National Survey to Evaluate the NIH SBIR Program

Final Report

National Institutes of Health
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EXECUTIVE SUMMARY

Established in 1982 through the Small Business Innovation Development Act, the Small Business Innovation Research (SBIR) program offers qualified small business concerns the opportunity to propose and develop innovative ideas with commercial potential while meeting the specific research and development (R&D) needs of the Federal government. SBIR legislation currently requires agencies with extramural R&D budgets that exceed $100 million to set aside 2.5 percent of their extramural R&D funds for an SBIR program. Among the 11 Federal agencies that currently participate in the SBIR Program, the National Institutes of Health (NIH) is the largest civilian agency and the second largest participating Federal agency overall. Since the inception of the program in 1982, NIH has invested over $5 billion in research support to small business concerns.

This report summarizes the findings from a 2008 survey of small businesses that competed successfully for SBIR Phase II awards in fiscal years (FYs) 2002-2006. This new survey was a logical next step in the NIH SBIR program evaluation and monitoring effort. A 2002 national survey to assess the outcomes of the NIH SBIR program had described NIH SBIR program performance of Phase II awardees funded from FYs 1992 through 2001. The 2008 survey included a new group of awardees. Both surveys addressed the same major evaluation issues:

- To what degree has the NIH SBIR program stimulated technological innovation?
- Has the NIH SBIR program's use of small business concerns satisfied Federal R&D needs?
- Has the NIH SBIR program increased private sector commercialization of innovations derived from Federal R&D funding?

Survey Response

To leverage NIH expenditures to date and also to promote comparability of results, the design and execution of the 2008 national survey to assess the outcomes of the NIH SBIR program was based on the same guiding principles used for the 2002 survey.

The survey was administered to all 918 eligible awardee small businesses that received an NIH SBIR Phase II award in FYs 2002-2006. There were 719 respondent companies, and the final response rate was 78 percent.

Respondents and nonrespondents were similar in terms of the Institute/Center (IC) that sponsored the Phase II award, the fiscal year of the award, and the geographic region in which the small business was located. Coupled with the high response rate, these similarities reduce the potential threat of nonrespondent bias to the survey results.

The largest percentage of respondents (32 percent) was located in the West, and the smallest percentage (16 percent) in the Midwest. Twenty-eight percent were located in the Northeast, and the remaining 24 percent were in the South.

Over one-fourth of respondents (28 percent) received their Phase II award in FY 2006; between 17 and 19 percent of the companies received their award in each of the other calendar years covered by the survey, FYs 2002-2006. The National Cancer Institute (NCI) supported 15 percent of all respondents, and the National Heart, Lung and Blood Institute (NHLBI) supported 13 percent. The National Institute

of General Medical Sciences (NIGMS); the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK); the National Institute on Aging (NIA); and the National Institute of Neurological Disorders and Stroke (NINDS) each awarded funds to another 6 to 8 percent of the companies that responded to the survey. The remaining awardee companies were funded by one of the other 16 participating ICs.

Overall, 41 percent of the respondents reported that their SBIR-funded product, process, or service was currently in the development phase at the time of the survey. Another 20 percent said that the SBIR-funded product, process, or service was being commercialized, and 22 percent stated that it was in use by the target population(s). Ten percent said that product, process, or service production was "on hold", awaiting the receipt of additional funding, or inactive for another reason. Eight percent of the awardee companies reportedly had discontinued work on the project. (Numbers total more than 100 due to rounding).

Summary of Findings

Three of the four program goals were the survey focus – stimulate technological innovation (Goal 1), use small business concerns to meet R&D needs (Goal 2), and increase the commercialization of innovations (Goal 4). The exhibit on the following page displays these three goals, related performance indices and measures promulgated by the NIH SBIR program Evaluation Framework for each, and the 2008 survey finding about the percentage of awardees that achieved each performance index.

Summary of 2008 Survey Findings: Performance of NIH SBIR Phase II Awardees in FYs 2002-2006*

NIH SBIR Performance Goal ***NIH SBIR Performance Index*** ▪ NIH SBIR Performance Measure	**Finding**
1.0 Stimulate Technological Innovation	
1.1 ***Whether or not sales have occurred, NIH SBIR awardees produce new or improved products, processes, usages, and/or services in support of the NIH mission.***	
▪ Percent of awardees developing new or improved products	**82%**
▪ Percent of awardees having published one or more technical articles on new or improved SBIR supported products	**53%**
▪ Percent of awardees having obtained one or more patents relevant to the core technology supported by the Phase II award	**31%**
1.2 ***NIH SBIR awardees receive additional Phase I or Phase II awards that relate to the core technology.***	
▪ Percent of awardees receiving additional Phase I or Phase II awards that related to the core technology	**58%**
2.0 Use Small Business Concerns to Meet Federal R&D Needs	
2.1 ***NIH awardees make contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease.***	
▪ Percent of SBIR awardees that have contributed to increases in knowledge regarding health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease	**82%**
2.2 ***NIH awardees are able to obtain and disseminate health-related information***	
▪ Percent of awardees that have disseminated or plan to disseminate SBIR supported technology and information among populations using and receiving health and health care resources	**82%**
2.3 ***NIH SBIR awardees express satisfaction with the usefulness of the NIH SBIR program***	
▪ Percent of awardees, depending on the program component, that are completely or mostly satisfied with the SBIR application, review, award, and post-administration of the program	**74 – 90%**
4.0 Increase the Commercialization of Innovations	
4.1 ***Companies with NIH SBIR awards commercialize new or improved products, processes, usages, and/or services in health-related fields.***	
▪ Percent of SBIR-supported products, processes, usages, and/or services that yield sales	**33%**
▪ Percent of awardees that have successfully executed licensing arrangements for their SBIR-supported product	**25%**
▪ Percent of awardees reported commercializing the core technology or information supported by their Phase II award	**61%**
▪ Percent of awardees obtaining additional non-SBIR funding for their Phase II product	**36%**
4.2 ***Companies with NIH SBIR awards grow their companies.*** ▪ Percent of awardees that believed that the SBIR Program had had an impact on their ability to grow their companies in terms of hiring additional personnel	**82%**
*******The survey assessed performance for Goals 1, 2, and 4 from the Evaluation Framework for the NIH SBIR program.*	

Customer satisfaction responses indicated that nearly all SBIR awardees (96 percent) were satisfied with their experiences in obtaining information about the Phase II program. Between 88 and 90 percent expressed satisfaction with the application, award, and post-award administration components of the Phase II program.

The 2008 survey instrument was essentially identical to that of the 2002 survey, so it was possible to compare outcomes for respondents to both surveys. For such comparisons, the respondent cohort for the 2002 survey was restricted to awardees that received grant funding during the last five-year period surveyed, FYs 1997 through 2001. This made the elapsed time from award receipt to survey administration as comparable as possible because the 2008 survey cohort also received grant funding for a five-year period, FYs 2002-2006.

