

Presentation to the BSA on SBIR Program Enhancements at the NCI

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- **Major NIH resource for technology commercialization:**
 - **Research tools**
 - **Medical devices**
 - **Therapeutics**
- **Helps investigators form new companies and/or initiate projects to translate emerging technologies**
- **One of the largest sources of early-stage life sciences financing**
- ***NIH can — and should — optimize the current \$650M Set-Aside program (\$104M at NCI)***

- **Establish NCI SBIR Development Center**
- **Focus Solicitations on Commercially Viable Technologies**
- **Co-invest With the Private Sector to Bridge SBIR Projects Toward Commercialization**
- **Assemble External SBIR Advisory Committee**

NCI proceeding with:

- **Piloting all four recommendations**
- **Working with other interested ICs**

Enhancement

Establish NCI SBIR
Development Center

- **Assemble the scientific and business expertise needed to optimally manage the SBIR program**
- **Integrate all SBIR initiatives with NCI's program priorities**
- **Foster collaborations with other ICs at NIH which share common technology needs**
 - **Offer services on a reimbursable basis**
- ***Increase the return on investment for the SBIR program***

Four Extramural Divisions

Current Staff: 49

Current grants & contracts: ~425

Cancer Prevention



Staff: 9
Awards: 30

Cancer Treatment & Diagnosis



Staff: 27
Awards: 300

Cancer Biology



Staff: 9
Awards: 45

Cancer Control & Population Sciences



Staff: 4
Awards: 50

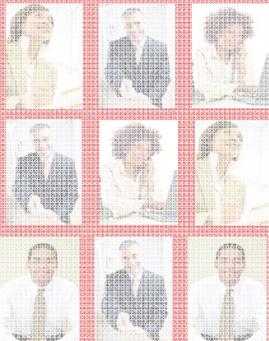
SBIR Development Center

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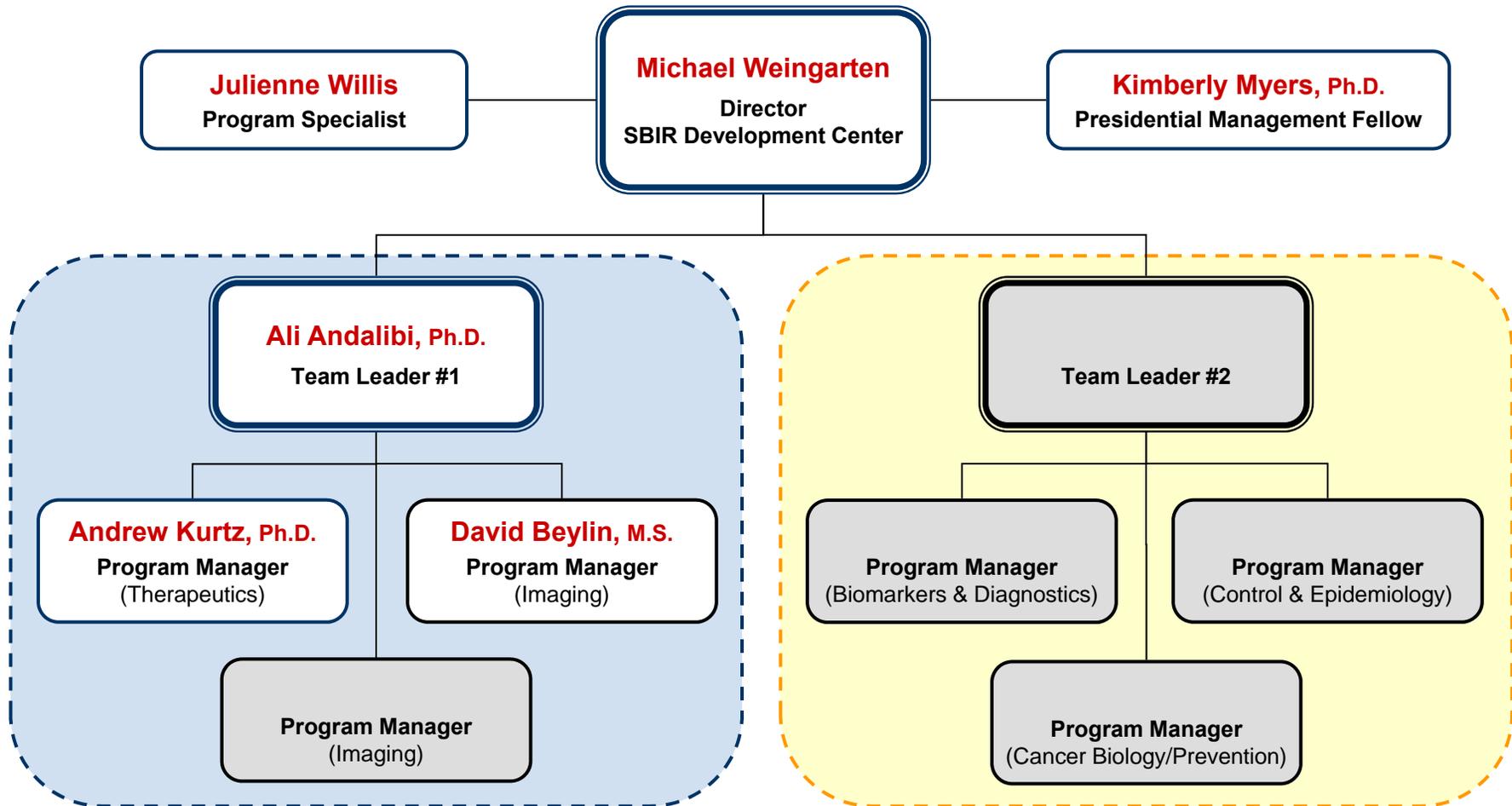
Cancer Control & Population Sciences



