

Accelerating the Transition from Lab to Market *for Health*

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National Commission on Forensic Science
Translation of Scientific Research into Forensic Practice
December 8, 2015

Office of Translational Alliances and Coordination

Division of Extramural Research Activities

National Heart, Lung, and Blood Institute

National Institutes of Health





National Institutes of Health

Turning Discovery Into Health

\$30 Billion

Basic and applied biomedical science

\$786 Million

Non-dilutive funding just for small businesses

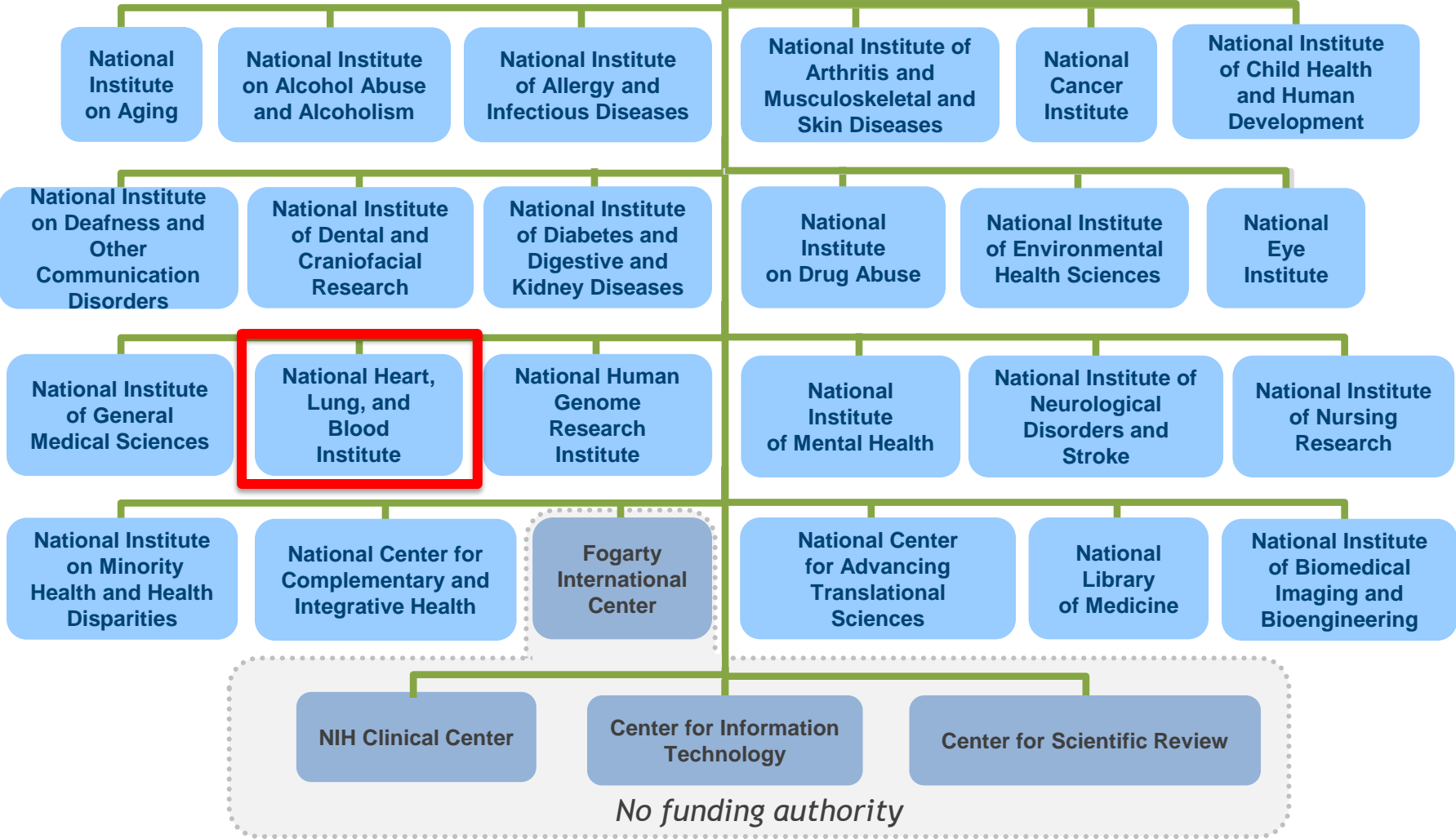


National Institutes of Health

Turning Discovery Into Health

Office of the Director

Office of Research Infrastructure Programs



No funding authority

NHLBI is Third-Largest Recipient of NIH Funds



\$3.1 Billion
Basic & Applied Research

\$92 Million

Just for small businesses

Cancer Institute



Health Challenges in the NHLBI Mission

Heart Disease



Sleep

Non-malignant
Blood Disorders



Lung Disorders

Protecting the Nation's
Blood Supply



Vascular Aspects
of Stroke

Obstacles to Translating from Lab to Market

Path to market is long & expensive

- Funding gaps
- Lack of non-technical expertise
- Knowledge gaps
- Decreased risk tolerance among investors



NHLBI Resources to Help Tackle Obstacles

Path to market is long & expensive

- Funding gaps
 - Small Business Funding (SBIR/STTR)
 - Product Development Services
- Lack of non-technical expertise
 - Advisory Experts
- Knowledge gaps
 - Education
- Decreased risk tolerance among investors
 - Partnership Facilitation



NHLBI Resources to Accelerate Translation

