National Cancer Institute

Building Public-Private Partnerships

For the NCI-Frederick Advisory Committee

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Advanced Technology Partnerships Initiative

ATPI Mission: Accelerate Translational R&D in Cancer & AIDS

Origins

- Numerous studies by the NCI, FDA, and GAO in 2004–2007 highlighted the need to boost success in translational medical science through application of advanced technologies and improved public–private partnerships
- NCI developed the ATPI concept in 2007

Mission

To accelerate the delivery of new medicines to patients afflicted with cancer and AIDS through the strategic application of advanced technologies and effective translational research partnerships

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

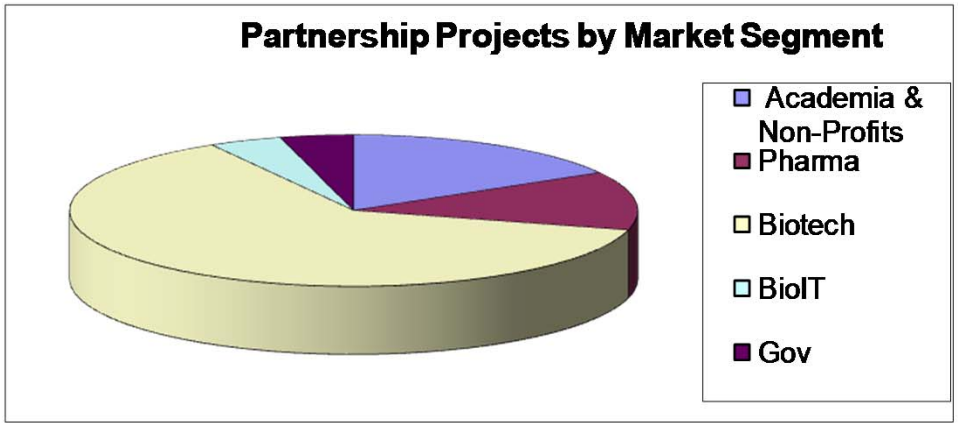
- **Advanced technologies; imaging, genomics, nanotechnology, *in silico* modeling, animal models, proteomics, bioinformatics**
- **cGMP capabilities: product development and pilot-scale manufacturing**
- **Clinical trials: first-in-man or drug combinations**
- **Biological and small molecules: develop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

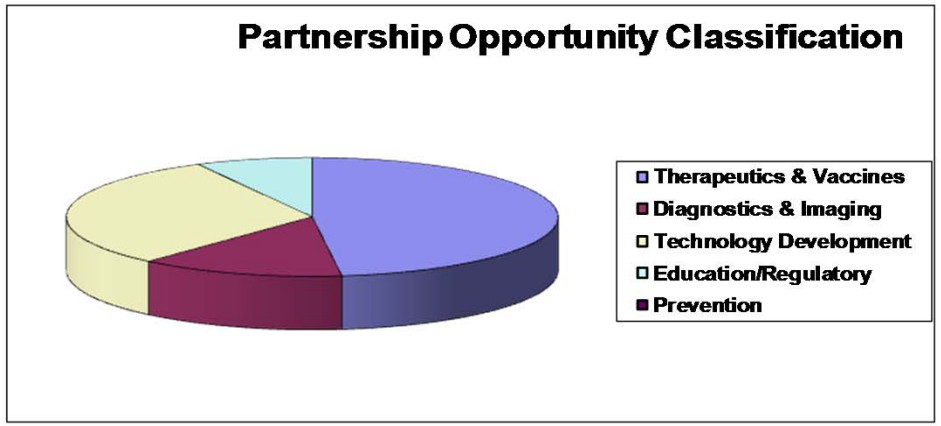
Partnerships Facilitated through NCI Mechanisms

Material Transfer Agreement (MTA)	• Research materials transferred (in or out); research plan • No fees; No IP; NCI can publish >90 days
β-Testing Agreement	• Technology development utilizing NCI resources • No fees; No IP; NCI can publish >90 days
Collaboration Agreement	• Research materials transferred (in or out); research plan • Both contribute intellectually; no $$ to NCI • Useful for proof-of-concept with minimal IP concerns
Cooperative Research & Development Agreement (CRADA)	• R&D collaboration both partners contribute intellectually • Both contribute resources; can include $$ to NCI • Partner has first right to license CRADA inventions
"Umbrella" CRADA	• Same as above, useful for multiple lab projects
Clinical Trial CRADA	• Similar to CRADA above, specific to clinical trial R&D

