

Commercial Application and Use of Emerging Innovative Molecular Analysis Technologies

Concept Review of New RFA

Presented by
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Presented to
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SBIR & STTR Programs



Set Aside

- **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization

2.5%

- **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization

0.3%

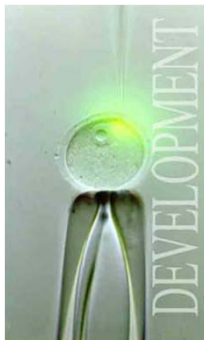
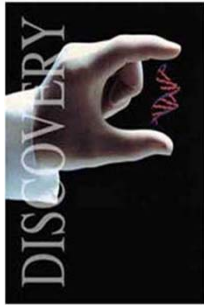
~\$108 million annually at the **NCI**

Why are SBIR and STTR Important to NCI?



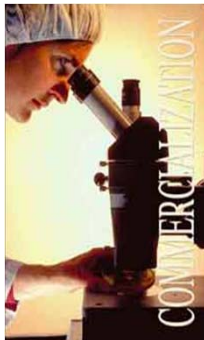
- A key NCI resource for enabling commercialization of innovative high impact technologies that can benefit patients, such as:
 - Cancer Diagnostics
 - Cancer Imaging
 - Small Molecules and Biologics
 - Electronic Health & Education Tools
- Provides seed funding for innovative technology development
 - A stable and predictable source of funding
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

SBIR & STTR: Three-Phase Program



PHASE II – R42, R44

- Full Research/R&D
- \$750K and 2-year Award (SBIR & STTR) *
- Commercialization plan required



PHASE III

- Commercialization Stage
- **Use of non-SBIR/STTR Funds**

* These funding levels are guidelines. Applicants should request the budget appropriate to accomplish the goals of the project.

SBIR IMAT Program



Innovative Molecular Analysis Technologies (IMAT)



Mission:

Revolutionize the state-of-the-science by stimulating the early-stage development of next generation molecular and cellular analysis technologies

Goals:

- To focus innovative technology development efforts from multiple communities on cancer
- To accelerate the maturation and dissemination of meritorious technologies from feasibility to development and/or commercialization.

Key Features:

- Emphasis on technology development (vs. traditional hypothesis-driven)
- Investigator-initiated, NCI Trans-divisional Program
- All communities (industry/academic, international) are invited to apply



INNOVATIVE MOLECULAR
ANALYSIS TECHNOLOGIES

<http://innovation.cancer.gov>

Three Thematic Areas

- **Innovative Technology Development for Cancer Research**
 - R21, R33, SBIR (R43/R44), STTR (R41/R42)
- **Application of Emerging Technologies for Cancer Research**
 - R21, R33, SBIR (R43/R44), STTR (R41/R42)
- **Innovative and Applied Emerging Technologies in Biospecimen Science**
 - R21, R33, SBIR (R43/R44), STTR (R41/R42)

Emphasis on high-risk, high-impact, and *high-payoff* technology development



Ambion®

IMAT Award: Enzymatic Tools for Degrading Tissue and Preserving RNA (*R43 – 2001, R44, 2005-2007*)

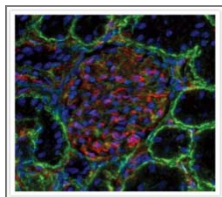
PI: Gary Latham, Ph.D



Illumina®

IMAT Award: Protein Profiling Arrays, Random Arrays for Gene Expression Profiling (*R43 – 1998, R44- 1999*)

PI: Mark Chee, Ph.D



invitrogen™

IMAT Award: Sensitive, Multiplexed Analysis of Breast Cancer Markers (*R44 - 1999*)

Quantum Dot Corp, PI: Robert H. Daniels, Ph.D.,

- **2009 SBIR IMAT Award Summary**
 - Innovative and Applied Molecular Analysis Technologies for Cancer (SBIR and STTR)
 - Innovative Technology Solutions to Cancer Sample Preparation (SBIR and STTR)
 - 34 applications / 4 funded in response to the last round (May 2009)
- **SBIR IMAT RFA **not** issued in 2009**
 - No awards in FY2010
- **Conducted an internal review within the SBIR Development Center to evaluate the SBIR/STTR IMAT RFAs**