- **Small Business Funding**
- Product Development Services
- Advisory Experts
- Education
- Partnership Facilitation

Small Business Mission and Program Goals

Both Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs

- Stimulate technological innovation.
- Increase private-sector commercialization of innovations derived from Federal R&D funding.

SBIR

- Meet Federal R&D needs.
- Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons.

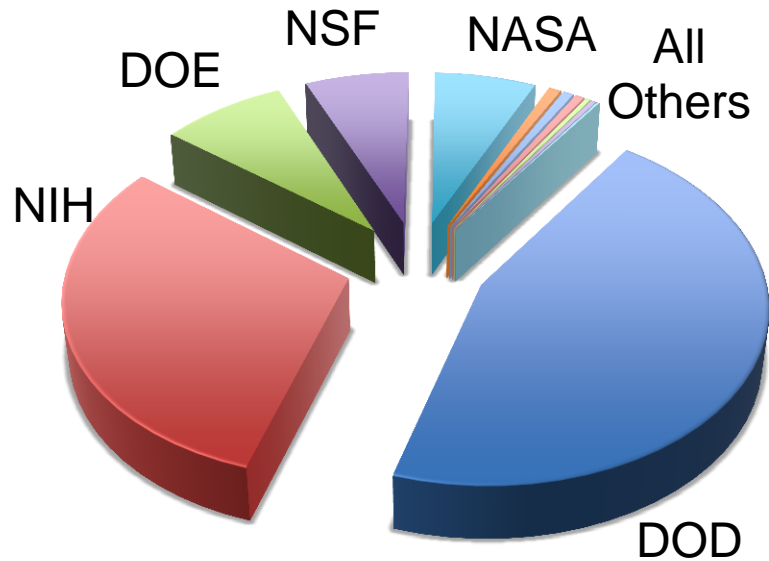
STTR

- Foster technology transfer through cooperative R&D between small businesses and research institutions.

Small Business Innovation Development Act of 1982

Small Business Technology Transfer Act of 1992

SBIR/STTR Budgets by Agency (FY2013)



**~ \$2.3B in FY13
across all
agencies**

Agencies with SBIR and STTR Programs	
Department of Defense (DOD)	\$ 1.0 B
Department of Health and Human Services: National Institutes of Health (NIH)	\$697.0 M
Department of Energy (DOE), including ARPA-E	\$183.9M
National Science Foundation (NSF)	\$153.0 M
National Aeronautics and Space Administration (NASA)	\$ 148.8 M
Agencies with SBIR Programs	
U.S. Department of Agriculture (USDA)	\$18.4M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$15.7 M
Department of Education (ED)	\$13.4 M
Department of Transportation (DOT)	\$7.6 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)	\$7.4 M
Environmental Protection Agency (EPA)	\$3.8 M

Reasons to Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
- Provides recognition, verification and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)
- **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

