Advancing Translational Research & Small Business Innovation: NCATS SBIR & STTR Funding Opportunities

Oct. 27, 2014
Cartier Esham, Ph.D.
Executive Vice President for Emerging Companies, BIO
Agenda

Advancing Translational Research & Small Business Innovation: NCATS SBIR & STTR Funding Opportunities

• Overview of NIH SBIR & STTR Programs

• Overview of NCATS SBIR & STTR Programs

• Other NCATS Small Business Resources

• Moderated Q&A
Overview of the NIH SBIR/STTR Program

Matthew Portnoy, Ph.D.
SBIR/STTR Program Coordinator,
Office of Extramural Research, NIH
SBIR/STTR Program Overview

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM
Set-aside program for small business concerns to engage in federal R&D — with potential for commercialization.

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions — with potential for commercialization.
PHASE I Feasibility Study
- Budget Guide: $150K (SBIR); $150K (STTR) total costs
- Project Period: 6 months (SBIR); 1 year (STTR)

PHASE II Full Research/R&D
- $1M (STTR); $1M (SBIR) over 2 years

PHASE IIB Competing Renewal/R&D
- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~$1M/year over 3 years

PHASE III Commercialization Stage
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
## SBIR and STTR

### Critical Differences

<table>
<thead>
<tr>
<th></th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Partnering Requirement</strong></td>
<td>Permits partnering</td>
<td>Requires a nonprofit research institution partner (e.g., university)</td>
</tr>
<tr>
<td><strong>Work Requirement</strong></td>
<td>Guidelines: May outsource 33% (Phase I), 50% (Phase II)</td>
<td>Minimum: 40% small business, 30% research institution partner</td>
</tr>
<tr>
<td><strong>Principal Investigator</strong></td>
<td>Primary employment (&gt;50%) must be with the small business</td>
<td>Employed by either the research institution partner or small business</td>
</tr>
</tbody>
</table>

**Award is always made to small business.**
SBIR Purpose and Goals

- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

*Small Business Innovation Development Act of 1982*

P.L. 112-81 re-authorizes program through FY2017.
• Stimulate and foster scientific and technological innovation through **cooperative research** and development carried out **between** small business concerns and research institutions

• Foster **technology transfer** between small business concerns and research institutions

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**Small Business Research and Development Enhancement Act of 1992**

P.L. 112-81 re-authorizes program through FY2017.
• Capital is in the form of grants and contracts
• Strategic investment in innovation
• Non-diluted funding:
  • No repayment
  • No debt service
  • No equity forfeiture
  • No intellectual property forfeiture
• Organized as for-profit U.S. business
• Small: 500 or fewer employees, including affiliates
• Work must be done in the U.S. (with few exceptions)
• Individual ownership:
  • Greater than 50% U.S.-owned by individuals and independently operated OR
  • Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR
  • Concern that is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (for FOAs after 1/28/2013)

Determined at Time of Award
STTR Eligibility Criteria

- 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 nonprofit research organization; federal R&D center
- Intellectual property (IP) agreement
  - Allocation of rights in IP and rights to carry out follow-on R&D and commercialization
### Success Rate of SBIR/STTR 2012 and 2013 by Phase

#### SBIR

<table>
<thead>
<tr>
<th>Phase</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast Track</td>
<td>15.9%</td>
<td>15.7%</td>
</tr>
<tr>
<td>Phase I</td>
<td>15.6%</td>
<td>13.2%</td>
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<tr>
<td>Phase II</td>
<td>39.9%</td>
<td>32.8%</td>
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#### STTR

<table>
<thead>
<tr>
<th>Phase</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast Track</td>
<td>34.4%</td>
<td>28.6%</td>
</tr>
<tr>
<td>Phase I</td>
<td>20.3%</td>
<td>18.7%</td>
</tr>
<tr>
<td>Phase II</td>
<td>39.4%</td>
<td>26.4%</td>
</tr>
</tbody>
</table>

The chart above illustrates the success rates for Fast Track, Phase I, and Phase II for both SBIR and STTR programs in 2012 and 2013.
NIH SBIR and STTR applicants may now switch programs at Phase II or Phase IIB.

a) Phase I STTR awardees may apply for NIH SBIR or STTR Phase II.
b) Phase I SBIR awardees may apply for NIH SBIR or STTR Phase II.
c) Phase II STTR awardees may apply for NIH SBIR or STTR Phase IIB.
d) Phase II SBIR awardees may apply for NIH SBIR or STTR Phase IIB.
2. NIH issued a Pilot SBIR Direct to Phase II solicitation, PAR-14-088.