Staff: 4

Awards: 50

New Organizational Structure



Key Activities and Metrics

Center Activities

- **Market the program** to attract the best companies
- Relationship building with stakeholders
- **Active management** of projects and better oversight

- Facilitate success through mentorship
- **Create investor networks** focused on commercializing cancer technologies
- Examine correlations between activities and outcomes; fine tune the program

Near-term Metrics (1-3 years)

- **Improvement Over Previous Rounds**
 - ✓ Number and quality of proposals received
 - ✓ Achievement of technical and commercial milestones
 - ✓ Number of Phase I awardees who successfully compete for a Phase II award

Long-term Metrics (3-5 years)

- **Innovation Metrics**
 - ✓ Invention disclosures, patents, publications
- **Commercialization Metrics**
 - ✓ Number of products impacting the cancer community, cumulative sales, license agreements
 - ✓ FDA approvals for marketing
 - ✓ Company sold or merged, acquisition of outside capital

Enhancement

Focus Solicitations on
Commercially Viable
Technologies

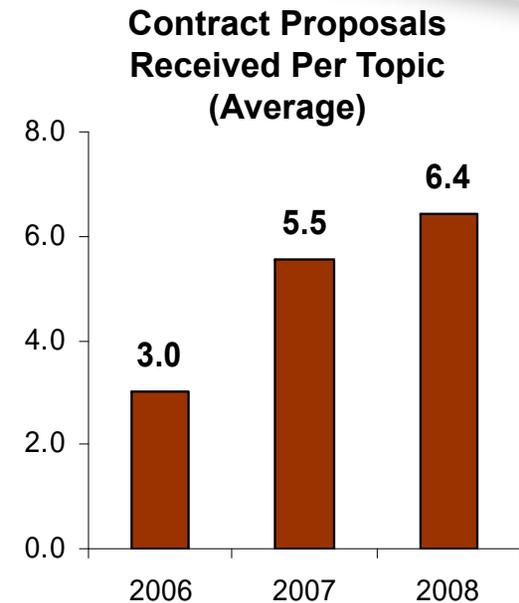
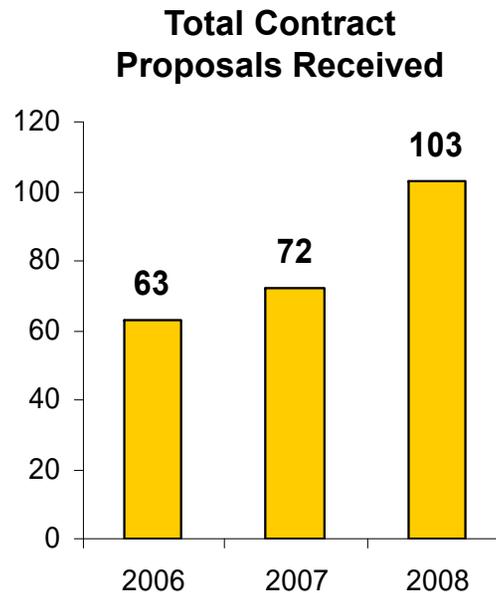
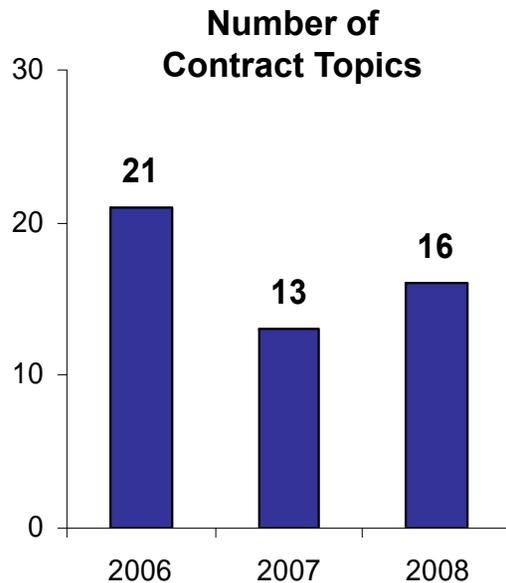
Goal is to improve commercialization success by:

- **Investing in technology priorities of NCI that also have the greatest potential for commercialization**
- **Catalyzing targeted technology development and drawing private sector investment in key areas (e.g., therapeutics)**

NIH Benefits

- **Ability to manage the awardee's progress toward specific milestones and the development of a product**

Focused Topics Yield Better Results



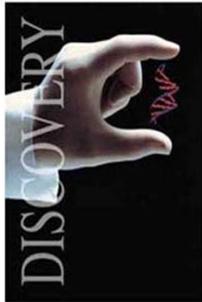
Strategic shift toward focused contract topics in FY 2007

- **Response:** Average number of proposals received (per topic) has more than doubled over the last two years
- **Quality:** Between 2006 and 2007, the average score of proposals rated “technically acceptable” improved 5.0% from 681 to 731

Enhancement

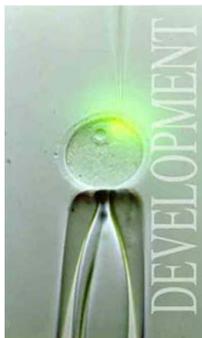
Co-invest With the Private
Sector to Bridge SBIR Projects
Toward Commercialization

SBIR & STTR: Three-Phase Program



PHASE I – R41, R43

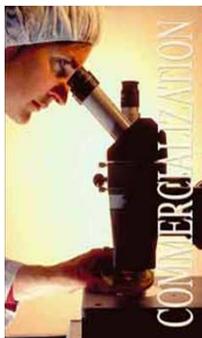
- Feasibility Study
- \$100K and 6-month (SBIR) *
- *or* 12-month (STTR) Award



PHASE II – R42, R44

- Full Research/R&D
- \$750K and 2-year Award (SBIR & STTR) *
- Commercialization plan required

Phase IIB Bridge Award



PHASE III

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

* Note: Actual funding levels may differ by topic.

