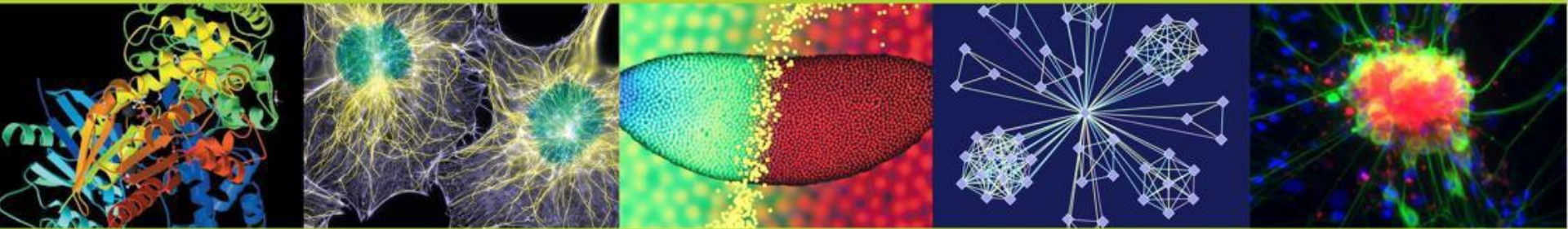


# Break Out Session II

## 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-Authorizes 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**

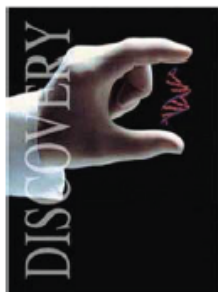
- SBIR: Primary (>50%) employment **must** be with small business concern

- STTR: PI may be employed by either research institution or small business concern

**Award is always made  
to Small Business Concern**

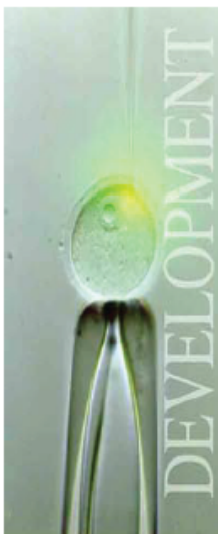






## PHASE I Feasibility Study

- 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

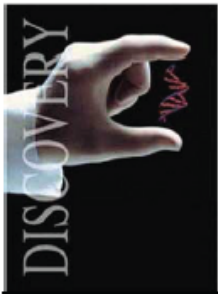
- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~\$1M/year; 3 years



## PHASE III Commercialization Stage

- NIH, generally, not the “customer”
- Consider partnering and exit strategy early





## PHASE I Feasibility Study

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- Project Period: 6 months (SBIR); 1 year (STTR)

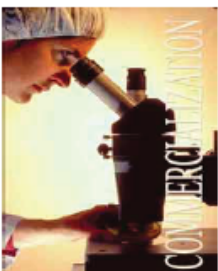


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# Budgets Caps

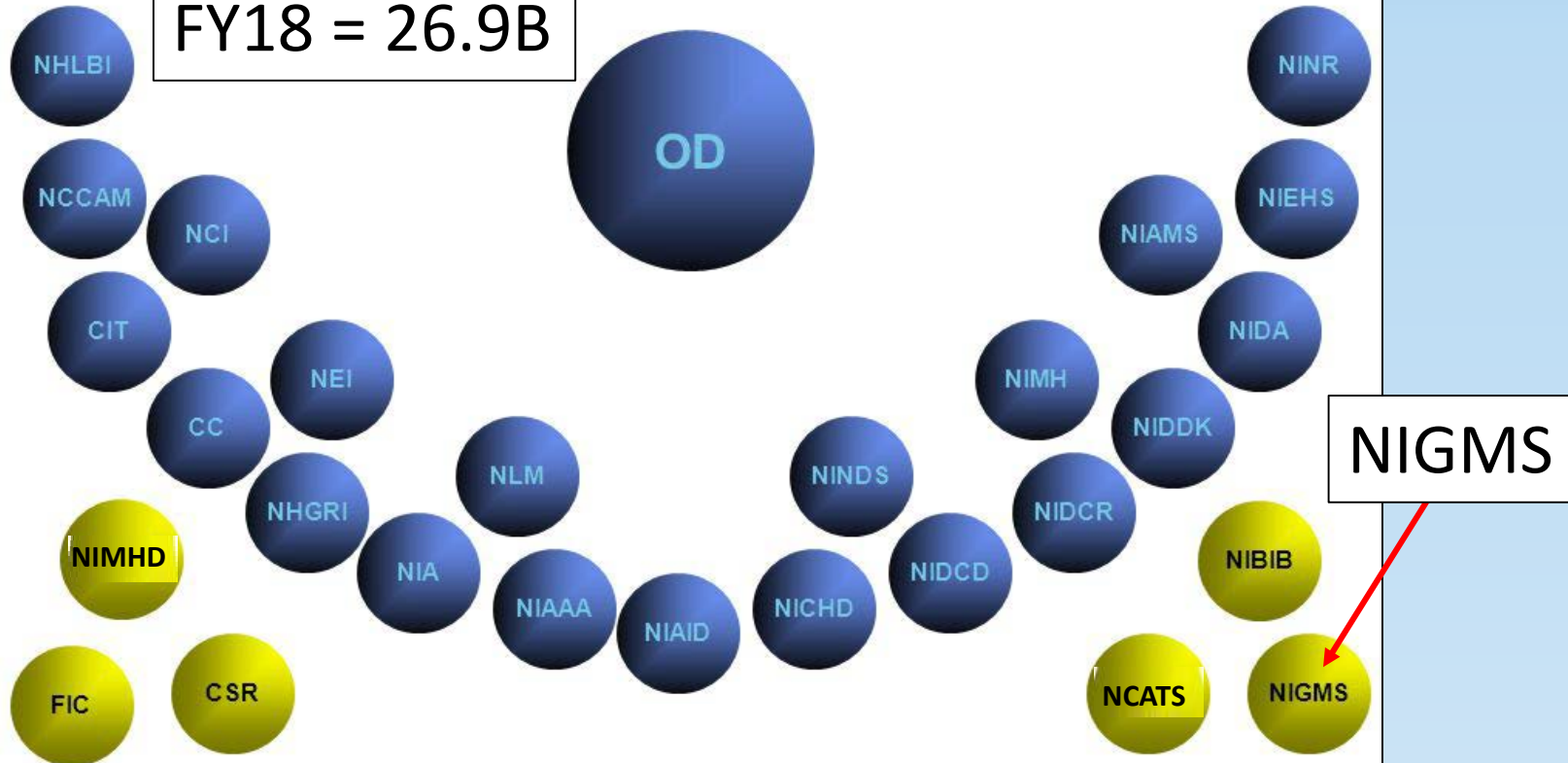
- Phase I awards – normally may not exceed \$150,000 total costs (direct costs, indirect costs and fee). With appropriate justifications, the total cost may be requested up to \$225,000 total costs.
- Phase II awards – normally may not exceed \$1,000,000 total costs. With appropriate justifications, 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