3. Venture capital–backed companies (VCOC, hedge fund, private equity firm) can apply to NIH SBIR opportunities (since May 2013).

4. SBA company registry at SBIR.gov is required for all submissions.
Overview of NCATS
SBIR & STTR Programs

Lili M. Portilla, M.P.A.
Director, Strategic Alliances
NCATS, NIH
About the National Center for Advancing Translational Science (NCATS)

**FOCUS**
To transform the translational science process so new treatments and cures for disease can be delivered to patients faster

**GOAL**
Seeks to increase small business participation in federally supported R&D and private-sector commercialization of technology

**FUNDING**
$17.6 million annually, allocated for small business innovation research and technology transfer
What Are the SBIR & STTR Programs?

**Small Business Innovation Research (SBIR)** supports early-stage research and development projects at small businesses.

**SBIR & STTR Programs** help entrepreneurial researchers as they launch businesses, engage in research and development and seek to commercialize new products that will have public benefit.

**Small Business Technology Transfer (STTR)** helps small businesses formally collaborate with a research institution in Phase I and Phase II.
Benefits of NCATS SBIR & STTR Funding

• One of the largest funding sources of early-stage life sciences in the country (stable & predictable)

• IP rights are retained by the small business

• Not a loan; non-dilutive capital

• Projects undergo NIH’s rigorous scientific peer review that provides recognition, verification and visibility

• Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)
Select SBIR & STTR Topics of Interest to NCATS

Drug Discovery
- Innovative platforms for identification and prioritization of targets for therapeutic intervention
- Co-crystallization high-throughput screening techniques

Drug Development
- Technologies to determine alternative uses for existing therapeutic interventions
- Improving predictivity or efficiency of medicinal chemistry, biologic or other intervention

Clinical Research Tools and Informatics
- Tools, technologies and computational informatics approaches that increase the efficiency of human subjects research
- Educational tools for clinical and translational research
When Are SBIR & STTR Appropriate?

- Innovative solution to significant unmet clinical need
- Solution has significant commercial potential
- Leverages company/founder expertise
- Seeking funding to produce feasibility data (Phase 1)
- Seeking funding for development (Phase 2)
- Start-up company, too early for private investment
- Early-stage business run by socially and economically disadvantaged persons (SDB) and women-owned small businesses (WOSB)
- Established SBC, seeking funding to pursue a new project (and board supports SBIR application)
When Are SBIR & STTR Not Appropriate?

- Chasing NIH funding solicitations – “why not?”
- Need cash urgently
  - Time from application to award is 8 – 12 months
  - Should be part of a larger financing strategy
- “Me too” product matching competitor’s capabilities
- Incremental innovation: no change to clinical paradigm
- Basic research still required to demonstrate commercial and clinical feasibility
- Trying to bridge the gap from lost R01
Before Writing an Application

- Consider your company’s strengths and how to exploit them
- Consider your company’s weaknesses and how to address them
- Contact an appropriate NIH Program Director in advance — at least 1 month before due date! — to discuss your specific aims and receive feedback
- Review similar, currently-funded NIH projects
  - NIH RePORTER
NIH RePORTER

http://projectreporter.nih.gov
NIH RePORTER

http://projectreporter.nih.gov
IMPORTANT: Start the Application Process Early

• Strong proposals take time to develop!

• Carefully read the funding solicitation and allow time to address all of the key requirements
  - Assemble a strong scientific team
  - Gain access to equipment and other resources
  - Obtain letters of support from collaborators

• Complete the necessary administrative registrations
  - Start at least 2 months before the deadline
  - See SF424 application guide (grants.gov, eRA Commons)
On average, it can take 7 – 12 months following each deadline for successful applicants to receive awards.

Proposals for NCATS contract topics are due November 5.