Follow-On Award to the SBIR Phase II Award

- **Goal is to help early-stage companies cross the “Valley of Death” by:**
 - **Helping to facilitate partnerships with third party investors/strategic partners**
 - **Incentivizing partnerships earlier in the development process by sharing in the investment risk**
- **The concept is modeled after NSF’s “Phase IIB Option” and has the same key feature:**

➤ **Requires the SBIR company to raise matching funds from the investment community or strategic partners**

EXAMPLE: Phase IIB Bridge Award Drug Development



The "Valley of Death" is the problem

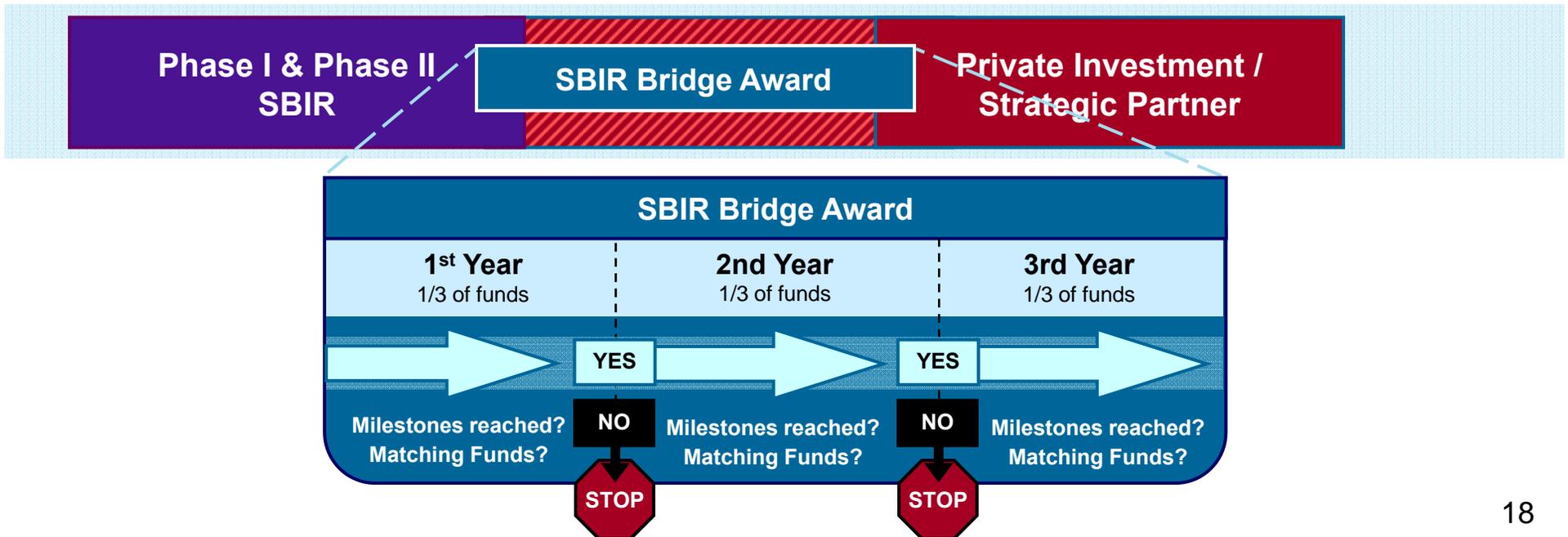
SBIR Bridge Award addresses the problem by bridging the "Valley of Death"

EXAMPLE: Phase IIB Bridge Award Drug Development



SBIR Bridge Award allows NIH to share investment risk by incentivizing **Private Investors** to evaluate projects and commit funds much earlier

Milestone-Based Awards



Pilot will focus on cancer therapeutics and cancer imaging

- \$1 MM (NCI SBIR set-aside dollars) per year for ≤ 3 years
- Requires a minimum one-to-one match from the investor(s)