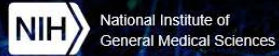


NIGMS





# National Institute of General Medical Sciences



Search...



RESEARCH AREAS

RESEARCH TRAINING

CAPACITY BUILDING

GRANTS AND FUNDING

SCIENCE EDUCATION

NEWS AND EVENTS

ABOUT NIGMS

## Welcome to NIGMS

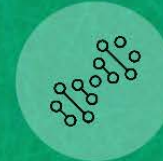
The National Institute of General Medical Sciences (NIGMS) supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention.



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.

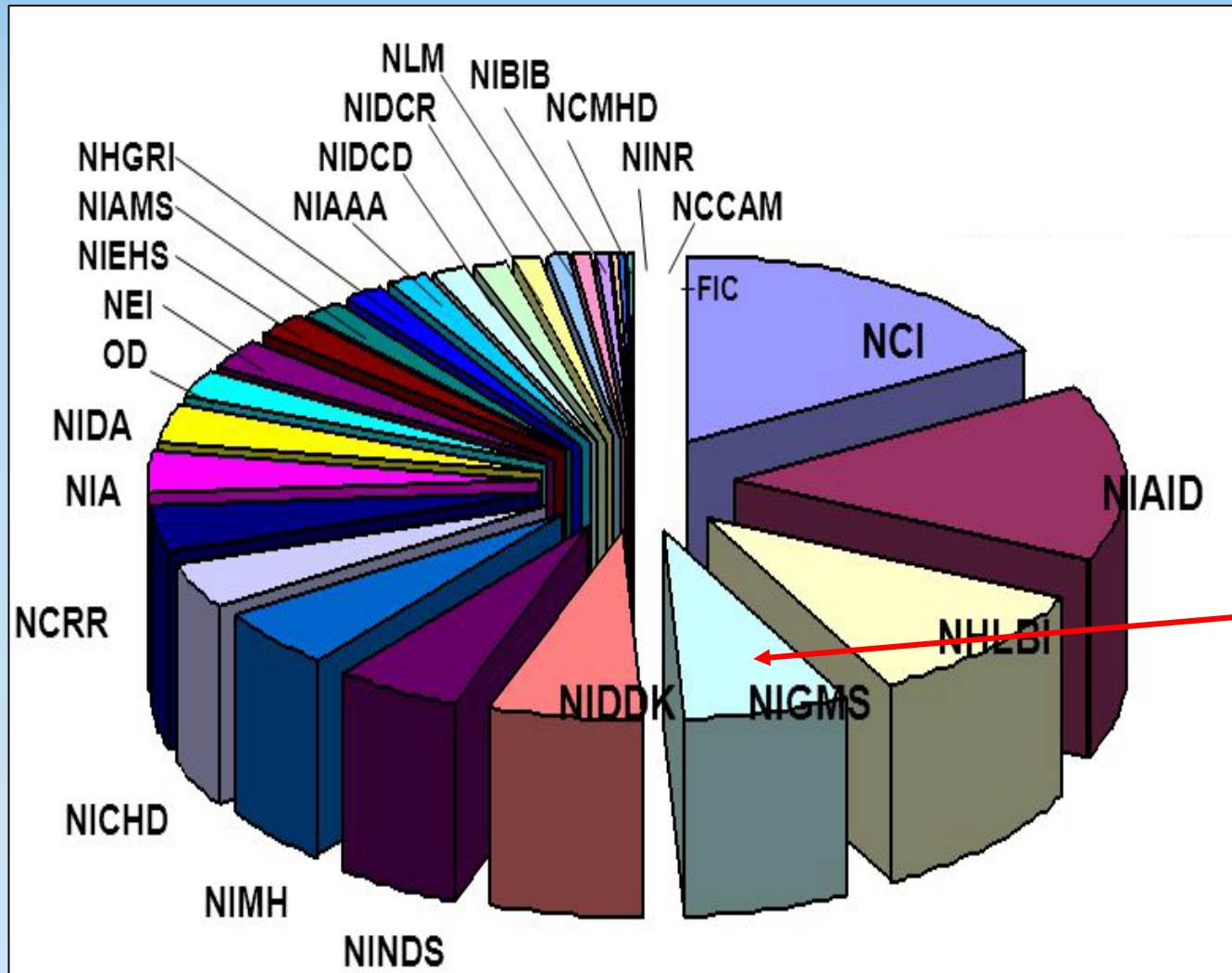


Science Education

**SEPA** SCIENCE EDUCATION  
PARTNERSHIP AWARD  
SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH



# National Institute of General Medical Sciences



NIGMS

FY18 =  
\$2.8B



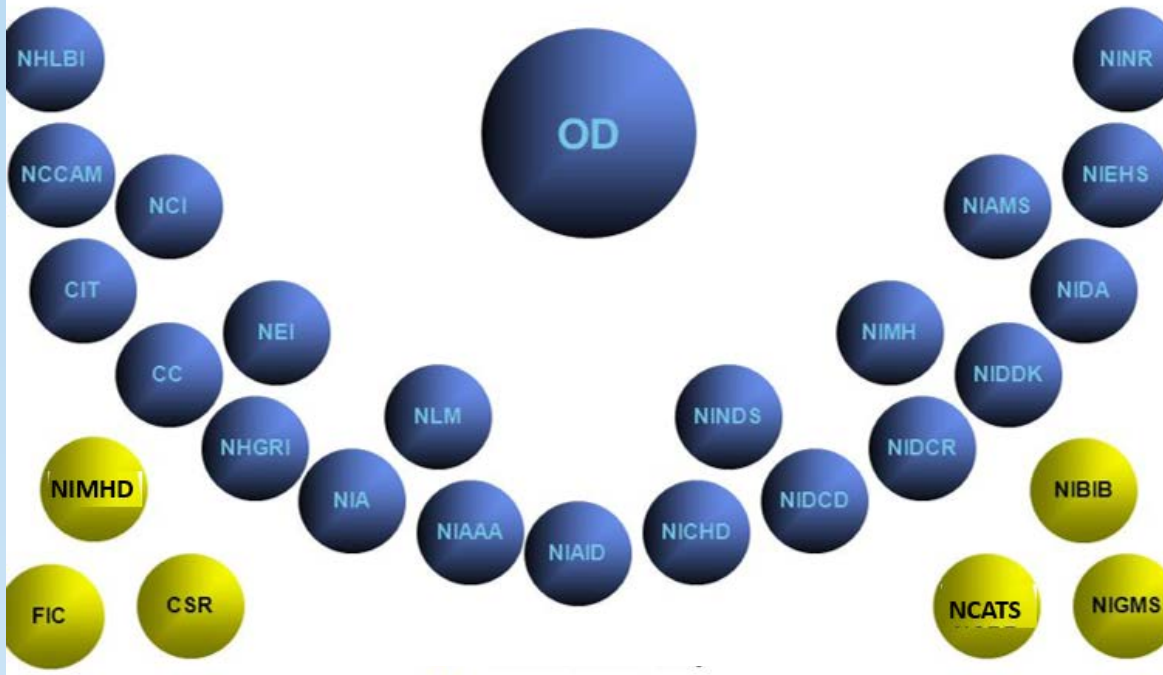
