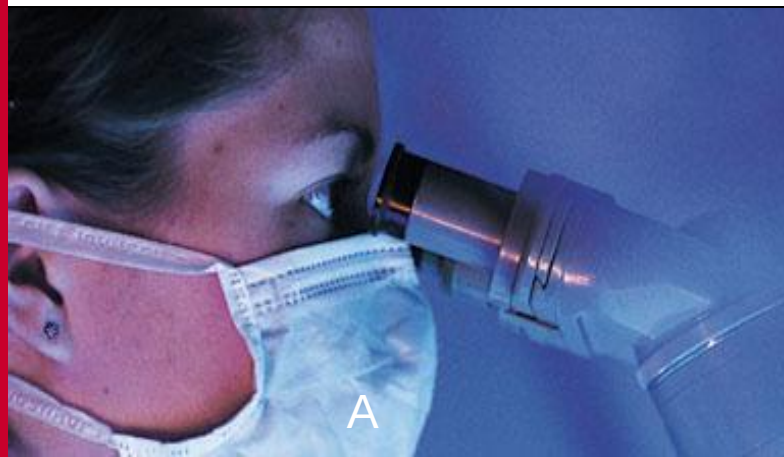
National Cancer Institute



Bringing Medical Devices for Cancer to the Marketplace: 2014 Overview of the NCI Small Business Programs



Greg Evans, PhD

Team Leader

Cancer Imaging/Biology/Control

NCI SBIR Development Center

Monday July 21, 2014

AAPM Annual Meeting

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Congressional Goals

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

Congressionally-Mandated Programs

SBIR & STTR

Small Business Innovation Research (SBIR)

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

Federal agencies with an extramural R&D budget > $100M

Small Business Technology Transfer (STTR)

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

Federal agencies with an extramural R&D budget > $1B

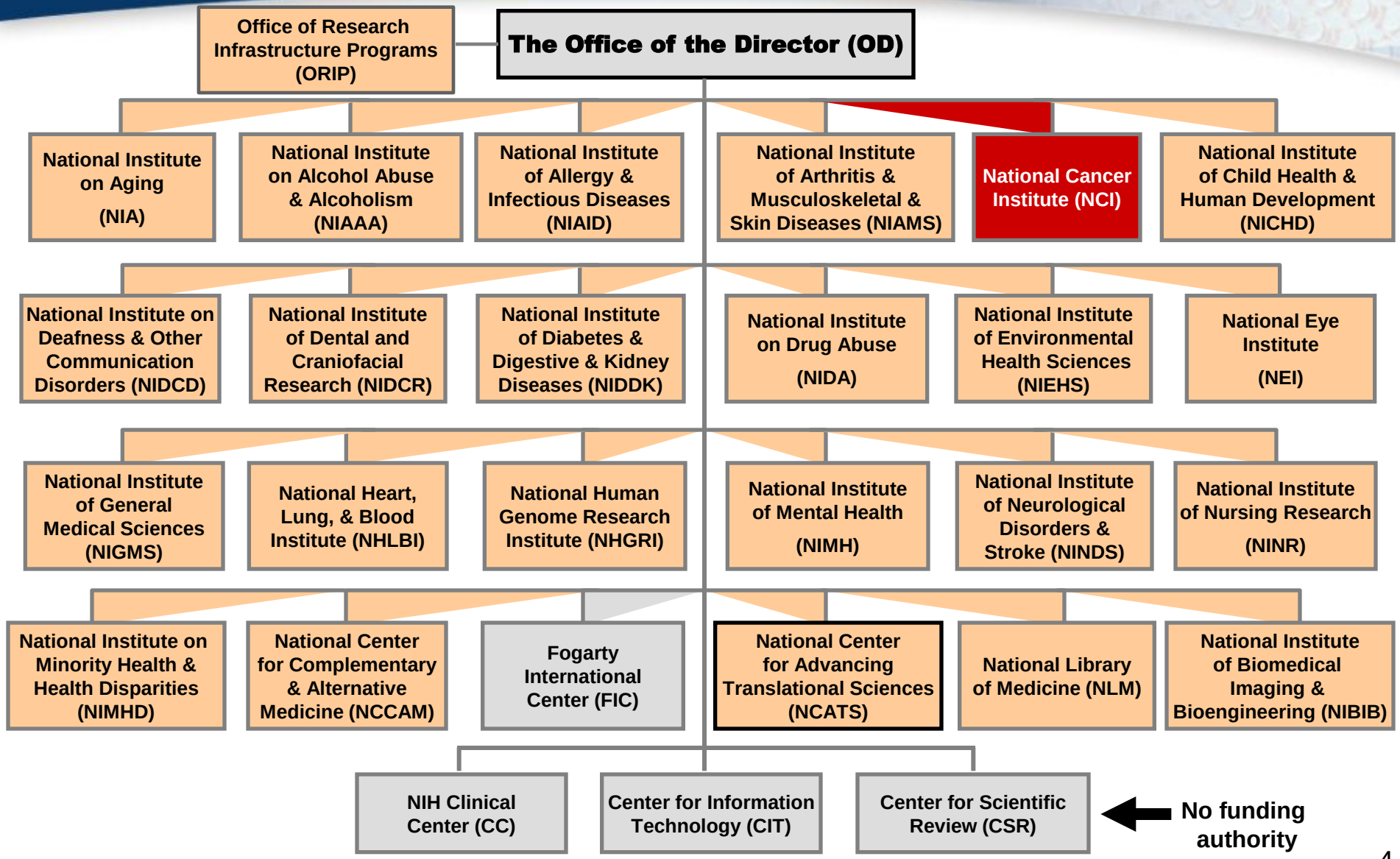
Set Aside $$	
FY14	FY17
2.8%	3.2%
0.40%	0.45%