Performance of the two cohorts did not significantly differ for the majority of outcomes. The earlier cohort did have significantly higher percentages of awardees that published one technical article (68 percent versus 43 percent); made conference presentations (79 percent versus 73 percent); and were granted at least one patent for an SBIR-supported product (39 percent versus 31 percent).

1. INTRODUCTION

The Small Business Innovation Research (SBIR) program, first authorized in 1982, occupies a key niche in the nation's scientific research and development arena. The program encourages small businesses to explore their technological potential and provides the incentive to profit from commercializing products, processes and services developed with SBIR support.

Through a competitive, three-phase award system, the program provides qualified small business concerns with opportunities to propose and develop innovative ideas that meet the mission or specific research and development (R&D) needs of the Federal government.

- *Phase I*. The objective of Phase I is to establish the technical merit, feasibility, and potential for commercialization of the proposed research or R&D efforts, and to determine the quality of performance of the small business awardee organization prior to providing further Federal support in Phase II. Support under Phase I normally may not exceed $100,000 for total costs for a period normally not to exceed six months.

- *Phase II*. The objective of Phase II is to continue the R&D efforts initiated in Phase I. Funding is based on the results achieved in Phase I and the scientific and technical merit and commercial potential of the project proposed in Phase II. Only Phase I awardees are eligible for a Phase II award. Support for SBIR Phase II awards normally may not exceed $750,000 in total costs for a period normally not to exceed two years.

- *Phase III*. The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR/STTR funds the commercialization objectives resulting from the research and R&D activities of Phases I and II. Phase III may involve follow-on non-SBIR funded R&D or production contracts for products, processes or services intended for use by the U.S. Government.

The National Institutes of Health (NIH) is the largest civilian agency and the second largest participating agency of the 11 Federal agencies participating in the SBIR program. Since the inception of the program in 1982, NIH has invested over $5 billion in research support to small business concerns. The NIH SBIR program is intended to foster the agency's mission to "uncover new knowledge that will lead to better health for everyone," particularly in translating research results into tangible products and services that will improve human health.

In late 2006, NIH SBIR program administrators from a cross-section of the Institutes and Centers (ICs) decided to sponsor a survey of Phase II awardees whose awards were granted in fiscal years (FYs) 2002-2006. This survey was planned as a next step in documenting NIH SBIR program outcomes. The first step was the 2002 National Survey to Assess the Outcomes of the NIH SBIR Program, which described NIH SBIR program performance from FYs 1992-2001. For both surveys, the major evaluation questions addressed targeted performance related to three program goals:

- To what degree has the NIH SBIR program stimulated technological innovation?

- Has the NIH SBIR program's use of small business concerns satisfied Federal R&D needs?

- Has the NIH SBIR program increased private sector commercialization of innovations derived from Federal R&D funding?

This report documents the 2008 national survey to assess the outcomes of the NIH SBIR program:

- Chapter 1 discusses background issues that influenced and prompted the study and also summarizes the study methodology.
- Chapter 2 notes characteristics of potential and actual survey respondents.
- Chapters 3-5 describe study findings about each of the three key evaluation questions.
- Chapter 6 presents study conclusions and recommendations.

1.1 Background

Before 2003, there was little formal analysis of either the overall SBIR program or the one administered by the NIH, with the exception of a few studies by the Government Accountability Office (GAO), the Office of the Inspector General (OIG), and the Small Business Administration (SBA). These early studies raised questions about program performance, prompting a series of recent evaluations of both the Federal program and its NIH component.

1.1.1 2002 National Survey to Evaluate the NIH SBIR Program

Beginning in the late 1990s, NIH SBIR program administrators from a cross-section of ICs took a heightened interest in the success of the NIH SBIR program. By 2001, they formalized consensus about how to evaluate the program in a manner that would assess responsiveness to Congressional intent for the SBIR program. They produced an Evaluation Framework document that reflects their agreement about standards, indices, and measures for describing how well the NIH SBIR program is performing in meeting all Congressional program goals. The Framework is, to their knowledge, the first such guide for any SBIR program about why and how to evaluate overall performance.

The NIH administrators then decided to survey NIH awardees to learn about program performance. They developed a draft survey instrument to query NIH awardees about performance of three of four program goals. A focus group of nine principal investigators (PIs) who had won Phase I and Phase II SBIR awards provided feedback about the questionnaire, the most survey appropriate respondents, the response burden, the best metrics for measuring successful award outcomes, and motivations for participating in the survey.

Based on the focus group findings, NIH revised the survey instrument and then sponsored an online pretest to further assess its potential. The online pretest and subsequent telephone debriefings with nine PIs whose small businesses had won Phase II awards prompted further refinements to planned approaches. The final survey questionnaire used in 2002 incorporated those changes and clarifications. It also conformed to the Paperwork Reduction Act standards to minimize respondent burden. *Appendix A, Evaluation Framework,* shows both the framework and a map of survey questionnaire items to the NIH SBIR program objectives.

In 2002, the NIH implemented the first National Survey to Assess the Outcomes of the NIH SBIR Program. This survey was a census of all small business awardees that had been awarded NIH SBIR

Phase II grants in FYs 1992-2001. Each awardee response described experience on one Phase II award. For the 32 percent of the businesses that received more than one Phase II award during the study period, the survey focus was a single award chosen through random selection. Due to vigorous follow-up effort to maximize survey participation, 758 of the 905 eligible awardee companies surveyed completed the questionnaire, yielding an 85 percent response rate.

Survey results indicated that NIH SBIR awardees stimulate technological innovation and contribute significantly to the body of scientific knowledge related to health issues. In addition, NIH SBIR-supported technologies generate substantial commercial activity. Respondents judged the NIH SBIR program to be quite valuable, allowing them to further develop their businesses and pursue high-risk ideas. The primary study recommendation was to continue building on this systematic assessment by maintaining a performance monitoring system to document NIH SBIR program progress toward achieving performance outcome targets.[1]

1.1.2 Subsequent Performance Monitoring and Evaluation

Since 2003, the NIH SBIR/STTR program has been developing a Performance Outcomes and Data System (PODS) to respond to the 2002 survey recommendation about monitoring SBIR performance. PODS affords authorized NIH personnel easy access via the NIH Intranet to SBIR awardee information, the most recently reported data measuring award outcomes, and user-defined lists and tables of awardee information and outcome measures.

PODS contains data from the 2002 survey and from subsequent voluntary updates by survey respondents. Seventy-four percent of the original survey respondents—or 568 awardees—have participated in at least one of five voluntary update opportunities since the 2002 survey. Considering that about 280 of the original 758 awardee respondents had either discontinued their projects or were no longer in business by 2007, the response is especially impressive.

