National Institute of General Medical Sciences

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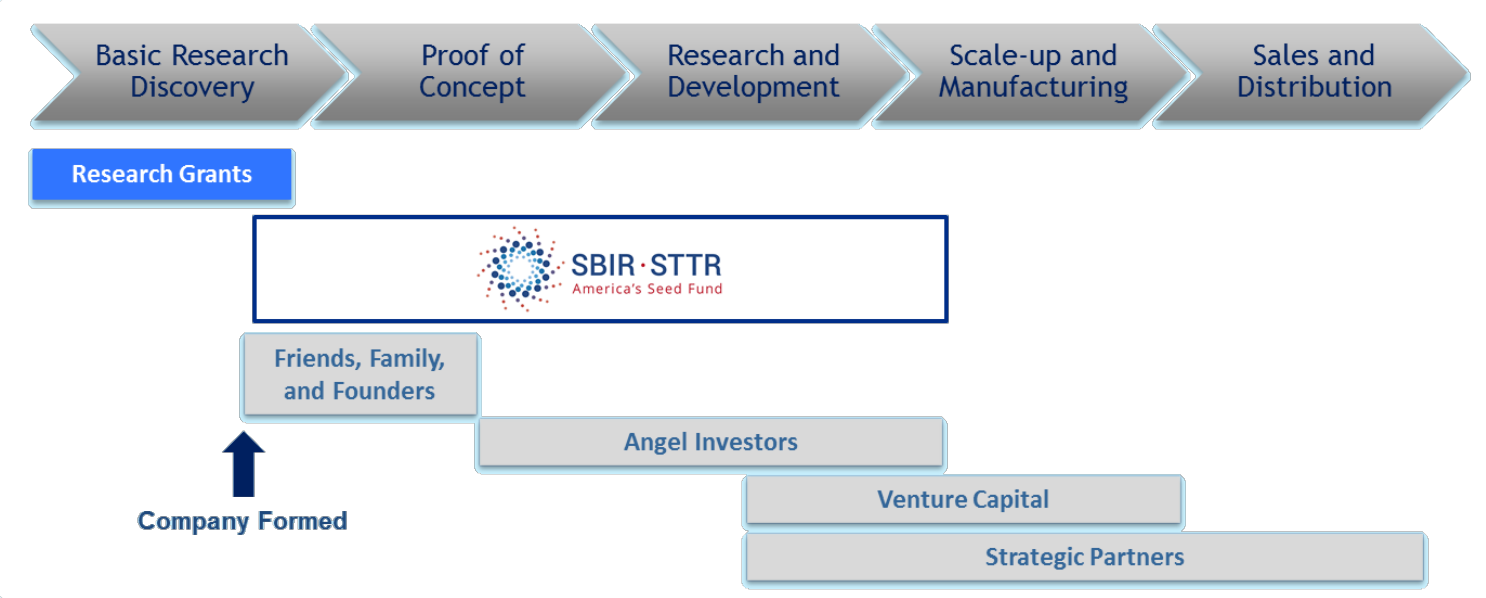
Commercialization Hubs (REACH and I-RED)

Background: NIH SBIR/STTR Funding

SMALL BUSINESS INNOVATION RESEARCH (SBIR) and SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Is a Congressionally mandated set-aside program for small business concerns to engage in federal R&D with potential for commercialization and facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