~$757 M in FY14 at NIH
~$119 M in FY14 at NCI

NIH = 27 Institutes & Centers

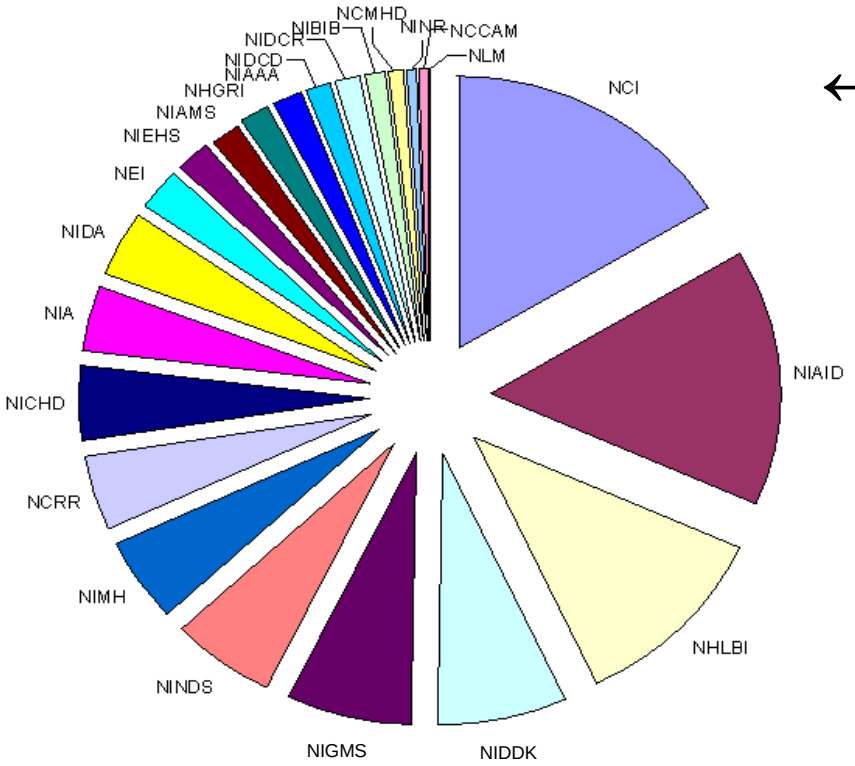
24 Participate in the SBIR/STTR Program

SBIR & STTR