➤ **Third party matching funds may include**

- Cash, liquid assets, convertible debt

➤ **Sources of funds may include:**

- Another company, venture capital firm, individual “angel” investor, foundation, state or local government, or any combination

Third party investors are expected to bring:

- Rigorous commercialization due diligence
- Commercialization guidance during the award
- Additional financing beyond the initial matching funds

Phase IIB: 8 Year Track Record of Success at NSF

- In FY 06, NSF invested \$18M in Phase IIB companies that in turn raised \$58M in matching funds
- Recent data show that five years after beginning the Phase II SBIR award:
 - Phase IIB awardees have commercialization success rate = **70%**
 - Companies that don't receive a Phase IIB have a success rate = **30%**

NCI's Due Diligence



University Venture Capital



Director, New Ventures, Office of Technology Development



Associate Director, Center for Innovative Ventures



Traditional Venture Capital



Partner



General Partner



georgia venture partners

Managing Director

Corporate Venture Capital



Vice President, New Ventures



Managing Director, Novartis Option Fund

Strategic Partners



Vice President, Executive Director
Biogen Idec Innovation Incubator (bi3)

SRI International

Senior Director, Business Development
Biosciences Division

State-Sponsored Technology Funds

LIFE SCIENCES GREENHOUSE of Central Pennsylvania

President and CEO

Angel Networks

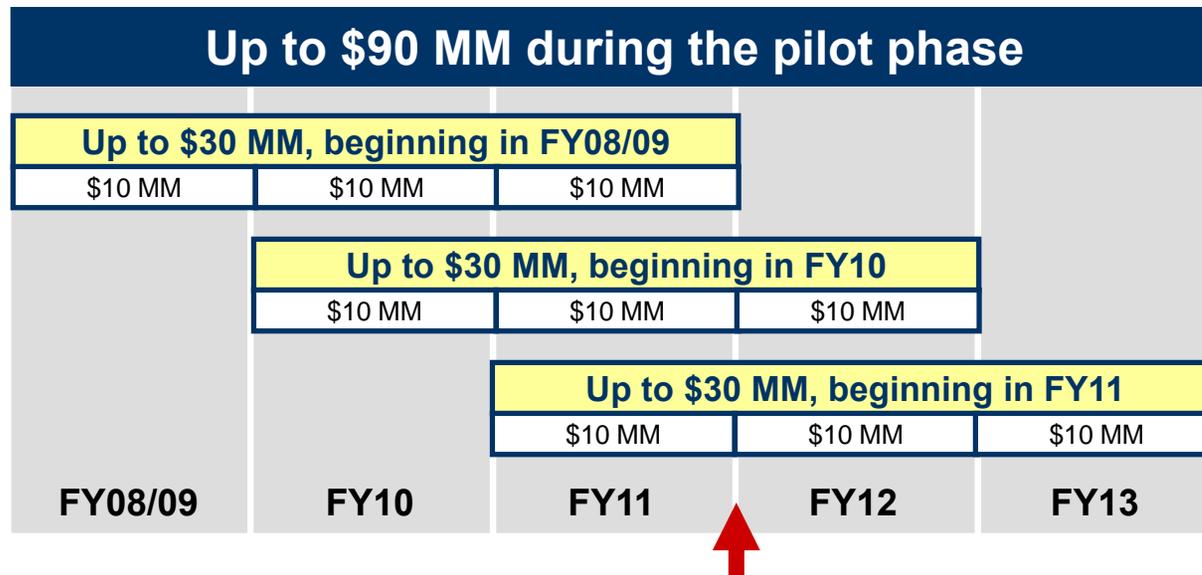


Phase IIB Pilot at NCI



First awards will use the cooperative agreement mechanism

- Initial RFA: up to 10 new awards in FY08/09
- Intend to fund 20 additional awards in FY10 and FY11



Comprehensive outcomes assessment after three years

- Go/No Go decision to continue Phase IIB beyond pilot

Timeline for First Awards

RFA: U44 cooperative agreement

