

**Bringing Science to the Market:
The NCI SBIR Program**

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NCI SBIR Development Center

***IMAT Principal Investigators Meeting
November 14th, 2011***



- **Overview & Eligibility**
- **NCI SBIR Development Center**
- **NCI SBIR Initiatives**
- **SBIR and IMAT**
- **NIH SBIR/STTR Funding Opportunities**

- 1. Stimulate technological innovation**
- 2. Use small business to meet Federal R&D needs**
- 3. Increase private-sector commercialization innovations derived from Federal R&D**
- 4. Foster participation by minority and disadvantaged persons in technological innovation**

Small Business Innovation Development Act of 1982

Small Business Technology Transfer Act of 1992

Set Aside

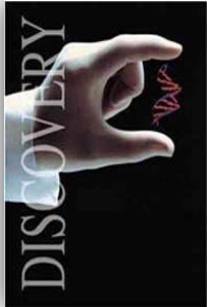
- **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization
- **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization

2.5%

0.3%

~\$110 million annually at the NCI
~\$650 million annually at the NIH

- Provides seed funding for innovative technology development
- Provides recognition, verification and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)
- **Not a Loan**
 - ∴ No repayment is required
 - ∴ Doesn't impact stock or shares in any way (i.e. non-dilutive)
- Intellectual property rights retained by the small business
 - *Bayh-Dole Act (1980)*



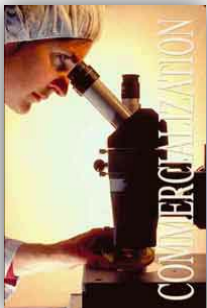
PHASE I – R41, R43

- Feasibility Study
- \$150K and 6-month (SBIR) *
- or 12-month (STTR) Award



PHASE II – R42, R44

- Full Research/R&D
- \$1M and 2-year Award (SBIR & STTR) *
- Commercialization plan required



PHASE III

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

* Note: Actual funding levels may differ by topic.

- Applicant must be a **Small Business Concern (SBC)**
- Organized for-profit U.S. business**
- 500 or fewer employees, including affiliates**
- PD/PI's primary employment (i.e., >50%) must be with SBC at the time of award and for duration of the project period**
- At least 51% U.S.- owned by individuals and independently operated**

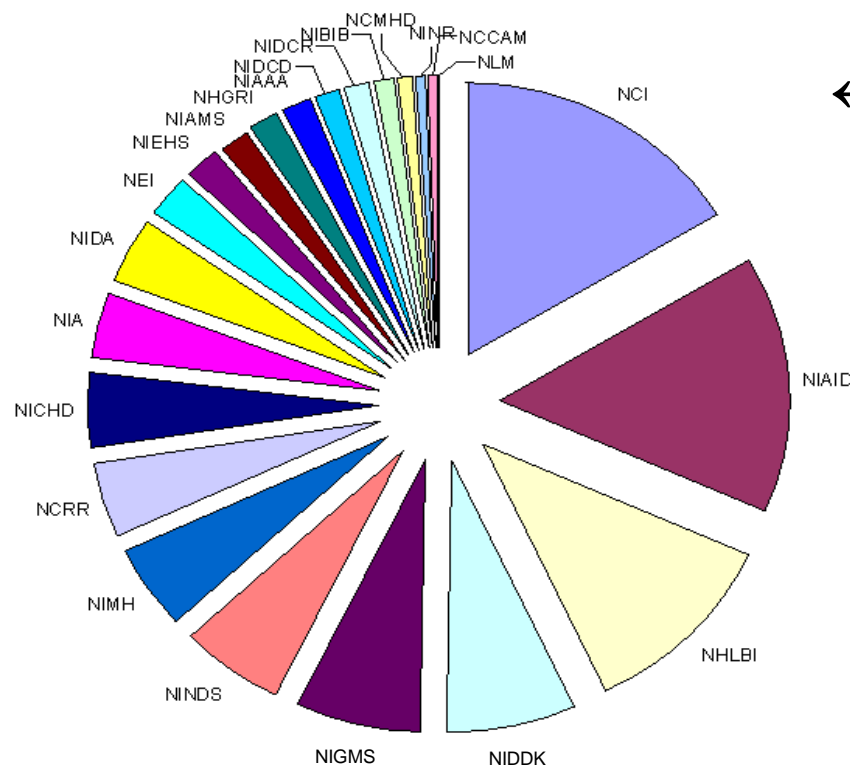
OR

At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals

- Applicant is a Small Business Concern**
- Formal Cooperative R&D Effort**
 - *40% by small business*
 - *30% by U.S. research institution*
- U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)**
- Intellectual Property Agreement**
 - *Allocation SBC of IP rights (to SBC) and rights to carry out follow-on R&D and commercialization*
- Principal Investigator's primary employment may be with either the Small Business Concern or the research institution**

