NCI SBIR&STTR: Advancing the Commercialization of New Cancer Innovations

http://sbir.cancer.gov

Sept 16, 2014
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NCI SBIR Development Center

Today's Presentation

- Overview & Eligibility
- The NIH SBIR/STTR Programs
- The NCI SBIR Development Center: Special Initiatives at NCI
- Funding Opportunities
- Practical Strategies on Applying

Congressionally-Mandated Programs

SBIR & STTR

Set Aside (FY14)

➢ 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

2.8%

➢ 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

0.4%

~$700M annually at NIH
~$119M annually at NCI

Reasons to Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development

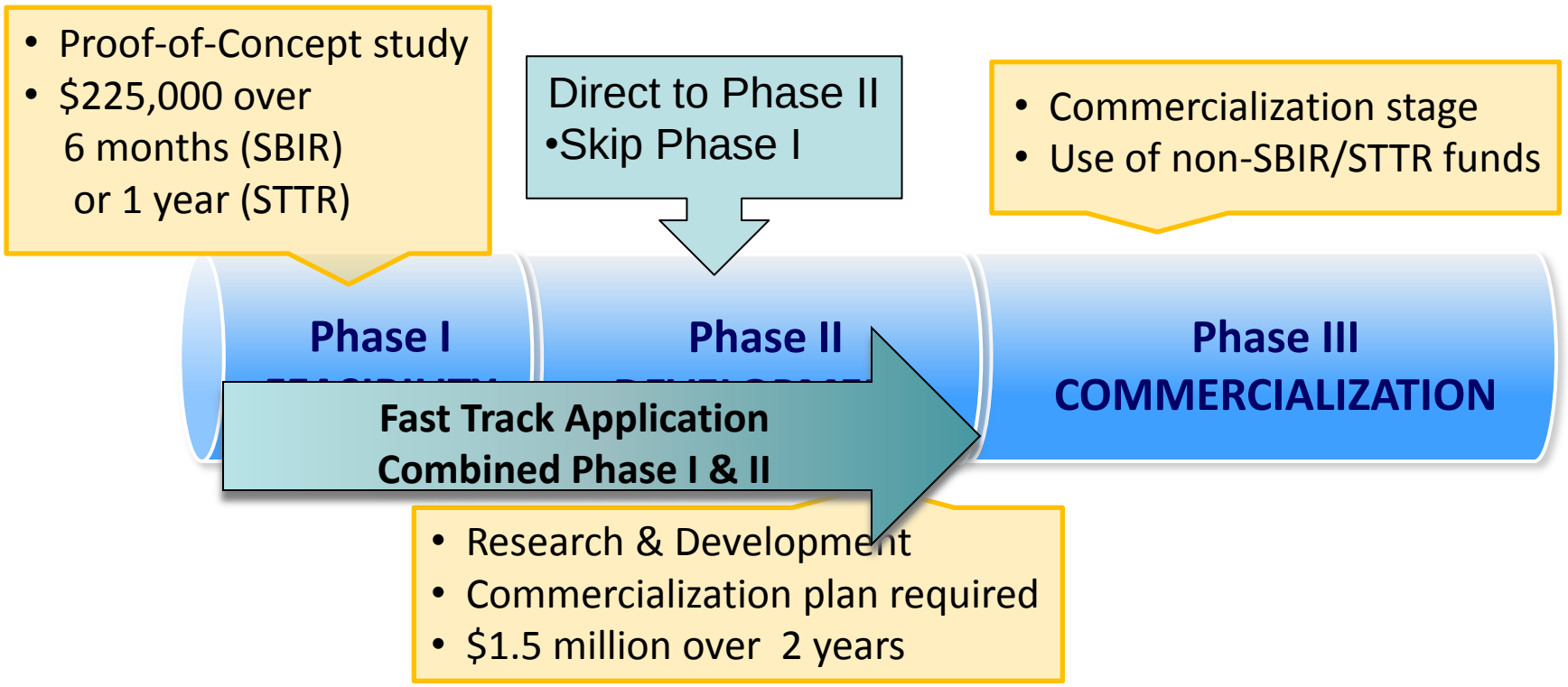
➢ Not a Loan

∴ 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
- Provides recognition, verification, and visibility
- Helps provide leverage in attracting additional funding or support (*e.g.*, venture capital, strategic partner)

SBIR & STTR: Three-Phase Program



- Hard caps on award sizes: $225,000 for Phase I; $1.5 million for Phase II
- Certain awards may exceed these caps if covered by topic-specific waivers
- Actual funding may vary by topic

NCI SBIR Phase IIB Bridge Award

- Provides up to $1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners *earlier in the development process*
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., ≥ 1:1 match)

Milestone-Based Awards

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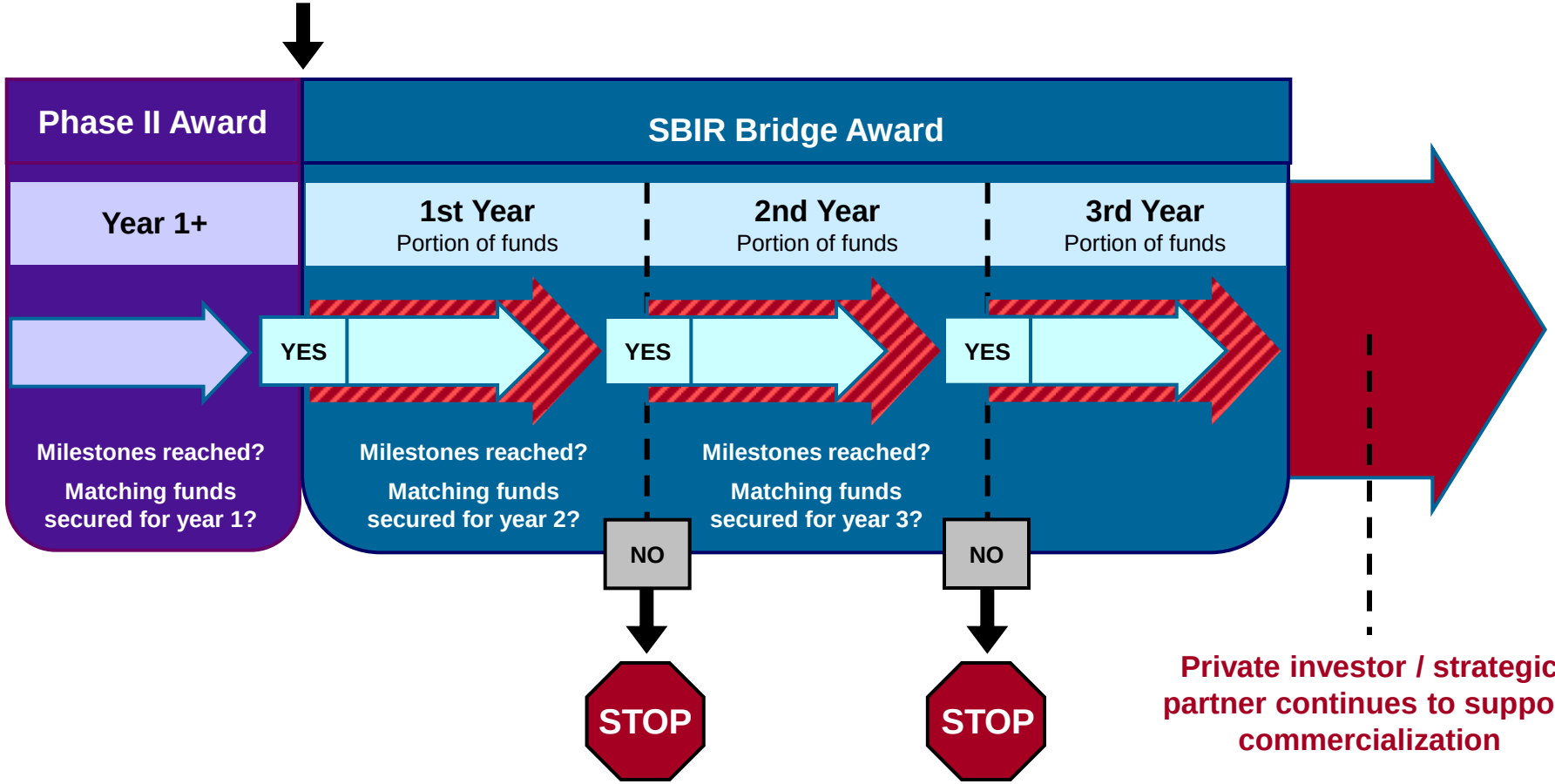
Ability to raise matching funds is a component of the Phase II Bridge Award



