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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.

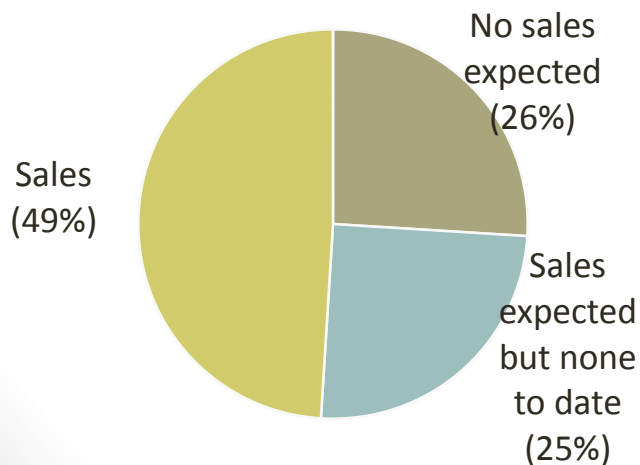
# Fostering Entrepreneurship and the Go/No-Go Decision

- 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

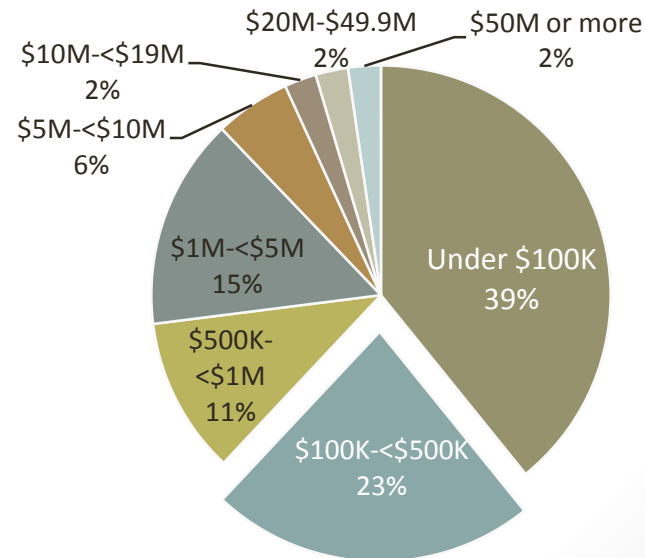
# Commercialization

- **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

**NIH SBIR/STTR Projects  
(% of respondents)**



**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