ATPI: Agreements Summary Aug ’08—Dec ’11

110 Partnerships—Majority with Biotechs





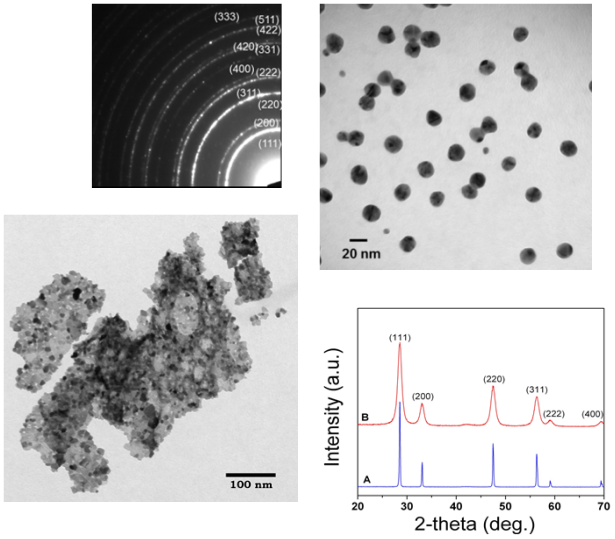
- **68** Material Transfer Agreements (MTA)
- **28** Collaboration Agreements
- **6** β- Testing Agreements
- **7** NCI CRADAs
- **1** NCI Umbrella CRADA

Inter-Agency Agreement : NIEHS

Plans for ATRF Co-location Underway

- Interagency agreement with NIEHS to provide physicochemical characterization for nanomaterial risk/hazard assessment studies.
  - NCL provides key infrastructure support for NIEHS' U01/U19 nanotechnology centers of excellence
  - NCL is characterizing 12 nanomaterials/year, including cerium dioxide, nanosilver, and carbon nanotubes.
  - $1M/year, starting in 2010. Initial agreement for 2 years, with the possibility 3 years extension.
    - This work supports 5 NCL FTEs.

NIEHS
National Institute of Environmental Health Sciences



Collaboration Agreement : Sporian Microsystems and FDA

FFRDC Alliance Translates Lab Unit into Field Prototype

SPORIAN MICROSYSTEMS, INC

Optical-electronics and device engineering

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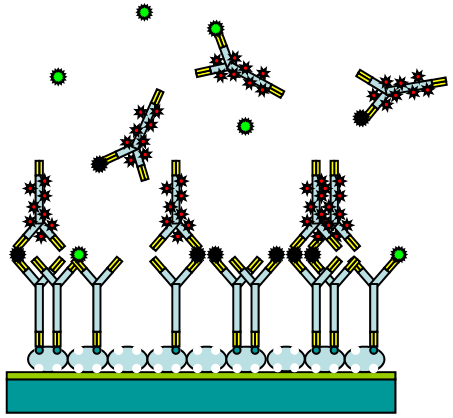

Assay reagent characterization and qualification

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FDA

Field-based assay expertise and applied testing

Proof-of-Concept HIV detection assay for testing in remote regions

FFRDC Partnering Authority - CRADAs

Cooperative Research and Development Agreements (CRADAs)

- Make Government facilities, intellectual property, and expertise available for collaborative interactions to further the development of scientific and technological knowledge into useful, marketable products

- Appropriate where collaborators make significant intellectual contributions to the research project or contribute research or materials not otherwise available to the NIH

- NIH Laboratory can contribute personnel, services, facilities, and equipment, with or without reimbursement; but not funding

- A Materials CRADA (m-CRADA) involves the transfer of proprietary material to the NIH laboratory where no collaborations is intended

Source : NIH Office of Technology Transfer website

NCI-F : CRADAs only through the NCI

SAIC-F scientists can enter into external CRADAs only through NCI processes using NCI agreements. This introduces certain NIH Policy-driven limitations :

- **Scope**
  - CRADAs for research and development
  - SAIC-F scientists can be Principal Investigators on a CRADA collaboration only with special individual approval by NCI
- **Timing**
  - OTT estimates an average of 4 to 8 months to negotiate and execute a CRADA, with more than 8 separate approval steps
- **Intellectual Property rights**
  - Collaborator is granted an option to negotiate a non-exclusive or exclusive commercial license
    - Terms not pre-determined