SBIR Eligibility Requirements

New Rules starting 1/28/13

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- **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 Requirements

- **Applicant is a Small Business Concern (SBC)**
- **Organized for-profit U.S. business**
- **Formal cooperative R&D effort**
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- **US Research Institution: college or university; non-profit research organization; Federally-Funded R&D Center (FFRDC)**
- **Principal Investigator's primary employment may be with either the SBC or the research institution**
- **SBC must have right to IP to carry out follow-on R&D and commercialization**

SBIR vs. STTR: Which Program is Best for You?

	SBIR	STTR
Research Partner	Permits partnering *Small business must do 67% Phase I, 50% Phase II*	**Requires** partnering with US research institution *Small business min. 40%, Research institution min. 30%*
Principal Investigator	Primary employment **must** be with small business	PI may be employed by either small business or research institution, and must commit minimum of 10% effort to project

Small Business Concern is **ALWAYS** Applicant/Awardee Organization

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The NIH SBIR/STTR Programs

NIH = 27 Institutes & Centers

24 Participants in the SBIR/STTR Program

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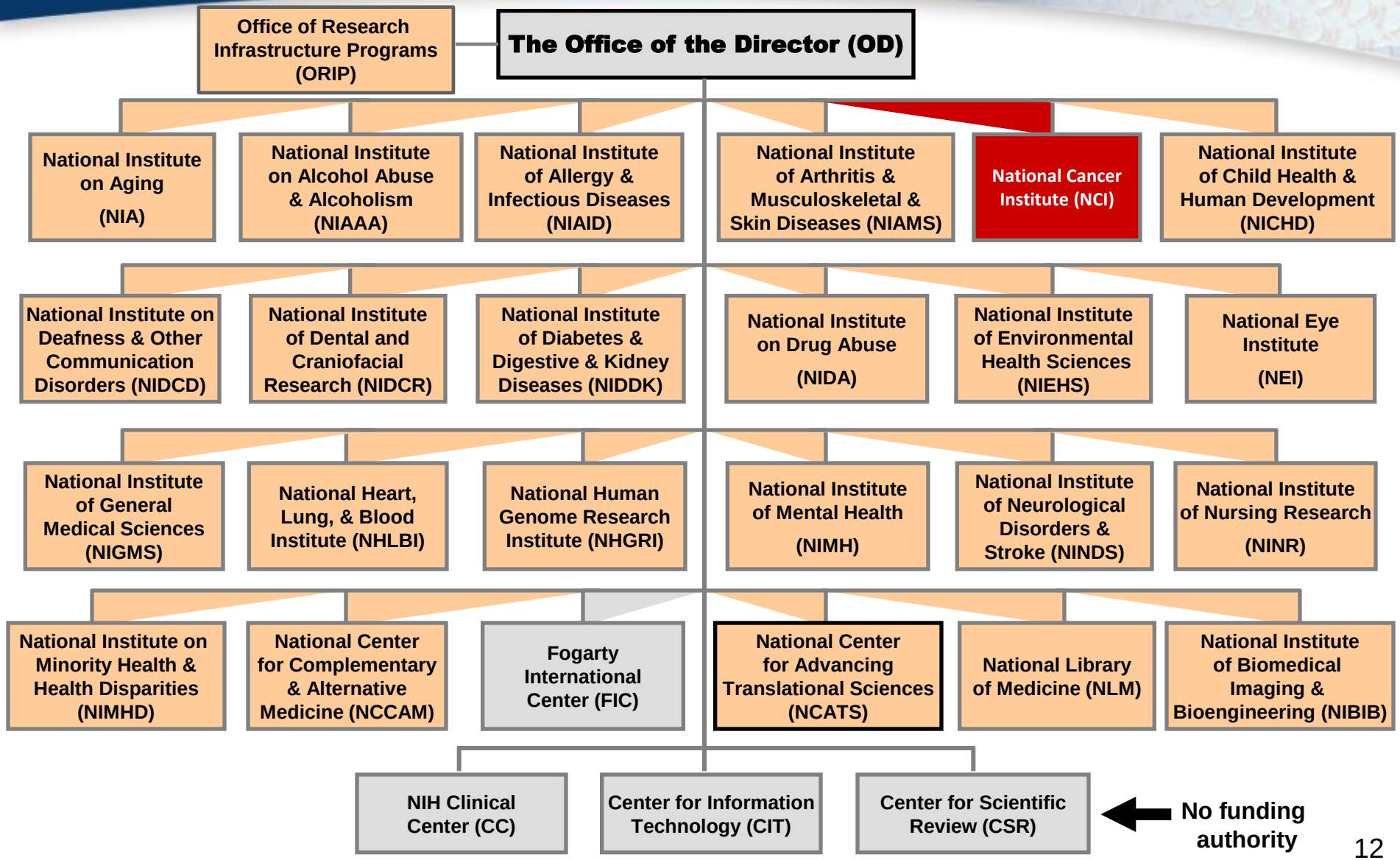
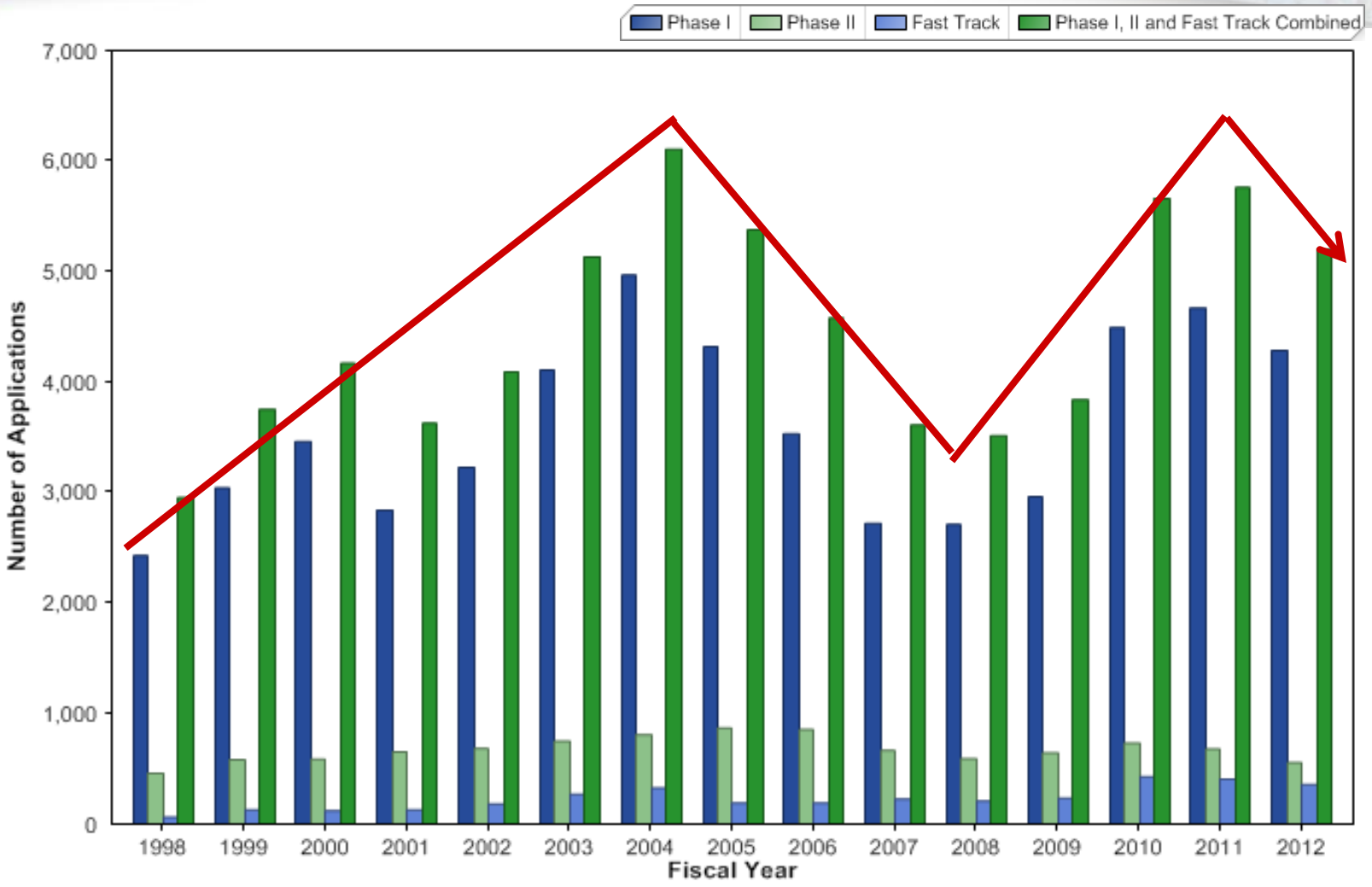


