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

- **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
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

Public Sector

- Federal, state and local government
- Academia/grantees
- Publicly-funded technology incubators

Private Sector

- Pharmaceutical firms
- Top-tier biotech and IT firms
- SBIR/STTR recipients
- Equipment and device manufacturers

NCI Facilitates 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
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, and 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.
• 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.
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?