Break Out Session II

SBIR/STTR

Tony Beck, PhD, Division for Research Capacity Building, NIGMS
Krishan Arora, PhD, Division for Research Capacity Building, NIGMS
Richard Giersch, Director of Health Sciences Innovation Center, WVU
SBIR/STTR Purposes 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-Authorsizes program through FY2017
Small Business Innovation Research (SBIR) supports early-stage research and development projects at small businesses.

SBIR & STTR Programs support entrepreneurial researchers as they 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.
SBIR and STTR Critical Differences

• **Research Partner**
  - SBIR: **Permits** partnering 33% Phase I and 50% Phase II
  - STTR: **Requires** partnering with research institution. *Small business (40%) and U.S. research institution (30%)*

• **Principal Investigator**
  - SBIR: Primary (>50%) employment **must** be with small business concern
  - STTR: PI may be employed by either research institution or small business concern

Award is always made to Small Business Concern
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 two years

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

PHASE III  Commercialization Stage
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
NIH SBIR/STTR 3-Phase Program

**PHASE I** Feasibility Study
- Budget Guide: $150K (SBIR); $150K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)

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**PHASE III** Commercialization Stage
- NIH, generally, not the “customer”
- Consider partnering and exit strategy early
• Phase I awards – normally may not exceed $150,000 total costs (direct costs, indirect costs and fee). With appropriate justifications, the total cost may be requested up to $225,000 total costs.

• Phase II awards – normally may not exceed $1,000,000 total costs. With appropriate justifications, the total costs may be requested up to $1,500,000 total costs.
National Institute of Health (NIH)

NIH consists of 27 Institutes and Centers

FY18 = 26.9B

NIGMS
Welcome to NIGMS
The National Institute of General Medical Sciences (NIGMS) supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.

Undergraduate and Predoctoral Programs
Postdoctoral Programs
Research Programs
Educational Resources

Science for the Public
Strengthening public understanding and appreciation of science is a key NIGMS goal. As part of its efforts, the Institute provides free science education materials on a range of topics.

Science Education
SEPA SCIENCE EDUCATION PARTNERSHIP AWARD
SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH
National Institute of General Medical Sciences

FY18 = $2.8B
Omnibus vs. NIGMS
Omnibus

MOST NIH INSTITUTES AND CENTERS
Omnibus & NIGMS

3X/year

Sept 5
Jan 5
Apr 5
NIH Omnibus (FOA)

PHS 2017-02 Omnibus Solicitation Small Business Innovation Research (SBIR) Grant PA-18-573

standard receipt dates
Development of Highly Innovative Tools and Technology for Analysis of Single Cells (SBIR) (R43/R44)
PA 17-147, [exp. Jan 2020]

Tools for Cell Line Identification (SBIR) (R43/R44)
PA 16-186 [exp. Apr 2019]

New Technologies for the Glycosciences (SBIR) (R43/R44)
PA 16-157 [exp. Apr 2019]

New Technologies for the Glycosciences (STTR) (R41/R42)
PA 16-158 [exp. Apr 2019]

standard receipt dates
NIGMS Funding Opportunity Announcements (FOA)

Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR, STTR)
Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR, STTR)
Krishan Arora, Ph.D.

Program Director

Division for Research Capacity Building

National Institute of General Medical Sciences

Biomedical Entrepreneurship in IDeA States
Biomedical Entrepreneurship in IDeA States:
Translating Your Innovative Ideas into a Marketable Product

- Regional Technology Transfer Accelerator Hubs for IDeA States
- I-Trep Program – Fostering IDeA state Entrepreneurship
- Other NIH-funded Programs
Regional Technology Transfer Accelerator Hubs for IDeA States

- **A New Initiative:** In response to Congressional directive

- **Intent:**
  - One shared regional technology transfer accelerator hub in each of the four IDeA regions (*Central, Northeast, Southeast and Western*)
  - Form regional consortia to provide infrastructure and build an entrepreneurial culture at the IDeA institutions
Regional Technology Transfer Accelerator Hubs for IDeA States

Purpose:
- Develop, implement, and test a comprehensive program for promoting:
  - entrepreneurship
  - technology transfer
  - intellectual property
  - small business finance and management, and
  - business skills
- Generate educational and training tools – i.e., curricula, texts, webinars and modules
- For details on Hubs,
STTR Regional Accelerator Hub: Collaboration between Small Business Concern (SBC) & Academic Institutions in IDeA States

From any state in the U.S. (IDeA or non-IDeA)

New Accelerator Hubs and Their Major Academic Partnering Institutions – Funded in FY 2018

<table>
<thead>
<tr>
<th>IDeA Region</th>
<th>Grant Number</th>
<th>Program Name</th>
<th>Small Business Concern</th>
<th>Major Academic Partnering Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>UT2GM130176</td>
<td>DRIVEN: Accelerating Medical Entrepreneurship in the Northeast</td>
<td>CELDARA MEDICAL, LLC (Lebanon, New Hampshire)</td>
<td>University of Vermont, Burlington</td>
</tr>
<tr>
<td>Central</td>
<td>UT2GM130175</td>
<td>The Sustainable Heartland Accelerator Regional Partnership (SHARP) Hub</td>
<td>BBC ENTREPRENUERIAL TRAINING AND CONSULTING, LLC (Chelsea, Michigan)</td>
<td>University of Kansas Medical Center, Kansas City</td>
</tr>
<tr>
<td>Western</td>
<td>UT2GM130166</td>
<td>ASCEND, Accelerating Solutions for Commercialization and Entrepreneurial Development in the Mountain West IDEa States</td>
<td>VIRTICI, LLC (Seattle, Washington)</td>
<td>University of New Mexico Health Sciences Center, Albuquerque</td>
</tr>
<tr>
<td>Southeast</td>
<td>UT2GM130174</td>
<td>Southeast Xlerator Network</td>
<td>XLERATEHEALTH, LLC (Louisville, Kentucky)</td>
<td>University of Kentucky, Lexington</td>
</tr>
</tbody>
</table>
Fostering Biomedical Entrepreneurship in IDeA States