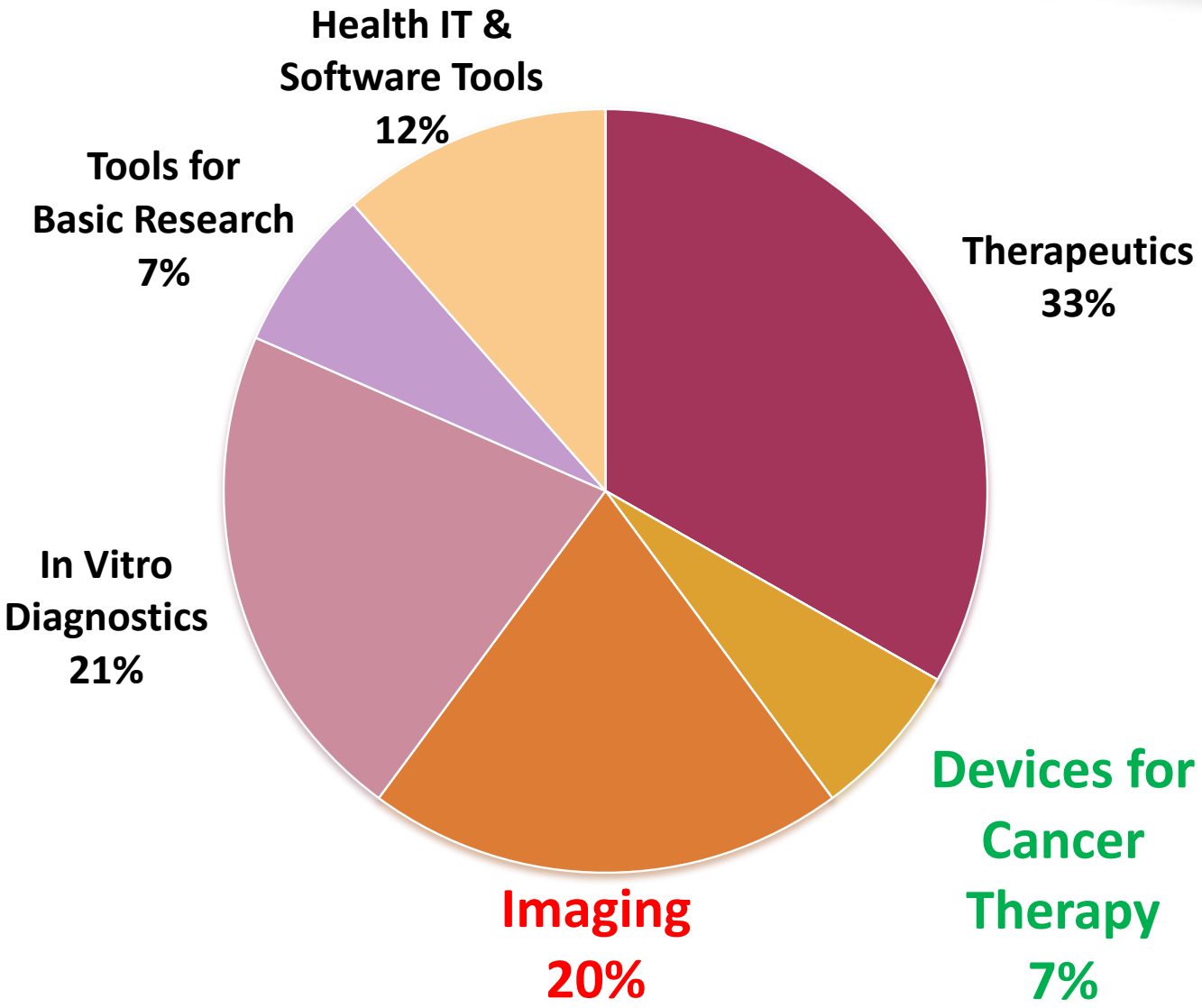
FY2013 SBIR/STTR Funding Levels

Agency/Institute	SBIR	STTR	SBIR+STTR
NIH	$620M	$80M	**$717M**
NCI	$97M	$13M	**$110M**



