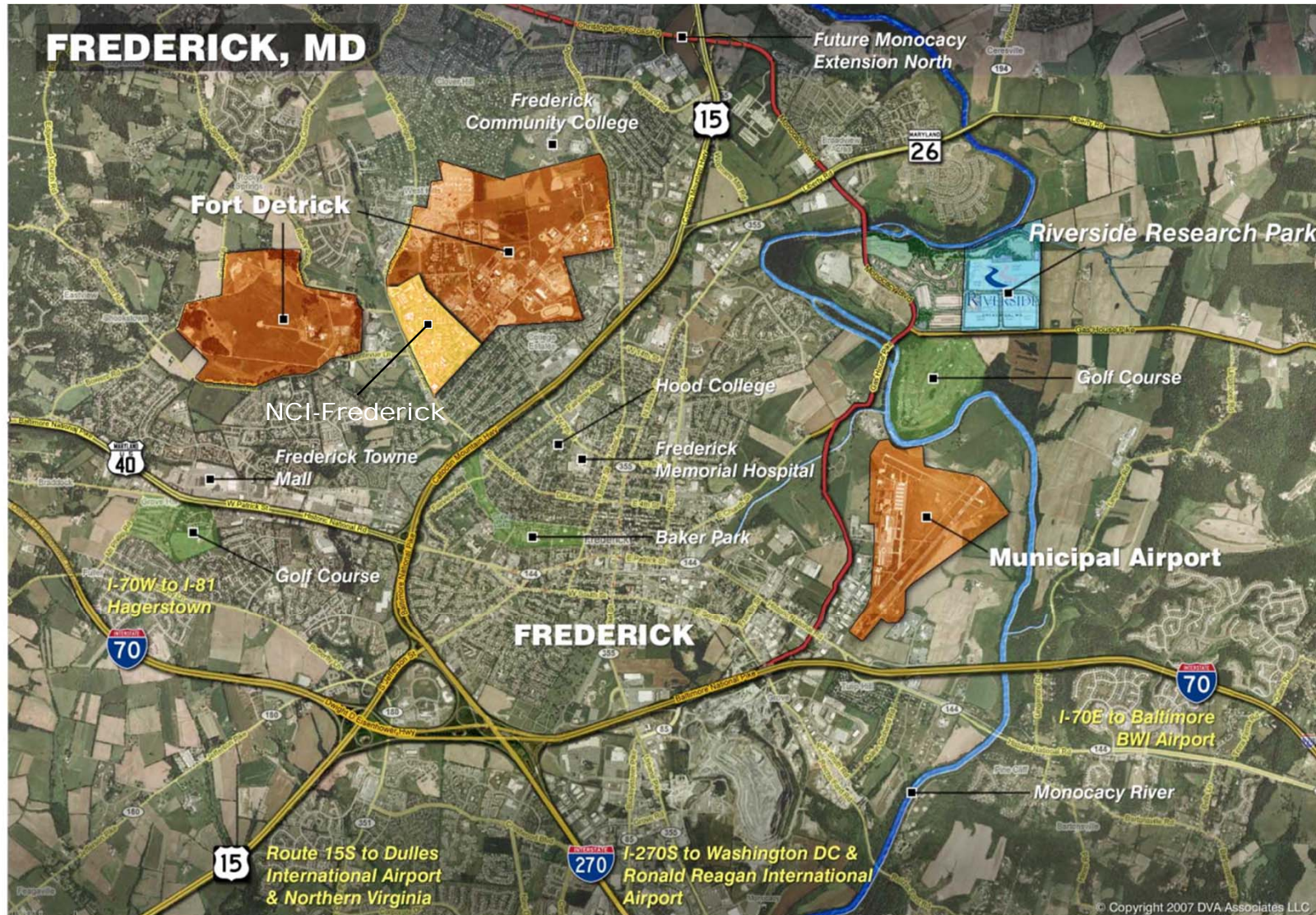
- FFRDC contractor has signed the lease with the developer
- 10-year base term with 2 10-year option periods
- Annual termination for convenience provisions
- Government retains the right to purchase at fair market value
- Lease is assignable to FFRDC successor contractor

- **Timeline**

- Base building construction underway and scheduled for completion September 2010
- Build out scheduled to begin September 2010
- Occupancy scheduled for late 2011 - early 2012



# Proximity of the ATRF to the NCI-Frederick



# Summary

- The NCI Advanced Technology Partnership Initiative (ATPI) will accelerate the delivery of new products to cancer patients - through the strategic application of advanced technologies and development of effective translational research partnerships.
- The Advanced Technology Research Facility (ATRF) will facilitate the development of these partnerships through the confluence of technologies that will promote efficiency, synergism, and collaboration.



# Discussion and Questions

How can the ATPI and ATRF more effectively serve the future cancer research needs of the nation - including the academic, industry, and small business communities?