Omnibus vs. NIGMS





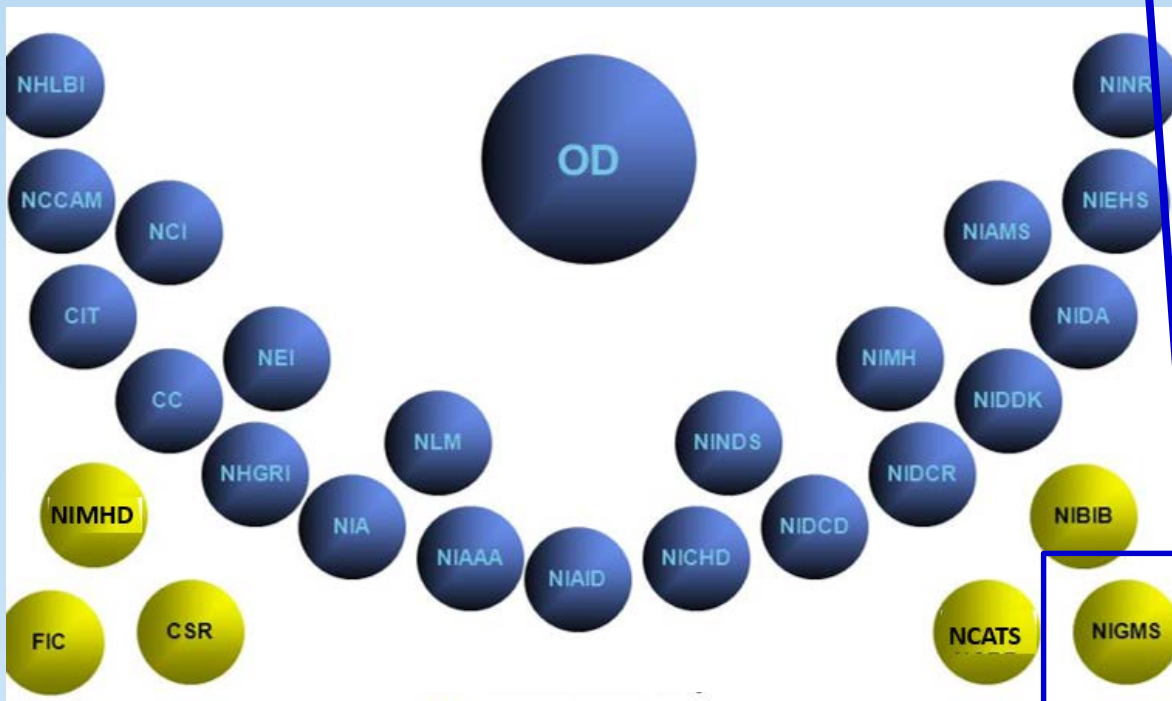
# Omnibus

MOST NIH INSTITUTES AND CENTERS





# NIGMS FOAs



NIGMS ONLY

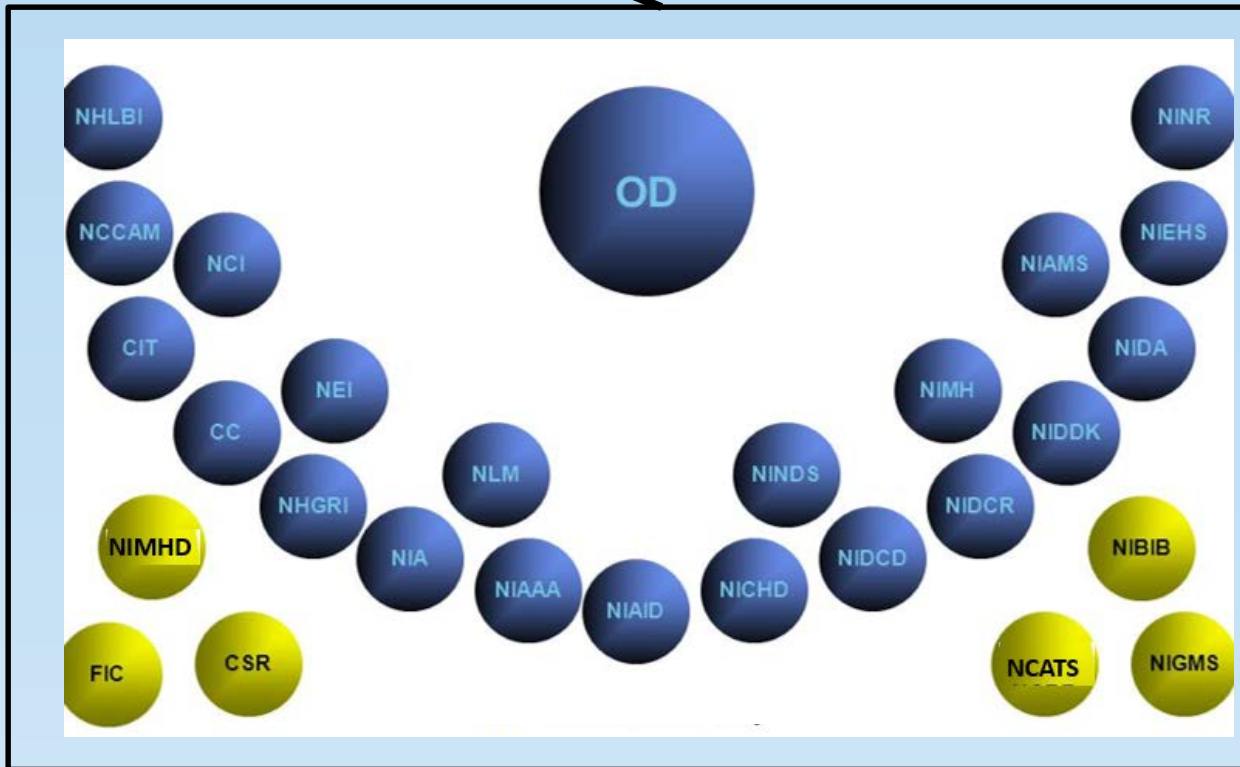


Omnibus

&

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*



# NIGMS Funding Opportunity Announcements (FOA)

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)

