NIH's SBIR Programs and Opportunities for US/EU Small Businesses

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SBIR & STTR

NATIONAL CANCER INSTITUTE

The NIH SBIR/STTR Programs

http://sbir.nih.gov

NIH = 27 Institutes & Centers

24 Participants in the SBIR/STTR Program

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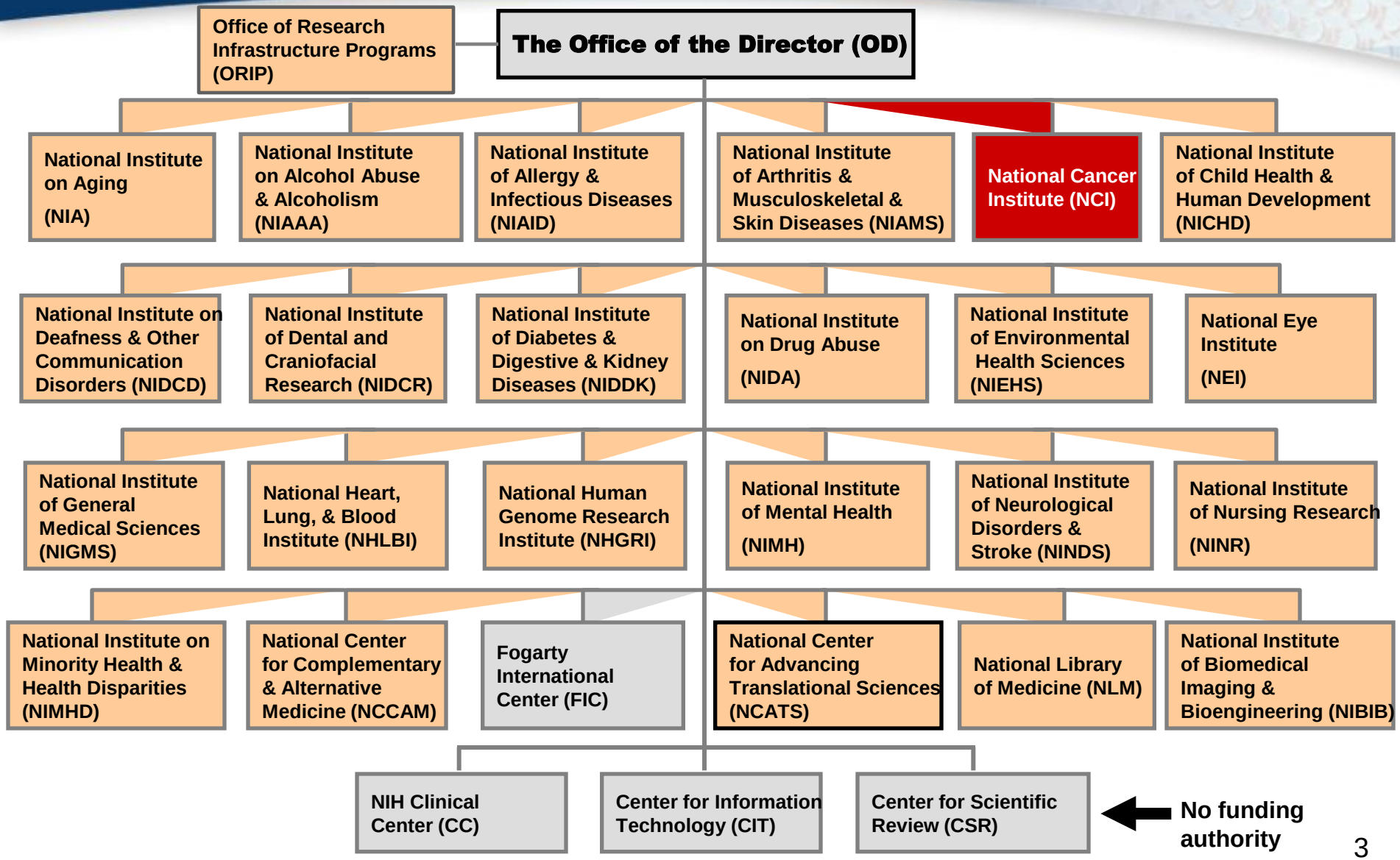