CRADA : General Electric

Move Novel Cancer Diagnostics to Clinic

- Pre-clinical Characterization of General Electric's Nanoparticle-based Diagnostics Imaging Agents
- First NCI CRADA with SAIC-F lab director approved as Principle Investigator (Contractor P.I.)
- Research plan:
  - Leverage NCL assay cascade and imaging knowledge
  - Evaluate feasibility of GE's proprietary nanoparticle diagnostic imaging agents

Partnership established 2008, extended in 2011 to new agents

Umbrella-CRADA : Amplimmune

Accelerating Therapeutics to Clinic

"We look forward to collaborating with investigators at NCI and feel that these collaborations will have a significant impact on accelerating development and advancing AMP-224 and AMP-110 into the clinic…"

Michael Richman, President & CEO
Amplimmune, Inc.
NCI/Amplimmune Press Release, October 2009

CRADA est. with NCI
August 2009

→ Collaborative cancer modeling/MOA studies

→ Amplimmune signs WW clinical dev. agreement August 2010

gsk GlaxoSmithKline

NCI / Amplimmune Umbrella-CRADA:
Using Internal Expertise to Explore MOA

Amplimmune

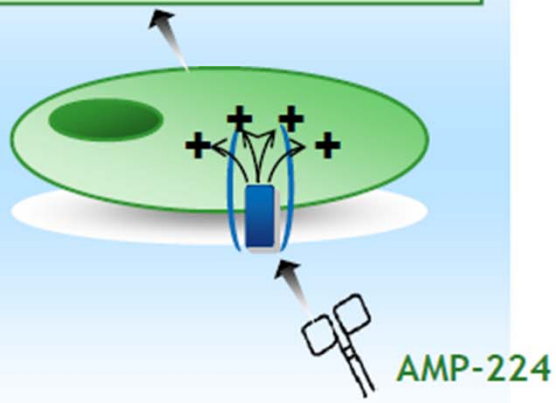
Novel Class of Protein Therapeutics: New Mechanisms of Action

Restoring Immune Function

Cancer/Infectious Disease

AMP-224

- Restores T Cell Function
- Kills Tumors/Treat Infectious Diseases
- Induces Memory Responses

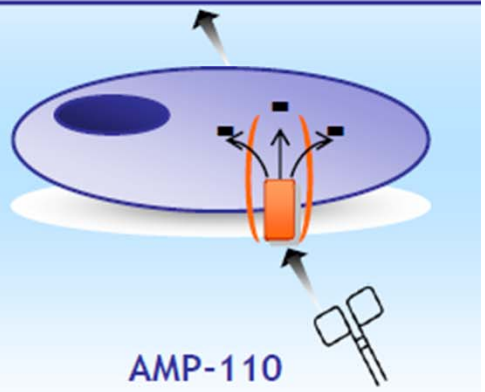


Attenuating Immune Response

Autoimmune/Transplantation

AMP-110

- Inhibits Inflammatory T Cells
- Promotes Treg Function
- Alleviates Autoimmune Disease



Information Provided by Amplimmune, Inc., JP Morgan Conference 2012

NCI/Amplimmune Umbrella-CRADA Partnership: Numerous Studies Performed to Accelerate Pre/Clinical Development

Amplimmune

Contribution of the NIH to Amplimmune's product development

- *As a result of our collaboration with the NIH/NCI through our broad CRADA, Amplimmune was able to test its product candidates in otherwise inaccessible infectious disease models and test novel therapeutic combinations*
- *In particular, based on combination therapy with a peptide based cancer vaccine (in collaboration with Samir Khleif) we were able to refine our understanding of the mechanism of AMP-224*
- *This led to the co-submission of manuscripts to JI that are under review:*

Treatment with CTX + B7-DC Ig Promotes Tumor Eradication Via A Novel PD-1 Targeted Mechanism

Shannon A. Marshall, Susannah D. Barbee, Monchou Fann, Thomas J. O'Neill, Karla Maloveste, Sarah Flies, Rong Zeng, Leighton Hyde, Nathanial Macapagal, Erika McAfee, Sharon Polidoro, Paul Renaut, Jean N. Welch, Pauline Wong, James Bingham, David Fischer, Rena May, Linda Liu, Jeffrey Stavenhagen, Lieping Chen, Drew Pardoll, and Solomon Langermann