NIH relies on PODS updates to document the continued achievements of SBIR awardees (FYs 1992-2001) over time:

- The number of awardees with FDA-approved projects increased 51 percent, from 59 in 2002 to 89 in March 2007.
- The estimated cumulative sales to date achieved by awardees' commercialized projects increased over 200 percent, from $821 million in 2002 to $1.95 billion in March 2007.
- The number of awardees receiving additional non-SBIR funding or capital increased 33 percent, from 281 in 2002 to 375 in March 2007.

[1]"National Survey to Evaluate the NIH SBIR Program"; available from http://grants.nih.gov/grants/funding/sbir_report_2003_07.pdf; Internet; accessed 10 December 2008.

Building on the results of NIH's 2002 survey, the National Research Council (NRC), an arm of the National Academy of Sciences, expanded the NIH assessment to include all agencies that participated in the SBIR program.[2] This evaluation included an online survey of a probability sample of FY 1992 through 2001 awardees that incorporated many of the same questions as the 2002 NIH instrument; a survey of Phase I awardees; case studies of awardee companies; and interviews with NIH staff, grantees, and other stakeholders.[3] The NRC survey conclusions mirrored those of the 2002 NIH survey. NRC commended the NIH SBIR program, both for its meaningful achievements and also for its evaluation efforts. The report further recommended that the SBIR program receive more funding for administration, evaluation, and testing of new initiatives to enhance commercialization and program operations.

1.2 Methodology for the 2008 NIH Survey

By 2006, the NIH decided to sponsor a second national survey of Phase II SBIR awardees. The purpose of this initiative was to describe the performance of a second group of awardees—those whose NIH SBIR awards were made from FYs 2002-2006. Learning about the performance of these awardees would be a logical follow on to the 2002 survey. It could enable program sponsors to add contact and performance data about a new cohort to PODS. Doing so could improve the NIH SBIR program's ability to assess performance of more recent program activities.

The 2008 survey implementation mirrored that of the 2002 NIH survey implementation.

- Use the Evaluation Framework to develop the questionnaire to ensure that the data include metrics for answering all study questions.
- Conduct a census of awardees rather than a survey, if the sample universe for the study period is not too large.
- Update the contact information before fielding the survey to maximize respondent participation.
- Construct the survey to facilitate response and minimize respondent burden.
- Use information technology for implementing the survey online to reduce respondent burden.
- Maximize the response rate to the survey to minimize nonresponse bias.
- Clean and code the survey data to produce an accurate data file.

The following sections discuss the implementation of these survey principles and refer to sections in the appendices that contain additional information.

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[2]Charles W. Wessner, ed. *An Assessment of the Small Business Innovation Research Program.* (Washington, D.C.: National Research Council, 2007).

[3]The NRC survey sampled individual awards rather than awardee companies. Of the 1,127 awards for which the PI was asked to complete the questionnaire, 496 responded, resulting in a response rate of 44 percent.

1.2.1 Questionnaire

Appendix B, Survey Instrument, contains a copy of the survey questionnaire. With the exception of very minor revisions to the wording of several response categories and the addition of several options, the 2002 and 2008 survey questionnaires are the same. The minor modifications were based on responses to several items in the 2002 survey for which more than a few respondents supplied the same specific answers in the "Other" response category. These same responses became new categories in the 2008 survey questionnaire.

To encourage response, the questionnaire design enabled respondents to answer all items within 15 to 30 minutes, including any time needed to retrieve information or consult other sources. The survey questionnaire was as precise as possible, used consistent terminology, and continually referenced the randomly selected award that was the focus of the survey. The intent was to have respondents answer all questions in terms of the "referenced SBIR award" and the "product, process, or service" planned and developed under the supported "project." Since selecting a response makes it easier for most respondents to answer a question, the questionnaire tended to provide close-ended response categories. Sometimes it was appropriate also to provide respondents with the opportunity to choose an "Other (please specify)" open-ended response to encourage their answering a question when they did not wish to select a closed-end response. In keeping with accepted guidelines for online surveys,[4] the questionnaire prompted respondents to answer positively or negatively to each response for lists of optional answers.

1.2.2 Sampling

Like the 2002 NIH survey, the 2008 National Survey to Evaluate the NIH SBIR Program is a census of all Phase II NIH SBIR awardee recipients, funded during the study period. This sample includes awards from 23 NIH ICs, as shown in Exhibit 1-1 on the following page.

[4]Don A. Dillman. *Mail and Internet Surveys: The Tailored Design Method* (New York: John Wiley and Sons, 2000), 398-399.

EXHIBIT 1-1
NIH Institutes and Centers within the 2008 Survey Sample

Awarding NIH Institute or Center	
Abbreviation	**Title**
NCI	National Cancer Institute
NCCAM	National Center for Complementary and Alternative Medicine
NCMHD	National Center on Minority Health and Health Disparities
NCRR	National Center for Research Resources
NEI	National Eye Institute
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases Extramural Activities
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine

Just as in 2002, awardee respondents answered survey questions about one randomly selected single award. This sampling approach helped minimize respondent burden and provided a single, consistent focus for respondents' assessments.

The sampling approach uses these definitions:

- *Unit of Study*. The unit of study for the survey is the award within the awardee.
- *Award*. The award is a single NIH SBIR Phase II grant awarded from FYs 2002-2006.
- *Awardee*. The awardee is the small business that received the grant.
- *Project*. The project is the R&D undertaken and supported by the award.
- *Respondents*. The eligible survey respondents for each awardee, in order of desirability, are: (1) the Principle Investigator (PI) on the SBIR award application, (2) the replacement PI, if the original one was no longer employed by the awardee, and (3) the business official who signed for the awardee company on the award application, if there was no replacement PI.
- *Study Period*. The study period included in this evaluation is FYs 2002-2006.

- *Stratification*. There was no stratification of the sample by funding institute or IC (an initial plan prior to the 2002 survey) because of the decision to conduct a census. Post-sample stratification using various criteria, such as grouping the smaller ICs, is part of the data analysis.

- *Usable Sample Units*. Usable sample units are existing, nonduplicate awardee small businesses located within the U.S.

- *Eligible Respondents*. Eligible respondents are employed by the awardee small business, reside within the U.S., and are capable of interviewing in English.

1.2.3 Contact Database Update

NIH databases of contact information for awardees and respondents were from one to six years old, so a contact database update was the initial phase of the survey implementation. The purpose was to: (1) confirm that the small business still existed, (2) learn the status of the business and resolve any name changes resulting from mergers and acquisitions, (3) update the business's email address and telephone number, (4) determine the eligible respondent, and (5) update the respondent's business email address and telephone number.