Congressionally-Mandated Programs

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	Set Aside (FY14)	Set Aside (FY15)
Small Business Innovation Research (SBIR)	2.8%	2.9%
Small Business Technology Transfer (STTR)	0.4%	0.4%

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

~$750M annually at NIH
~$119M annually at NCI

Reasons to Seek SBIR/STTR Funding

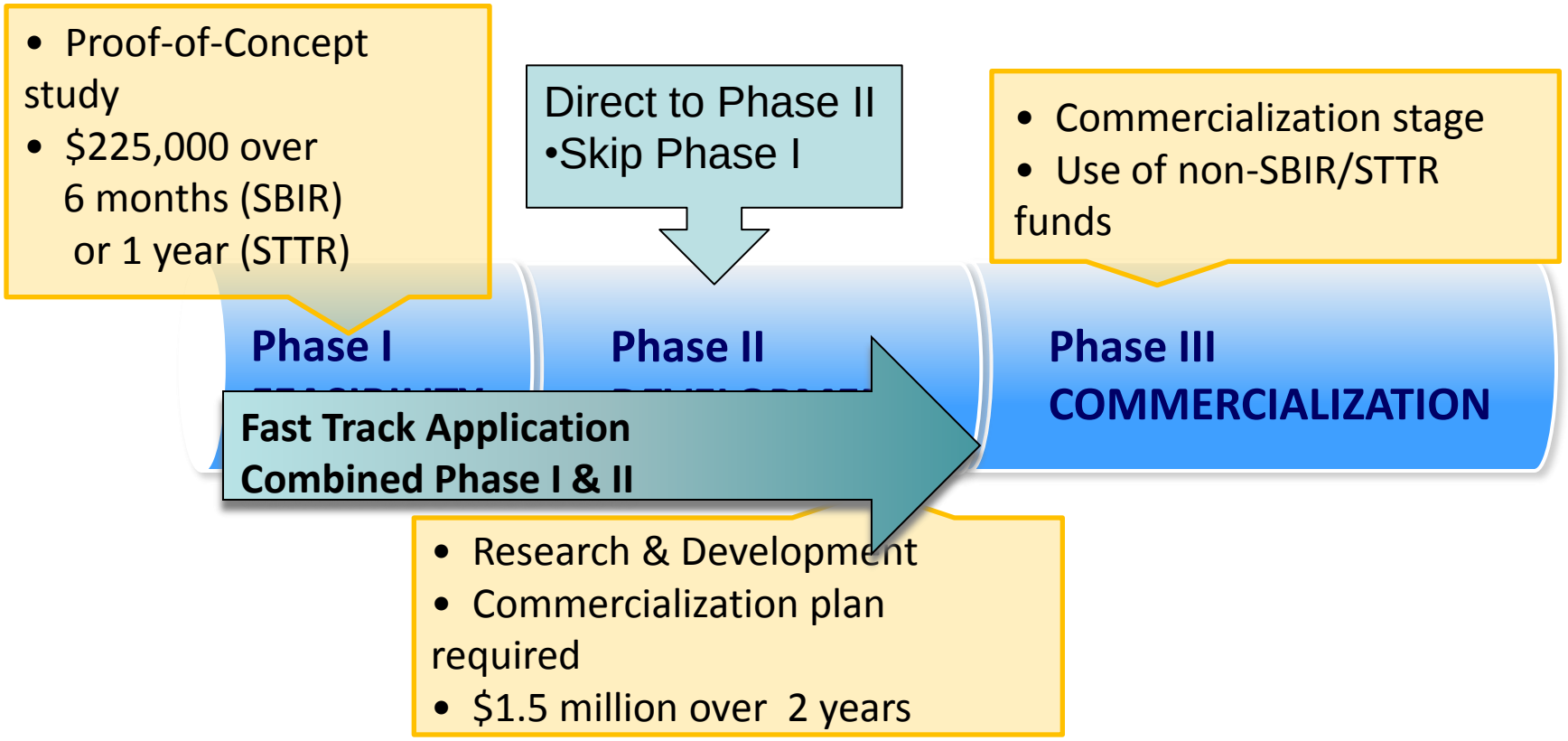
- One of the largest sources of seed funding for innovative technology development by small businesses
- We fund small businesses at a very early stage.