What did we find:

- Greatest opportunity for supporting small business awards is in the area of molecular analysis technologies
- Shortage in the number and quality of applications in the area of Sample Prep

There is still a need for SBIR IMAT RFA

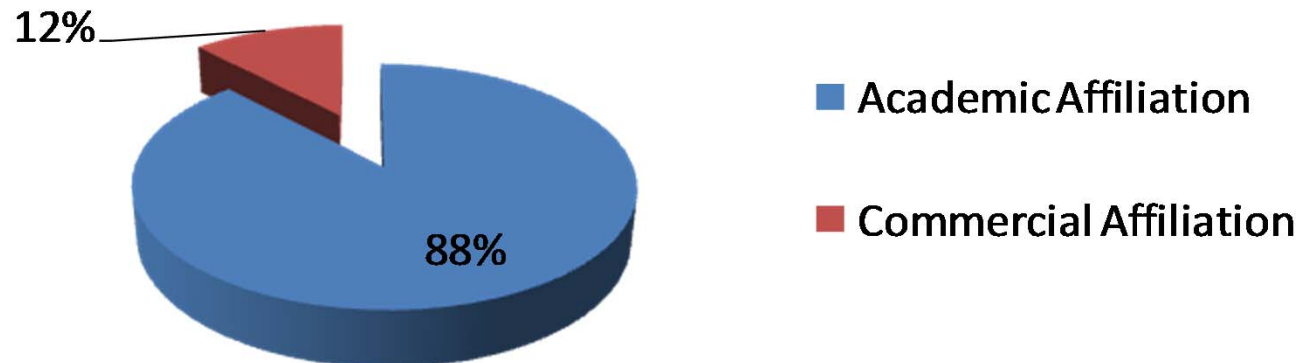
Scope of R21/R33 IMAT RFAs is limited to early-stage development of innovative technologies and prototype validation

- Does not support commercial validation activities.
- Thus, creates a significant funding gap for those who have a prototype but have not mitigated sufficient technical risk to attract investors.

- **Proposed RFA: Commercial Application and Use of Emerging Innovative Molecular Analysis Technologies (R43/R44)**
 - Focus on commercial validation of molecular analysis technologies
 - Support the pursuit of commercially relevant milestones
 - Feasibility data or a prototype is required (need not be IMAT funded)
 - Broad scope allows for investigator flexibility
 - Sample prep will be covered by targeted contracts
 - Recommend a major emphasis on the commercialization aspects of review, which can be accomplished by a special review by NCI's DEA
- **Proposed Budget Request:** Fund 5-7 Phase I and Phase II (and Fast track) projects in FY11
 - \$2 MM for the first year (total \$4 MM for entire project duration)
 - 150K for Phase I and ~ 750K for Phase II

Source of funds will be the SBIR set-aside

**All R21 & R33 Applications Received for IMAT
in September 2009 receipt date
(not including Biospecimen Sciences)**

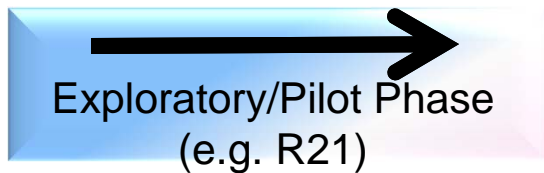


12% of all applications (excluding Bio-specimen Sciences) received in Sept 2009 for IMAT were affiliated with a commercial organization

IMAT Pipeline



Proof-of-principle to technical maturation



Innovative Technology or approach
No Preliminary Data Required



Prototype Validation
Completed Milestones



Prior IMAT Funding NOT necessary to apply

Commercial Feasibility
Scale Up

SBIR Development Center



- **Old SBIR Management Model at NCI**
 - Awards were managed by 40-50 people who each spent only a fraction of their time managing small business awards
 - Few of these NCI program managers had significant industry experience or commercialization expertise

- **New Development Center at NCI**
 - Established in 2007 at the request of the NIH and NCI Directors
 - Exclusively focused on the management of NCI's SBIR/STTR portfolio
 - Team of 8 Program Directors and one Director, spend 100% of time on SBIR/STTR
 - PDs have previous industry experience and professional networks to help mentor awardees