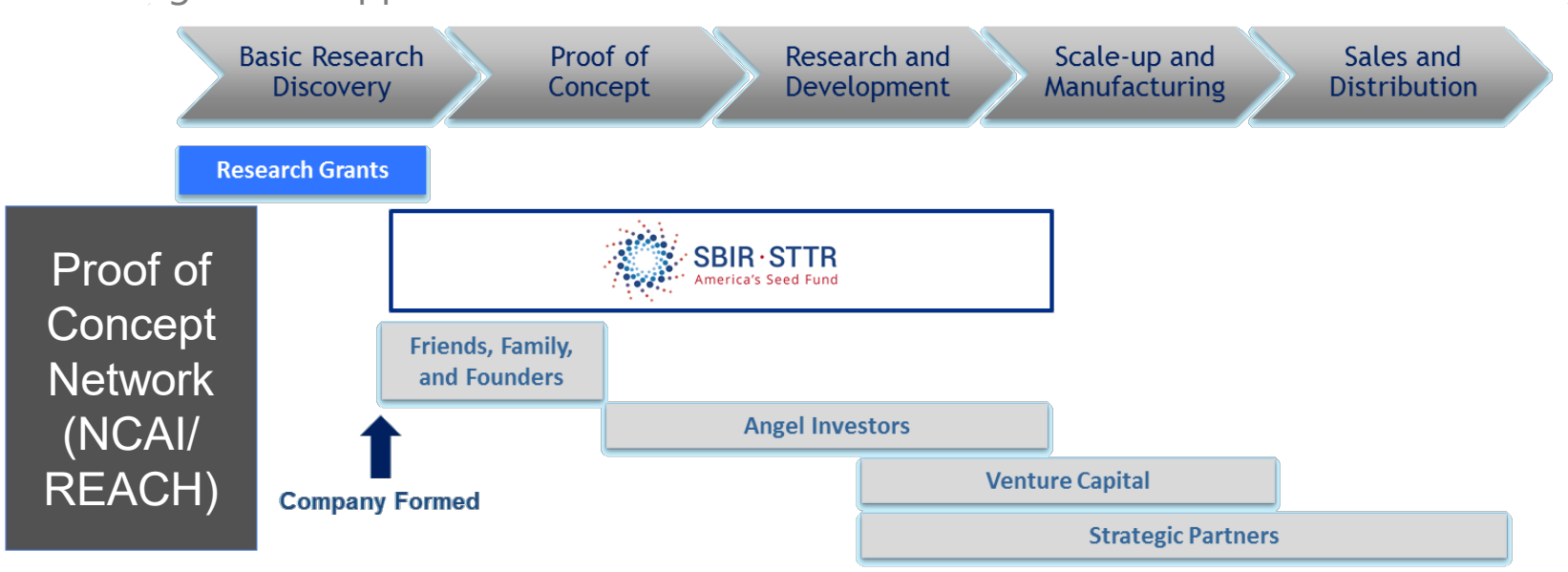


NIH SBIR/STTR Funding Includes Research Evaluation and Commercialization Hubs (STTR Phase 0)

- **NIH Centers for Accelerated Innovation (NCAI) 2013-2022**
- **Research Evaluation and Commercialization Hubs (REACH) 2015-2020 and 2019 - ongoing**

The program focuses on bringing basic science discoveries to market by providing:

•Entrepreneurial training for innovators on how to bring technologies to market
•Feedback from federal and industry experts
•Funding to support early-stage product definition studies
•Project management support

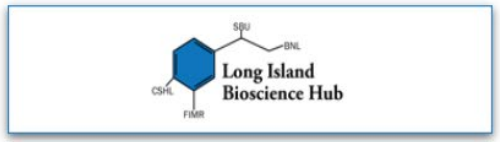


Research Evaluation and Commercialization Hubs (REACH) and NIH Centers for Accelerated Innovation (NCAI)

NCAI Centers

NCAI: NHLBI only

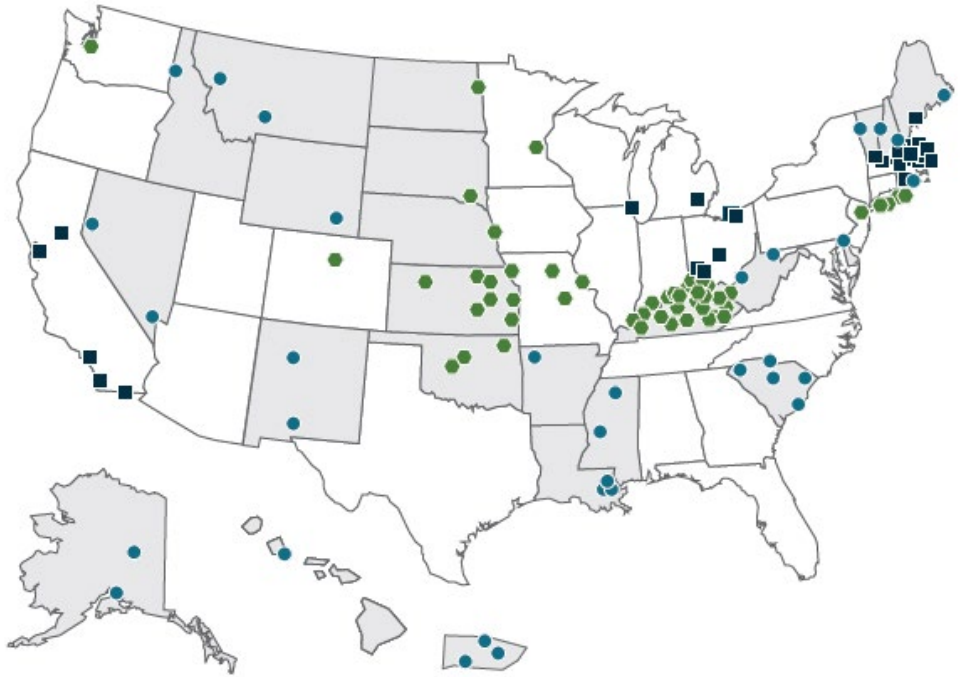
REACH Hubs



REACH 2015 and 2019:
Led by NHLBI and SEED office

https://seed.nih.gov/programs-for-academics/academic-entrepreneurship-and-product-development-programs/reach