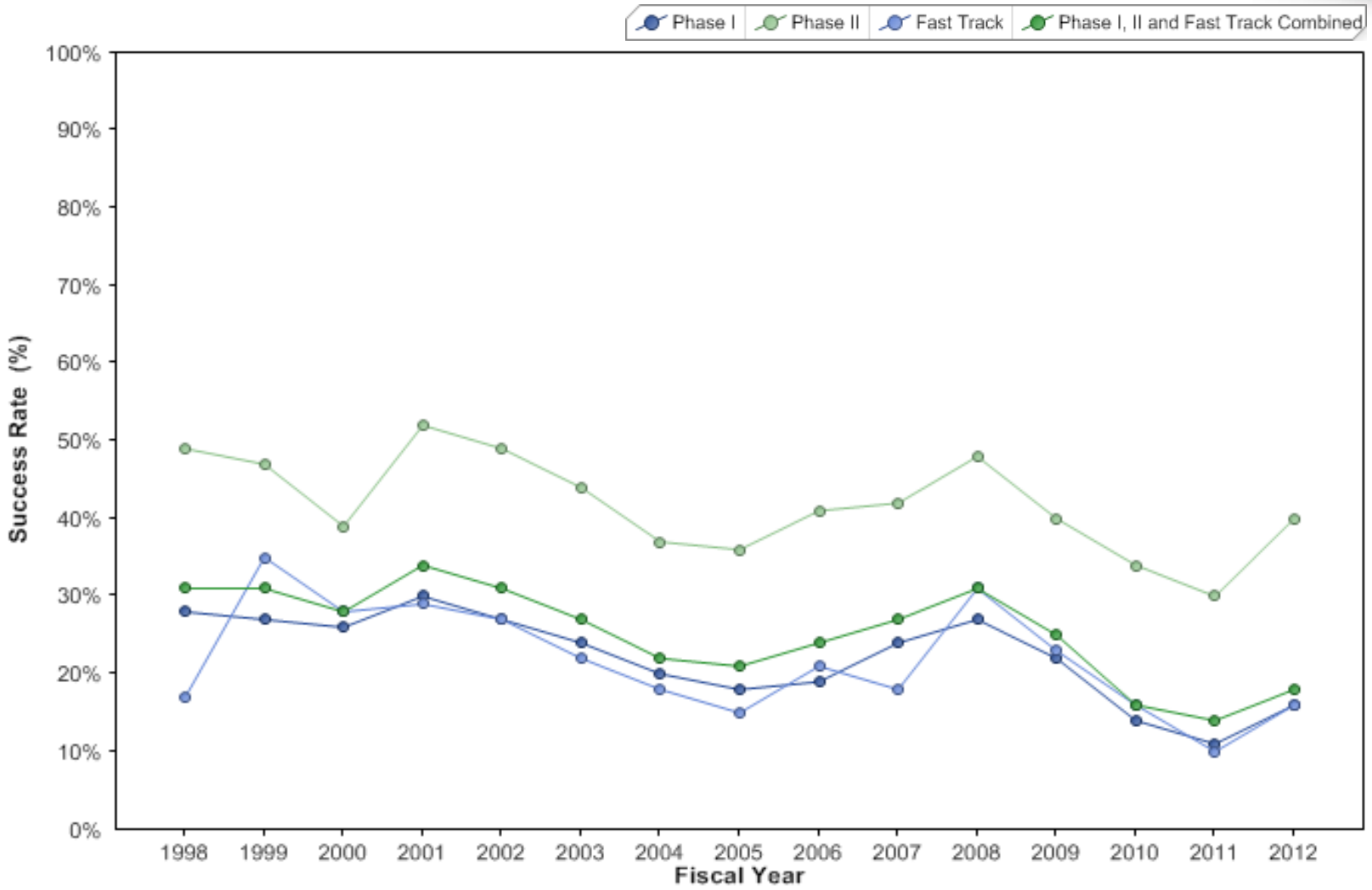
Competition Has Increased

NIH SBIR competing applications (1998 – 2012)



Success Rates Have Decreased

NIH SBIR success rates (1998 – 2012)



NIH Data Book – http://report.nih.gov/ndb/index.aspx
Data provided by Division of Information Services, Reporting Branch

NIH SBIR/STTR
Program Changes

SBIR/STTR Reauthorization Act of 2011

Set-aside is Increasing

FY	SBIR Set-aside	STTR Set-aside
2011	2.5%	0.30%
2012	2.6%	0.35%
2013	2.7%	0.35%
2014 (current)	2.8%	0.40%
2015	2.9%	0.40%
2016	3.0%	0.45%
2017	3.2%	0.45%

Good News

New Provisions in Current Omnibus Grant Solicitations

- 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).
- Hard caps on award sizes (Ph I $225k, Ph II $1.5M)
- Applicants can request $5000 in Technical Assistance, beyond award cap. If requested, cannot participate in NIH Technical Assistance Programs.

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The NCI SBIR Development Center