➢ **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



- 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

Multiple Funding Solicitations

Know the Application Deadlines

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- **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 2014

  Receipt Date: **November 2014**

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

NIH Timeline for New Applications

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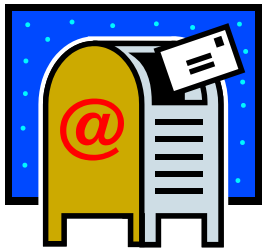
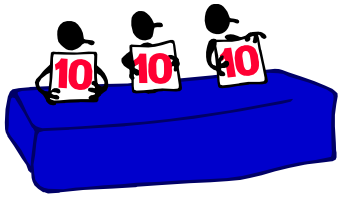
6 - 9 months





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

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The NCI SBIR Development Center

http://sbir.cancer.gov

Why are SBIR and STTR Important to NCI?

NCI's primary resource for enabling commercialization of high impact technologies that can benefit patients, such as:

- **Small Molecules and Biologics**
- **Cancer Diagnostics**
- **Cancer Imaging**
- **Electronic Health & Education Tools**

A $119M Program at the NCI

New Model: NCI SBIR Development Center

Development Center staff are responsible for:

- **Conducting regular outreach events to help recruit more focused, commercially-minded SBIR applicants**
- **Coaching applicants on developing stronger applications**
- **Providing oversight and active management of projects**
- **Mentoring and guiding companies throughout the award period**
- **Facilitating matchmaking with potential third-party investors and strategic partners**

NCI SBIR Development Center Program Staff

Michael Weingarten, MA *(Director)*

Previous

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

Greg Evans, PhD *(Lead Program Director)*

Previous

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

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
- **Trega Biosciences, Inc** – Director, Microbiology & Immunology

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)

Christie Canaria, PhD *(AAAS S&T Policy Fellow)*

Previous

- **Lawrence Berkeley National Laboratory –** Research Scientist; Manager, Imaging Facility
- **Illumina, Inc.–** Chemistry Researcher

Andrew J. Kurtz, PhD *(Lead 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 Director)*

Previous

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

Amir Rahbar, PhD, MBA *(Program Director)*

Previous

- **NCI**– Program Manager, Center for Strategic Scientific Initiatives
- **BioInformatics, LLC** – Senior Science Market Analyst
- **Naval Research Laboratory** – Research Scientist

Ming Zhao, PhD *(Program Director)*

Previous

- **NCI**– Program Director, Center to Reduce Cancer Health Disparities
- **GE Global Research** – Senior Scientist
- **Pfizer** – Scientist

Challenges facing Small Business Concerns (SBCs)

- Entrepreneurial education
- Gaps in funding
- Access to private capital
- Navigation around U.S. Federal regulatory and reimbursement requirements

NSF-NIH I-Corps Program
(Launched June 2014)

