



Seed Funding for Commercialization of Oncology Products: the SBIR Program at National Cancer Institute

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Indiana Cancer-Oncology Summit

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- **Overview of NCI SBIR/STTR Program (Eligibility Requirements)**
- **NCI Funding Opportunities for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR)**
- **Snapshot: Indiana, How Well are You Competing for NCI SBIR/STTR Funding in 2008?**

Why are SBIR and STTR Important?



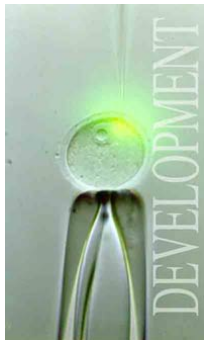
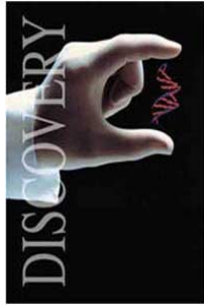
- **NIH's primary resource for enabling commercialization of innovative high impact technologies, such as:**
 - **Research tools**
 - **Medical devices**
 - **Therapeutics**
- **Provides incentive to academic investigators to translate technology (new company formation)**
- **One of the largest sources of early-stage life sciences financing**

Reasons to Seek SBIR & STTR Funding



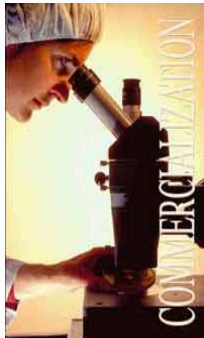
- **Provides seed funding for innovative technology development projects**
- **Intellectual property rights are retained by the small business concern**
- **Not a loan – no repayment is required**
- **Doesn't impact stock or shares in any way (no dilution of capital)**
- **Can be a leveraging tool to attract other funding (VC, etc.)**

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. You should request the budget needed to accomplish the goals of the project.

Set Aside

- **SBIR: Set-aside Program for Small Business Concerns to engage in Federal R&D with 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%