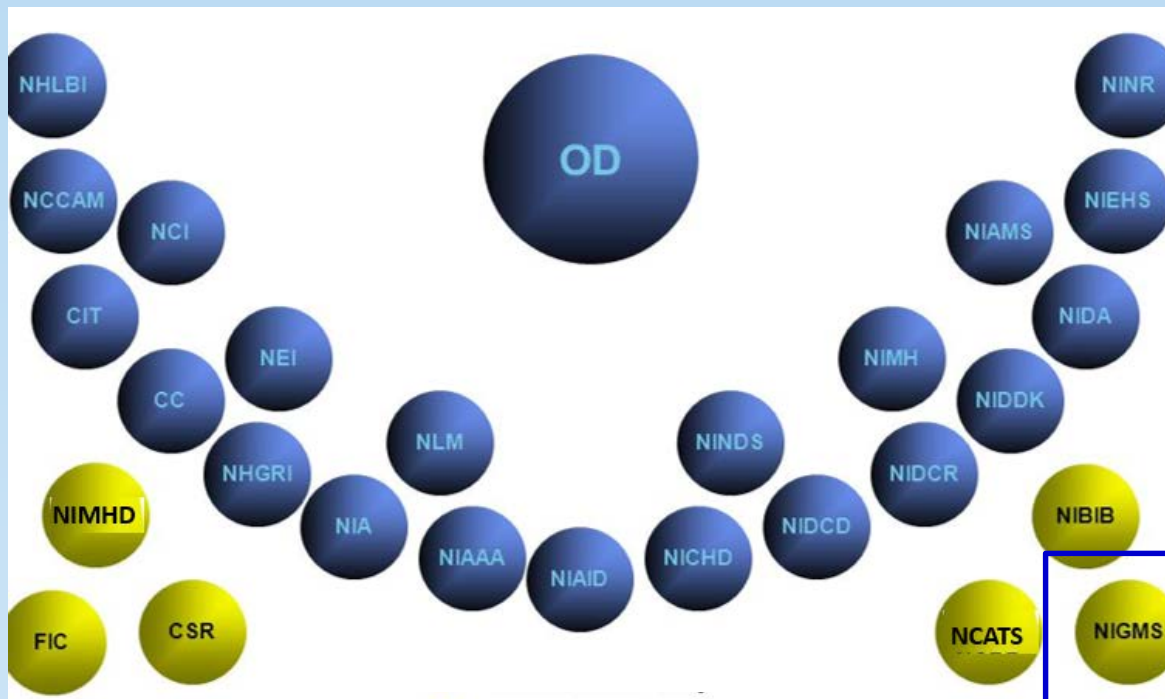
Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences  
(SBIR, STTR)

PAR-18-403, PAR-18-403 [exp. Sept 2019]



# Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR, STTR)

PAR-18-403, PAR-18-403 [exp. Sept 2019]



1X/year

Sept 5

NIGMS ONLY

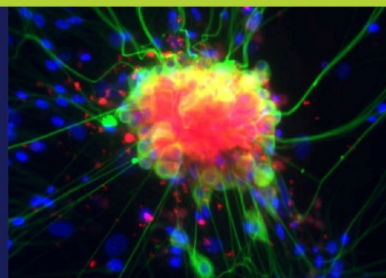
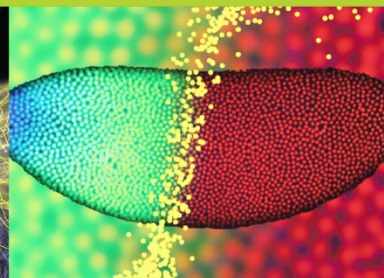


Krishan Arora, Ph.D.