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

NCI SBIR/STTR Active Portfolio: Pipeline of 400+ Vetted Projects



Reasons to Seek SBIR/STTR Funding

- **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**

SBIR Eligibility Requirements

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

OR

- **> 50% owned and controlled by other business concern/s that is/are > 50% owned and controlled by one or more individuals***

OR

- **> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these ***

*Formerly >= 51%; *New rule starting 1/28/13, **NIH SBIR only**

STTR Eligibility

- ✓ **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 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 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

NCI Has Multiple Small Business Solicitations

Know the Application Deadlines

SBIR & STTR

- **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: typically early August

  Receipt Date: *only once per year,* typically early November

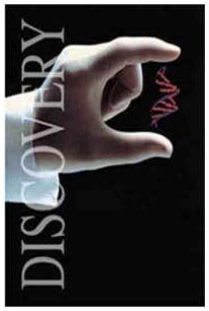
- **See the NIH Guide for other Program Announcements (PA's) and Requests for Application (RFA's), i.e. grants**

  Release: Weekly

  Receipt Dates: Various

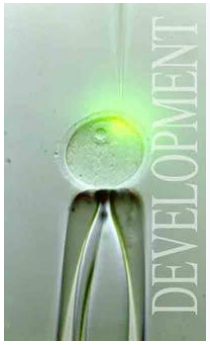
http://grants.nih.gov/grants/guide

NCI Offers Three SBIR/STTR Award Stages



PHASE I – R41, R43 Grant, or Contract

- **Feasibility Study**
- **$300K over < 12 months (rarely 18-24 months**



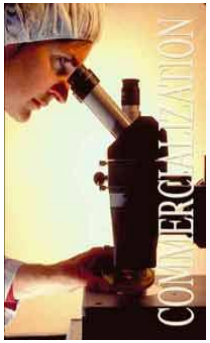
PHASE II – R42, R44 Grant, or Contract

- **Full Research/R&D**
- **$2.0M over 2-3 years**
- **Commercialization plan required**

Phase IIB Bridge Award

$1M per year for 3 years, with matching $$

(also NHLBI, NINDS)



PHASE III

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

New Provisions in Current Omnibus Grant Solicitations, Enacted in Last 2 Years

- SBIR/STTR applicants must register at the SBA Company registry at SBIR.gov.
- VC-backed companies (VCOC, hedge fund, private equity firms) **CAN NOW** apply (NIH SBIR only).
- Applicants can request $5000 in Technical Assistance, beyond award cap. If requested, cannot participate in NIH Technical Assistance Programs.

Newest Provisions Implemented

- FY15 allows switching between STTR and SBIR mechanisms
  - Applicants may apply for Phase II SBIR funding based on Phase I STTR award or vice versa.

- Direct to Phase II applications for SBIR

SBIR/STTR Success Rates NIH-Wide

Fiscal Year	SBIR/STTR	Phase	Number of Applications Reviewed	Number of Applications Awarded	Success Rate	Total Funding
2013	SBIR	Fast Track	313	49	15.7%	$13,981,386
2013	SBIR	Phase I	3,738	495	13.2%	$114,040,157
2013	SBIR	Phase II	542	178	32.8%	$136,348,846
2013	STTR	Fast Track	42	12	28.6%	$2,542,128
2013	STTR	Phase I	583	109	18.7%	$24,138,629
2013	STTR	Phase II	72	19	26.4%	$10,985,373
2013	**FY TOTAL**		**5,290**	**862**	**16.3%**	**$302,036,519**

Success rates are defined as the percentage of reviewed grant applications that receive funding.

Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care (SBIR-IMAT, PAR-13-327)

SBIR & STTR

Goal: To support the development, maturation, and dissemination of novel and potentially transformative next-generation technologies through an approach of balanced but targeted innovation in support of clinical, laboratory, or epidemiological research on cancer.

- Molecular and cellular analytical technologies for cancer detection and/or characterization *in vitro, in situ,* or *in vivo*

Next receipt dates: **May 28, 2014**
November and May through 2016

Contact Dr. Amir Rahbar: rahbaram@mail.nih.gov

http://sbir.cancer.gov/funding/technology

Innovative Health IT for Broad Adoption by Healthcare Systems & Consumers (PA-12-196)

Goal: Accelerate development & commercialization of evidence-based consumer health IT to:

- Prevent or reduce the risk of cancer
- Facilitate patient-provider communication
- Improve disease outcomes in consumer & clinical settings

- Phase II or Fast-Track applications only
- Strong applicants will have a **partnership with large business** (e.g. commercial IT firm, EMR vendor, healthcare systems, etc.)

Next receipt dates: **April 5, 2014**

August 5, December 5 through 2014

Contact Dr. Patricia Weber: weberpa@mail.nih.gov

http://sbir.cancer.gov/resource/hit/

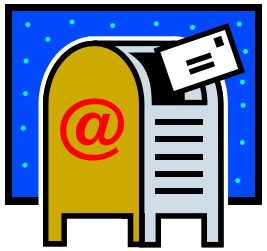
Know NIH SBIR/STTR Grant Review Criteria

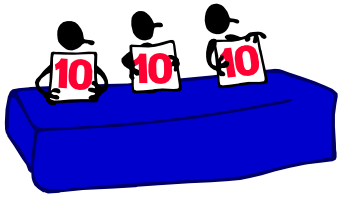
Significance	• **Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?**
Approach	• **Are design and methods well-developed and appropriate? Are problem areas addressed?**
Innovation	• **How novel is the product and the approaches proposed to test its feasibility?**
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?**