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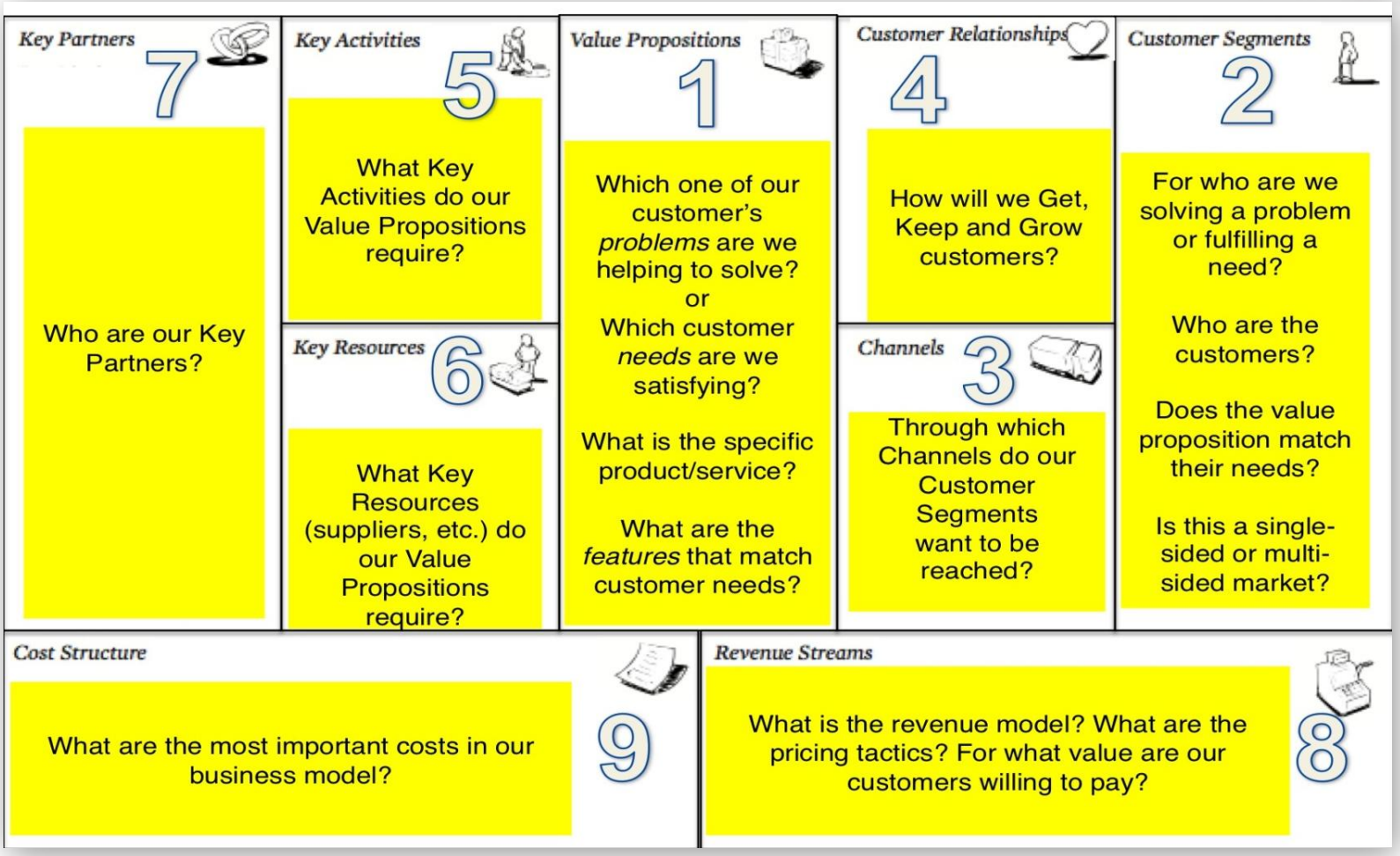
- **Teaches teams of scientists how to be entrepreneurs**
  - **How to evaluate the value of their intellectual property**
  - **A process for how to build a business model around the technology they've developed.**
- **Teams are "taught" and guided by a group of experienced faculty (e.g., serial entrepreneurs, venture capitalists, etc.)**
- **Process: gather as much information and insight as possible by conducting 100 interviews from customers and potential partners.**
- **Use of "Business Model Canvas" imposes a strategy for gathering and analyzing information to determine if there is a product/market fit.**