*Program Director*

*Division for Research  
Capacity Building*

*National Institute of  
General Medical  
Sciences*





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

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



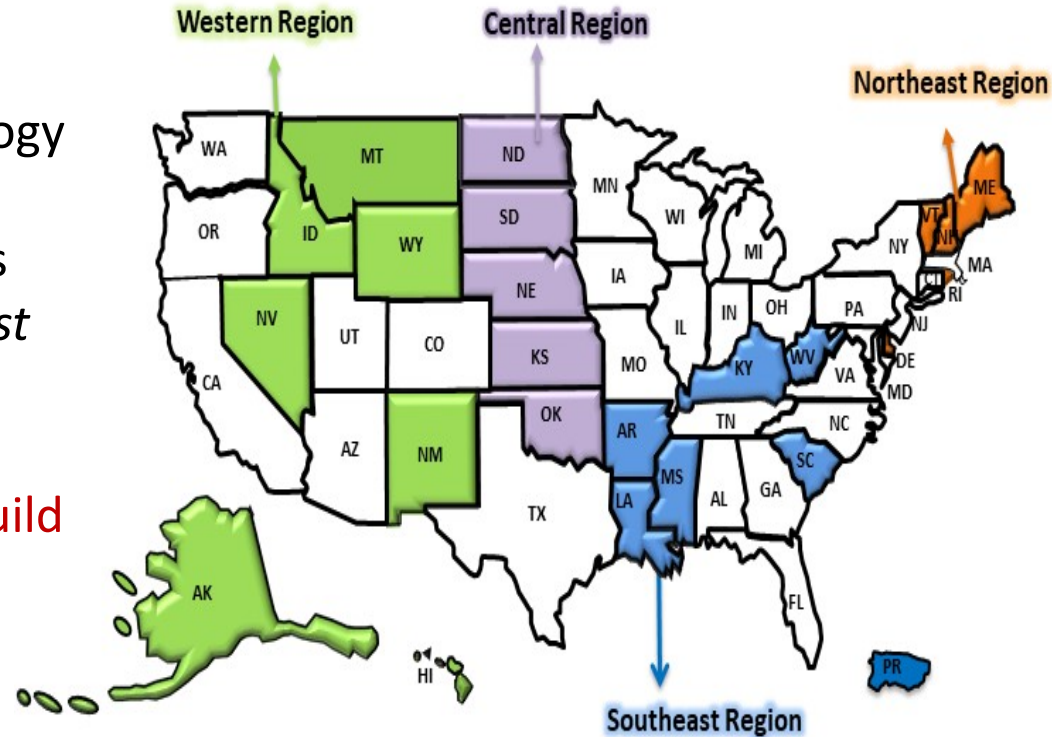


# Regional Technology Transfer Accelerator Hubs for IDeA States

❖ **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

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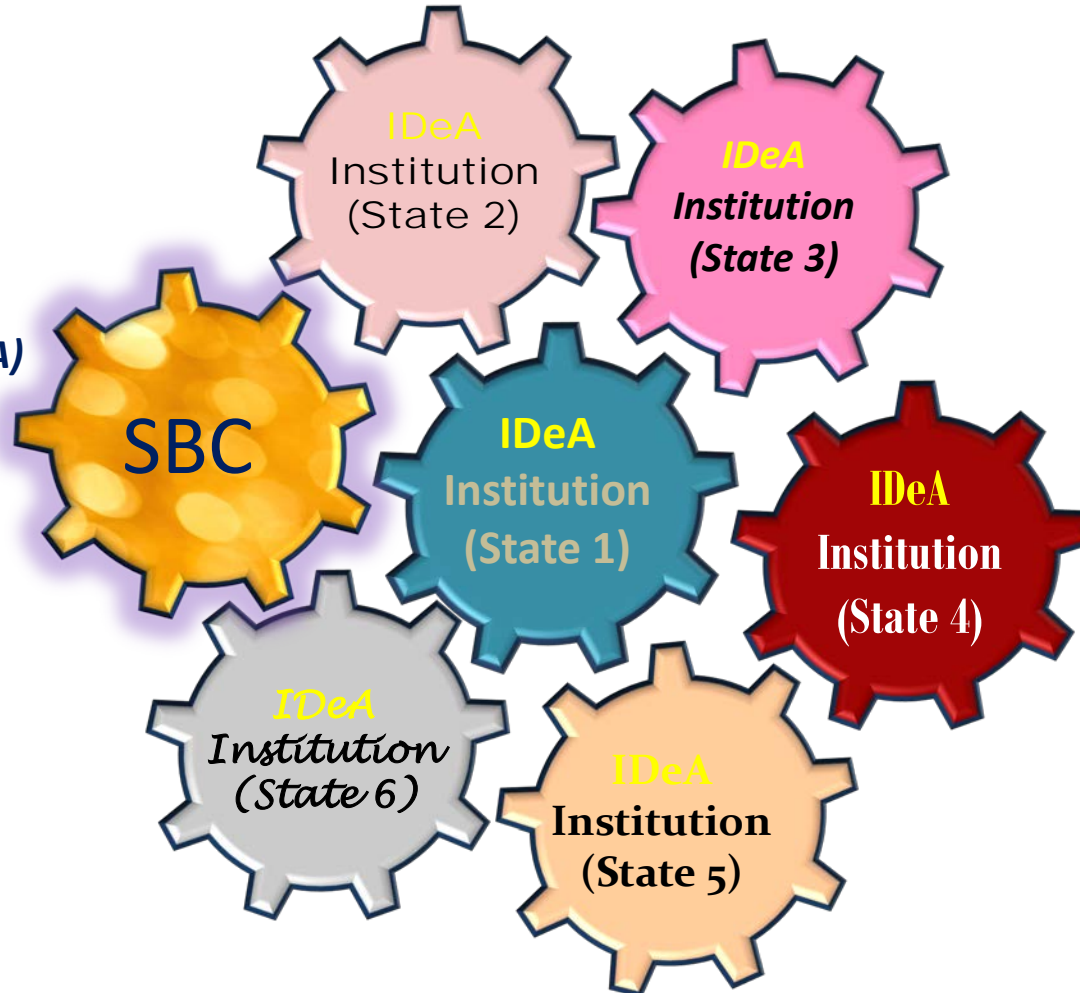
## ❖ Purpose:

- 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,  
<https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-18-001.html>



