



# Commercialization Support for Life Science Innovations

*SBIR/STTR and the Commercialization Challenge*

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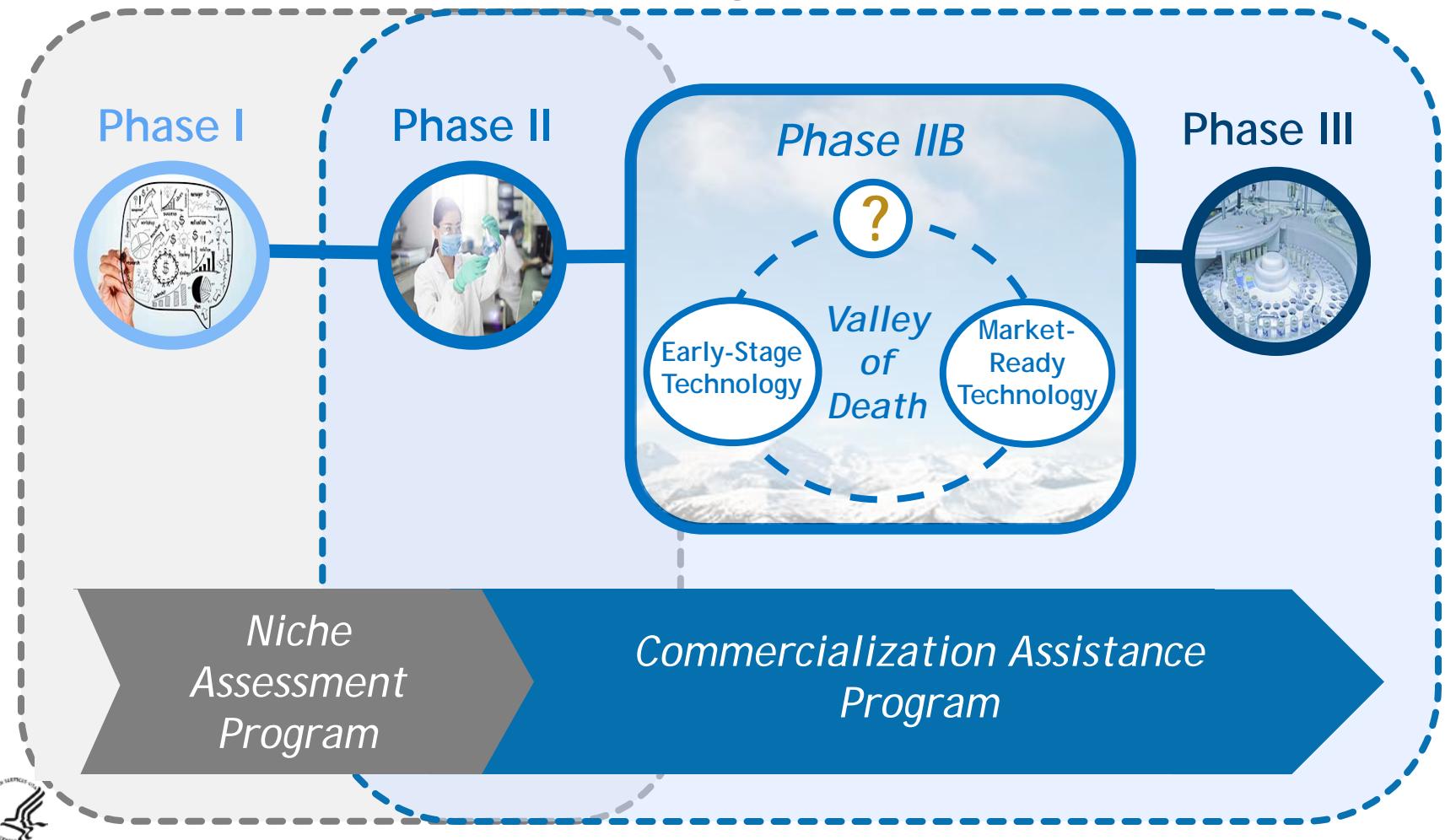
- Technical Assistance Programs
  - Niche Assessment Program
  - Commercialization Assistance Program
- Phase 0 Proof of Concept Centers
  - REACH Hubs
- iCorps @ NIH Pilot
- Phase IIB Program
- Commercialization Readiness Pilot Program (CRP)