NIH Academic Proof of Concept Network



Developing a scalable model and best practices for accelerating academic discoveries into products that improve health

NCAI, REACH, NIGMS Hubs

NIH Centers for Accelerated Innovation (NCAI) - 2013

- Heart, Lung, Blood, and Sleep focused
- 3 centers - 28 institutions in 7 states

Research Evaluation And Commercialization Hubs (REACH) – 2015 and 2019

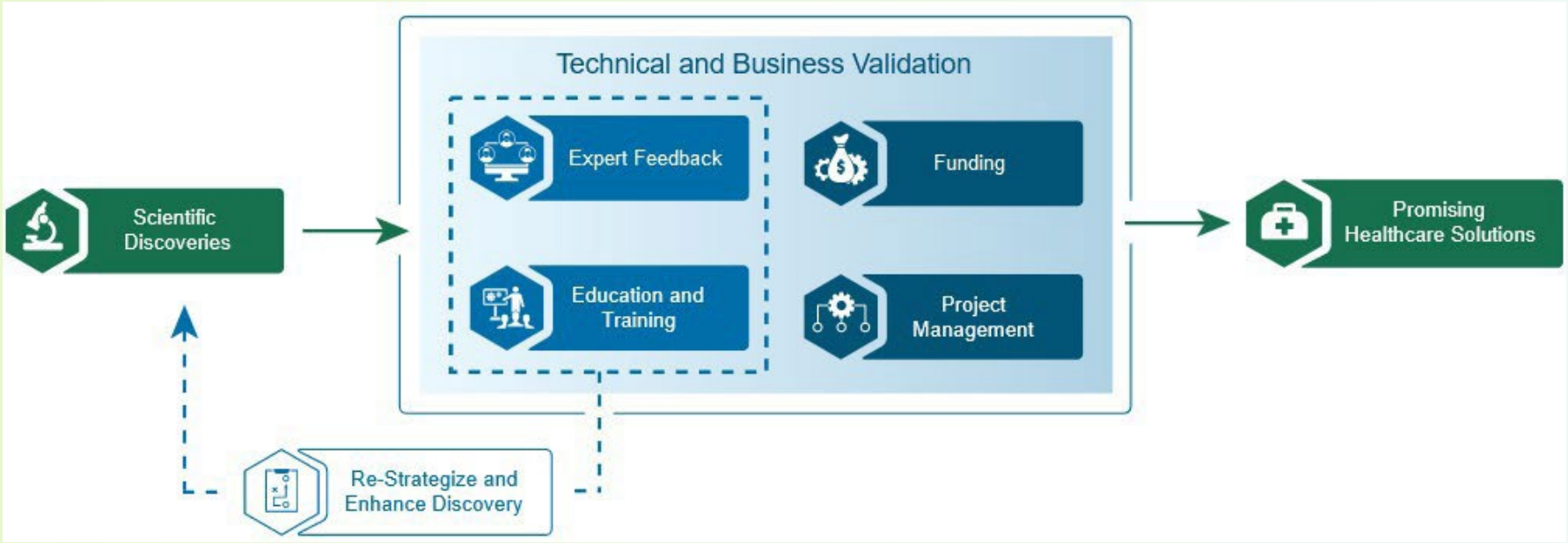
- Trans-NIH
- 3 hubs - 6 institutions in 3 states
- 5 hubs – 42 institutions in 10 states

NIGMS IDeA States Regional Technology Transfer Accelerator Hubs – 2018

- Develop innovative entrepreneurial training resources
- 4 hubs – partnership between 4 small businesses and 48 institutions in 23 states and Puerto Rico

New REACH FOA RFA-OD-23-005

REACH: Anatomy of a Research Evaluation and Commercialization Hub



NIH SEED

NCAI/REACH: Unique Program Offerings

- NCAI and REACH 2015 Pilot Programs served as a model for current REACH 2019
- Establishing best practices for effective technology translation