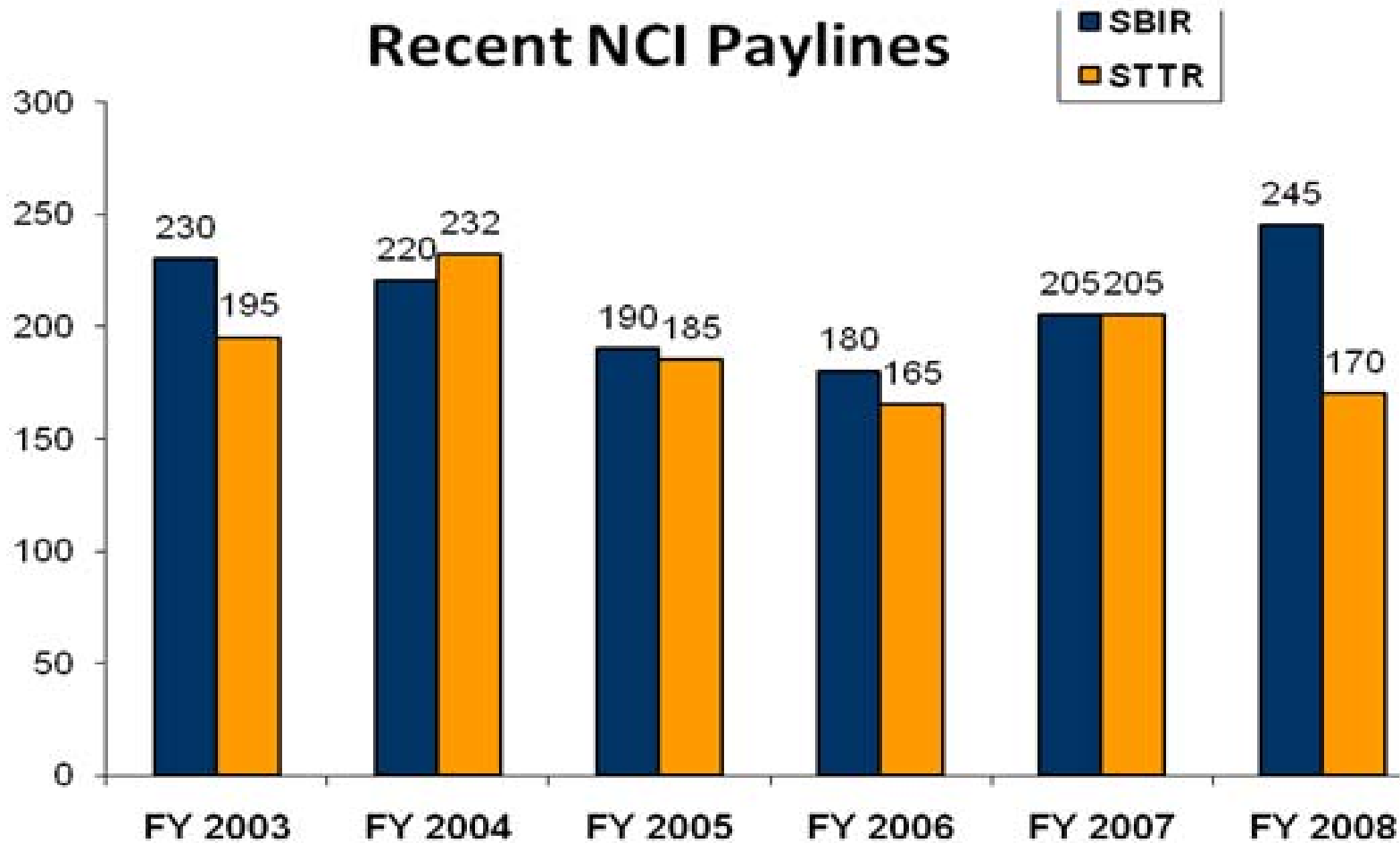
0.3%

**A \$104M Program at the NCI
(2008)**

NCI SBIR/STTR Pay Lines, 2003-2008



Recent NCI Paylines



Small Business Concern

- **Organized for-profit U.S. business**
- **500 or fewer employees, including affiliates**
- **Must be:**
 - **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**
- **Principal Investigator's primary employment must be with the Small Business Concern**

STTR Eligibility Requirements



- **Applicant is a Small Business Concern**
- **Formal Cooperative R&D Effort**
 - **Minimum 40% by small business**
 - **Minimum 30% by U.S. research institution**
- **U.S. Research Institution**
 - **College or University**
 - **Other non-profit research organization**
 - **Federal R&D center**
- **Intellectual Property Agreement**
 - **Allocation of IP rights 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 and STTR Programs (Critical Differences)



SBIR

- **Permits** research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities

STTR

- **Requires** research institution partners (e.g., universities)
- Minimum 40% of the work should be conducted by the small business concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)

Award always made to small business

SBIR/STTR Omnibus Grant Solicitation

Release: January

Receipt Dates (3): April 5, August 5, and December 5

SBIR Contract Solicitation (NIH [NCI**], CDC)**

Release: Summer 2009

Receipt Date (1): Fall 2009

NIH Guide for Grants and Contracts

Release: Weekly

Receipt Dates: Various

**For more information visit:
<http://sbir.cancer.gov>**

New Phase II SBIR Bridge Pilot at NCI

RFA-CA-08-021



Pilot will focus on **cancer therapies and cancer imaging**

- Budgets up to **\$1 million per year for up to 3 years from NCI**
- Development efforts must be predicated on a previous SBIR Phase II grant and may include:
 - Pre-clinical R&D needed for regulatory filings (e.g. IND or IDE)
 - Clinical trials
- Application Dates: **February 27, 2009** (and September 19, 2008)
- **NCI intends to commit up to \$10M in FY 2009 to Bridge Awards**
- Open to current and recently expired NIH SBIR Phase II projects

Indiana- How Competitive Have You Been Recently for NCI SBIR Funding?