B7-DC-Ig enhances vaccine effect by a novel mechanism dependent on T cell subsets PD-1 expression level

Mikayel Mkrtichyan , Yana G. Najjar , Estella C. Raulfs , Shannon Marshall, Linda Liu, Solomon langerman, Geoffrey Guittard, Laurent Ozbun, Samir N. Khleif

Expanding the Partnering Base
FFRDC CRADA opportunities

- **FFRDC's are permitted by federal law to have their own CRADA programs ("Contractor CRADA")**
  - Enables CRADA directly between contractor and partner
- **CRADAs are widely utilized by DOE FFRDCs to expand access to their technology and know-how**
- **Unlike DOE FFRDC's, SAIC-Frederick has no independent CRADA program**
  - Determination of Exceptional Circumstance (DEC) under the Bayh-Dole Act conveys all intellectual property developed by SAIC-F to the government, due to the exceptional access to specialized government programs conveyed by the FFRDC contract
    - SAIC-F cannot assign IP to any party other than the Government, as an independent Contractor CRADA would require

NCI-F Contractor CRADA

An independent contractor CRADA program will expand the impact of the FFRDC on the biological understanding, prevention, diagnosis, and treatment of cancer and AIDS

- **Key issues to address**
  - Amend the DEC and OTS contract to enable SAIC-F to independently negotiate and manage CRADAs and CRADA-subject inventions
  - Establishment of processes to support new agreements
    - Contracts, Workflow, IP, Funding, etc.
    - Build off of DOE FFRDC best practice
- **Status**
  - DEC Amendment under review within NIH Office of the Director
  - Work flow proposal and draft CRADA templates submitted to the NCI
  - Contract modification drafted and ready for execution following the approval of the DEC Amendment

Contractor CRADA
Key anticipated features

- **Support for ongoing government programs under FFRDC OTS contract always has priority**
  - Excess or collaborator-funded new capacity available for contractor CRADAs
- **Use full CRADA authority under CRADA statutes**
  - CRADAs for Research, Development, and Testing collaborations
  - "M-CRADAs" for evaluation of proprietary partner materials, AIDS testing kits, etc.
- **Intellectual property rights**
  - SAIC-F is the custodian of joint or sole IP emerging from the CRADA
  - Streamlined assignment of exclusive commercialization rights
  - Any royalty streams support FFRDC R&D efforts
- **Processes**
  - Focus on speed
  - Local government review
    - Verify excess capacity and alignment of workplan with NCI mission

Contractor CRADA
Key Benefits to NCI-F

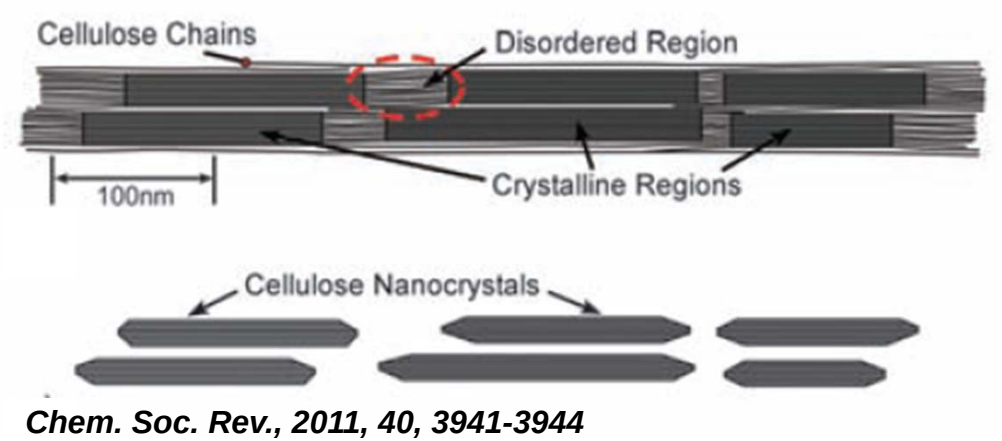
- Expands extramural and commercial access to FFRDC science, technology, and expertise with cost recovery capabilities
- Enables streamlined management of external collaborations
- Enhances the branding, recognition, and implementation of the unique capabilities of the Advanced Technology Research Facility and facilitates bringing in external partners
- Supports the Oct 28, 2011 Presidential Memorandum : "Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses"