http://sbir.cancer.gov

NCI SBIR Development Center Program Directors

Michael Weingarten, MA
Director
NCI SBIR Development Center

Greg Evans, PhD
Lead Program Director
Cancer Biology, E-Health, Epidemiology, Research Tools

Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics, Biologics, SBIR Investor Forum, FRAC Workshop

Deepa Narayanan, MS
Program Director
Cancer Imaging, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop

Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

Christie Canaria, PhD
AAAS Science & Technology Policy Fellow
Research Tools, Imaging, I-Corps, Policy, Scientific Communications

Andrew J. Kurtz, PhD
Lead Program Director
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award

Jian Lou, PhD
Program Director
In-Vitro Diagnostics, Theranostics, early-stage drug development , Bioinformatics, FRAC Workshop

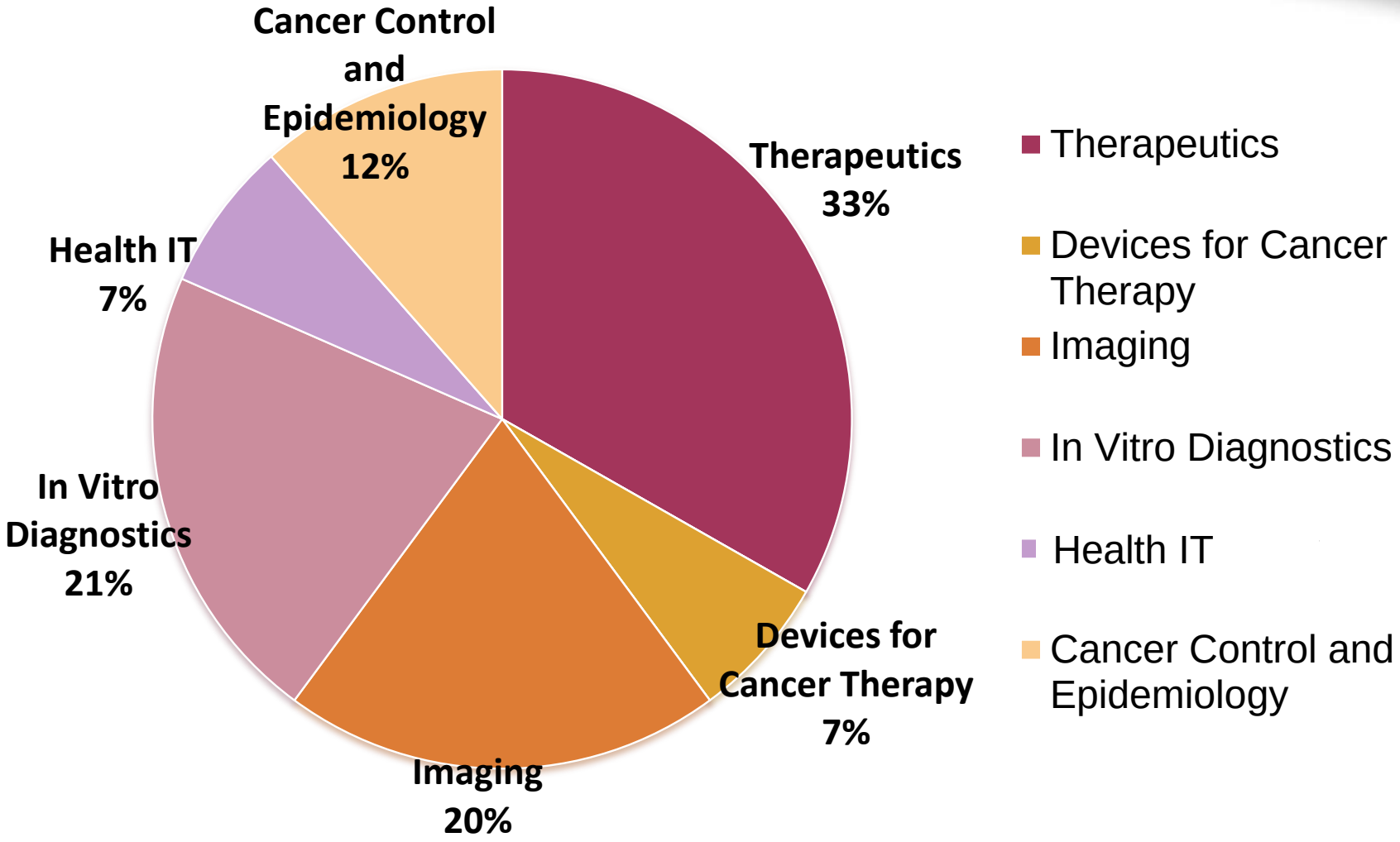
Todd Haim, PhD
Program Director
Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop

Amir Rahbar, PhD, MBA
Program Director
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics, SBIR Investor Forum

Jonathan Franca-Koh, PhD, MBA
Program Director
Therapeutics, Small Molecules and Cell-based therapy

Kory Hallett, PhD
AAAS Science & Technology Policy Fellow
Policy, Scientific Communications

Pipeline of 400+ vetted projects



NCI SBIR Investor Forum

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Exclusive opportunity for some of the most promising NCI-funded companies to showcase their technologies

http://sbir.cancer.gov/investorforum/

- 2014 NCI SBIR Investor Forum, November 13, 2014
- In 2012, 18 top SBIR-funded companies presented
- Over 200 life science investors & leaders
- 150+ one-on-one meetings
- **2010 Investor Forum: 8 out of 14 presenting companies closed deals valued at over $230M**

2010 Investor Forum Results

- **8 out of the 14 presenting companies have closed deals valued at over $230M**
  - **Zacharon, a company focused on developing therapeutics for rare diseases and cancer, finalized a major partnership with Pfizer worth up to $200M**
  - **Lpath** closed a $4.9 Million Equity Financing round to fund continued development of two drug candidates
  - **MagArray** closed a strategic partnership deal with IMRA America for $10M to continue development of its cancer diagnostic platform
  - **ImaginAb** raised $12.5M in a Series A round to engineer antibodies into *in vivo* PET imaging agents for targeted molecular diagnostics.

Workshop on Federal Resources to Accelerate Commercialization

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Bringing together NCI SBIR/STTR awardees to move funded technologies from bench to bedside

http://sbir.cancer.gov/FRACWorkshop

- May 7, 2013 at NCI Shady Grove
- Speakers from FDA, CMS, USPTO, and White House OSTP
- Panels on other sources of federal funding, resources & collaborative programs at NIH, and unique life science investment organizations
- One-on-one meetings with program directors and speakers

I-Corps™ @ NIH Pilot Program

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- **A pilot program that's a partnership between NSF and NIH.**
  - 4 participating NIH Institutes
  - NCI, NHLBI, NINDS, NCATS

- **Goal – to accelerate development of biomedical technologies into viable products & services.**

I-Corps™ @ NIH: Format

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- A nine-week business strategy boot camp
- Teams are “taught” and guided by a group of experienced faculty (e.g., serial entrepreneurs, venture capitalists, etc.)
- Develop a viable business model around their technology focusing on key questions like their value proposition and revenue model.

I-Corps™ @ NIH: Format

- **Process: gather as much information and insight as possible by conducting 100 interviews with potential customers and partners.**
- **Adjust business strategy based on direct customer feedback.**
- **Use of "Business Model Canvas" provides a framework for analyzing information to determine if there is a product/market fit.**

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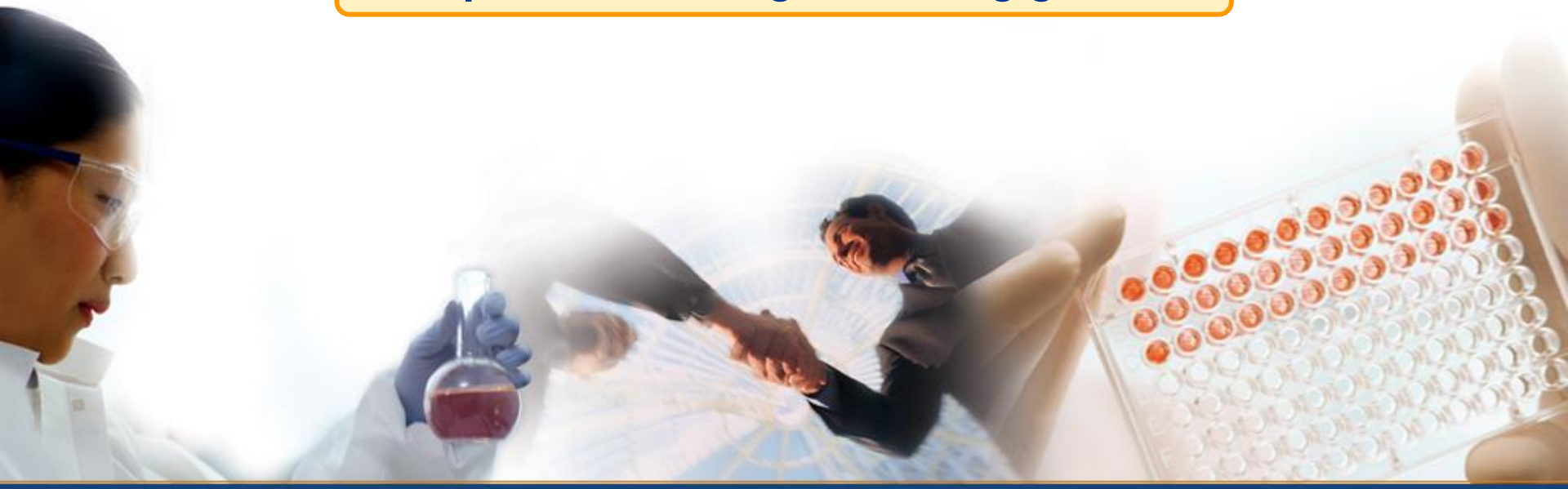
NCI SBIR
Grant Funding Opportunities

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



Multiple Funding Solicitations

Know the Application Deadlines

- **SBIR & STTR Omnibus Solicitations for Grant Applications**

  Release: January

  Receipt Dates: April 5, August 5, and December 5

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

  Release: Weekly

  Receipt Dates: Various

- **Solicitation of the NIH & CDC for SBIR Contract Proposals**

  Release: August – *sign up for the email list to get notified!*

  Receipt Date: Early November

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

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

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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 date: **December 5, 2014**

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

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

Development of Highly Innovative Tools and Technology for Analysis of Single Cells (PA-13-140)

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Goal: Development of next-generation tools to better define cell heterogeneity in situ, with substantially increased sensitivity, selectivity, spatiotemporal resolution, scalability or non-destructive analysis of multiple global or functional measures of single cells.

- Affiliated with the Single Cell Analysis Program (SCAP) through the NIH Common Fund
- New analytical measures and manipulations of cellular contents, structure and activity beyond those currently available
- First-in-class and/or cross-cutting techniques

Next receipt date: **December 5, 2014**

Contact Dr. Xing-Jian Lou: loux@mail.nih.gov

http://commonfund.nih.gov/Singlecell/

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

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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: **November 4, 2014**; May 28, 2015
November and May through 2016

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

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

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Contract Funding Opportunities

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

SBIR Contracts vs. Grants

	Funding Solicitations for SBIR Grants	Funding Solicitation for 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**
Basis for Award	Based on score during peer review	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
Reporting	One final report (Phase I); Annual reports (Phase II)	Monthly or quarterly progress reports
Set-aside of funds for particular areas?	NO	**YES**

Topic 336: Development of Novel Therapeutic Agents That Target Cancer Stem Cells

(Fast-Track proposals will be accepted.)