Regional Technology Transfer Accelerator Hub

Skills Development Mentoring Education Training & Outreach

Entrepreneurship Ecosystem

Biomedical Research and Innovations

Commercialization

Patient Needs

NIH National Institute of General Medical Sciences
Fostering Entrepreneurship in Biomedical Research in IDeA States

NIGMS IPERT (R25) grant award to Univ. Vermont (2016-2021)
PI: Dr. Mercedes Rincon
Partners with 5 other IDeA states

I-Trep

Entrepreneurship

Skills Development, Mentoring & Outreach

Entrepreneurship Ecosystem

Innovative therapy, diagnosis, devices

Commercialization

Patient needs
<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 10, 2018</td>
<td>An introduction to venture capital in healthcare</td>
<td>Ross Jaffe, Managing Director, Versant Ventures</td>
</tr>
<tr>
<td>March 26, 2018</td>
<td>Learn what the I-Trep program offers for you</td>
<td>Mercedes Rincon, I-Trep Program director</td>
</tr>
<tr>
<td>February 22, 2018</td>
<td>Journey as an entrepreneur</td>
<td>Robert Devore, President, Stonybrook</td>
</tr>
<tr>
<td>January 22, 2018</td>
<td>De-risking product development for medical devices</td>
<td>Rick Greenwald, President, Simbex Medical</td>
</tr>
<tr>
<td>December 4, 2017</td>
<td>How to monetize your inventions and avoid your competitors</td>
<td>William Rowland, Group Chair, Buchanan Ingersoll $ Rooney firm</td>
</tr>
<tr>
<td>November 13, 2017</td>
<td>Six simple strategies to strengthen your SBIR/STTR submission</td>
<td>Yolanda Nesbeth, Director Celdara Medical</td>
</tr>
<tr>
<td>October 10, 2017</td>
<td>SPARK Global- A new worldwide initiative to improve translation of medical research to benefit patient health</td>
<td>Michael Wallach, Director, SPARK Sydney Program, Australia</td>
</tr>
<tr>
<td>May 19, 2017</td>
<td>Nontraditional funding for startups- Revenue and Grants</td>
<td>Seth Finklestein, Founder/CEO Stemetix</td>
</tr>
<tr>
<td>May 1, 2017</td>
<td>Giving a great startup pitch: Lessons Learned</td>
<td>David Bradbury, President VCET</td>
</tr>
<tr>
<td>April 17, 2017</td>
<td>ABC's of working with the FDA</td>
<td>Sarah O'Connell Kalil, CEO CoreMap Inc</td>
</tr>
<tr>
<td>March 2, 2017</td>
<td>Writing a successful SBIR/STTR application</td>
<td>Martin Mattessich, CEO L2-Dx</td>
</tr>
<tr>
<td>January 23, 2017</td>
<td>Navigating the stages of biotech entrepreneurship: From Discovery to Exit</td>
<td>Jake Reder, Co-founder/CEO Celdara Medical</td>
</tr>
</tbody>
</table>
Goal of IPERT program: support educational activities that complement and/or enhance the research training of a workforce to meet the nation’s biomedical, behavioral and clinical research needs.

Support creative educational activities with a primary focus on

- Courses for Skills Development,
- Mentoring Activities and
- Outreach


Application Due Date: January 23, 2019

Program Contact: Dr. Michael Sesma (msesma@nigms.nih.gov)
REACH and NCAI: Support of “Phase 0” Activities

NCAI Centers

- B-BIC: Translating Discoveries Into Products
- NCAI-CC: NIH Center for Accelerated Innovations at Cleveland Clinic
- UC CAI: University of California Center for Accelerated Innovation

REACH Hubs

- Long Island Bioscience Hub
- ExCITE: an NIH REACH Hub
- MN REACH

https://ncai.nhlbi.nih.gov/ncai/
REACH and NCAI: Support of “Phase 0” Activities

- **Research Evaluation and Commercialization Hubs (REACH)** and **NIH Centers for Accelerated Innovations (NCAI)** are public-private partnerships designed to accelerate translation of scientific discoveries into products.

- **NCAI Hubs** in Boston, Cleveland, and Los Angeles.

- **REACH Hubs** in Long Island, Kentucky, and Minnesota.

- **Goals**: identify and commercialize promising technologies from academia, provide access to appropriate federal and private expertise, and change institutional culture to encourage and reward commercialization activities.

https://ncai.nhlbi.nih.gov/ncai/
Save the Date!

20th Annual HHS SBIR/STTR Conference – Dallas, TX

A Better Tomorrow – Big Ideas in BioTech

October 30-November 1, 2018

You will have the opportunity to:

❖ Meet One-on-One with over 100 HHS representatives and discuss research opportunities
❖ Understand HHS SBIR/STTR programs and funding opportunities
❖ Learn about HHS assistance programs offered to awardees
❖ Learn about the HHS SBIR/STTR application, review and award processes
❖ Discuss specific questions with HHS SBIR/STTR subject-matter experts
❖ Build relationships with like-minded innovators, potential partners, and investors
Thank You

Questions?