



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



# Commercialization Support for Life Science Innovations

*SBIR/STTR and the Commercialization Challenge*

April 2016

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Office of Extramural Research, NIH

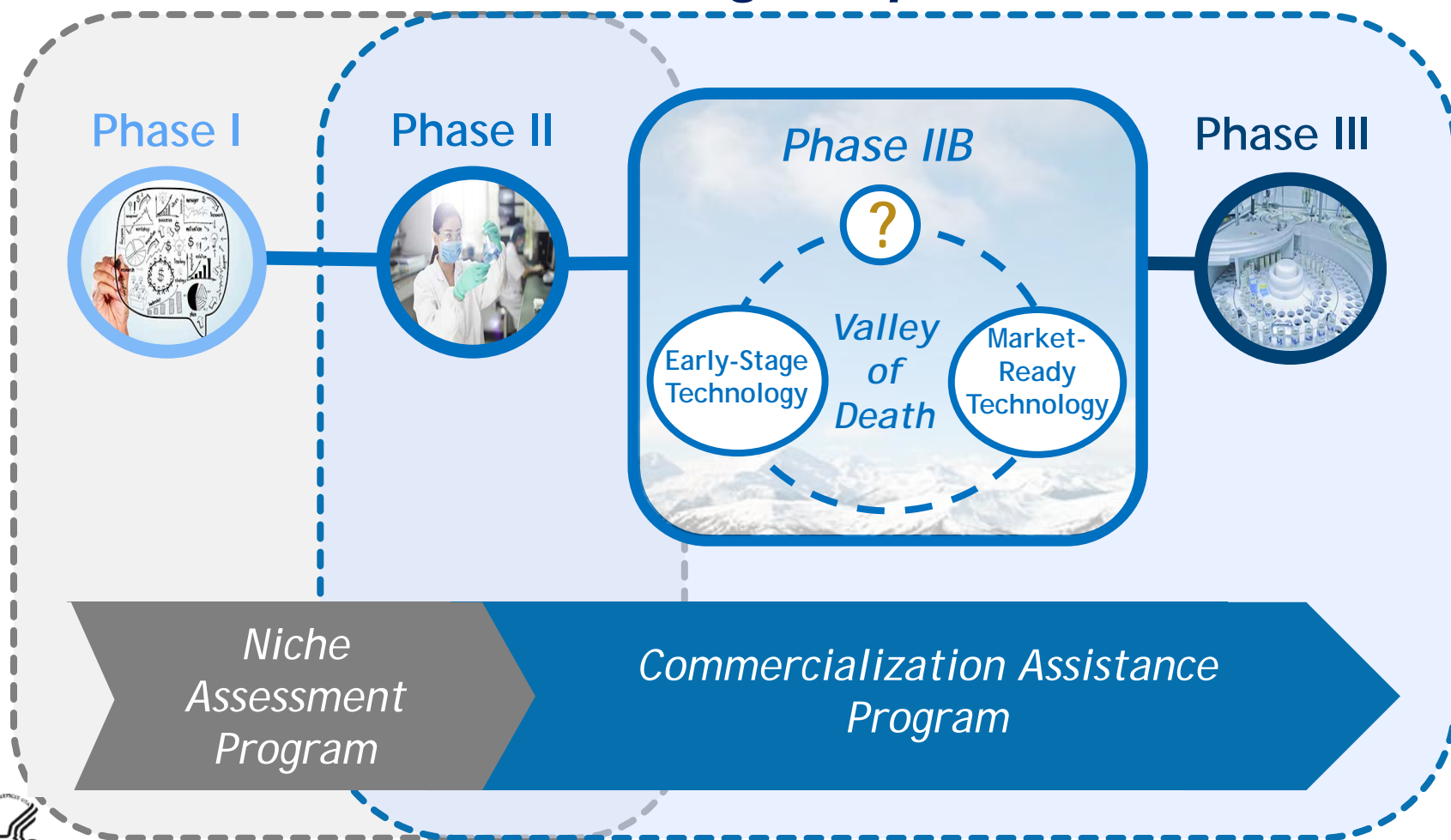




- Technical Assistance Programs
  - Niche Assessment Program
  - Commercialization Assistance Program
- Phase 0 Proof of Concept Centers
  - REACH Hubs
- iCorps @ NIH Pilot
- Phase IIB Program
- Commercialization Readiness Pilot Program (CRP)



## Helping Companies cross the “Valley of Death”

[sbir.nih.gov/tap](http://sbir.nih.gov/tap)