An initial contact email message addressed to the PI on the SBIR award application asked the PI to update information about the status of the awardee business and its contact information using an online form. If the contact information was correct, the PI could merely reply to the email message with the word "COMPLETE" in the subject or body of the email reply.

For nonresponders to the update request, contact methods included emails, telephone calls, web searches, and research using databases available through the NIH eRA Commons. Contact activities attempted to reach each nonresponder and obtain: (1) updated email contact information for the awardee business, (2) the name and email address for the eligible respondent, and (3) when appropriate, information that the awardee business was no longer in existence (and could therefore be classified as unusable sample). *Appendix C, Email Messages and Telephone Follow-up Briefing*, contains copies of the update email message, the online response form, and all other communications used during survey fielding and follow-up with nonrespondents.

The result of the update phase was a database of 1,037 unique awardee small businesses with current (or presumed current) contact information for the 89 percent (928) of the awardees deemed usable sample units, inasmuch as they were still operating and located in the U.S. Nearly all of these small businesses (918) could be deemed eligible sample. Chapter 2 presents details about analyses of usability and eligibility aspects of the quality of the survey sample data.

Appendix D, Response Rate—Final Disposition of Sample, describes the final disposition of sample. For additional information about the response rate, sample disposition, and online calculator, please see this appendix. It also includes a final disposition of the sample.

Appendix E, S*urvey Sample*, contains more detailed information about the SBIR awardee database, the selection procedure, and possible limitations to the database. While limitations conceivably could result from the random procedure used to select the single award for awardees with multiple awards, comparison confirms that the randomly selected awards are indeed representative of the universe of awards.

1.2.4 Survey Implementation

Online access and use of the Internet are now common for the respondent population, so the survey was administered online only. (The 2002 survey had offered online, mail, and telephone response options.)

Online implementation minimized respondent burden—for most respondents, it is easier and less time consuming to click on the appropriate answer than to check it on paper, or to type in an open-ended response than to write it out. Online surveys typically elicit quicker response than do paper ones, and they reduce data entry errors and costs associated with key-entering data.

The automated survey process included security and confidentiality safeguards. The survey was implemented using Secure Socket Layer (SSL) encryption technology. The access process required respondents to input their user name and unique password before they could begin the survey. Respondents could save their responses, leave the online survey, and return to the survey later to enter more responses.

The online implementation allowed each respondent to complete only a single survey. Submitting the survey stored the survey responses in a secure database.

All survey communications were sent using personalized email messages. Using email allows prospective respondents to receive communications nearly instantaneously and to respond to the survey merely by clicking the embedded link to the online implementation. The communications included the following.

- Initial update email to update contact information
- Email verification message
- Advance email about the upcoming survey
- First cover letter email
- Reminder/thank you email
- Second cover letter email to nonresponders
- Thank-you for promising to respond email
- Incomplete email to those who started the online survey but did not submit it
- Last call email to nonresponders from NIH SBIR/STTR Program Coordinator

All but the first two email messages included the survey link, the user name and password, and telephone numbers to call for additional information about the survey or for assistance with any technical problems.

1.2.5 Survey Response

As in 2002, the 2008 survey had a goal of achieving participation from 80 percent of the usable and eligible awardees. This is an extremely high response rate, which is typically achieved only when respondents believe the survey has high interest and importance or when respondents receive other valued incentives. Past NIH experience indicated that the 2008 survey's awardee spokespersons would view this survey as important and worthy of participation.

In addition to the multiple email communications itemized in Section 1.2.4, a professional telephone center promoted survey response. Supervisors and interviewers at the center received training about the background and goals of this assessment and how to administer a brief telephone script approved by NIH.

Interviewers made up to nine attempts (staggered across days and time periods) to contact all nonresponders, update awardee and respondent contact information, and elicit a promise to complete the online survey. After the telephone center elicited a promise to complete, all those who agreed to complete an online survey received new email messages containing the survey link, user name, and password.

An online response rate calculator, accessible at any time by authorized NIH personnel, monitored the survey response rate on a live, continuous basis. In addition to showing the current response rate, it tracked the number of usable and eligible potential respondents, the number of completed surveys, and the status of various incomplete and promised surveys.

The 2008 survey achieved a 78 percent response rate (719 respondents from the pool of 918 eligible awardees). This rate is relatively high but not as high as the 85 percent rate achieved in the 2002 survey. The lower response rate may be due to two factors. First, interviewers who contacted nonresponders were not told to administer the survey on the telephone either on the spot or at a convenient appointment time for the survey recipient. (In the 2002 survey, interviewers were told to administer the survey, and 11 percent of respondents completed telephone interviews.) Second, online surveys are no longer the novelty that they were in 2002.

1.2.6 Data Cleaning and Coding

Minimal cleaning is required for data from an online survey because the logic used by the implementation program controls the skipping of questions, allows input of only displayed response codes, and checks the ranges of uncategorized numeric data. Online implementation minimizes errors and typos that can occur from the manual input of data from paper questionnaires.

Two survey coding schemes facilitated data analysis:

- Coding to categorize the narrative responses to open-ended questions
- Construction of subgroups of survey participants to facilitate comparing responses among key subgroups, using statistical criteria to identify differences[5]

The number of respondents for an individual IC often was too small (i.e., less than 30 awardees) to allow precise estimates of outcomes. Constructing two clusters of the small ICs made it possible to compare these ICs' performance in certain areas of interest to project sponsors. Assignment of ICs to one or the other cluster depended on the type of products that were supported by the Phase II award. One cluster comprised ICs where more than half of the sponsored projects' product development primarily relied on biological and physical sciences research (e.g., drugs, biologics, and genomics). The second cluster included the remaining ICs. ICs in the second cluster were those whose projects were being developed by behavioral, social science, or statistical research techniques (e.g., educational materials, psychological

[5]The appropriate use of statistical tests requires that the data are robust—that is, that they do not violate the test's assumptions. Often, these assumptions involve having subgroups of sufficient size to avoid confounding normal sampling variability with significant differences between the groups.

assessments and interventions, and statistical software); ICs whose projects were fairly evenly distributed among both types also were included in this cluster.

IC groups constructed for the 2002 and 2008 surveys are not comparable. One reason is that they use different grouping schemes. While the 2008 groups are constructed on the basis of project type, the 2002 survey groups were constructed on the basis of number of awards made by the IC. Another difference is that the 2008 survey describes performance of ICs that either did not sponsor SBIR awards in 2002 (National Center on Minority Health and Health Disparities and National Institute of Biomedical Imaging and Bioengineering) or had no eligible respondents from ICs whose awardees responded to the 2002 survey (National Library of Medicine).

1.2.7 Analytic Strategies and Reporting Practices

The analysis compared responses for two categories of respondents.