Program Funding

- Identify projects
- Up to $400K in project funding (1:1 *non-federal match required*)

Training and Resources

- Business development
- Regulatory planning
- Financing and partnerships

Educational Coaching

- Project management and coaching by industry experienced mentors

Personalized feedback

- FDA, CMS, NSF, USPTO
- Kaiser Permanente
- Life science industry experts

OUTCOMES

435 projects

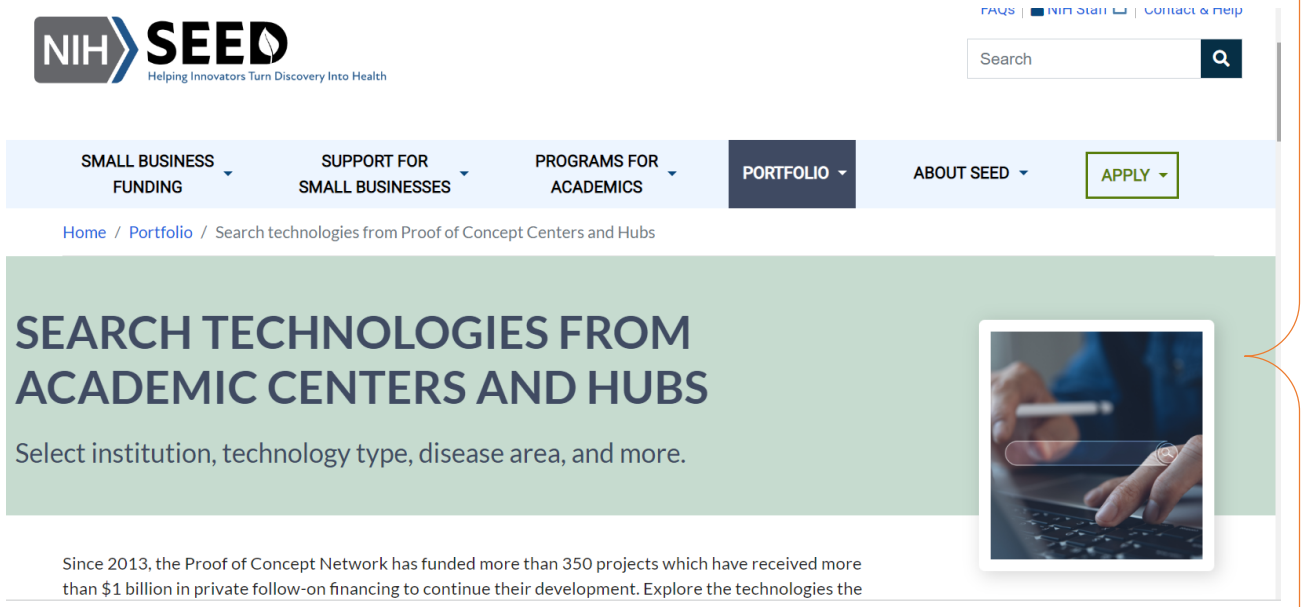
125 startups

>$2B follow-on $

> 3000 academic innovators trained

New REACH RFA-OD-23-005

NIH Proof-of-Concept Network Projects



https://seed.nih.gov/portfolio/technologies-proof-of-concept-centers-hubs

- Gene Therapy for Sickle Cell Disease
- Blood & Transfusion Support System
- Electric Nitric Oxide for Medical Purposes
- Snoring Reduction App
- HemeChip Sickle Cell Disease Diagnostic
- Nutrient Database Research System
- Custom Patient-Specific Airway Stents
- First Responder Toolkit

REACH 3.0: NIGMS & SEED

- Program Objectives: to facilitate and accelerate the translation of academic biomedical discoveries into products that improve patient care and public health.
- RFA-OD-23-005 NIH Research Evaluation and Commercialization Hubs (REACH) Awards (U01 Clinical Trial Optional) due date was February 2023
- Progress: Applications are undergoing peer review and 5 hubs will be funded in FY2023

REACH Hub Requirements

Leadership	Leadership has documented track record of success in biomedical product development
Collaborations & partnerships	Develop necessary collaborations and partnerships with stakeholders (e.g., academia, non-profits, industry, and existing federal resources)
Regional & local impact	Make an impact on small business development, entrepreneurial culture, workforce diversity, and health disparities
Technology development	Demonstrate the ability to support technology development from early-stage technology feasibility through pre-clinical technologies across the breadth of the NIH mission