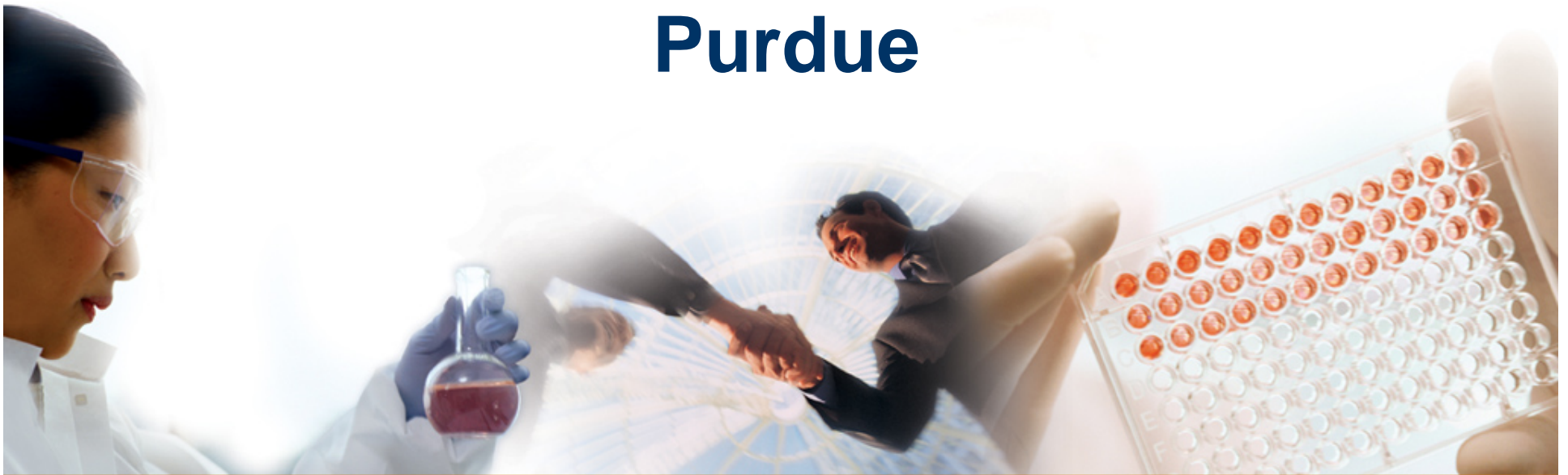


- **Ranks 20th out of 39 states for number of NCI SBIR awards received for fiscal years 2004- 2008 (15th by population)**
- **There were 10 awards (9 SBIR, 1 STTR), made to 7 companies: Molecular Kinetics, Focus Surgery, Piezotech, Endocyte, Yinnel Tech, Advanced Process Combinatorics, and Gabriel Interactive**
- **Products: software to ID druggable sites in cancer proteins; anti-smoking video game; ultrasound combined with immunotherapy for prostate cancer; a protein solubility enhancer for cancer proteomics studies; folate-conjugated drugs; and nuclear imaging reagents**

From NIH CRISP public database

Thanks:

**Indiana Health Industry Forum (IHIF)
Indiana University
Purdue**



18 New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd



- **Biopsy Instruments and Devices that Preserve Molecular Profiles in Tumors**
- **Development of Molecular Pharmacodynamic Assays for Targeted Therapies**
- **System to Analyze and Support Biomarker R&D Strategies**
- **Development of Anticancer Agents**
- **Innovative Methods for Manufacturing Safe, Effective Cancer Therapeutics**

18 New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd



- **Innovative Strategies to Protect Radiosensitive Organs and Structures During Radiation Therapy**
- **Quantitative Tissue Imaging for Clinical Diagnosis and Treatment**
- **Antibody Array for Cancer Detection and Diagnosis**
- **Novel and Improved Assays for Detecting Epigenetic Modifications**
- **Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer**

