Technology Transfer and its Role in Advancing NCI's Objectives for IMAT

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Overview

- Use of technology transfer to achieve IMAT oriented goals
- NIH policy considerations for IMAT grantees
- A Few IMAT-sponsored accomplishments

NCI's Goals for IMAT

Develop and carry out pilot applications of novel technologies that will enable the molecular analysis of cancers and their host environment.

The IMAT Program

The IMAT Program was designed with three objectives:

- **To focus innovative technology development efforts on the field of cancer**
- **To solicit highly innovative technology development projects from the scientific and medical communities**
- **To accelerate the maturation of meritorious technologies from feasibility through to development and/or commercialization**

Therefore, proper attention to technology transfer (by the NCI and by IMAT grantees) is paramount in order for the IMAT program to meet these objectives.

Technology transfer to advance the IMAT mission

Publishing of research findings is at its core the most common modality for transferring technology; other ways include:

- Patent protection
- Exchanges of information by way of Confidentiality Agreements (CDAs)
- Exchanges of materials by way of Material Transfer Agreements (MTAs)
- Collaborations with academic/industry partners (sponsored research agreements)

What is the Output?

- Information
- Research tools
- Platforms with many potential applications
- Commercial products for research use
- Commercial products with clinical applications, e.g., diagnostic/prognostic

Potential challenges encountered by IMAT investigators

- Problems with patenting due to poor documentation or public disclosure
- Coordination among multiple collaborating institutions
- Investigator concerns about licensing of invention to company:
  - Loss of control/participation in development
  - Freedom to operate for future projects
- Licensee “sits” on technology and fails to meet critical milestones
- Early stage technology will require the interaction of multiple players (academic & commercial) to advance the technology to a useable platform for commercial development
- Financial and regulatory (product development) concerns

NIH Funding Requirements and their relevance to IMAT

- Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (1994)
- Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts (1999)
- NIH Data Sharing Policy (2003)
- NIH Policy on Sharing of Model Organisms for Biomedical Research (2004)

Sponsored Research Agreements Policy

Provide grantees with issues and points to consider in developing sponsored research agreements with commercial entities, where such agreements may include research activities which are fully or partially funded by NIH.

The intent is to assist grantees in ensuring that those agreements comply with the requirements of the Bayh-Dole Act and NIH funding agreements.

- Basic principles of academic freedom
- Disseminate research results
- Promote utilization of technology

Sharing of Biomedical Resources Policy

- **Principles:**
  - **Academic freedom/publication**
  - **Appropriate implementation of Bayh-Dole**
  - **Minimize impediments to research**
  - **Disseminate research resources (research tools)**
- **Guidelines**
  - **Specific suggested language**
- **http://ott.od.nih.gov/NewPages/RTguide_final.html**

What is a “Research Tool”

- Is it primarily useful as a tool for discovery or as an FDA-approved product (or integral component of said product)?
- Is it readily useable or distributable as a tool or is private sector involvement necessary as the most expedient means for developing or distributing this resource?

Research Tool Guidelines

- Unique research resources arising from NIH-funded research are to be made available to the scientific research community
- Obligations to other sources of funding of projects in which NIH funds are co-mingled are to be consistent with the Bayh-Dole Act and NIH funding requirements.
- Exclusive licenses for research tools are acceptable for:
  - Diagnostic and therapeutic uses as long as research uses remain available
  - Research uses when licensee agrees to make the research tool widely available to researchers

Data Sharing Policy

- Timely release and sharing of final research data from NIH-supported studies for use by other researchers no later than acceptance for publication of main findings
- Required for investigator-initiated applications with direct costs more than $500,000
- Must address data sharing in applications and explain any limitations in data sharing plans
- Data sharing may be limited by: (1) institutional policies, local IRB rules, and local, state and federal laws/regs; and (2) the need to protect patentable and other proprietary data, including data subject to third party restrictions
- http://grants.nih.gov/grants/policy/data_sharing/

Model Organism Sharing Policy

- Covers all projects that produce or may produce model organisms, regardless of the amount of the budget
- PIs submitting an NIH application (including competing renewals) are expected to include a concise plan addressing the timely distribution of organisms and resources, unless the proposed research will not generate new model organisms and related resources, OR state appropriate reasons for why such sharing is restricted or not possible.
- Model organisms include but are not restricted to mammalian (e.g., mice) and non-mammalian (e.g., zebra fish) models
- This policy only applies to non-human model organisms. Other than established cell lines, human specimens would require informed consent. This policy does not apply to human cells that are not commercially available.

NCI IP Management Plans

- To help address some of the IP challenges of NCI-funded research, NCI now requests when appropriate that grant applicants submit IP management plans.
- Purpose is to ensure that applicant investigators work with tech transfer offices & sponsored research offices to think through potential issues prospectively.
- http://ttc.nci.nih.gov/intellectualproperty/sample.php

NCI IP Management Plans for IMAT

- Address coordination of patent prosecution and licensing if necessary to enable licensee to access IP to take product to market
- Suggested strategies provided in RFA
- Technology transfer official submits
- Just-in-time requirement

Options for coordinating rights

- Inter-institutional agreements to bundle technologies
  - **Lead institute manages patents, licenses**
  - **Costs and licensing revenue shared**
- Assignment of inventions from several institutions to a single invention management firm
- Formal patent pooling

Suggestions for IMAT Investigators

- Consider commercial applications of technology
- Discuss issues with your technology transfer office:
  - to develop IP management plan
  - address issues during collaborations
  - timely report inventions
  - explain context of project for invention
- Make sure you talk with all appropriate personnel during the process (“cradle to grave”)

Some of our IMAT Successes

Jonathan Oliner, Ph.D., Affymetrix

IMAT award: Reverse-Engineering Signal Transduction Networks

- Impact: Gene expression arrays allow researchers to follow the downstream effects of perturbations to biochemical pathways or networks by highlighting changes in gene expression

And more successes…

Gary Latham, Ph.D., Ambion, Inc.

IMAT award: Enzymatic tools for degrading tissue and preserving RNA

- Impact: researchers can store tissue samples without significant loss of RNA integrity

Successes

John Yates, Ph.D., University of Washington/Scripps

IMAT award: Direct MS analysis of complex protein mixtures

- Impact: The MudPit (multi-dimensional protein identification technology) platform marks the transition from traditional 2-D gel electrophoresis to 2-D liquid chromatography

Successes

Mark Chee, Ph.D., Illumina, Inc.

IMAT award: Gene expression analysis on randomly ordered DNA arrays

- Impact: The ultra-high-throughput Illumina bead platform allows researchers to simultaneously assay over 100,000 points for gene expression, alternative splice detection, and protein expression

Successes

Dave Krizman, Ph.D., Expression Pathology

IMAT award: Protein arrays for molecular analysis of cancer tissue

- Impact: New technology that permits effective, high-throughput discovery and analysis of protein biomarkers in formalin-fixed, paraffin-embedded (FFPE) tissue

Successes

Robert Daniels, Ph.D., Quantum Dot Corp.

IMAT award: Sensitive, multiplexed analysis of breast cancer markers

- Impact: Quantum dots (semi-conductor nanocrystals) are photostable labels that emit extremely bright light in a range of colors enabling researchers to monitor complex interactions within living cells or in situ on tissue microarrays

Questions for me

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