I-Corp Business Model Canvas



NCI SBIR Phase IIB Bridge Award

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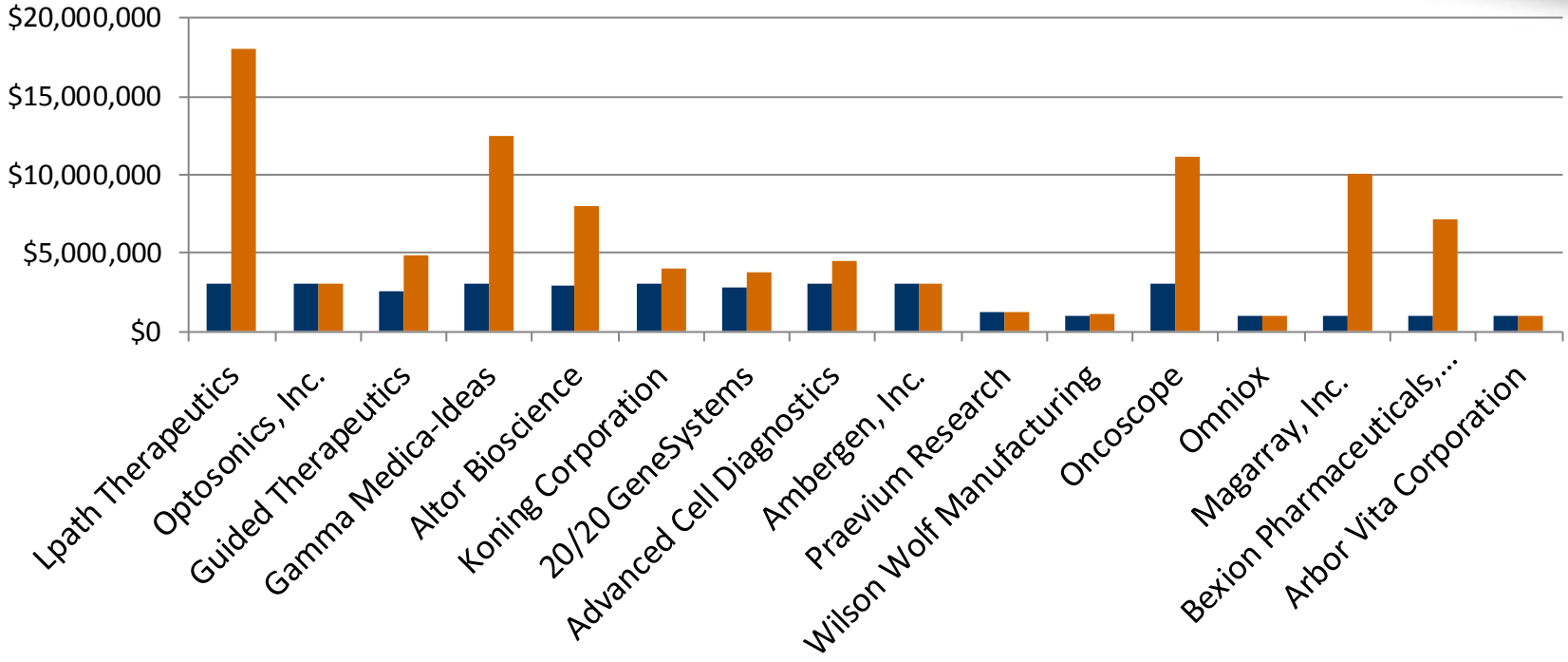
- Provides up to $1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners *earlier in the development process*
- Competitive preference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

16 Bridge Awards To Date



NCI Total	**$35,262,319**
Third-Party Investments	**$94,300,756**
Leverage	**> 2 to 1**

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

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/

- 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 collectively 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**

Additional NIH Programs Open to Small Businesses

NCI Experimental Therapeutics Program (NExT)