CoaguChek®
Because it's my life



illumina®



MedImmune


THORATEC®
CORPORATION



LEVITRONIX®

Genentech
IN BUSINESS FOR LIFE



Small Business Innovation Research (SBIR) vs. Small Business Technology Transfer (STTR)

	SBIR	STTR
Program Size (Set-aside)	2.9% (FY15 \$691M, NIH) 3% (FY16)	0.4% (FY15 - \$95M, NIH) 0.45% (FY16)
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business
Work Requirement	Guidelines: May outsource up to 33% (Phase I), 50% (Phase II)	Minimum Work Requirements: 40% Small Business 30% Research Institution Partner

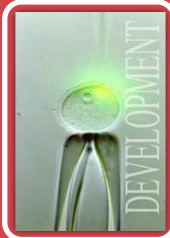
Award is always made to the small business

Phased Development (SBIR/STTR)



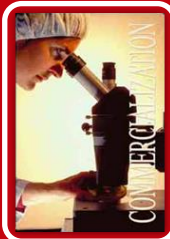
PHASE I

- Feasibility Study
- Up to \$225K and 1 year



PHASE II

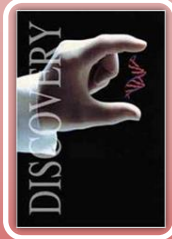
- Continued Research/R&D
- Up to \$1.5M and 2 years
- Commercialization plan required



PHASE III

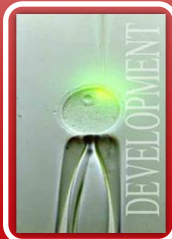
- Commercialization Stage
- Use of non-SBIR/STTR Funds

Fast Track (SBIR/STTR)



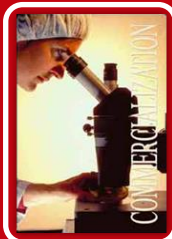
PHASE I

- Feasibility Study
- Up to \$225K for 1 year



PHASE II

- Continued Research/R&D
- Up to \$1.5M for 2 years
- Commercialization plan required



PHASE III

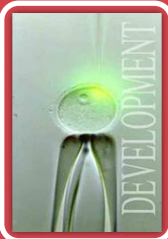
- Commercialization Stage
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Direct to Phase II (SBIR only)



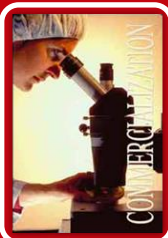
PHASE I Equivalence

- No SBIR/STTR money



PHASE II

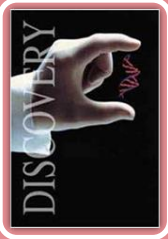
- Continued Research/R&D
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PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

NHLBI Phase IIB Bridge and Small Market Awards



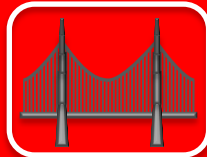
PHASE I – R41, R43

- Feasibility Study
- \$225K for 6-12 months



PHASE II – R42, R44

- Continued Research/R&D
- \$1.5M for 2 years



Bridge and Small Market Awards (R44)

- Supports products requiring FDA clearance/approval



- Use of non-SBIR/STTR Funds
- Not generally funded by NIH

Bridge Awards

- [RFA-HL-16-009](#)
- Expectation of 1:1 match
- \$3M over 3 years

Small Market Awards

- [RFA-HL-14-012](#)
- Rare diseases, pediatric populations
- Expectation of 1:3 match
- \$1M per year for 3 years

Funding Opportunities

- Investigator Initiated Grants
 - Omnibus Solicitations
- Targeted Grant Funding Opportunities
 - Variety of topics, release and receipt dates
- Contract Funding Opportunities
 - Annual NIH & CDC SBIR Contract Solicitation
 - Application process different from grants



NHLBI Resources to Accelerate Translation

- Small Business Funding
- **Product Development Services**
- Advisory Experts
- Education
- Partnership Facilitation