SBIR/STTR Funding Distribution

2010 Budget	SBIR	STTR	SBIR+STTR
NIH	\$616M	\$74M	\$690M
NCI	\$99M	\$12M	\$111M



← *The annual SBIR/STTR budget for each participating Institute or Center (IC) is proportional to the total annual budget appropriation for that IC*

Old SBIR Management Model at NCI

- Awards were managed by 40-50 people who managed a combination of NIH grant mechanisms
- The majority of these NCI program officers managed predominantly academic mechanisms and thus had an academic focus

New Development Center at NCI

- Team of 9 Program Managers/Directors, and one Center Director, entirely funded by NCI
- Exclusively focused on the management of NCI's SBIR/STTR portfolio
- Directors have previous industry experience and professional networks to help mentor awardees in commercialization strategy and process
- Center is developing a range of new activities to help small businesses
- Center staff continues interactions with NCI program staff concerning cancer research



Michael Weingarten, MA (*Director*)

Previous

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



Greg Evans, PhD (*Team Leader*)

Previous

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



Jian Lou, PhD (*Program Director*)

Previous

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



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 (*Team Leader*)

Previous

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



Andrew J. Kurtz, PhD (*Team Leader*)

Previous

- **NIH** – AAAS Science & Technology Policy Fellow
- **Cedra Corporation** – Research Associate, Bio-Analytical Assay Development



Patricia Weber, DrPH (*Program Director*)

Previous

- **International Heart Institute of Montana** – Manager, Tissue Engineering and Surgical Research
- **Ribi ImmunoChem Research, Inc.** – Team Leader, Cardiovascular Pharmacology & Licensing
- **Trega Biosciences** - Director, Microbiology & Immunology



Todd Haim, PhD (*Program Manager*)

Previous

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



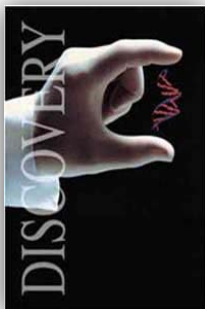
Julienne Willis (*Program Specialist*)

Goal

- To work closely with promising SBIR Phase II awardees in order for them to advance their technologies towards the clinic

Path

- Active management of projects and better oversight
- Mentor and guide companies throughout the award period
- Provide Phase II awardees access to regulatory consultants to accelerate the FDA approval process for drugs, biologics and devices
- When appropriate, act as a liaison to bring investors and NCI SBIR companies together



PHASE I – R41, R43

- Feasibility Study
- \$100K and 6-month (SBIR) *
- *or* 12-month (STTR) Award



PHASE II – R42, R44

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

Phase II Bridge Award



PHASE III

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

* Note: Actual funding levels may differ by topic.

Follow-on to SBIR Phase II

- **Helps early-stage companies cross the “Valley of Death” by:**
 - Facilitating partnerships with third-party investors & strategic partners
 - Incentivizing third-party investments earlier in the development process
 - **NCI is sharing in the investment risk with other investors**

Incentive Structure

- **Gives competitive preference and funding priority to applicants that can raise third-party funds (i.e., 1:1 match)**
 - Affords NIH the opportunity to leverage millions in external resources
 - Provides valuable input from third-party investors in several ways:
 1. Rigorous commercialization due diligence prior to award
 2. Commercialization guidance during the award
 3. Additional financing beyond the Bridge Award project period

Technical Scope: Cancer Therapies, Imaging Technologies & Diagnostics

- Need for large amounts of capital for clinical validation and FDA approvals
- Opportunity to make a significant impact on many projects in the SBIR portfolio

Mechanism & Budgets

- Uses the SBIR Phase II (R44) competing renewal mechanism
- **Provides up to \$1 M per year for up to 3 years**
- Available to current Phase II grant awards, and those that ended within last 2 years