- **Subgroups of special interest to NIH**. Subgroups of interest included fiscal year of award, IC that sponsored the award, type of SBIR-supported product, and current status of the Phase II project. For comparisons that involved two categorical variables, chi square tests determined if there was a relationship between the two variables (e.g., type of product and current project status).[6] For outcomes that were interval-level variables (such as number of publications) t-tests and analyses of variance determined if differences between subgroups were statistically significant.

- **2002 and 2008 survey populations.** In reporting attainment of performance indices and measures, the narrative describes performance of the entire 2002 and 2008 survey respondent populations. Comparisons of other types of performance take account of the fact that the 2002 survey describes a ten-year award period (FYs 1992-2001), while the 2008 survey describes a five-year award period (FYs 2002-2006). To construct more equivalent groups in terms of the award period being described, these comparisons describe (1) only the 2002 survey participants whose awards were made in the last five-year period, FYs 1997-2001 and (2) all 2008 survey respondents.

These general practices are used in reporting the survey results.

- **Descriptive statistics.** In reporting descriptive statistics summaries for a major index and associated measure in the Evaluation Framework, the values for means, medians, and standard deviations are rounded to the nearest tenth. Data are summarized for each major index and associated measure in the Evaluation Framework. For categorical variables, percentages are rounded to the nearest percentage point; this may result in the percentages for all categories of a variable not summing to 100 percent.

[6]The chi-square test statistic only indicates that there is a statistically significant relationship between two variables; it does not provide information about the nature of the relationship. To determine this, we used adjusted residuals, which compare the frequencies that were observed with the frequencies that would be expected if the two variables were not related.

- **Key comparisons.** In reporting key comparisons of respondent subgroups, results of the relevant statistical tests are reported (1) in the notes to graphs and tables that present the result of statistical analyses, and (2) in the text itself, when comparing other variables of interest.

1.3 Strengths and Limitations of the Evaluation

The 2008 survey collected information about a set of awardees that had not yet been surveyed—those small business awardees that received SBIR Phase II grants from FYs 2002-2006. It generated a written report and a standard data set. These products add to the NIH SBIR program's body of knowledge for a new set of awardees. They provide information that can facilitate understanding of program performance over time.

One strength of the study described in this report is the relatively high 78 percent response rate. Another positive aspect of the study is the fact that the 2002 and 2008 surveys were essentially identical, thus, allowing comparison of the two studies and their results.

Certain limitations exist, of course. One major limitation is that all data on outcomes are based solely on information reported by the awardees themselves. Another limitation is that it was not possible to make valid comparisons of FYs 1997-2001 and FYs 2002-2006 outcomes for outcomes of interest that could only be answered with data from two questions that were revised in 2008.

- Question 18 queried awardees about the current status of their SBIR-funded project. Ten percent of 2008 respondents selected a response option, "on hold," to describe the current status of their SBIR-supported project. This option was not available to 2002 respondents. Because current project status was used in conjunction with other questions about key outcomes (developing new or improved products; contributing to increases in health knowledge, research tools, and health promotion; and disseminating SBIR-supported technology and information to populations using and receiving health and health care resources), comparisons of these outcomes between the two cohorts of awardees were not possible.

- Question 23 asked for the dollar range of total cumulative sales through December 2007 for the product developed under their Phase II award. The response option in the 2002 survey ("$5,000,000-$49,999,999") was divided into two separate categories in the 2008 survey ("$5,000,000-$24,999,999" and "$25,000,000-$49,999,999"). This revision precluded making comparisons of the two survey cohorts for estimated total and average cumulative sales in those categories; estimates are derived using the midpoints of response categories, and the response categories are now different for the two cohorts.

One other limitation is that small businesses that were liquidated, had merged with another company, or had been acquired by another business were defined as unusable and thus not included in the survey sample. If these events had indeed occurred for these unusable awardees, performance on some outcomes (such as commercialization and sales) may have been even stronger than that described in this report.

2. CHARACTERISTICS OF SURVEY RESPONDENTS

This chapter describes the characteristics of survey respondents. It presents information about the usability and eligibility of the pool of potential respondents, awardees who received NIH SBIR grants from FYs 2002-2006. Then it discusses characteristics of the respondent spokespersons who completed the survey questionnaire, the awardee small businesses with which they are associated, and the products whose development was supported by an NIH SBIR Phase II award from FYs 2002-2006.

2.1 Usability and Eligibility of Potential Respondent Small Businesses

NIH databases provided contact information about a pool of potential respondents—1,037 small businesses that were awarded a Phase II SBIR grant from FYs 2002-2006. Approximately 89 percent of the entire sample of potential respondents was deemed both usable and eligible.

Usability. Pre-survey searching strategies determined that 933 awardee businesses were potentially usable for the survey because they were still operating and located in the U.S. One hundred and nine of these awardees were unusable for one of these reasons:

- Awardee business reportedly had been liquidated or dissolved (22 or 2 percent)
- Awardee business reportedly had merged with or been acquired by other companies (45 or 4 percent)
- Valid contact information about awardee businesses was not available to the survey team, even after extensive tracking efforts (37 or 4 percent)

An additional five awardees completed the survey questionnaire and were deemed unusable because they reported having merged with or been bought by another company.

The usable sample for the 2008 survey was 928, or 89 percent of the total available sample of 1,037 awardees.[7] The geographic locations of usable and unusable awardees did not differ significantly.

Unusable awardee companies were significantly more likely to have been awarded a Phase II award in the earlier years of the survey period than were usable awardees. Whereas the usability rates were between 81 and 82 percent for FYs 2002 and 2003, they ranged from 91 to 97 percent for FYs 2003 through 2006 (chi square statistic=45.6, df=4, $p < 0.0001$).

Usability rates differed somewhat among awardees of different Institutes and Centers (ICs). Between 94 and 98 percent of Phase II awardees funded by the National Center for Research Resources (NCRR), National Institute on Aging (NIA), National Institute of Child and Human Development (NICHD), and the National Institute of Digestive, Diabetic, and Kidney Diseases (NIDDK) were usable. The same was

[7]Being purchased by or merging with another company can be regarded as a successful outcome for a Phase II awardee. The decision to designate these companies as unusable is primarily based on the substantial difficulty in obtaining recent contact information for both the company and the PI. Exclusion of these companies, however, always introduces the issue of potential bias in the survey results. Given the high usability rate in the 2008 study, the degree of bias is most likely extremely small.

true for the cluster of ICs that included the National Institute on Alcohol and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the National Institute of Nursing Research (NINR), and the National Center for Minority Health Disparities (NCMHD).