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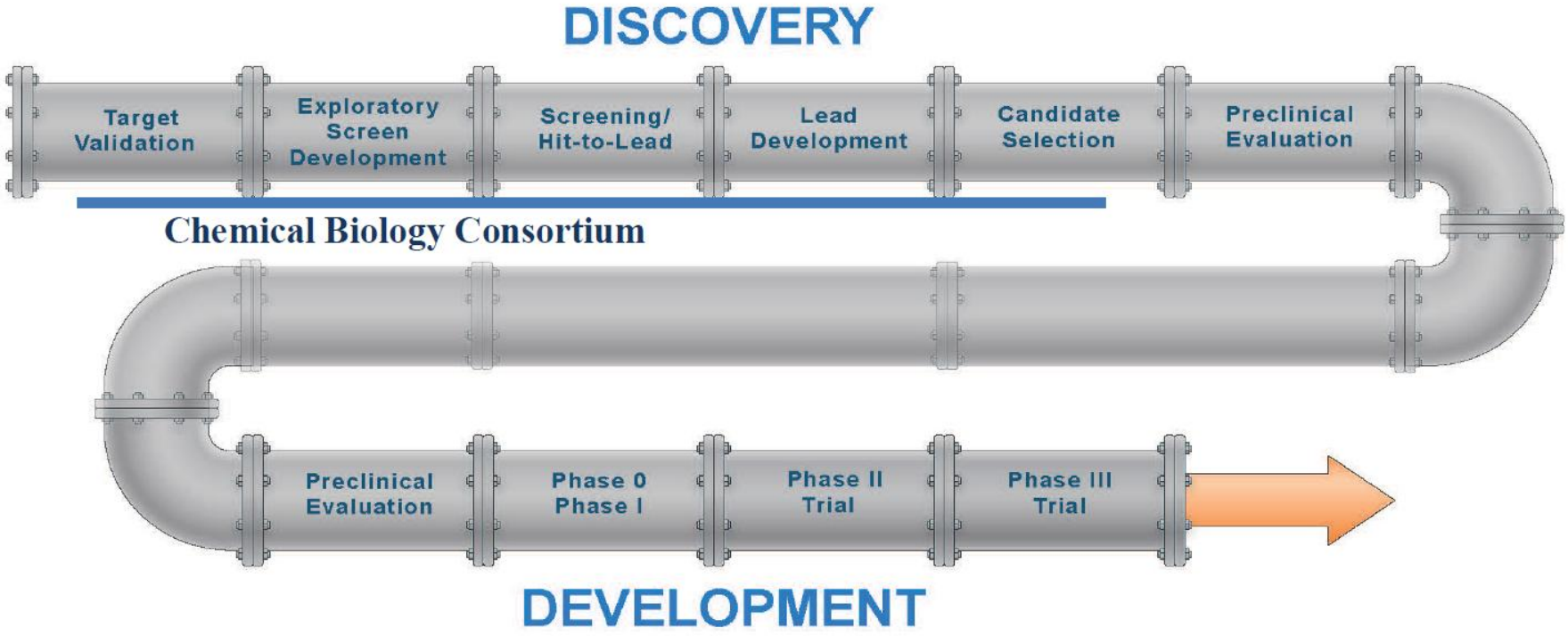

One Pipeline, Many Points of Entry

INCLUDES

- **Investigational drugs, biologics, NPs, biomarkers**
- **Investigational imaging agents and theranostics**
- **Academic, Biotech, Pharma, Government**
- **Includes Phase 0, I and II Programs**

Chemical Biological Consortium

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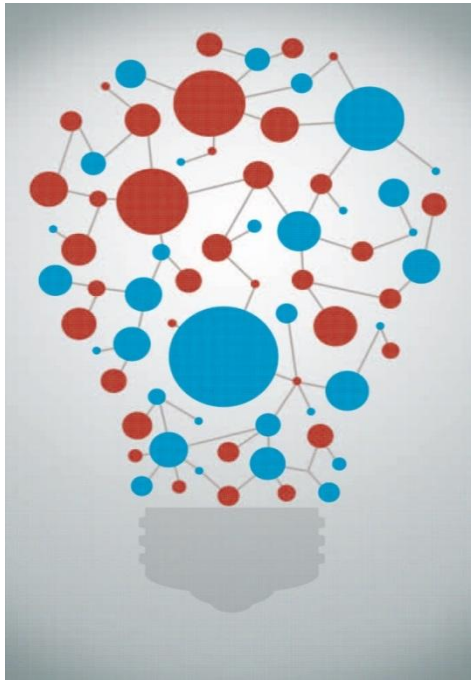

RFP issued in Oct 2008 seeking technical proposals from screening and chemistry centers to support early drug discovery activities.

August 2009 11 centers awarded contracts.