18 New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd



- **Multifunctional Therapeutics Based on Nanotechnology**
- **High Level Programming Language to Expedite Development of User Interfaces**
- **Mobile Computing for Consumer-centered Cancer Prevention and Control**
- **Health Information Technology to Facilitate Patient-centered Communication in Cancer-related Care**

18 New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd



- **Development of shRNA Library Screening Technology for Cancer-Related Targets**
- **Novel Antibody Epitope Mapping Technologies**
- **Development of Novel Protein Expression Technologies for Glycosylated Cancer Related Proteins**
- **Peptide Aptamers: New Tools to Capture and Study Protein Interactions in Lieu of Immunological Reagents**

Keys to a Strong Application



- **Significant, innovative, and focused science**
- **Significant product and/or commercial potential**
 - **A product-focused application is more likely to have support of business reviewers**
 - **A project with sound financial projections is more likely to attract a partner**
- **Translational research/clinical applications projects should involve the appropriate collaborators**
 - **Oncologists**
 - **Pathologists**
 - **Statisticians**

Know NIH SBIR/STTR Review Criteria



Significance

- Does the study address an important problem and have commercial potential?

Approach

- Are design and methods well-developed and appropriate? Are problem areas addressed?

Innovation

- Are there novel concepts or approaches? Are the aims original and innovative?

Investigator

- Is the investigator appropriately trained and capable of managing the project?

Environment

- Does the scientific environment contribute to the probability of success? Is the environment unique?

Commercialization

- Is the company's business strategy one that has a high potential for success?

Key #1

Start Application Process Early!



- **Start developing your application as early as possible. You need time to develop a strong proposal.**
- **Seek help of experienced applicants early in process**
- **Assemble a strong scientific team**
 - If you have a weakness or gap in expertise, fill it early

Key #2

Consider Your Company's Strengths and Weaknesses



- **Consider your company's strengths**
 - Try to exploit those strengths to address a specific NIH Program initiative
- **Consider your weaknesses too**
 - It is rare that a small company will have all the necessary expertise for a strong application
 - If you have no track record of commercialization, consider getting a partner who does
- **Partner with other companies or academics to fill gaps**
- **Contact NIH Program Director in advance to discuss your proposal and receive feedback**
- **Review similar currently funded projects in the NIH CRISP database (<http://crisp.cit.nih.gov/>)**

Key #3

Always Consider the Reviewers



- **What are they looking for?**
 - Readable and understandable application
 - Do not assume they will know everything you know
 - You understand your application best so convey it to them
 - Clear and concise language, “lay summary”
 - Clear plan for Phase I, II and commercialization
 - Feasible methods
 - Appropriate objective tests of success for each Specific Aim
 - Promising preliminary data are very influential
 - Solid letters of support for commercialization

Key #3

Always Consider the Reviewers



- **Read your material critically as if you were the Reviewer**
 - What are the weaknesses?
 - Point out potential difficulties, do not hide them
 - Suggest ways to address them or provide rationale
 - Recruit an independent reader
- **Provide alternative methods if a particular approach is not successful**

Help the Reviewer write his/her analysis

Follow-On Award to the SBIR Phase II Award

- **Goal is to help early-stage companies cross the “Valley of Death” by:**
 - **Helping to facilitate partnerships with third party investors/strategic partners**
 - **Incentivizing partnerships earlier in the development process by sharing in the investment risk**
- **The Bridge Award is modeled after NSF’s “Phase IIB Option” and has the same key feature:**

➤ **SBIR company is expected to raise third-party funds. Competitive preference & funding priority will be given to applicants who do so.**

- **Third-party funds are expected to equal or exceed NCI funds being requested**

➤ **Third-party funds may include:**

- Cash, liquid assets, convertible debt

➤ **Sources of third-party funds may include:**

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

Third-party investors are expected to bring:

- **Rigorous commercialization due diligence**
- **Commercialization guidance during the award**
- **Additional financing beyond the initial third-party investment**