The National Heart, Lung, and Blood Institute (NHLBI) and the National Institute on Allergy and Infectious Diseases (NIAID) had the lowest usability rates (83 percent). For the remaining ICs, usability rates fell between 87 and 91 percent.[8]

Eligibility. Of the 928 usable awardee businesses, nearly all (918) were determined to be eligible. The ten companies that were ineligible were so designated because the Principal Investigator (PI) was unavailable (either due to death or departure from the company), and no other individual with adequate knowledge to complete the questionnaire could be identified.[9]

2.2 Spokesperson Characteristics

Exhibit 2-1 on the next page displays selected characteristics of individual spokesperson respondents who completed the survey. Approximately 80 percent of the individuals who completed the 2008 questionnaire were the original PIs listed on the Phase II SBIR award application. Another 11 percent were individuals who later had been designated as the replacement PI, typically as a result of the initial PI leaving the company. As such, a total of 91 percent of respondents were directly responsible for the work under the award at some point during the award period. The remaining 9 percent of respondents were either the business official listed on the SBIR application or another contact at the company; these individuals agreed to complete the survey because the original PI could not be located.

Survey respondents often performed many roles in the awardee business. Approximately 36 percent functioned in only one capacity—as owners (13 percent), part of the managerial team (13 percent), employees (9 percent), and, in a few cases, shareholders (3 percent). The largest group of respondents (40 percent) reported serving in multiple roles whereby they not only owned the company but also served in a managerial role and were shareholders. Substantially smaller percentages held two roles.

[8]See Appendix D, Response Rate—Final Disposition of Sample.

[9]Statistical comparisons were not performed, given the small number of ineligible respondents.

EXHIBIT 2-1
Characteristics of Survey Respondents

Characteristic	*N*	Percent
Respondent role		
Initial PI	574	80
Replacement PI	82	11
Business official	33	5
Other company contact	27	4
Relationship to awardee company		
Owner		
Owner only	90	13
Owner and manager	27	4
Owner and shareholder	9	1
Owner, manager, and shareholder	281	40
Part of management		
Management only	89	13
Manager and shareholder	90	13
Employee		
Employee only	61	9
Employee and shareholder	20	3
Shareholder only	19	3
Other (e.g., former employee)	15	2

Note. Information on respondent role was provided by 716 awardees; the corresponding figure for relationship to the awardee company was 701. The percentages for respondent roles are column percentages and may not sum to 100 percent due to rounding.

Most respondents were either the original PI or a replacement PI. Respondents tended to report multiple relationships within the awardee small business; most typical were owner, and part of management.

2.3 Awardee Small Businesses

This section compares characteristics of awardee small businesses that were eligible for the survey. It then provides additional detail about the characteristics of eligible awardees who responded.

2.3.1 Nonrespondent and Respondent Awardee Comparison

Approximately 78 percent of eligible respondent awardee companies participated in the 2008 survey. Exhibit 2-2 on page 2-4 shows fiscal year of award, sponsoring IC, and region of the country for respondent and nonrespondent awardees.

EXHIBIT 2-2
Selected Characteristics of Nonrespondent and Respondent SBIR Awardee Small Businesses

Characteristic	Nonrespondents (*N* = 199)		Respondents (*N* = 719)	
	N	%	*N*	%
Fiscal Year of Award				
2002	45	23	122	17
2003	26	13	131	18
2004	38	19	135	19
2005	42	21	130	18
2006	48	24	201	28
Sponsoring IC				
NBIB, NCRR, NHGRI, NIAMS, NIDCD, NIDCR, NIEHS, NCCAM, and NLM	40	20	154	21
NCI	36	18	110	15
NIA	7	4	40	6
NIAAA, NIDA, NINR, and NCMHD	5	3	33	5
NIAID	21	11	59	8
NICHD	14	7	47	7
NIDDK	11	6	48	7
NIGMS	18	9	59	8
NIMH	9	5	33	5
NINDS	12	6	40	6
NHLBI	26	13	96	13
U.S. Region				
Midwest	31	16	114	16
Northeast	60	30	203	28
South	35	18	174	24
West	73	37	228	32

Note. The percentages are column percentages and may not sum to 100 percent due to rounding. The full titles of the sponsoring ICs are shown in Exhibit 1-1 on page 1-6.

Non-respondents and respondents were similar in terms of the IC that sponsored the Phase II award, the fiscal year of the award, and the geographic region in which the small business was located.

As shown by Exhibit 2-2, over one-fourth of the 719 respondent awardees received their Phase II award in FY 2006. Between 17 and 19 percent of the companies each received their award in one of the earlier years included in the evaluation (FYs 2002-2006).

The NCI supported the largest number of awards during this five-year period, funding 110 companies or 15 percent of all respondents. The NHLBI supported the second largest number, making Phase II awards

to 96 companies (13 percent). Six ICs each funded another 6 to 8 percent of the companies that responded to the survey; these included NIAID, National Institute of General Medical Sciences (NIGMS), NIDDK, NICHD, NIA, and National Institute of Neurological Disorders and Stroke (NINDS). The remaining awardee companies were funded by other ICs.

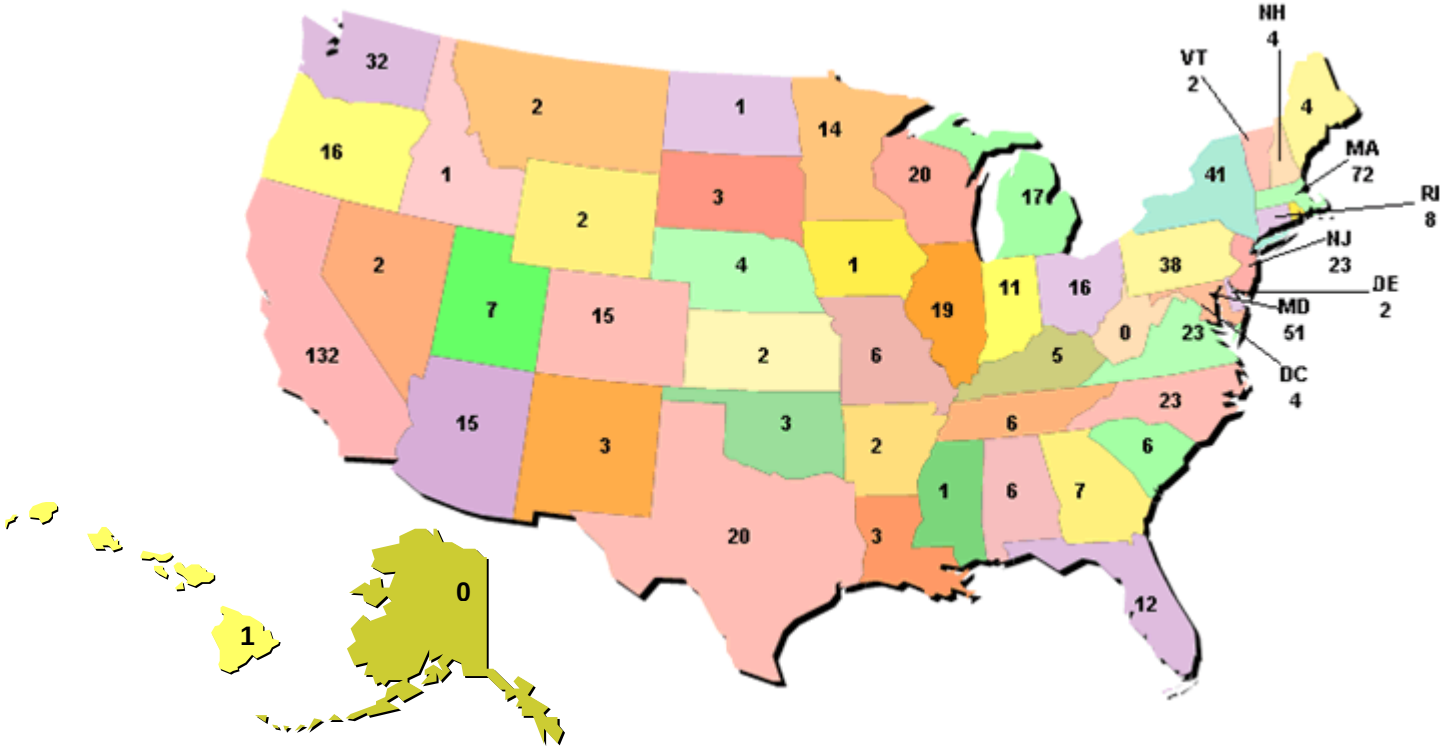
The largest percentage of respondent companies (32 percent) was located in the West, and the smallest percentage (16 percent) in the Midwest. Twenty-eight percent were in the Northeast, and the remaining 24 percent were in the South.