NHLBI Resource Programs

- **Clinical Specimen and Data Repository**



biolincc.nhlbi.nih.gov

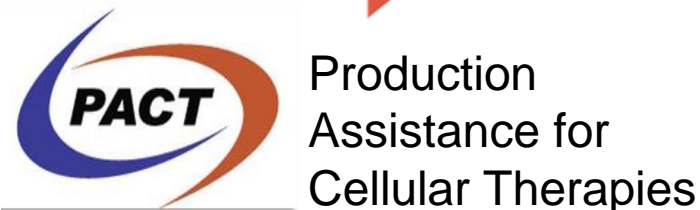
- **IND-Enabling Programs**



gtrp.org



nhlbismartt.org



pactgroup.net

NHLBI Resources to Accelerate Translation

- Small Business Funding
- Product Development Services
- **Advisory Experts**
- **Education**
- Partnership Facilitation

Office of Translational Alliances and Coordination (OTAC)



Matt McMahon
Director



Jodi Black
Acting Director (2011-2015)



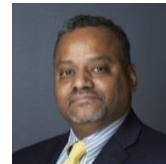
Kurt Marek
Deputy Director



Kathleen Rousche
NCAI Program Director



Jennifer Shieh
Small Business Coordinator



Eric Padmore
Program Analyst



Gary Robinson
Business Development Advisor



Steve Flaim
Investor-In-Residence



Chris Sasiela
Regulatory Strategist



Ethel Rubin
Entrepreneur-In-Residence



Gautam Prakash
Intellectual Property Specialist

Advisory Experts: Not Your Typical NIH Office



Jennifer Shieh
Small Business Coordinator



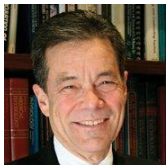
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Steve Flaim
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Ethel Rubin
Entrepreneur-In-Residence

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NHLBI Small Biz Hangouts



National Heart, Lung,
and Blood Institute



<http://bit.ly/SmallBizHangouts>



Regulatory

- Navigating the FDA Website
- "First Contact" with FDA
- Finding the Right Regulatory Consultant
- Developing a Target Product Profile



Commercialization

- Writing your Phase II Commercialization Plan
- Identifying and Connecting With Your Customer
- How Pharma Evaluates New Therapeutic Opportunities



Intellectual Property

- Intellectual Property Basics for the New Innovator
- Making Your Mark: The Use and Care of Trademarks
- Patent Litigation: Basics, Defense, and Offense – Parts 1 & 2

NHLBI Small Biz Hangouts



National Heart, Lung,
and Blood Institute



<http://bit.ly/SmallBizHangouts>

Regulatory

- Navigating the FDA Website
- "First Contact" with FDA

January 12, 2 pm ET

Reimbursement 101

Jennifer Fillman

Jan Nielsen

Cardinal Health

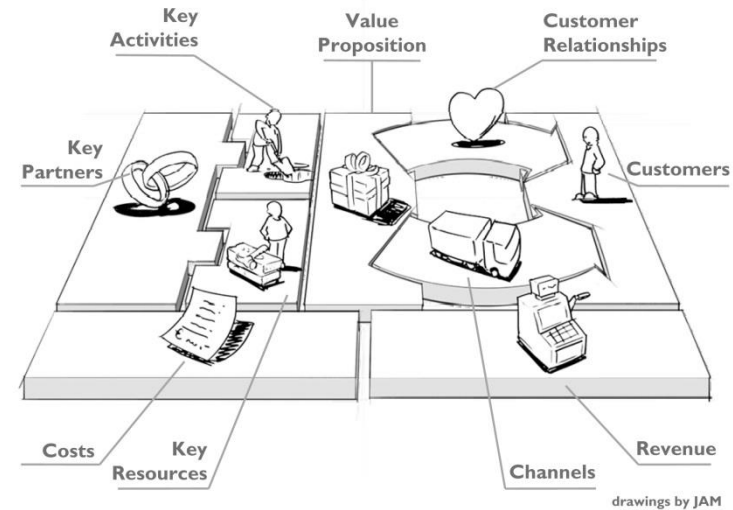
<http://bit.ly/ReimbursementBasics>

- Intellectual Property Basics for the New Innovator
- Making Your Mark: The Use and Care of Trademarks
- Patent Litigation: Basics, Defense, and Offense – Parts 1 & 2

Entrepreneurial Education for SBIR/STTR Phase I Awardees

I-Corps™ at NIH

- Immersive entrepreneurial education
- Focused on customer discovery to inform product development
- Multiple institutes across NIH
- <http://sbir.cancer.gov/icorps>