Preferred Third-Party Matching Funds

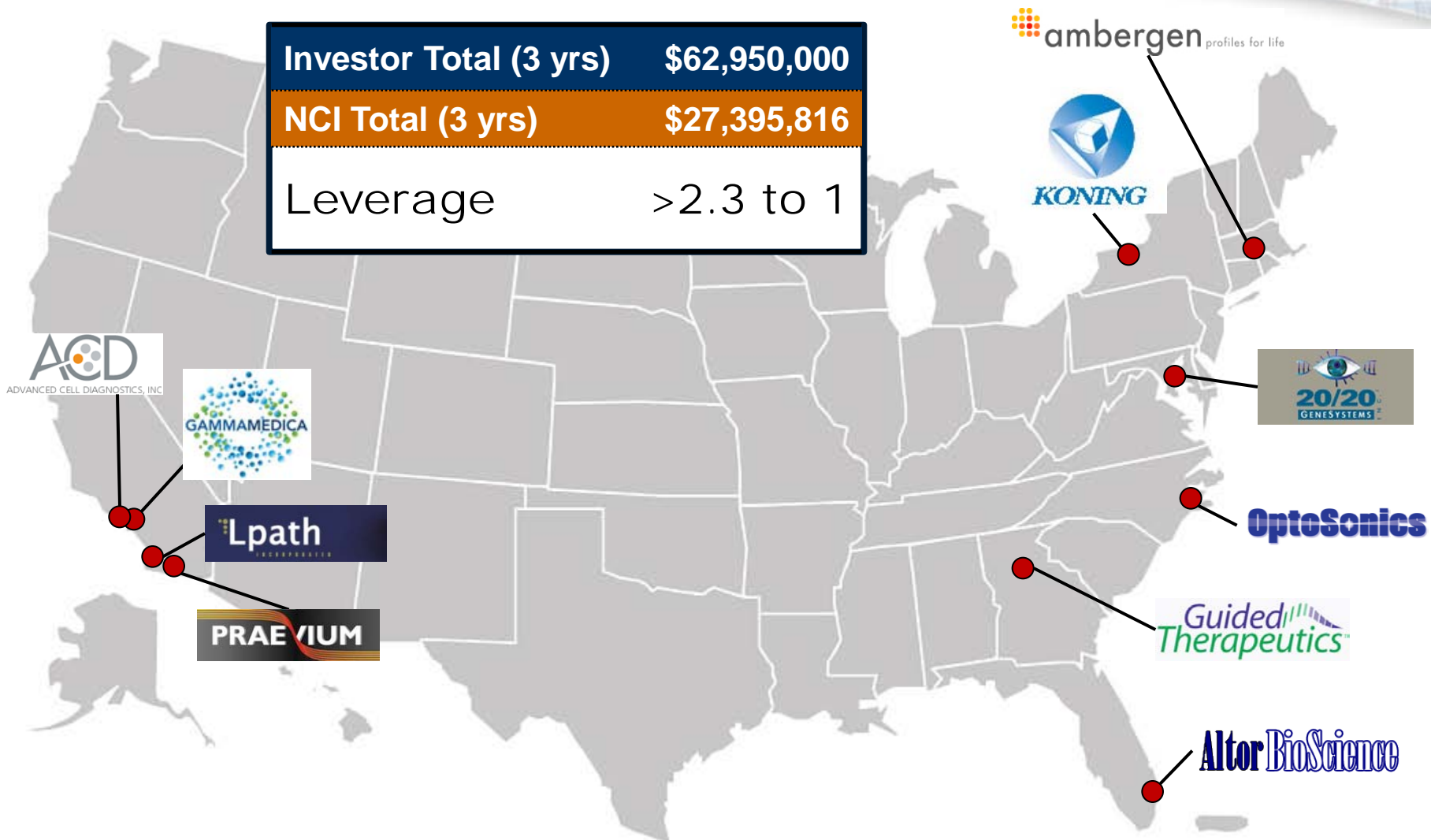
- Cash, liquid assets, convertible debt

Sources of Funds

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

10 New Bridge Awards FY2009 + FY2010

Investor Total (3 yrs)	\$62,950,000
NCI Total (3 yrs)	\$27,395,816
Leverage	>2.3 to 1





*Exclusive opportunity for 14
NCI-funded companies to
showcase their technologies*
<http://sbir.cancer.gov/investorforum/>

Featured Small Businesses

- Opportunity to pitch and network with >150 investors and potential strategic partners