# 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)



<https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-18-001.html>



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

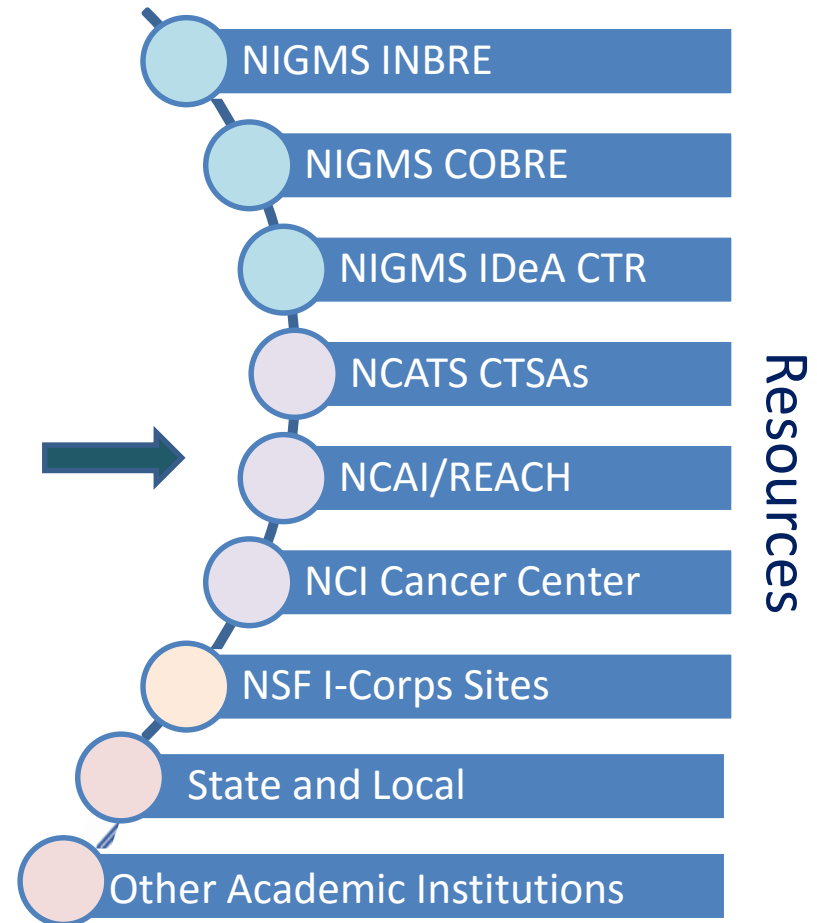
IDeA Region	Grant Number	Program Name	Small Business Concern	Major Academic Partnering Institution
Northeast	UT2GM130176	DRIVEN: Accelerating Medical Entrepreneurship in the Northeast	CELDARA MEDICAL, LLC (Lebanon, New Hampshire)	University of Vermont, Burlington
Central	UT2GM130175	The Sustainable Heartland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





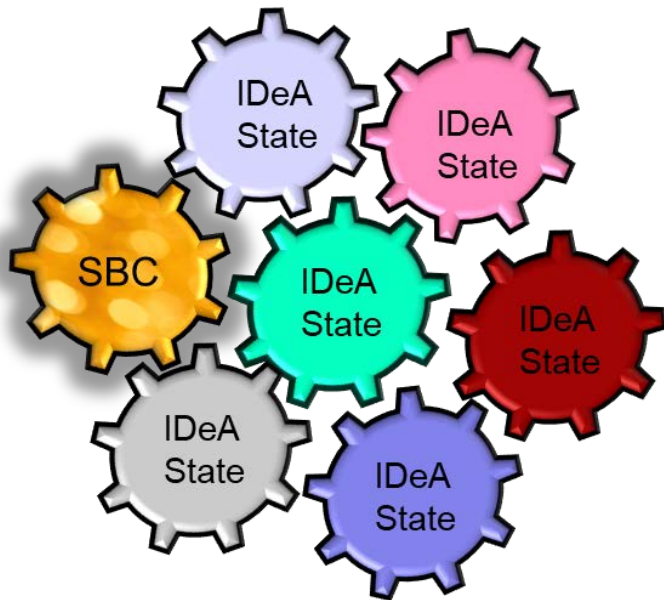
# Southeast IDeA Accelerator Hub and Resources

## SE Xlerator Network



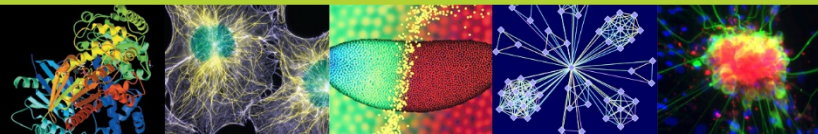
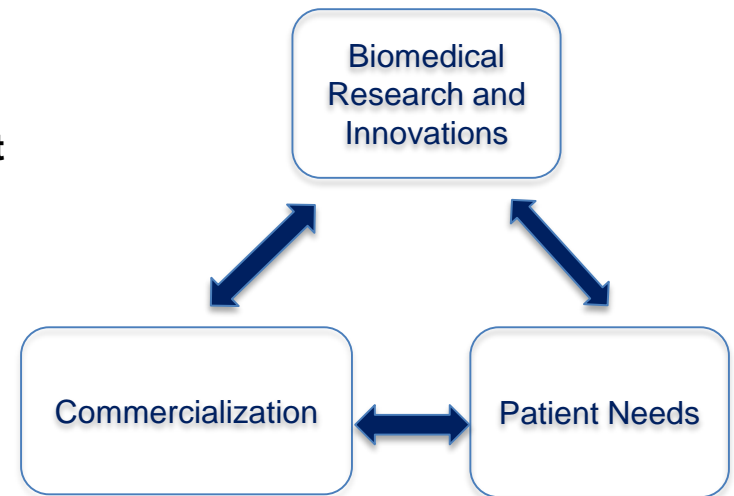
# Fostering Biomedical Entrepreneurship in IDeA States