Coulter College Commercializing Innovation (C3i)

- Focused on medical device development
- Provides mentoring and expert consulting services

Commercial Insights for SBIR/STTR Awardees

Niche Assessment Program (NAP)

- Market assessments for products developed by **Phase I** awardees
- *Foresight Science & Technology* does research & prepares report
- **NOT-OD-16-013** (Accepting applications)
 - <http://bit.ly/nihNAP-2016>
 - <https://sbir.nih.gov/nap>

Commercialization Accelerator Program (CAP)

- Commercialization & regulatory assistance for **Phase II** awardees
- Dedicated advisors work with companies for 9 months
- Run by *LARTA* under contract with NIH
- **NOT-OD-15-144** (Closed)
 - <http://bit.ly/nihCAP-2015>
 - <https://sbir.nih.gov/cap>

Commercial Insights for SBIR/STTR Awardees

Commercialization Readiness Pilot (CRP) Program

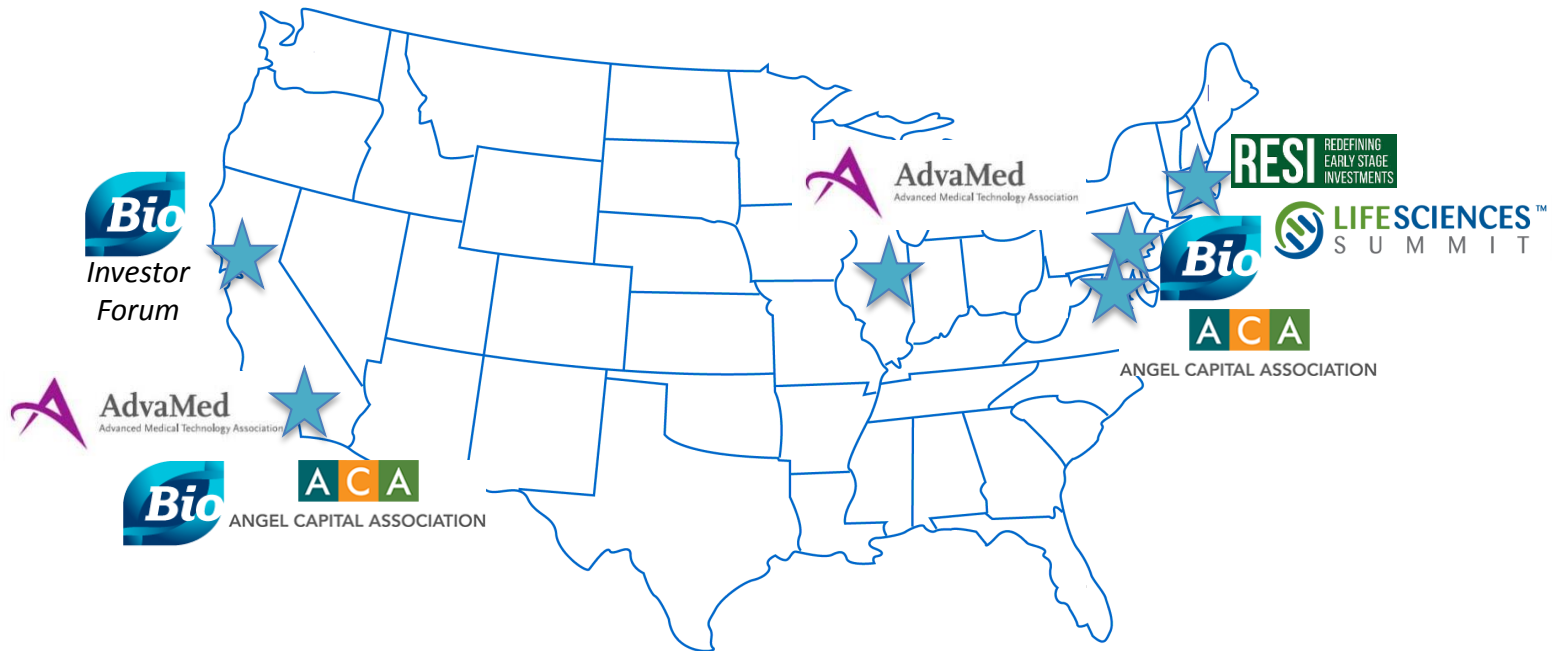
- Facilitate transition of Phase II projects to commercialization
- Up to \$50K funding for activities not typically supported through Phase II grants or contracts, *e.g.*,
 - Regulatory advice and documentation
 - Intellectual property strategy
 - Clinical trial planning
- **PAR-16-026** – *First Receipt Date January 5*
 - Webinar December 2: <http://bit.ly/CRPwebinar>
 - <http://bit.ly/PAR-16-026>; <http://bit.ly/PAR-16-026-HL>