Investors

- Opportunity to evaluate NCI's top companies with innovative technologies
- Exclusive one-on-one meetings

MagArray

Omniox
Targeted oxygen delivery



LEAP OF FAITH® TECHNOLOGIES

SOFINNOVAVENTURES

Venrock

Genentech
A Member of the Roche Group

SBIR Contract Solicitation



➤ **PHS-2012-1 “Solicitation of NIH and CDC for SBIR Contract Proposals”**

➤ **ONE application receipt date per year:** published in late August

~~Receipt Date: November 7, 2011~~
(CLOSED)

➤ **RFP can be found at:**

➤ <http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf>

➤ **NCI published twelve topics in the areas:**

➤ Drugs

➤ Diagnostics

➤ Imaging

➤ Health IT

➤ Research tools

- (*) 255 Development of Anticancer Agents
- (*) 277 Development of Companion Diagnostics
- (*) 291 Development of Radiation Modulators For Use During Radiotherapy
- 300 Reformulation of Cancer Therapeutics using Nanotechnology
- 301 Probing Tumor Microenvironment Using In-vivo Nanotechnology-based Sensors
- 306 Development of Innovative Algorithms for Processing & Analysis of *In Vivo* Images
- (*) 307 Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging, and Treatment
- 308 Automated Collection, Storage, Analysis, and Reporting Systems for Dietary Images
- 309 Development of Low Cost, Small Sample Multi-Analyte Technologies for Cancer Diagnosis, Prognosis and Early Detection
- (*) 310 Simplified Tissue Microarray Instrument For Clinical and Research Settings (NIH Technology Transfer)
- 311 High Throughput Isolation of Antigen Specific T-cells for Cancer Therapy (NIH Technology Transfer)
- 312 Generation and Qualification of Site-specific Post-translationally Modified Proteins for Use as Calibrators in Pharmacodynamic (PD) Assays

Differences between SBIR grants and contracts

	Omnibus Solicitation for SBIR Grants	Solicitation for SBIR Contracts
Scope of the proposal	Investigator-defined (within mission of NIH)	Defined by the NIH (focused topics)
Questions during solicitation period?	May speak with any Program Officer	<u>MUST</u> contact the contracting officer
Basis for Award	Based on the score received during peer review	If proposal scores well during peer review, must then negotiate a contract with NIH
Reporting	Final report (Phase I); Annual progress reports (Phase II)	Monthly progress reports
Phase II transition	May apply as soon as Phase I aims are completed	Must be invited by the NIH to submit Phase II proposal
Set-aside of funds for particular areas?	NO	YES

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



<http://innovation.cancer.gov>

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.

SBIR/IMAT Collaborations:

- Catalyze targeted technology development and commercial validation in the area of molecular analysis technologies thru a set aside.
- Provide a cohesive program that is aligned with the goals of the IMAT R21/R33 programs
- Emphasis on the commercialization

Proof-of-principle to technical maturation

Idea

Proof Of Principle

Development

Prototype Validation

Product Development

Market

R21

Exploratory/Pilot Phase
Innovative
Technology/approach
No Preliminary Data Required

R33

Developmental Phase
Prototype Validation
Completed Milestones

R43/44

Beyond Prototype Phase
Commercial Feasibility
Scale Up

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 Investor Forum
- Commercialization Assistance
 - Phase IIb Bridge Award
 - Regulatory Assistance Initiative



Ambion®

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

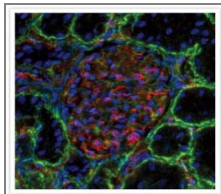
PI: Gary Latham, Ph.D



illumina®

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

PI: Mark Chee, Ph.D



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

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

invitrogen™

- **NIH SBIR/STTR Omnibus Solicitations for Grant Applications**
Release: January
Receipt Dates: April 5, August 5, and December 5
- **Solicitation of the NIH & CDC for SBIR Contract Proposals**
Release: August
Receipt Date: Early November
- **See NIH Guide for various other Program Announcements (PAs) and Requests for Application (RFAs), i.e. other grants**
Release: Weekly
Receipt Dates: Various

<http://sbir.cancer.gov/funding/>

<http://sbir.cancer.gov>

NCI SBIR Development Center

Phone: 301-594-7709

E-mail: ncisbir@mail.nih.gov

**Register on web site for funding
opportunity updates**