## *Regional Technology Transfer Accelerator Hub*



Skills Development  
Mentoring  
Education  
Training  
→  
& Outreach

## *Entrepreneurship Ecosystem*



# Fostering Entrepreneurship in Biomedical Research in IDeA States



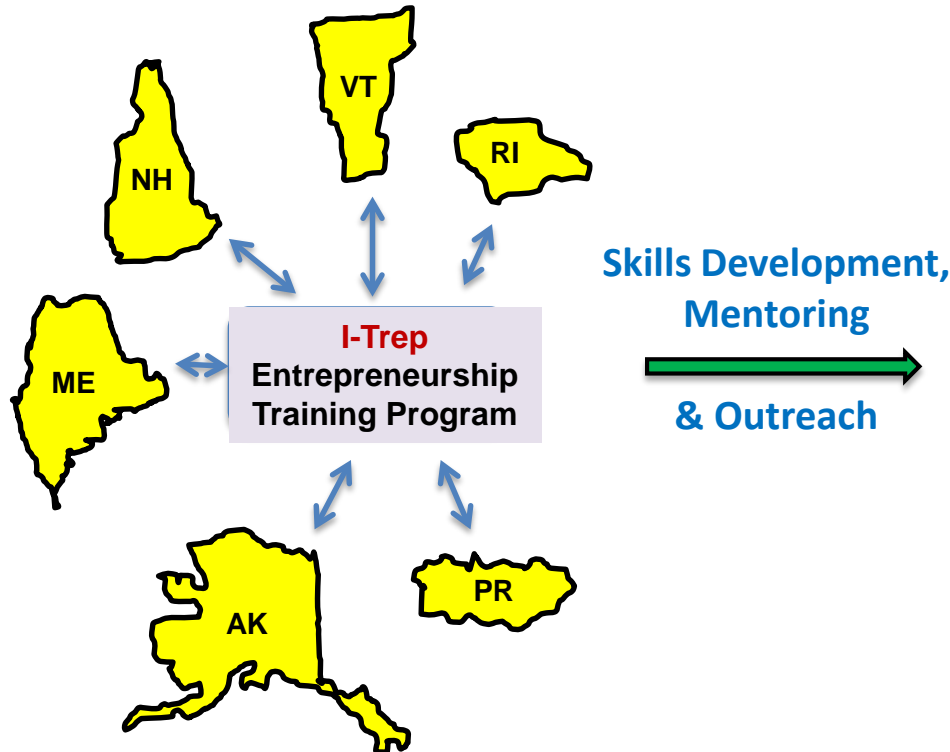
Fostering IDeA state  
Entrepreneurship

# I-Trep

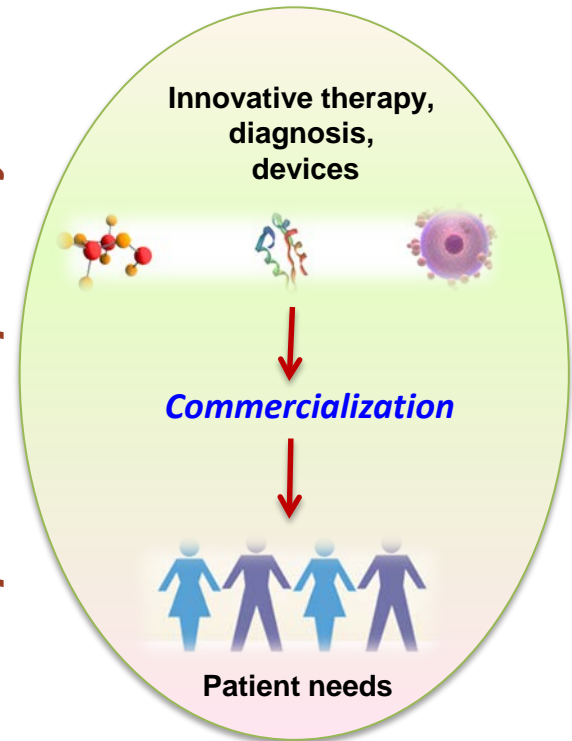
NIGMS IPERT (R25) grant award to **Univ. Vermont (2016-2021)**

PI: Dr. Mercedes Rincon

Partners with 5 other IDeA states



*Entrepreneurship Ecosystem*



# I-Trep Webinars 2017-2018

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





# NIGMS: Innovative Programs to Enhance Research Training (IPERT)

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- ❖ **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*
- ❖ **More information** at <https://grants.nih.gov/grants/guide/pa-files/PAR-17-070.html>
- ❖ **Application Due Date:** January 23, 2019
- ❖ **Program Contact:** Dr. Michael Sesma ([msesma@nigms.nih.gov](mailto: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

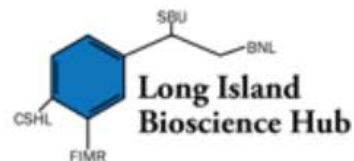


UC CAI

University of California Center for Accelerated Innovation

Advancing Health, Improving Life, and Reducing Stress and Anxiety

## REACH Hubs



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 ?

