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SBIR-STTR at the National Institutes of Health

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Overall Findings

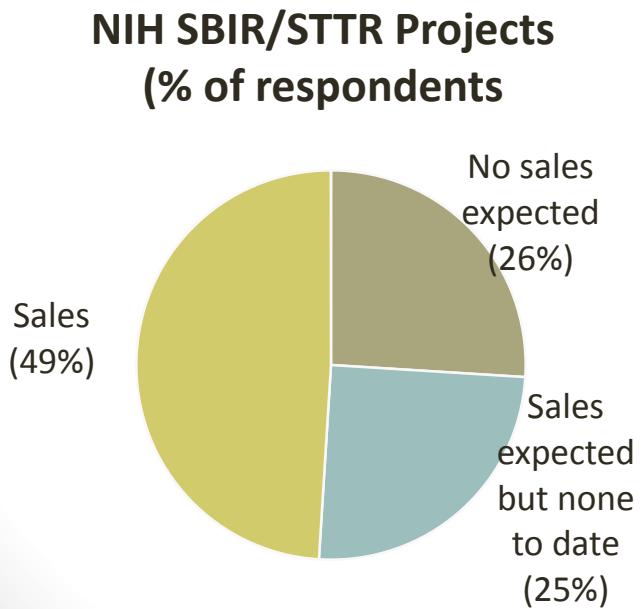
- The SBIR program at the NIH is having a positive overall impact.
- It is meeting 3 of its 4 legislative objectives
 - Stimulating technological innovation,
 - Meeting federal R&D) needs through small business
 - Increasing private-sector commercialization of innovations from federal R&D.
- The legislative diversity goal is not yet being effectively met
 - More needs to be done to foster participation by minority-owned and women-owned small businesses.
- The NIH STTR program is similarly meeting its statutory objectives.

Fostering Entrepreneurship and the Go/No-Go Decision

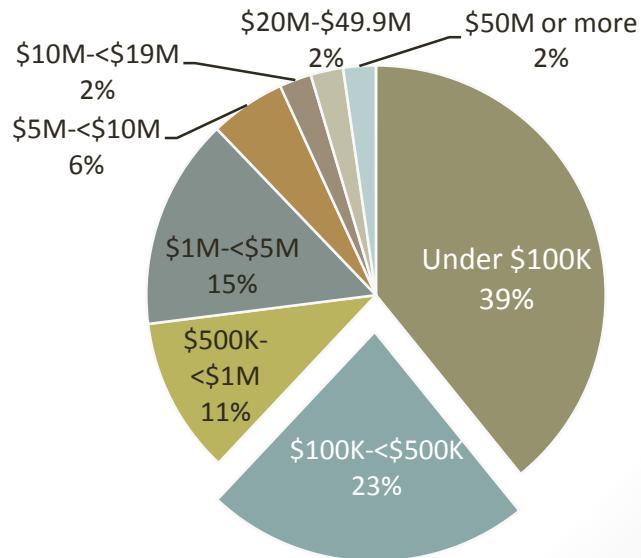
- The NIH program does help to fill the early-stage funding gap for some small businesses
 - Almost 75% of survey respondents would likely, or definitely not have proceeded without SBIR/STTR
- Of the ~25% who say their project might have proceeded without SBIR/STTR funding :
 - 2/3rds believed that project scope would have narrowed
 - 3/4ths believed that substantial delays would have resulted and that the project timeline would have lengthened
 - 3/4ths believed that the project would not have hit critical milestones

Commercialization

- SBIR/STTR projects at NIH commercialize at a similar rate to other agencies
- Room for improvement: While many reach the market, few can be described as hugely successful
- Unique time and money requirements are formidable barriers to small business commercialization in life sciences
 - 45% of Phase II recipients required clinical trials leading to FDA approval



Distribution of total sales and licensing revenues by range



Diversity Goal Not Yet Met

- Participation by Black, Hispanic, and Native Americans in the NIH SBIR/STTR programs is very low
 - Black-owned small businesses = 0.7% of all 2014 survey respondents
 - Hispanic-owned = 1.7%
- Level of participation by women is also low
 - Women-owned small business = 10% of Phase I awards
 - These firms receive only 12 percent of Phase II awards.

Recommendations

Address Underserved Populations

- NIH must do more to meet the Congressional mandate to foster participation by underserved populations:
 - Examine and report on what works (best practices)
 - Adopt outreach and education programs that work
 - Measure and report the outcomes to demonstrate progress
 - Be consistent with consensus approaches (e.g., quotas not recommended)

Improve Commercialization

- NIH should continue to address the unique time and money barriers of life science innovation
 - Explore potential adjustments to Phase IIB
 - Explore support for awardees in dealing with FDA requirements
 - Explore helping awardees find strategic partners.
- NIH should review effectiveness of existing support and training initiatives and make changes as needed
 - Look to individual ICs for best practices
 - Closely track outcomes of experiments (e.g. at NCI and NHLBI)

Become Data Driven

- **Systematically collect and analyze outcomes data**
 - Data collection should be sufficiently detailed to judge program performance to Congressional goals
- **Use the outcomes data and analysis**
 - The goal is to improve overall program performance
- **Prepare an Annual Report to the NIH Director and Congress**
 - Beyond current SBA reporting, the objective is for NIH to hold itself accountable for improving program performance

Improve Program Management

- **Improve the NIH application review system**
 - Convene a high-level task force with two goals
 - Better prioritization and evaluation of commercial potential in the selection process for SBIR/STTR applications
 - Address improvement opportunities in program timelines, pre-review briefings for panelists, and the potential for a more interactive review process
- **Address the funding gap between Phase I and II awards**
- **Track and evaluate new program management initiatives**

Thank you