NIH Timeline for New Grant Applications

SBIR & STTR

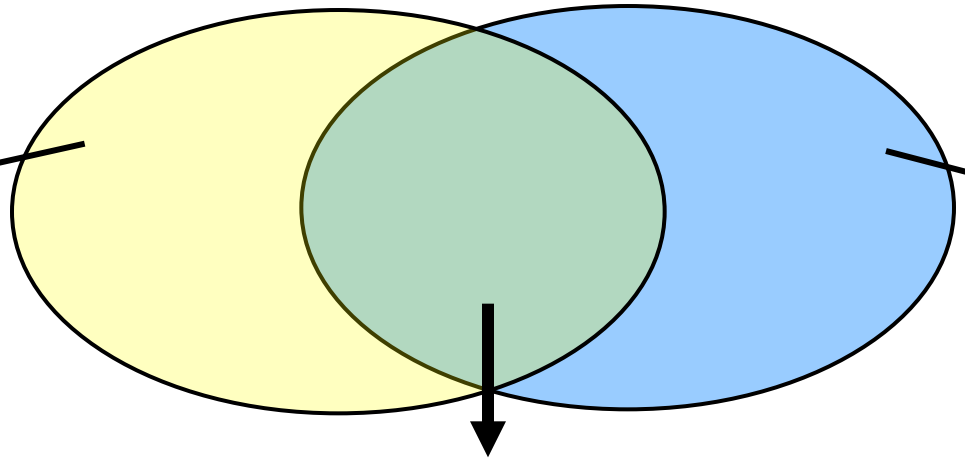
7-10 months

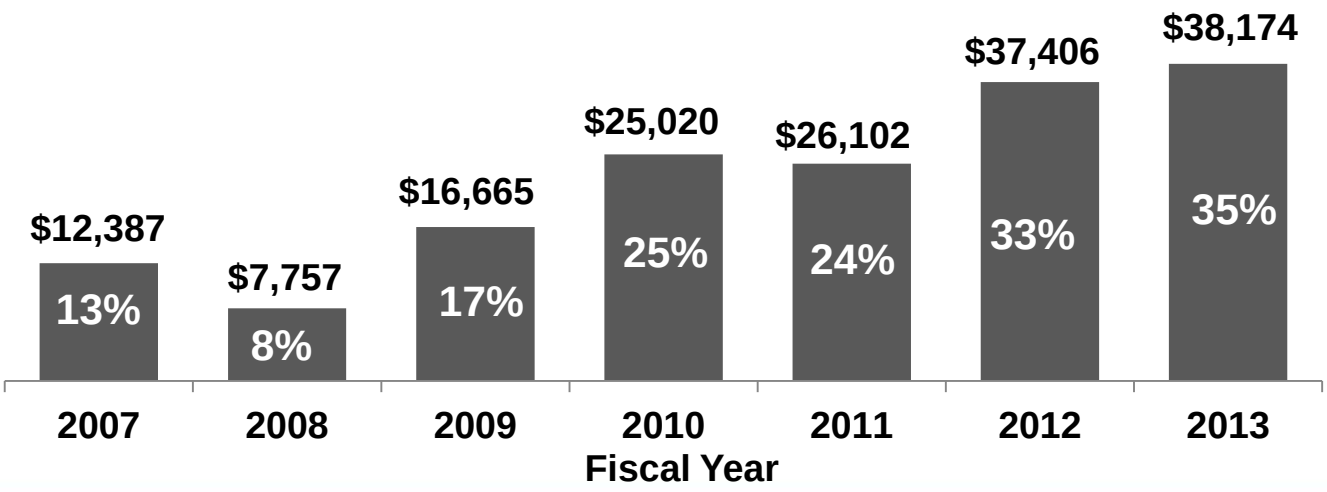




Due Date	Scientific Review	Council Review	Award Date (earliest)
April 5	July	October	December
August 5	October	January	April
December 5	March	May	July

Annual Solicitation for NCI SBIR Contract Topics





NCI SBIR contracts *(thousands)*

% of total NCI SBIR

NCI SBIR Contracts vs. Grants: What's the difference?

	SBIR Grants	SBIR Contracts
Scope of the proposal	Investigator-defined within the mission of NIH	**Defined by the NIH (focused)**
Questions during solicitation period?	May speak with any Program Officer	**MUST** contact the contracting officer
Receipt Dates	3 times/year for Omnibus	Only ONCE per year
Peer Review Locus	NIH Center for Scientific Review (CSR)	**NCI Division of Extramural Activities**
Basis for Award	Peer review score/ Program assessment	Peer review score/negotiation of technical deliverables, budget
Reporting	One final report (Phase I); Annual reports (Phase II)	Kickoff presentation, quarterly progress reports, final report, commercialization plan
Set-aside funds for particular areas?	No	**Yes**
Program Staff Involvement	Low	**High**

2013 NCI Contract Topics- last year

SBIR & STTR

http://sbir.cancer.gov/funding/contracts

Therapy & Diagnosis

- 326 Development of Novel Therapeutic Agents that Target **Cancer Stem Cell**s
- 327 **Reformulation** of Failed Chemotherapeutic Drugs
- 331 Development of a Biosensor-Based Core Needle **Tumor Biopsy Device**
- 332 Development of **Radiation Modulators** for Use During Radiotherapy