Respondents and nonrespondents were reasonably similar in terms of which IC sponsored the award. They also were similar in terms of the year in which the award was made and region of the country. This suggests that the threat of nonresponse bias is very small or nonexistent for survey responses that are strongly related to one or more of these three characteristics.

2.3.2 Awardee Small Business Respondents

Exhibit 2-3 shows a detailed picture of the geographical distribution of responding awardee small businesses, identifying the number of respondents by state. California by far had the heaviest concentration of respondents (132), followed by Massachusetts (72) and Maryland (51). Twenty-five percent of the states had between one and two awardees, and two states (Alaska and West Virginia) received no Phase II awards from FYs 2002-2006 and thus had no awardees that participated in the survey.

EXHIBIT 2-3
Awardee Small Business Respondents by State

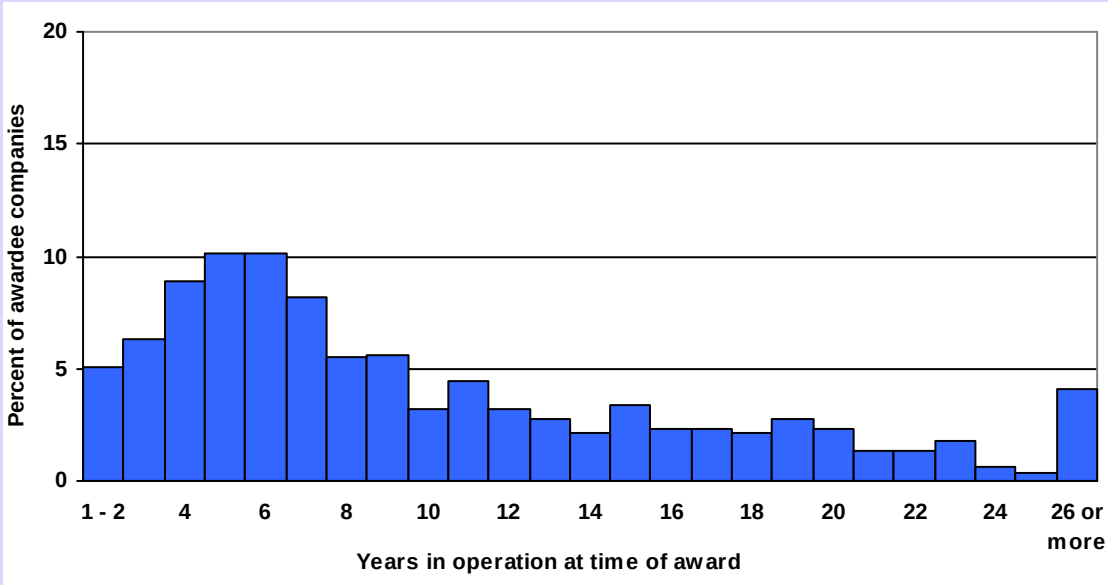


The largest numbers of awardee respondents were in California, Massachusetts, and Maryland. Five states had only one respondent. Alaska and West Virginia received no awards during FYs 2002-2006 and therefore had no respondents to the 2008 survey.

Twenty-four percent of awardee small businesses were founded in 2000 or later, and more than one-third (37 percent) began operations between 1995 and 1999. Sixteen percent were founded during the early 1990s, 12 percent between 1985 and 1989, and 7 percent between 1980 and 1984. Only a small percentage (5 percent) were established prior to 1980.

Looking at this another way, a significant percentage of awardee companies were starting operations at the time of the award. Exhibit 2-4 shows the distribution of awardee companies by years in operation at time of award. Awardee respondents to the 2008 survey reported a range of years in operation at the time of award from 1-2 to 26 or more years.

EXHIBIT 2-4
Years in Operation at the Time of the SBIR Award for Responding Small Businesses



Note. The total number of awardee businesses that provided this information was 711. Percentages may not sum to 100 percent due to rounding.

Phase II awardee businesses tended to be "young" in terms of how long they had been in operation at the time of award. Approximately 30 percent had been operating for five years or less.

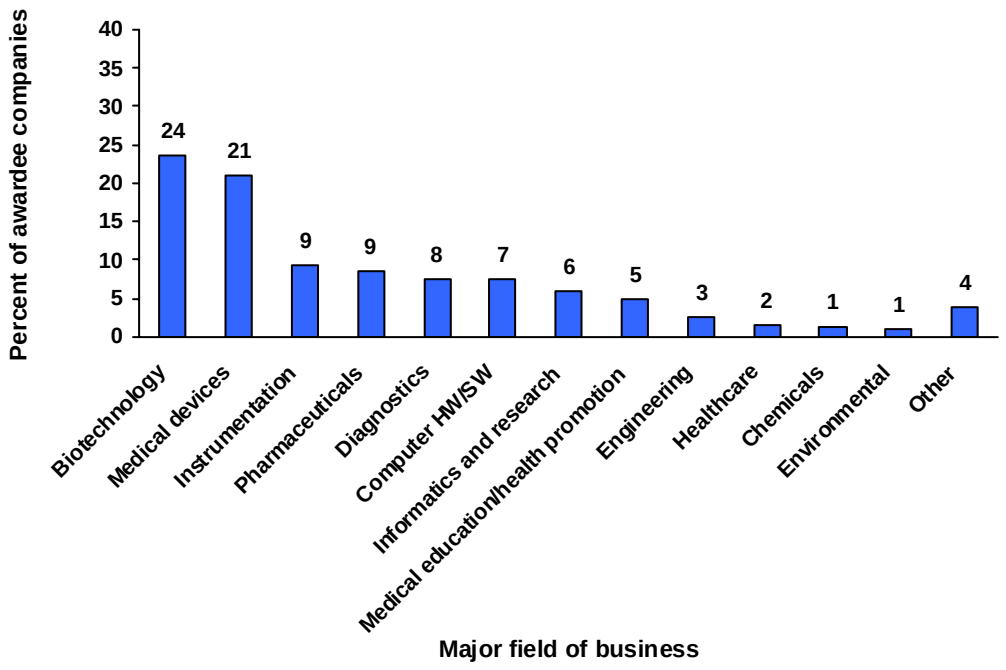
Overall, 54 percent of awardee businesses had been in operation for eight years or less at the time of the Phase II award.