NHLBI Resources to Accelerate Translation

- Small Business Funding
- Product Development Services
- Advisory Experts
- Education
- **Partnership Facilitation**

Facilitating Partnerships

Financial support and mentoring for awardees presenting at investor and partnering events



NHLBI Innovation Conferences

TECH COAST ANGELS

Edwards

West 2013

West 2015

Southwest 2012

Midwest 2014

Northeast 2014

Mid-Atlantic 2011

Southeast 2014

Mass Medical Angels

NEW ENGLAND VENTURE CAPITAL ASSOCIATION

BD

HATTERAS VENTURE PARTNERS

Boston Scientific Advancing science for life™

Pfizer

SHOWCASE

- NHLBI SBIR & STTR awardee pitches

CONNECT

- Innovators • Investors • Thought Leaders • NHLBI

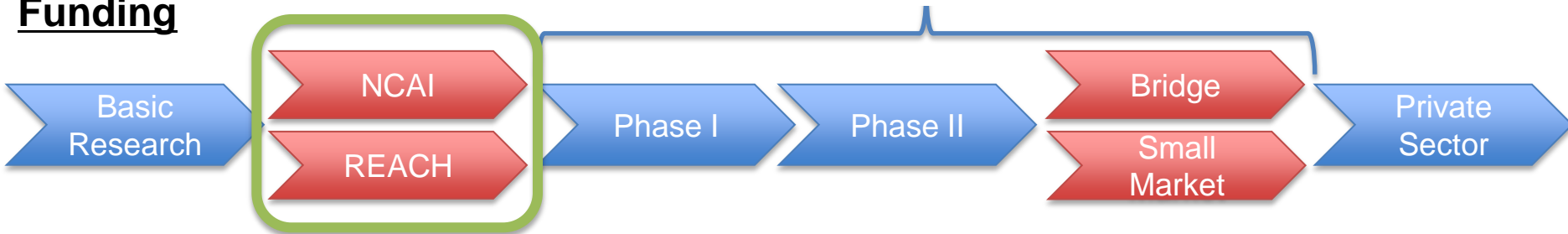
LEARN

- Insight about early-stage investing from industry leaders and investors

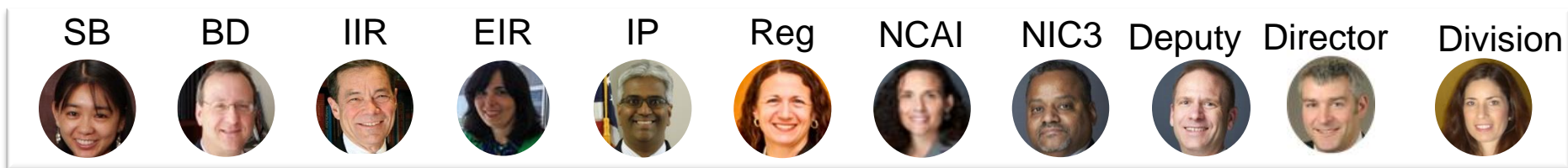
Comprehensive Strategies to Enable the Lab to Market Transition

Funding

Small Business Programs



Office of Translational Alliances and Coordination Resources



Partners



NHLBI Resources to Help Tackle Obstacles

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Phase 0 Proof-of-Concept Centers