- Investment = Cash Flow “Valley of Death”
- Market Validation = who will buy your product or pay for your service?
- Defining Your Customer – Is your technology a “needed” solution to a defined problem?
- Penetrating well-established/ crowded markets = Who is your competition versus strategic partner?
- Protecting Intellectual Property = your “worth”





## Phase I SBIR/STTR awardees

With current or soon to  
be awarded Phase I  
(Notice of Award)

Foresight S&T



## *Technology Niche Analysis*™

Report helps Phase II  
submissions:

Identify other uses of technology

Determines competitive  
advantages

Market size and potential

Barriers to entry & strategy

Feedback from potential end-  
users





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# Commercialization Accelerator Program (CAP) (11+ years)

## Phase II SBIR/STTR awardees

Active or 5 years since  
completion of project

Our Partner - Larta, Inc.



## *Personalized Business Mentoring; Knowledge Transfer; Business Outcomes!*

- Business & strategic planning
- Investor & partnership pitch
- Technology Value Proposition
- FDA regulatory requirements
- IP & Licensing Issues

## *Market Readiness*





- Customized Approach - **One size does NOT fit all!**
  - Commercialization Training Track
  - Accelerated Commercialization Track
  - Regulatory Training Track
- High-level industry and commercial expertise
  - Live feedback from active industry contacts
  - Mediated connections to industry partners and investors
- High-quality workshops and events
- Nationwide network of resources, referrals
- Building the Business, not just the technology



- How do we measure SUCCESS?
  - Met with or closed deals with investors
  - Met with the FDA or obtained approval
  - Launched a product
  - Achieved revenue
  - Signed licensing agreements
  - Hired new employees
  - Established partnerships
  - Signed CDA







**Purpose:** To support proof-of-concept centers (Hubs) that facilitate and accelerate the translation of biomedical innovations into commercial products that improve patient care and enhance health

**Long-term goals:** To foster commercialization success, economic development and culture change at the Hub institutions

## Program Components:

1

**Infrastructure** for identifying the most promising technologies

2

**Funding** for product definition studies  
(e.g. *feasibility studies, prototype development or proof-of-concept studies*)

3

**Access** to expertise in areas required for early stage technology development (*scientific, regulatory, reimbursement, business, legal and project management*)

4

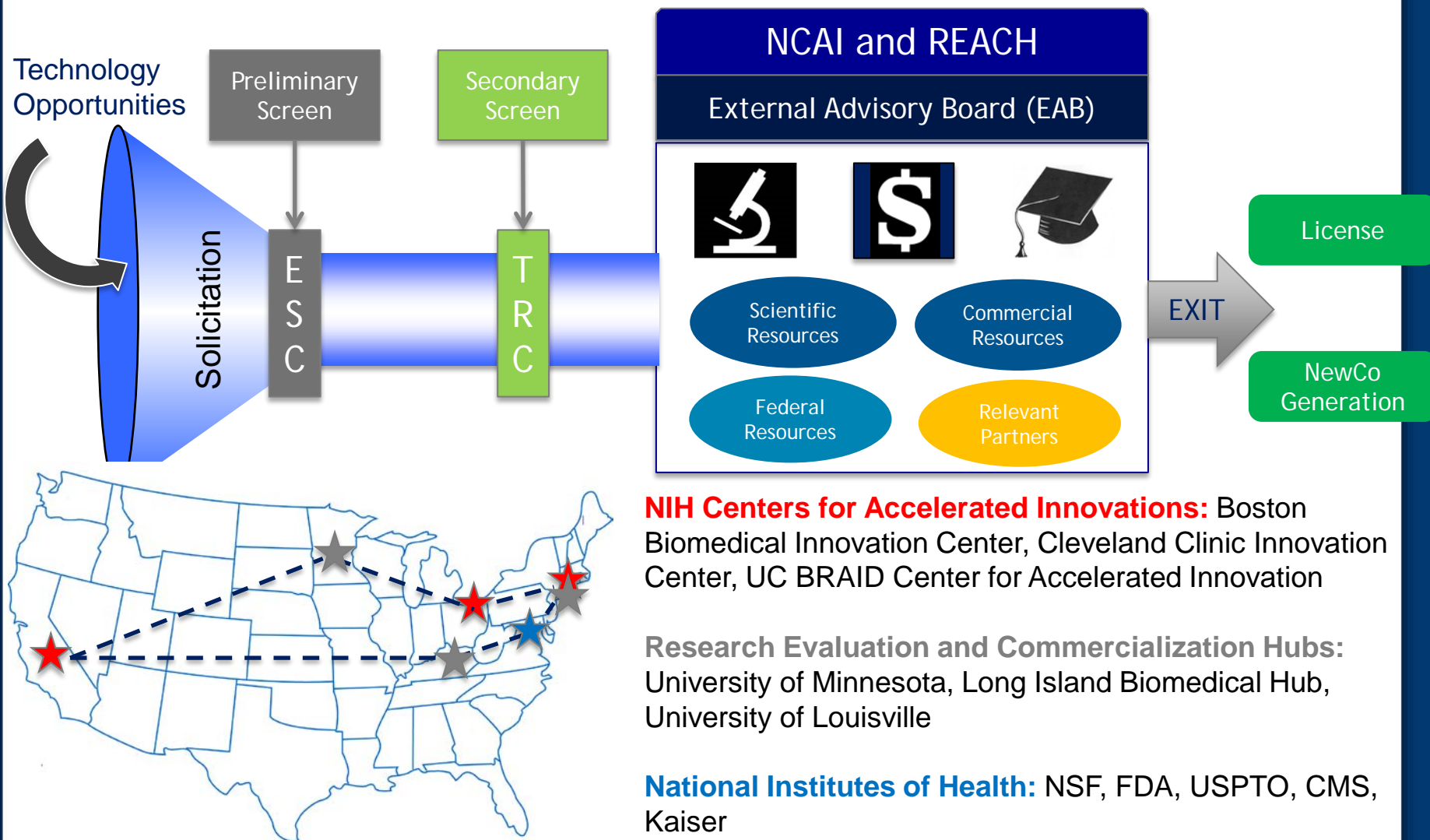
**Skills development** and hands-on experience in entrepreneurship