New Partnerships Under Discussion

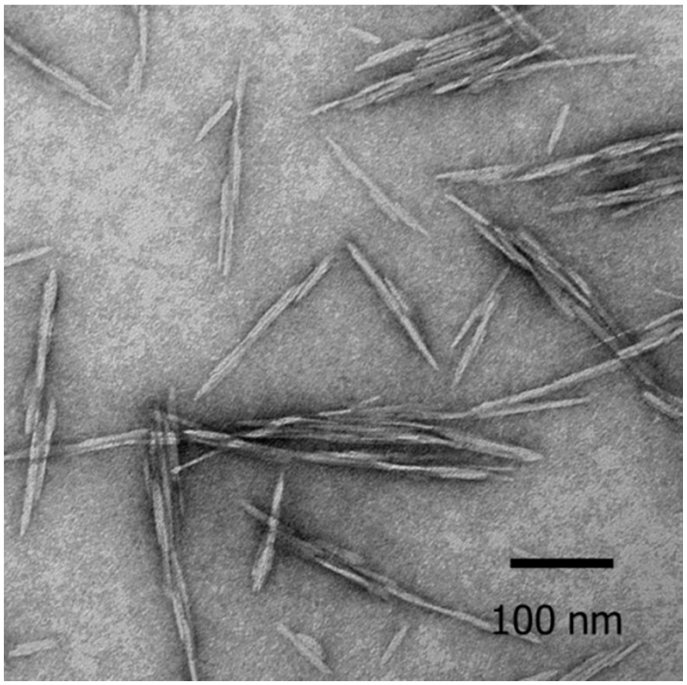
Contractor CRADA is Likely Mechanism

Partner	Project(s)	Business Development Stage
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.	Nanotechnology mAb therapeutics and assay development	30%
Fluidigm	Genome sequencing/expression array platforms for cancer biomarker applications	40%
Forest Service U.S. Department of Agriculture	Nanocellulose consortium seeking NCL co-development for production and testing	30%
sdix	Antibody engineering co-development platform and testing (ACL/clinical proteomics)	20%
FITC Frederick Innovative Technology Center, Inc.	• Medigen viral vector gene delivery tech • Feldan Bio, Inc. interested in BDP access partnership	40%

Nanocrystalline Cellulose (NCC)



Chem. Soc. Rev., 2011, 40, 3941-3944



Micrograph from ATP's Electron Microscopy Lab (EML)

- **Nanocrystalline form may be a "green" alternative to carbon nanotubes (CNTs)**
  - NCC has 18X the strength of titanium, stronger than Kevlar
- **It's a "natural product"**
  - Originates in the pulp/paper industry
- **Potential applications in a wide variety of products**

NCC Potential Collaboration

"Technical Association of the Pulp and Paper Industry."

– **Technical Association of the Pulp and Paper Industry (TAPPI) approached SAIC-F for**:
  - NCC characterization
  - Exploration of safety issues
  - Identification & evaluation of more efficient cellulases for production

– **Advanced Technology Program capabilities**:
  - Electron Microscopy Lab is performing imaging/characterization
  - The Nanotechnology Characterization Lab within ATP is conducting toxicity/safety testing
  - Protein Expression Lab is evaluating enzymes for NCC production

NCL= Nanotechnology Characterization Lab;
PEL = Protein Expression Lab;
EML = Electron Microscopy Lab;

Building Public-Private Partnerships
Additional Outreach Activities

• Global Connect Summit	Dec- completed
• Intramural Retreat	Jan – completed
• Drug Delivery Partnerships	Jan
• Pharma World Innovation Congress	Feb
• Oncology Global Partnering Congress	Feb
• FFRDC Capabilities brochure	Mar
• External-Facing Website	CRADA approval
• *Julie Hartman (NCI) – presentation to follow*	
• NCI-F “Branding”	?
• *At Discussion session today*	

Questions to the NFAC

- Does the planned Contractor CRADA and outreach activities meet your expectations to expand partnering with the FFRDC?
- Is there anything we can do to enhance the impact of the contractor CRADA for partners?
- Is there anything we can do to enhance the impact of our external-facing website?