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<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (Earliest)</th>
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<td>October</td>
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<td>March</td>
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Other NCATS Small Business Resources
NCATS Division of Pre-Clinical Innovation (DPI) Capabilities

Activities facilitated through in-house drug development experts and contracts

- New indications for clinical-stage drugs and repurposing-approved drugs
- Medicinal chemistry
- Rare disease bioassay development
- Efficacy, pharmacology, ADME, toxicology, PK/PD
- Compound scale-up, formulation
- Clinical and regulatory development strategy, natural history study assessments
- First-in-human clinical trials
Bridging Interventional Development Gaps (BrIDGs) Program

• **Model:** Contract access collaboration between DPI and extramural laboratories (formerly NIH-RAID program)

• **Projects:**
  - Enter with clinical candidate identified
  - Any disease eligible
  - Gap analysis followed by data generation using DPI contracts to generate data necessary for IND filing
  - Exit at or before IND
  - Milestone driven
  - Therapeutic modalities: any (small molecules, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins)

• **Eligible Applicants:**
  - Academic (U.S. & Ex-U.S.), Nonprofit, SBIR-eligible businesses
<table>
<thead>
<tr>
<th>Applicant</th>
<th>Organization Name</th>
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<td>Small business</td>
<td>Peptide</td>
<td>Atherosclerosis</td>
<td>Common Fund</td>
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BrIDGs Updates

• **Chronic Dry Eye**
  - **Collaborators:** Parion Sciences (Durham, North Carolina)
  - **Agent:** P-321 ophthalmic solution, a novel epithelial sodium channel (ENaC) blocker
  - **Milestones:**
    - Sept. 2011: P-321 selected by BrIDGs as pre-clinical candidate
    - March 2014: IND filed
    - **June 2014:** Option agreement with Santen Pharmaceutical announced

• **Acute Radiation Syndrome**
  - **Collaborators:** University of California (Oakland, California); Lawrence Berkeley National Laboratory (Berkeley, California)
  - **Agent:** Actinide decorporation agents
  - **Milestones:**
    - Dec. 2008: Accepted by BrIDGs
    - Sept. 2011: GMP material released and development assumed by NIAID
    - **Aug. 2014:** IND cleared by FDA

• **Stress-related Affective Illness**
  - **Collaborators:** Lehigh University (Bethlehem, Pennsylvania)
  - **Agent:** SRX246, a novel vasopressin 1a receptor antagonist
  - **Milestones:**
    - May 2007: Accepted by BrIDGs
    - Feb. 2009: IND filed
    - May 2009: Phase I clinical trials initiated
    - **April 2014:** Phase II clinical trial launched for the treatment of intermittent explosive disorder
Therapeutics for Rare and Neglected Diseases (TRND) Program

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

**Projects:**
- May enter at various stages of pre-clinical development
- Disease must meet FDA orphan or WHO neglected tropical disease criteria
- Taken to stage needed to attract external organization to adopt to complete clinical development/registration, max 2a
- Milestone driven
- Therapeutic modalities: small molecules, proteins
- Develop new generally applicable platform technologies and paradigms

**Eligible Applicants:**
- Academic, Nonprofit, Government Lab, Biotech/Pharma
- Ex-U.S. applicants accepted
<table>
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<tr>
<th>Therapeutic Area / Disease</th>
<th>Collaborator(s)</th>
<th>Agent</th>
<th>Status</th>
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<tr>
<td>Sickle Cell Disease</td>
<td>Aes-Rx, NHLBI</td>
<td>NME - Small Molecule</td>
<td>Clinical</td>
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<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>Leukemia &amp; Lymphoma Society, University of Kansas</td>
<td>Repurposed Drug - Small Molecule</td>
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<td>NME - Small Molecule</td>
<td>Clinical</td>
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<td>Niemann-Pick Type C1</td>
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<td>Repurposed Drug - Small Molecule</td>
<td>Clinical</td>
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<td>Duchenne Muscular Dystrophy</td>
<td>ReversaGen BioPharma</td>
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<td>Cryptococcal Meningitis</td>
<td>Viamet Pharmaceuticals, Inc.</td>
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<td>Core Binding Factor Leukemia</td>
<td>Liu; NHGRI</td>
<td>Repurposed Drug - Small Molecule</td>
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<td>Autoimmune Pulmonary Alveolar Proteinosis</td>
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<td>Schistosomiasis</td>
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<td>Creatine Transporter Defect</td>
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<td>Autosomal Dominant Retinitis Pigmentosa (adRP)</td>
<td>Bikam Pharmaceuticals</td>
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<td>Cell Based Therapy</td>
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<td>LEOPARD Syndrome</td>
<td>Kontaridis; Beth Israel Deaconess Medical Center</td>
<td>NME - Small Molecule</td>
<td>Preclinical</td>
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Collaboration: Successful Exit