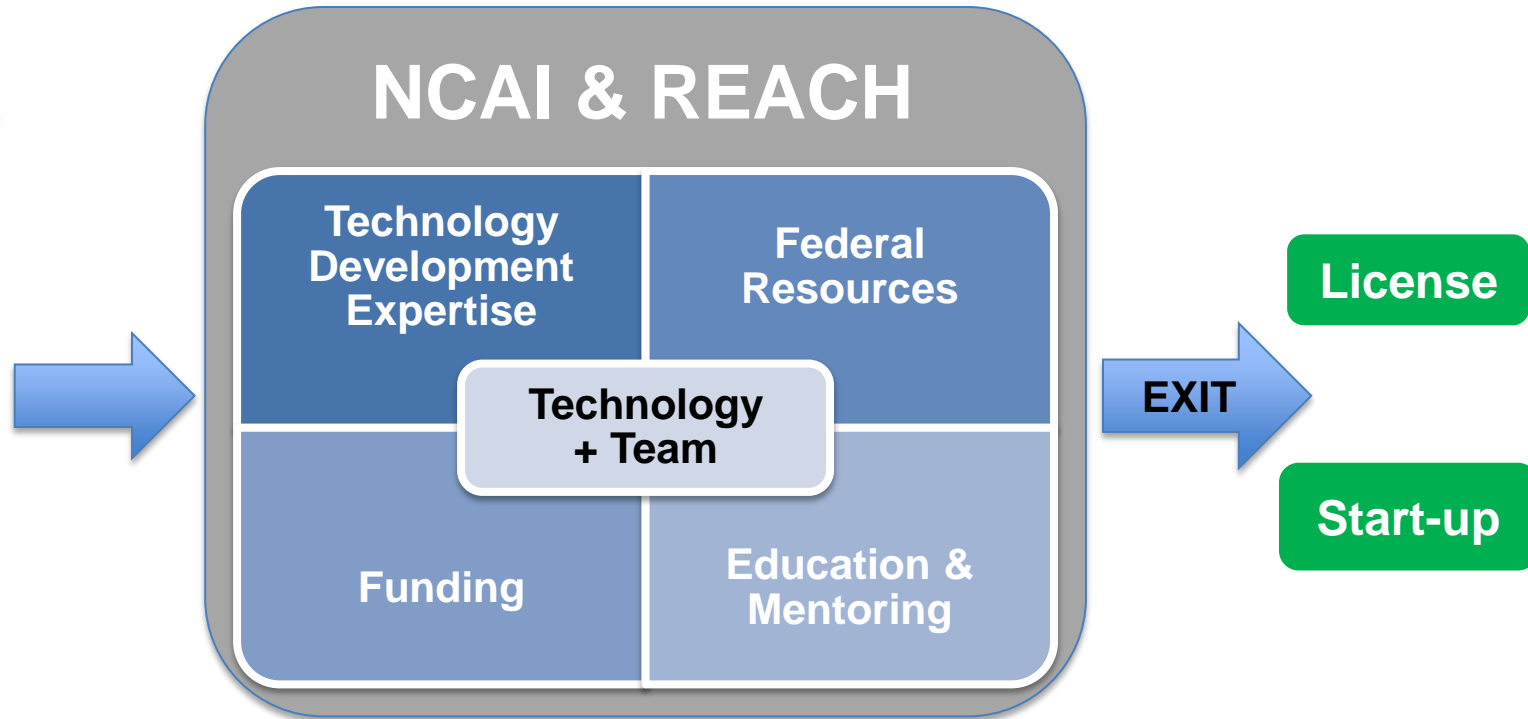
NIH Centers for Accelerated Innovations (NCAI)

Research Evaluation And Commercialization Hubs (REACH)

Improve how basic science advances and discoveries are translated into commercially viable products that improve patient care and advance public health

- **Educated Academic Workforce**
 - Commercialization Readiness Strategies & Requirements
- **Enhanced Multi-Stakeholder Partnerships**
 - Traditional and non-traditional
- **Collaborative Technology Transfer Relationships**
- **Adoptable Best Practices**