## Helping Companies cross the “Valley of Death”

***sbir.nih.gov/tap***





- 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**



**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)

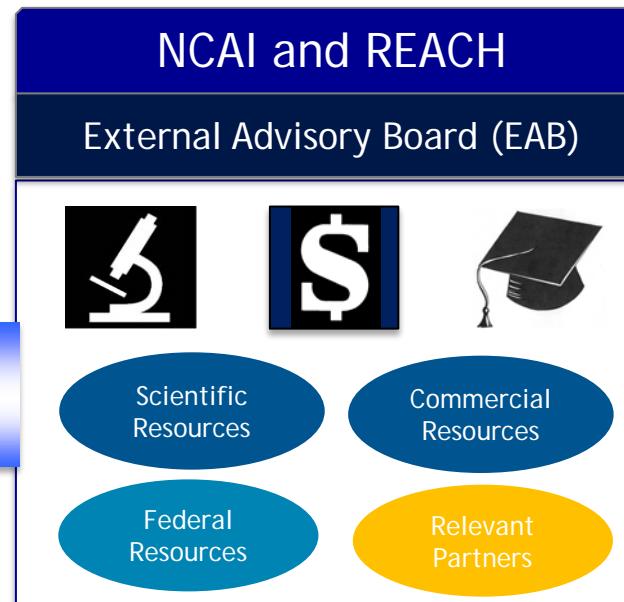
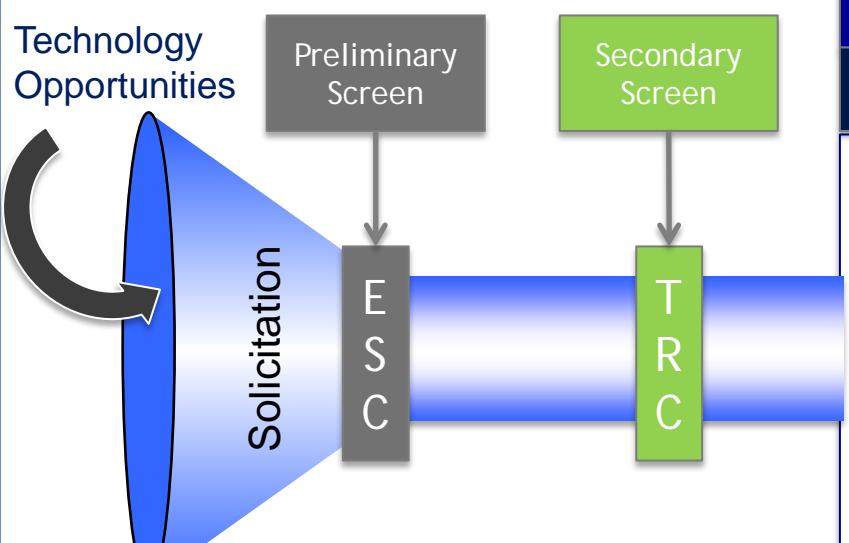
3

**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





**NIH Centers for Accelerated Innovations:** Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

**Research Evaluation and Commercialization Hubs:**  
University of Minnesota, Long Island Biomedical Hub,  
University of Louisville

**National Institutes of Health:** NSF, FDA, USPTO, CMS,  
Kaiser



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





## *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!**





# Commercialization Readiness Pilot (CRP)

## *Discovery Phase I*



## *Development Phase II*



## *Competing Renewal Award Phase IIB*

\$3M for up to 3 years

## *Commercialization Phase III*



**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!**





- 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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