Budget (total costs): PhI: $300,000 for 9 months; PhII: $2,000,000 for 2 years

Number of anticipated awards: 2-3

Project Goals: Proposals under this topic should be involved the development of novel therapeutic agents that target CSCs. These small molecules or biologics should be designed to target CSCs, CSC-related biomarkers, or CSC pathways that affect fundamental processes associated with carcinogenesis, tumor progression, maintenance, recurrence or metastasis. Particular emphasis is placed on agents that target CSC self-renewal, regeneration, or differentiation processes.

Phase I Activities & Deliverables:

- Demonstrate in vitro efficacy for the agent(s) that targets CSCs.
- Validate the effect of the agent(s) on CSCs. The offerors are required to provide evidence confirming that the agent(s) specifically targets CSCs (e.g., measurement showing reduced quantity, viability, or frequency of CSCs).
- Conduct structure-activity relationship (SAR) studies, medicinal chemistry, and/or lead antibody optimization (as appropriate).
- Perform animal toxicology and pharmacology studies as appropriate for the agent(s) selected for development.
- Develop a detailed experimental plan (to be pursued under a future SBIR Phase II award) necessary for filing an IND or an exploratory IND.

FY15 NCI Contract Funding Topics - Due Date: November 5, 2014

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Therapeutics

- 336 Development of Novel Therapeutic Agents that Target Cancer Stem Cells

In Vitro Diagnostics

- 337 Cell-Free Nucleic Acid-Based Assay Development for Cancer Diagnosis

Advancing Cancer Research

- 334 Vacutubes to Preserve the Viability of Circulating Tumor Cells
- 335 Development of Advanced Culture Systems for Expansion of Cancer Stem Cells

Medical Devices & Radiation Therapy

- 338 Predictive Biomarkers of Adverse Reactions to Radiation Treatment
- 339 Systemic Targeted Radionuclide Therapy For Cancer Treatment

Health IT

- 340 Validation of Mobile Technologies for Clinical Assessment, Monitoring, and Intervention

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Deciding to Apply

When is an SBIR/STTR application appropriate?

- Innovative solution to significant unmet clinical need
- Significant commercial potential
- Leverages company/founder expertise
- Need funding to produce feasibility data
- Need funding for development
- Start-up: Too early for private investment
- Established SBC: No resources to try new approach, but board supports SBIR

When NOT to Apply

- Chasing solicitations – “why not?”
- Chasing “cool” technologies
- Need cash urgently
  - SBIRs take 8-16 months or more to get and you must start with Phase I (~$225K)
- Incremental upgrade: no change to clinical paradigm
- “Me too” product matching competitor’s capabilities
- Basic research still required to demonstrate commercial and clinical feasibility

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What Does It Take to Get Funded?

Practical Strategies/ Tips on Applying

Understand the Application Process

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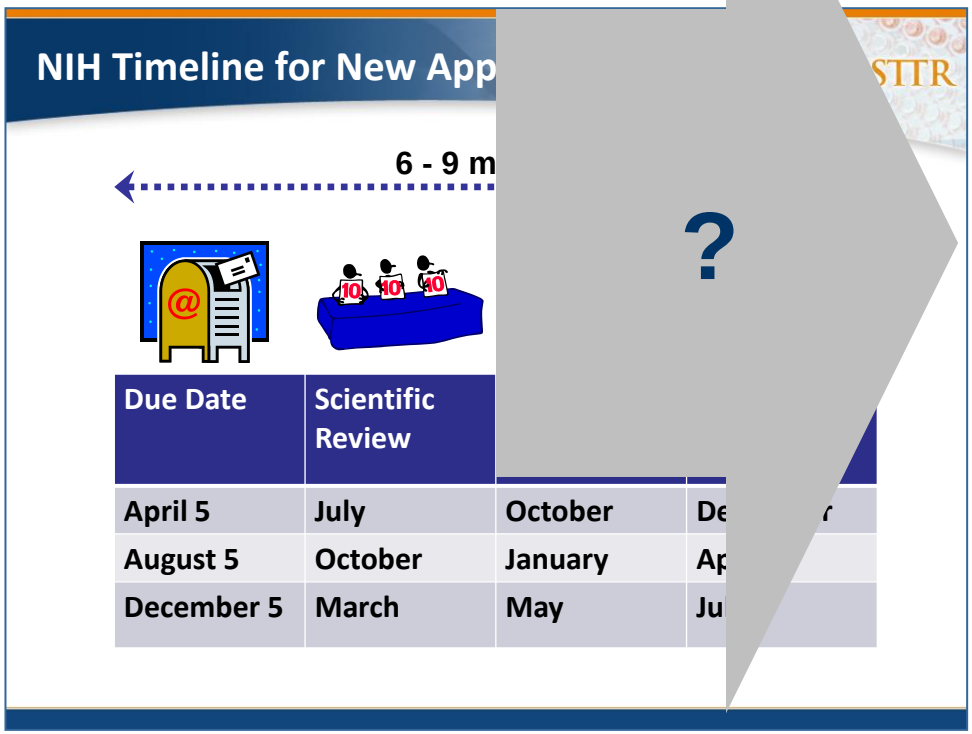
Decide to Apply → Build the application → Submit the application → Receive the Summary Statement → Receive the award

Resubmission

Start early

- **Strong proposals take time to develop**
- **Take care of the administrative registrations** (See SF424)**.** Start this at least 2 months before deadline!
  - http://sbir.nih.gov > *Electronic Submission*
- **Carefully read the Solicitation**
- **Need time to fill the gaps**
  - Assemble a strong scientific team
  - Get access to equipment and other resources
  - Get letters of support



Federal Funding: Not Easy Money

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- **SBIR/STTR awards are highly competitive**
  - **(It was not always like that)**
  - **Resubmissions have become the norm**
  - **Funding success rate around 10-15%**

- **Your competitors are smart, skilled, accomplished, and hail from top institutions**

- **Lots of great ideas**

- **Solution: Prepare a strong application**
- **Solution: Use help**

Before You Write an Application

- **Consider your company's strengths**
- **Consider your company's weaknesses**
- **Review similar, currently funded NIH projects**
  - NIH Project RePORTER
- **Contact NIH Program Director in advance (at least 1 month before due date!) to discuss your specific aims and receive feedback**