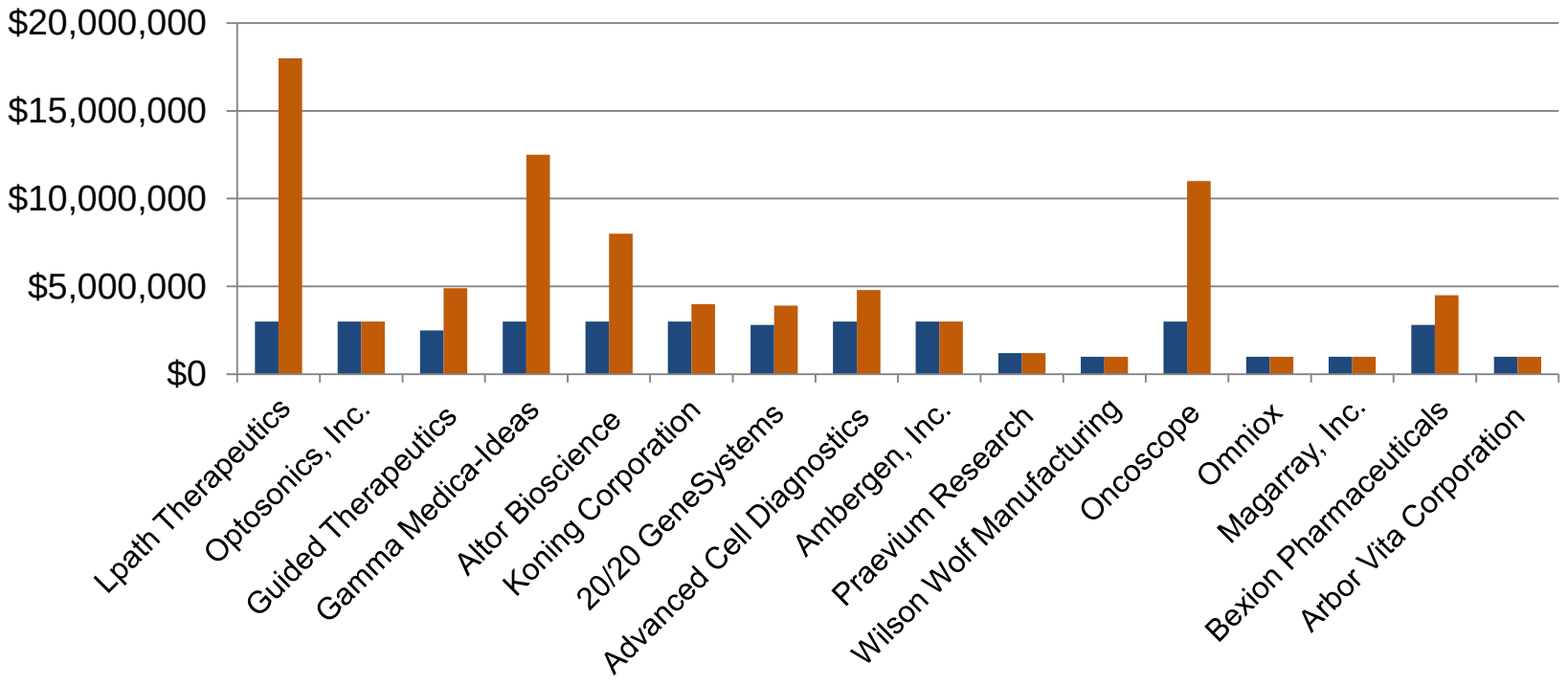
Advancing Cancer Research

- 328 Validation of 3D Human **Tissue Culture Systems** that Mimic the Tumor Microenvironment
- 329 **Proteomic** Analysis of Single Cells Isolated from Solid Tumors
- 330 Generation of Site-Specific **Phopho-Threonine Protein Standards** for Use in Cancer Assays

Health IT

- 333 **Software Tools** for the Development of Environmental Measures Related to Cancer Health Behavior and Resources

16 NCI Phase IIB Bridge Awards (to date)



NCI Total	**$37,160,051**
Third-Party Investments	**$82,502,379**
Leverage	**> 2 to 1**

Venture Capital:	**~1/3**
Strategic Partners:	**~1/3**
Individuals & Other:	**~1/3**

NCI SBIR Investor Forums- 2009, 2010, 2012, and 2014

SBIR & STTR

LEAP OF FAITH® TECHNOLOGIES

MagArray

Omniox
Targeted oxygen delivery

Venrock

SOFINNOVAVENTURES

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A Member of the Roche Group

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Digital Health, Bioinformatics, Research Tools, Evaluation, SBIR Investor Forum, FRAC Workshop

More Information on NCI SBIR & STTR Website

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http://sbir.cancer.gov

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