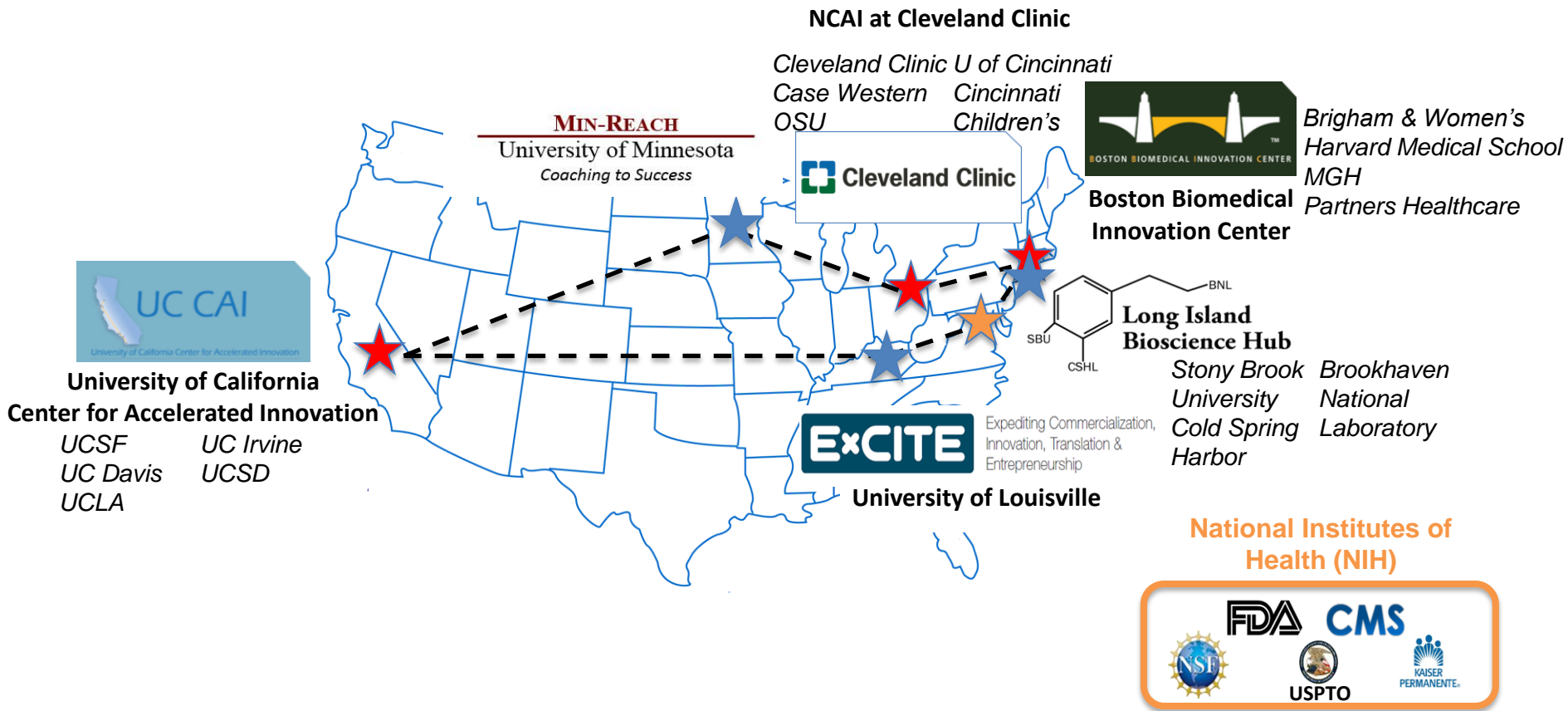
Proof-of-Concept Centers Support Milestone-Driven Development for Academic Innovators



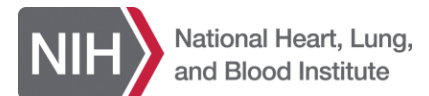
**NIH Centers for Accelerated
Innovations (NCAI)**

**Research Evaluation and
Commercialization Hubs (REACH)**

A National Proof-of-Concept Network



19 Academic Institutions **6** Federal Partners
Private Industry Partners



Potential Lessons for Forensic Science*

- More than just funding is needed
- FDA approval/clearance-based milestones drive biomedical technology development; legal standards for forensic science?
- Multi-stakeholder model
 - Getting end user feedback early in research to answer the right questions
 - Providing access to expertise through mentoring & education

Thank you

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Website www.nhlbi.nih.gov/sbir

Listserv <http://bit.ly/NHLBI-SBIR-Updates>