Search Previous Awards

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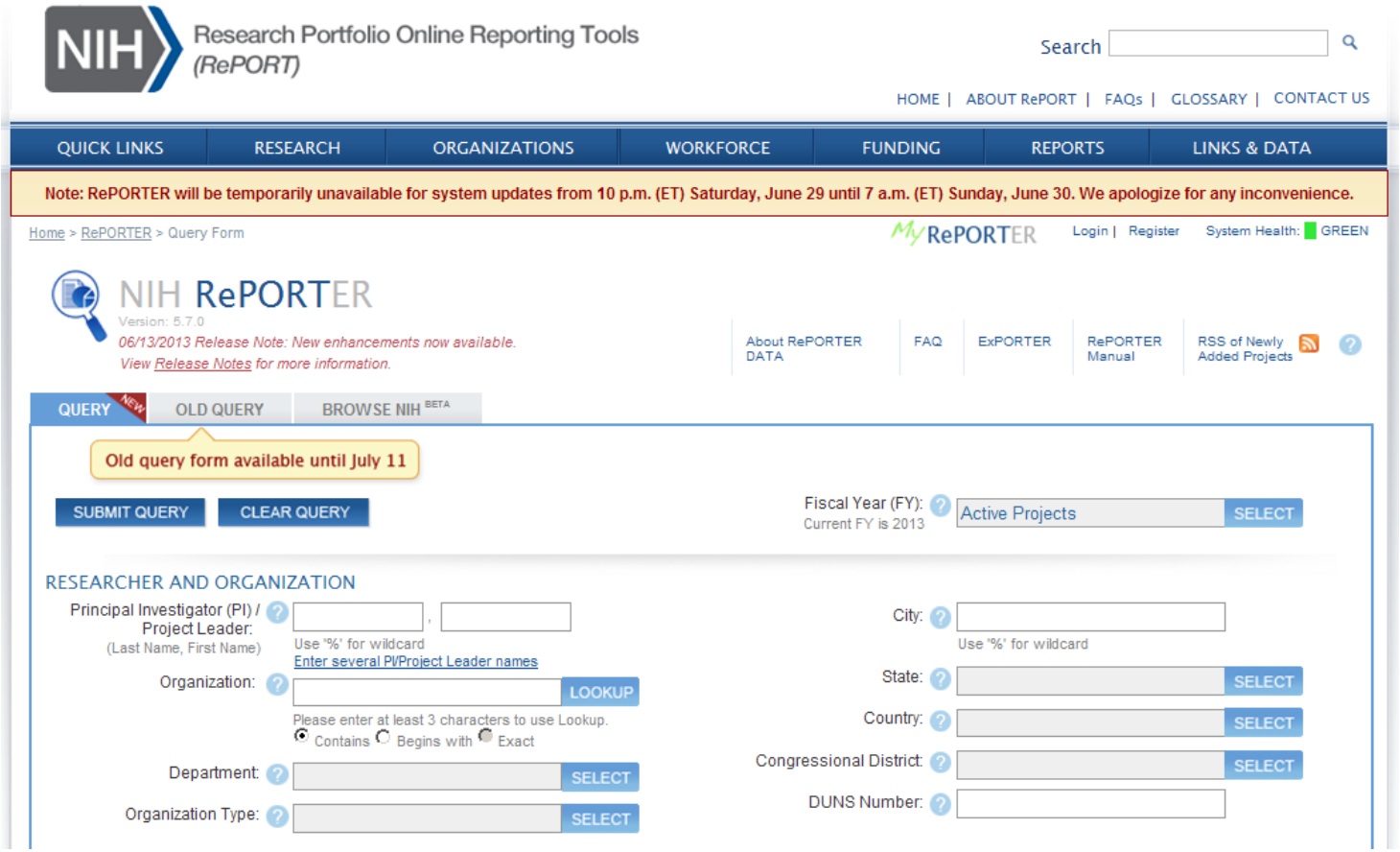
http://projectreporter.nih.gov



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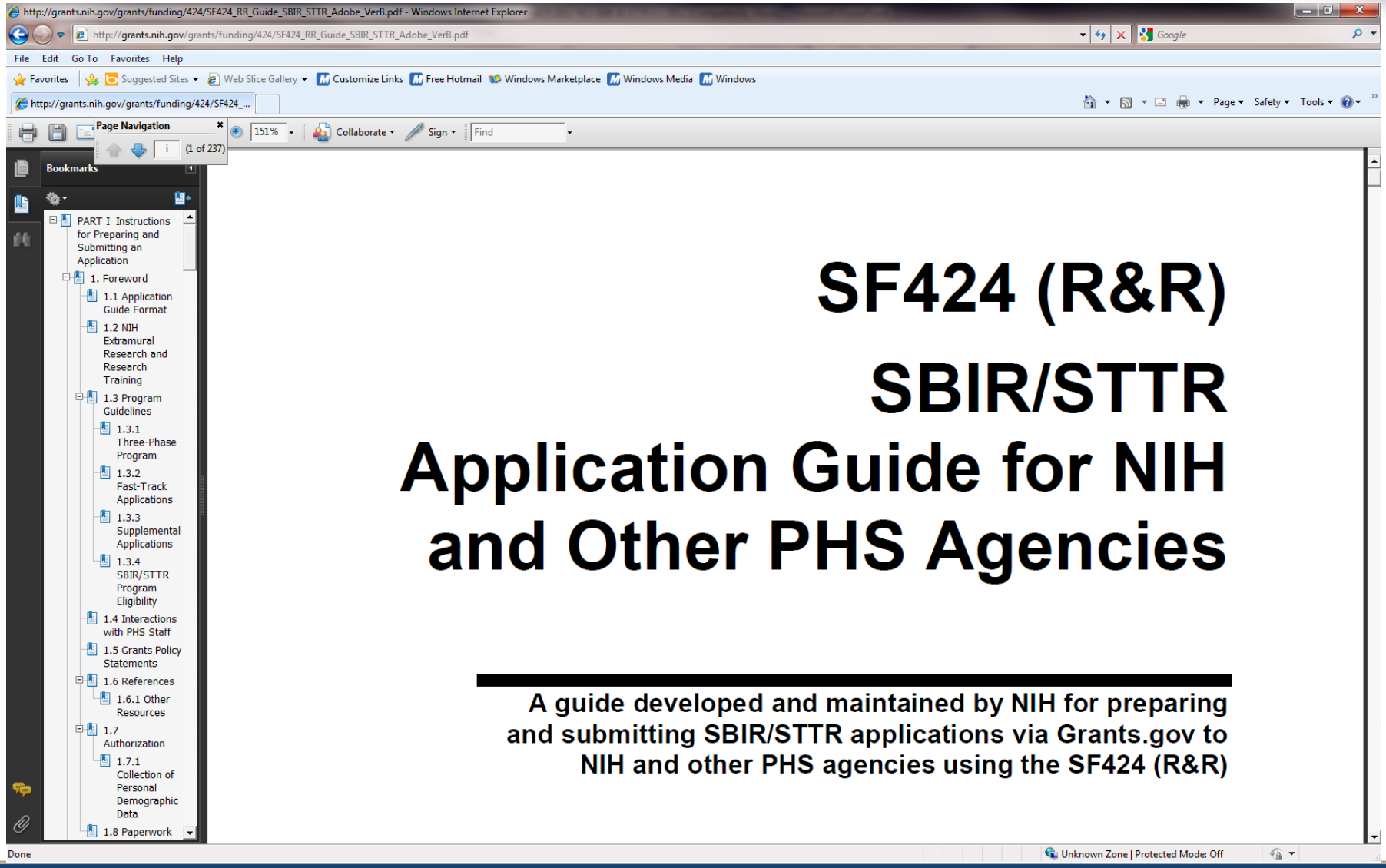
Building the Application