REACH Hub Requirements con’t

Project management	Develop and implement milestone-driven, market focused project management oversight and decision-making processes.
Educational activities	Provide innovators from diverse backgrounds, including innovators from underrepresented groups, access to skills development, hands-on experience and educational and networking activities
Sustainability plan	Develop and implement a plan for ensuring that capacity develop under their REACH award will be sustained at their institution

REACH Project Types

- **Small Molecule Therapeutics:** The compound is at the lead optimization or preclinical stage. The target is known, and/or there is some method or assay to determine its effect.
- **Biologics or Cell Based Therapies:** The biologic or cell population has been identified and some reasonable method of development, sourcing, manufacture, or proliferation is proposed. Mechanism of action has been determined to a sufficient level that there is a reasonable understanding of the product to be developed or tested in the project.
- **Interventional Medical Device:** Includes prototype development and testing, either on the bench or in animals. Physiologic experiments have been conducted or reported in the literature, providing rationale for prototype development.
- **Diagnostic Medical Device/IVD/MDx:** Includes prototype development and some method of testing.
- **Health IT, Software, Apps, and Algorithms:** Should be beyond the concept stage and already have an existing code base. The idea should be grounded in previous experiments or solid peer reviewed evidence.

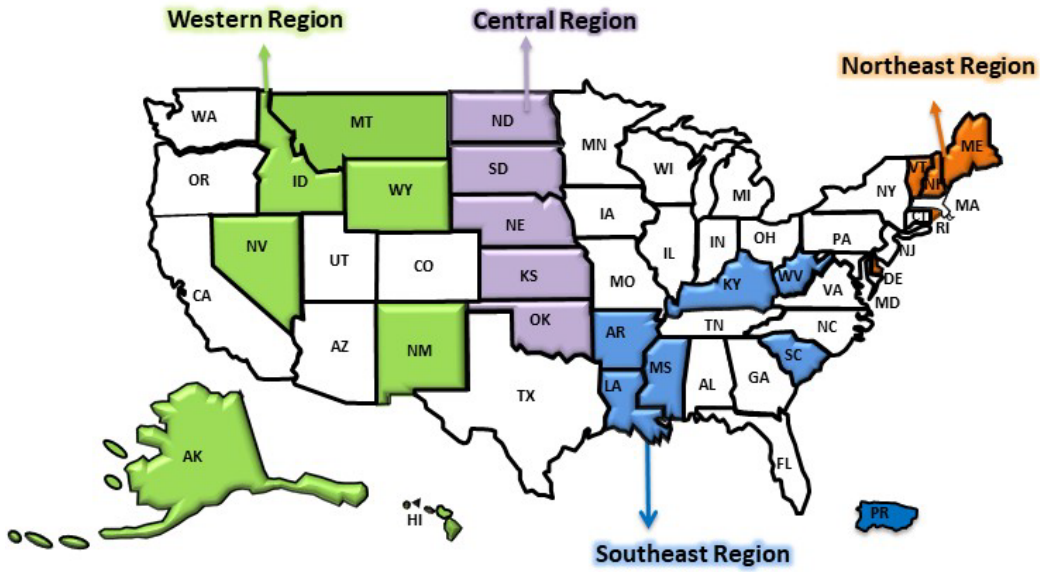
REACH Key Component: Enhancing Diverse Perspectives

- All applications must include a Plan for Enhancing Diverse Perspectives (PEDP)
- Describe strategies to advance the scientific and technical merit of the proposed project through enhanced inclusivity
- Provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application
- No more than one page
- Assessed as part of the scientific and technical peer review evaluation and considered among programmatic matters with respect to funding decisions
- For more information go to https://braininitiative.nih.gov/vision/plan-enhancing-diverse-perspectives

Facilitating Entrepreneurship: IDeA Regional Entrepreneurship Development (I-RED) Program

To support small business concerns in IDeA states to develop educational products that:

- enhance entrepreneurial knowledge and skills of faculty, postdoctoral fellows and students in each of the four IDeA regions
- provide hands-on training experience for investigators pursuing entrepreneurial ideas and opportunities
- strengthen institutional Technology Transfer Programs to facilitate transforming research into health products or services
- Uses non-IDeA funds



https://www.nigms.nih.gov/Research/DRCB/IDeA/Pages/default.aspx

Three of the four Regional Technology Transfer Accelerator Hubs funded in FY2018 have transitioned into the I-RED program. The fourth one will be funded in FY23.

Thank you!

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