- **Comprehensive Chemical Biology Screening Centers (4)**
  - ✓ **Identify targets, develop assays and adapt these assays to HTS platforms, screen numerous compounds against a variety of different assays each year, and provide Structure- Activity Relationship (SAR) analysis**
- **Specialized Application Centers (3)**
  - ✓ **Provide expertise and experience in specific technologies needed to successfully develop and implement complex and technically difficult assays that may not be amenable to HTS**
- **Chemical Diversity Centers (4)**
  - ✓ **Capable of applying medicinal and synthetic chemistry to advance hits to lead status**

Access to NExT

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http://next.cancer.gov

October 15, 2014; February 15, 2015

Therapeutics for Rare and Neglected Diseases (TRND) Program

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http://www.ncats.nih.gov/research/rare-diseases/trnd/trnd.html

- **Model: Comprehensive drug development collaboration between DPI and extramural labs with disease-area/target expertise**

- **Projects:**
  - May enter at various stages of preclinical development
  - Disease must meet FDA orphan or WHO neglected tropical disease criteria
  - Milestone driven project plans

- **Eligible applicants:**
  - Academic, non-profit, government lab, biotech/pharma
  - Ex-U.S. applicants accepted

Therapeutic Area / Disease	Collaborator(s)	Agent	Status
Sickle Cell Disease	Aes-Rx, NHLBI	NME – Small Molecule	Clinical
Chronic Lymphocytic Leukemia	Leukemia & Lymphoma Society, University of Kansas	Repurposed Drug – Small Molecule	Clinical
Hereditary Inclusion Body Myopathy	New Zealand Pharmaceuticals, NHGRI	NME – Small Molecule	Clinical
Niemann-Pick Type C1	Johnson & Johnson, Albert Einstein College of Medicine, Univ. of Pennsylvania, Washington Univ., NICHD, NINDS , NHGRI	Repurposed Drug - Small Molecule	Clinical
Duchenne Muscular Dystrophy	ReveraGen BioPharma	NME – Small Molecule	Preclinical
Cryptococcal Meningitis	Viamet Pharmaceuticals, Inc.	NME - Small Molecule	Preclinical
Core Binding Factor Leukemia	Liu; NHGRI	Repurposed Drug - Small Molecule	Preclinical
Autoimmune Pulmonary Alveolar Proteinosis	Trapnell; Cincinnati Children's Hospital	Repurposed Drug - Biologic	Preclinical
Fibrodysplasia Ossificans Progressiva	Bloch; Massachusetts General Hospital	NME - Small Molecule	Preclinical
Schistosomiasis	CoNCERT Pharmaceuticals	NME – Small Molecule	Preclinical
Creatine Transporter Defect	Lumos Pharma	NME - Small Molecule	Preclinical
Autosomal Dominant Retinitis Pigmentosa (adRP)	Bikam Pharmaceuticals	NME - Small Molecule	Preclinical
Hypoparathyroidism	Eli Lilly & Co.	NME - Small Molecule	Preclinical
Retinitis Pigmentosa	Klassen; University of California - Irvine	Cell Based Therapy	Preclinical
LEOPARD Syndrome	Kontaridis;Beth Israel Deaconess Medical Center	NME - Small Molecule	Preclinical

SBIR Awardee Case Study:

Insight Genetics

Enabling Precision Medicine in Cancer Care

Companion Diagnostics that indicate whether a patient will respond to a cancer therapy

INSIGHT GENETICS

INSIGHTGENETICS.COM

Insight Genetics: NCI Funding Enabled Initial Growth

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Pre-SBIR

→ Early-Stage Start-Up with 4 employees
→ $0 in Revenue
→ Angel Equity Investors

NCI Funding

→ Allowed hiring of additional scientists and staff
→ Expanded network of Academic Collaborators
→ Spurred Commercial Partnerships
→ Attracted additional Angel Equity & Strategic Investor

Today

→ Emerging Growth Company with 20+ Employees
→ Increased Revenues each of last 4 years
→ Major Expansion of Lab Space
→ Entering Market with first CDx (*Insight ALK Screen*) as RUO kit

THANK YOU

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http://sbir.cancer.gov
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