SF424 Application Guide



Take Time to Refine the Vision

- **Start informal discussions to clarify the product vision**
  - Potential customers
  - Technical experts
  - Potential investors & commercialization partners

- **Seek help early in process**
  - Experienced SBIR applicants
  - Academic collaborators with grant experience
  - Professional grant writers
  - **Engage with SBIR Program Staff**
    - **Email a short summary and request review of specific aims**

Build the Right Team

- **Choose the Principal Investigator (PI)**
- **Consider building multi-PI team**
  - Multidisciplinary proposals
  - PI lacks certain types of necessary expertise
  - Must appoint Contact PI (SBIR, > 50% of time w/ business)
- **Partner to fill the gaps**
  - Academic collaborations
  - Consultants
  - Other companies
- **Use SBIR application as engagement tool**
  - Academic researchers understand grants
  - Business executives understand product development and marketing

Reviewers Only See the Application

- **Specific Aims (1 page)**
  - Focal point of the application
  - Highlight the technology's major strengths
  - Describe goals of the application – be specific
  - Quantitative performance milestones
  - What is the problem you are uniquely able to solve? What is the unmet medical need?
- **Research Strategy**
  - Provide background information
  - Provide detailed technical plan to achieve Specific Aims
  - Propose realistic scope/budget/timeline
  - Preliminary data not required in Ph I, but often powerful
  - Describe potential pitfalls and alternative angles of attack

Reviewers Only See the Application

- **Other application components**
  - **Letters of support**
    - **Necessary from consultants and collaborators**
    - **Powerful from clinicians, end-users, and potential investors/partners**
  - **Phase II Commercialization Plan (12 pages)**
  - Cover Letter – Not seen by reviewers
    - Used to **request dual assignment**
    - Used to **request and justify a specific study section**
  - Biosketches for all senior and key personnel (< 4 pages each)
  - Budgets for each project period
  - Separate budgets for each subcontract
  - Descriptions of facilities and equipment
  - Human subject research section (if applicable)
  - Vertebrate animals section (if applicable)
  - Other information as required

Run Your Own "Peer Review"

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… before you submit

- **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
- **Ask all collaborators to review the application**
- **Recruit independent, technically-trained 'laymen' as readers**
  - Do they understand it?
  - Are they excited?

Know NIH Review Criteria

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- Significance
- Approach
- Innovation
- Investigator
- Environment
- *Commercialization*

- Does the product address an important problem and have commercial potential? Is there a market pull for the proposed product?
- Are desi and methoc ? Are probl alls and al vided?
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- Is the company's business strategy one that has a high potential for success?

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Summary Statement

Impact Score:
10-90

Identify Study Section

- **Identify the most appropriate Institute/Center**
  - Talk to a program director

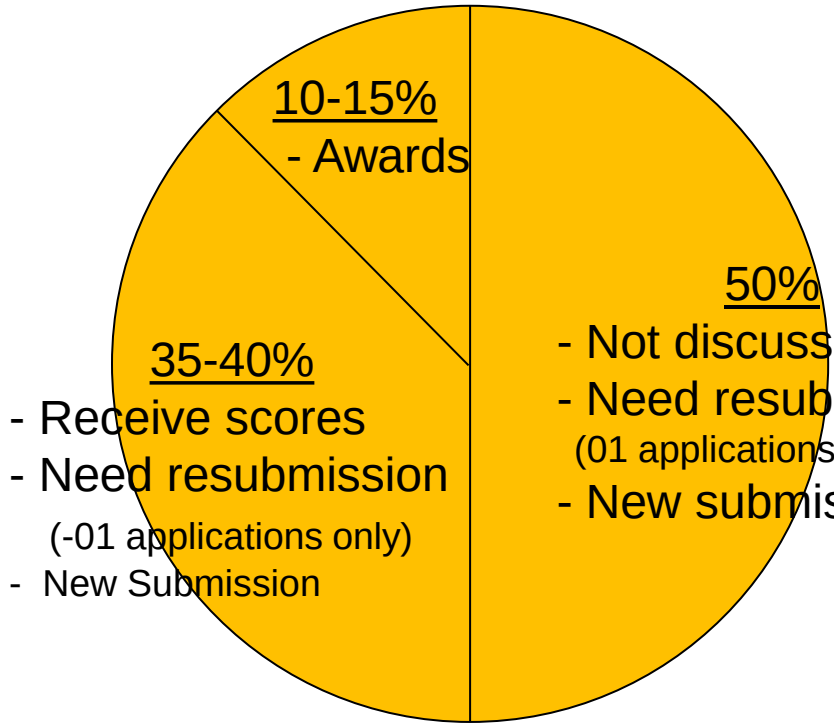
- **Identify the most appropriate study section BEFORE you submit your application and check after you're assigned**
  - See CSR website for study section descriptions http://www.csr.nih.gov/Roster_proto/sbir_section.asp
  - See the list of study section members
    - Do they have the right areas of expertise?
  - Request and justify a study section in the cover letter

Post Submission –What's next?

Receiving the Summary Statement

Receiving the award

?



If you are not funded the first time…

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- **Rejection is painful, but there is feedback to work with**
  - Respond to the Summary Statement carefully
  - Use peer review to improve your technology and presentation
  - Discuss with your NIH Program Director
- **Revise and resubmit**
  - Introduction Page: Response to reviewer critiques
  - Request review by PO
  - Be constructive not defensive
- **Learn more about SBIR/STTR grants**
  - Explore opportunities to serve on NIH peer review panels
  - Talk to successful applicants
  - Understand review process and dynamics - http://csr.nih.gov

Common Problems

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- **Significance**
- **Approach**
- **Innovation**
- **Investigator**
- **Environment**
- ***Commercialization***

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Summary Statement

- Reviewers did not understand your proposal.
- Reviewers do not think you are working on significant problem.
- Reviewers say the proposal is ‘not innovative’.
- Reviewers feel the team is not qualified to handle the problem.
- Reviewers are critical of the approach
- Reviewers did not see potential of commercialization

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NCI SBIR Development Center

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Thank You!