Sickle Cell Disease Project Acquired by Baxter Int’l

- Sickle cell disease drug candidate acquired by Baxter International in July 2014
- First time a company has acquired a drug candidate developed with TRND program resources
- Baxter will advance compound’s (Aes-103) clinical development activities required for regulatory approval and commercialization

“This success validates the NCATS model, which is based on a novel collaborative approach that de-risks intervention development programs to enable private-sector investment.”

– Chris Austin, Drug Discovery News
TRND Collaboration: Successful Exit

- **Collaborator:** Bikam Pharmaceuticals
- **Agent:** Small molecule for autosomal dominant retinitis pigmentosa (adRP)
- **Collaboration:**
  - Confirmed opsin chaperone activity of lead molecule
  - Improved throughput of key assay that can be applied to screening for new lead compounds
  - Contributed to de-risking the lead molecule by completing a dose range-finding toxicology study
  - Bikam acquired by Shire Pharmaceuticals to continue the development of the de-risked lead molecule for the treatment of adRP

**SHIRE PLC FORM 10-Q Filed on 08/01/14 for the period Ending 06/30/14:**

**Acquisition of Bikam**
- On July 9, 2014 Shire completed the acquisition of Bikam, a biopharmaceutical company with pre-clinical compounds that could provide an innovative approach to treating autosomal dominant retinitis pigmentosa (adRP).
Intellectual Property

- **Background IP**: Any IP generated *prior* to initiation of TRND collaboration are *retained* by the applicant as background IP.

- **New IP**: The potential for development of *new*, multi-party IP will depend on the stage at which the project enters into collaboration with TRND. TRND collaborators should anticipate that there *will be* joint IP development with NCATS employees.
  
  - **Inventorship**: Should *new* IP be generated during the TRND collaboration, inventorship will be determined according to U.S. patent law.
  
  - **Agreements**: Various model agreements are available at NIH, through which TRND collaborations are initiated and governed. The CRADA mechanism is the most commonly used for TRND.
    - NCATS will expect a CRADA or CRADA Letter of Intent to be executed before TRND proceeds with the project plan.
# Comparison of BrIDGs and TRND

<table>
<thead>
<tr>
<th></th>
<th>BrIDGs</th>
<th>TRND</th>
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<tbody>
<tr>
<td>Contract resource</td>
<td>Team-based collaboration</td>
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<tr>
<td>PI must have identified lead agent</td>
<td>PI may start with lead optimized</td>
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<td>No clinical trial support provided</td>
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<tr>
<td>IP retained by owner</td>
<td>TRND may generate IP</td>
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<td>Universal disease scope</td>
<td>Rare and neglected diseases only</td>
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<tr>
<td>Investigator prepares IND</td>
<td>Regulatory affairs assistance provided</td>
<td></td>
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</tbody>
</table>
# Key NCATS Contacts and Resources

| E-mail | Lili Portilla, M.P.A.  
|        | NCATSPartnerships@mail.nih.gov |
| Online | http://ncats.nih.gov/small-business.html |
| NCATS Topics of Interest: | http://ncats.nih.gov/sbir-topics.html |
Learn More about NCATS

Website: [www.ncats.nih.gov](http://www.ncats.nih.gov)

Facebook: [facebook.com/ncats.nih.gov](http://facebook.com/ncats.nih.gov)

Twitter: [@ncats.nih.gov](https://twitter.com/ncats.nih.gov)  #NCATSsbir

YouTube: [youtube.com/user/ncatsmedia](http://youtube.com/user/ncatsmedia)


Email us: **NCATS-SBIRSTTR@mail.nih.gov**  or  **portillll@mail.nih.gov**
Moderated Q&A

Share Your Questions in the Chat Window.

Cartier Esham, Ph.D.
Executive Vice President for Emerging Companies, BIO

Matthew Portnoy, Ph.D.
SBIR/STTR Program Coordinator, Office of Extramural Research, NIH

Lili M. Portilla, M.P.A.
Director, Strategic Alliances, NCATS, NIH