What the SBIR Development Center will offer applicants/awardees

- SBIR outreach programs
 - Workshops at scientific conferences and trade shows
 - Events with State Bio organizations
- Active management of projects
 - Mentorship of companies
 - Improved oversight, one-on-one coaching
- Matchmaking and Relationship building
 - Cultivating investor networks , (VCs & strategic partners)
 - NCI SBIR Investor Forum
- Facilitating Commercialization
 - Targeted funding solicitations, e.g contracts
 - Phase IIb Bridge Award
 - Regulatory Assistance Initiative

SBIR Development Center Staff



Michael Weingarten, MA (Director)

Previous

- **NASA** – Program Manager, NASA Technology Commercialization Program



Greg Evans, PhD (Branch Chief)

Previous

- **NHLBI/NIH** – Program Director, Translational and Multicenter Clinical Research in Hemoglobinopathies
- **NHGRI/NIH** – Senior Staff Fellow



Patti Weber, DrPH (Program Director)

Previous

- **International Heart Institute of Montana** – Tissue Engineering and Surgical Research
- **Ribi ImmunoChem Research, Inc.** – Team Leader, Cardiovascular Pharmacology



David Beylin, MS (Program Director)

Previous

- **X/Seed Capital Management, LLC**, Consultant
- **Naviscan PET Systems, Inc.**, Vice President, Research



Deepa Narayanan, MS (Program Director)

Previous

- **Naviscan PET Systems, Inc.**, Director, Clinical Data Management (Oncology Imaging & Clinical Trials)
- **Fox Chase Cancer Center**, Scientific Associate (Molecular Imaging Lab)



Ali Andalibi, PhD (Branch Chief)

Previous

- **NSF** – SBIR Program Director, Medical Biotechnology
- **House Ear Institute** – Scientist & Director, New Technology and Project Development
- **Trega Biosciences, Inc.** – Research Scientist



Natalia Kruchinin, PhD (Program Director)

Previous

- **QIAGEN, Inc.** – Molecular Diagnostics Applications Manager
- **Motorola, Inc.** – Senior Scientist, Gene Expression Assays



Andrew J. Kurtz, PhD (Program Director)

Previous

- **NIH** – AAAS Science & Technology Policy Fellow
- **Cedra Corporation** – Research Associate, Bio-Analytical Assays and Pharmacokinetics Analysis



Jian Lou, PhD (Program Director)

Previous

- **Johnson & Johnson** – Research Scientist, Target Validation & Biomarker Development
- **Lumicyte, Inc.** – Director, Molecular Biology Systems Analysis



Todd Haim, PhD (Program Analyst / AAAS Fellow)

Previous

- **National Academy of Sciences** – Christine Mirzayan Science and Technology Policy Fellow
- **Pfizer Research Laboratories** – Postdoctoral Fellow, Cardiac Pathogenesis & Metabolic Disorders

Partnership between IMAT and SBIR DC



SBIR Development Center	IMAT Program Staff
Issue/Manage Solicitation & review applications for responsiveness	Assist SBIR staff in reviewing all applications for responsiveness
Serve as administrative and technical POC	Serve as technical POC
Manage SBIR IMAT RFA Awards & provide periodic feedback to IMAT program staff	Provide technical expertise to SBIR DC as needed
Develop RFA/FOA	
Align Receipt Dates with those for IMAT FOA's	
Develop harmonized outreach strategy	
Develop plan for commercialization education to applicant community	

SBIR IMAT AWARDEES

INNOVATION

- ✓ Grant Milestones
- ✓ Commercial Grade Prototype
- ✓ Preliminary data for increased sensitivity and specificity
- ✓ Publications
- ✓ Patents
- ✓ Copyrights & Trade Marks

COMMERCIALIZATION

- ✓ Number of new products
- ✓ \$ Value of Cumulative Sales
- ✓ License Agreements
- ✓ M&A
- ✓ Acquisition of outside capital

REGULATORY

- ✓ 510(K) approvals
- ✓ PMA
- ✓ IDE
- ✓ Successful CLIA Certifications