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## Commercially Relevant Technology Sourcing Followed by Milestone-Driven Development





**Pilot Program** was developed specifically for NIH SBIR & STTR Phase I grantees

- Administrative supplements to current SBIR/STTR Phase I **grants** to support I-Corps™ training
- Provide **three-member project teams** with access to instruction and mentoring
- Adjustments to the I-Corps curriculum to address challenges unique to life science companies





- **C-Level Corporate Officer**
  - “Chief” Executive Officer (CEO), “Chief” Operating Officer (COO), etc.
  - Relevant knowledge of the technology
  - Deep commitment to investigate the commercial landscape
  - Substantial decision-making authority within the company
- **Industry Expert**
  - Experience in translating technologies to the marketplace
  - Can be someone that has an established relationship with the company OR someone selected as a third-party resource
- **PD/PI**
  - PD/PI on the SBIR/STTR Phase I award





# Phase IIB Competing Renewal Award

## Discovery Phase I



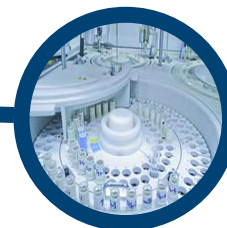
## Development Phase II



## Competing Renewal Award Phase IIB



## Commercialization Phase III



- SBIR/STTR Phase II awardee
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- Awards up to **\$1M/year for up to 3 years**
- IC must accept Competing Renewal applications (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS NHLBI, NIMH, NINDS, NCATS, ORIP, NCI, NHLBI, NINDS)

**Contact NIH Program Staff to discuss!**





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# Commercialization Readiness Pilot (CRP)

*Discovery*  
**Phase I**



*Development*  
**Phase II**



*Competing Renewal Award*  
**Phase IIB**



\$3M for up to 3 years

*Commercialization*  
**Phase III**



*Commercialization  
Readiness Pilot (CRP)*

\$3M for up to 3 years

**PAR16-026:** Technical Assistance  
**PAR16-027:** Technical Assistance and  
Late Stage Development

Webinar materials  
available at [sbir.nih.gov](http://sbir.nih.gov)

**Contact NIH Program  
Staff to discuss!**





# Commercialization Readiness Pilot Program (CRP)

- CRP may fund work that is **not** typically supported through SBIR/STTR Phase II or Phase IIB awards, including:
  - Preparation of documents for a Food and Drug Administration (FDA) submission
  - Development of an intellectual property strategy
  - Investigational New Drug (IND)-enabling studies
  - Clinical studies
  - Manufacturing costs
  - Regulatory assistance
  - Subcontracted work to other institutions, including contract research organizations (CRO)
  - A combination of services
- HHS CRP Informational Webinar (December 2, 2015)
  - View slides, audio, transcript: [http://bit.ly/SBIR\\_CRP](http://bit.ly/SBIR_CRP)





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## NIH SBIR/STTR Program Office

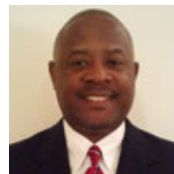


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