There were no significant differences among awardees in the average age when examined by fiscal year of the award or type of product. On the other hand, significant differences did appear for different types of awardee businesses. Biotechnology, pharmaceutical, diagnostic, medical devices, and computer software/hardware companies were significantly likely to be "younger" than either instrumentation companies or companies in the other category (i.e., healthcare, engineering, chemical, and environmental businesses).

Company age at the time of the award was similar among the ICs, with one exception. Small businesses that were supported by the NIAAA and NIDA had been in operation significantly longer than those supported by other ICs. This is primarily a function of the fact that a larger percentage of NIAAA and NIDA awards were in businesses that specialized in medical education and health promotion—a group that also tended to have been in existence longer (mean of 11.1 years at the time of the award) than other types of businesses.

When asked about their major field of business, the 612 companies that responded to this question represented a varied group of companies (see Exhibit 2-5). Two areas were predominant—biotechnology (24 percent) and medical devices (21 percent). Between five and nine percent of all businesses were in each of six fields, including medical education and health promotion, informatics, research, and statistics, pharmaceuticals, diagnostics, computer hardware and software (HW/SW), and instrumentation. Much smaller percentages were in as healthcare, chemicals, and environmental fields.

EXHIBIT 2-5
Major Field of Business Reported by SBIR-Funded Awardees for FYs 2002-2006



Note. The total number of awardee businesses that provided this information was 612. Percentages may not sum to 100 percent due to rounding.

By far, biotechnology and medical devices were the most common major fields of business for Phase II SBIR-funded awardee respondents.

Of the 719 awardee companies that completed the survey, 107 (15 percent) did not report their major field of business. Including the missing responses in the analysis, did not noticeably change the percentages or relative ranking of the different major fields, although the amount of missing data suggests caution in interpreting these percentages. It is not clear why 15 percent of respondents failed to answer the question about major field of business. Because of the amount of missing data, this variable is not used in analyses of responses to the three key study questions.

2.4 SBIR-Supported Projects and Products

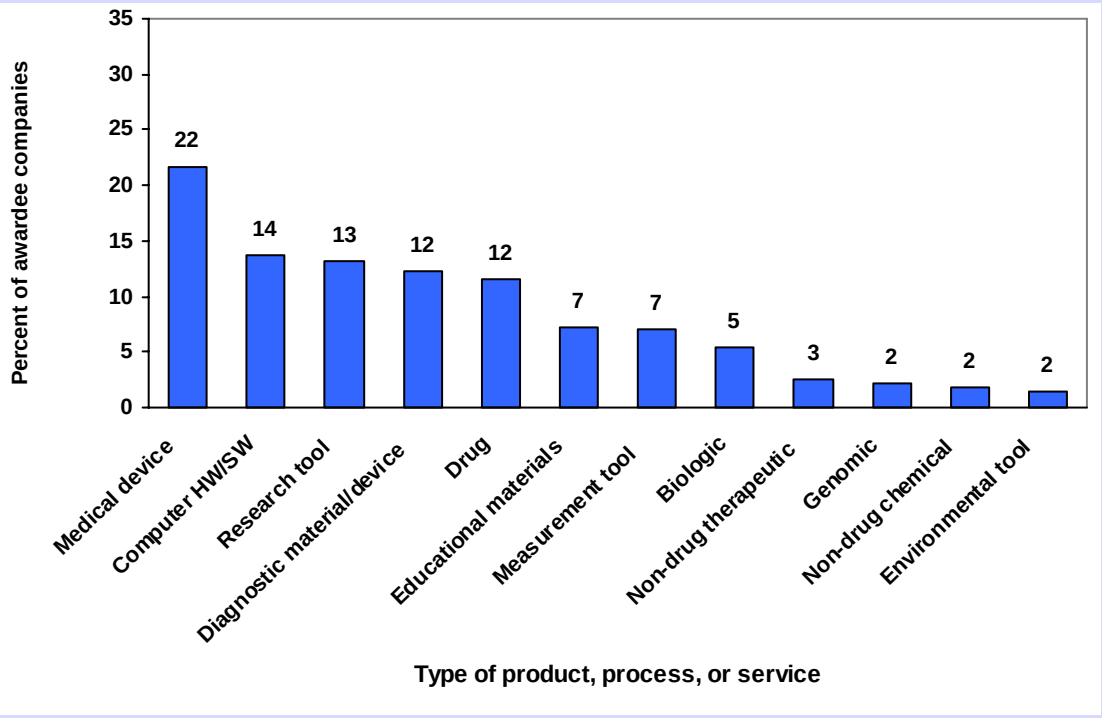
The SBIR program supported a diverse group of projects and their product-related activities.[10] The majority (70 percent) of the projects involved the development of a totally new product, and one-fifth (20 percent) focused on improving an existing product. Another 7 percent sought to develop a combination of new products, and 3 percent intended to create a new use for an existing product. These percentages did not differ by the year of the award or the sponsoring IC. They also were nearly identical to those found in the 2002 survey.

As shown by Exhibit 2-6 on the next page, when asked about the specific type of product that was the focus of the award, 22 percent of the awardees reported having received SBIR funding to develop medical devices. Computer hardware and software, research tools, diagnostic materials and devices, and drugs each comprised between 12 and 14 percent of the projects.

Educational materials were identified by approximately 7 percent of the small businesses, as were measurement tools. Noticeably smaller percentages (2 to 3 percent) of the companies funded work was in genomics, non-drug therapeutics, environmental tools, and chemicals and chemical processes.

[10] For the ease of the reader, henceforth we use the term "product" throughout this report to represent the products, processes, and services that were planned by awardees.

EXHIBIT 2-6
Type of Planned Product for SBIR Funded Awardees

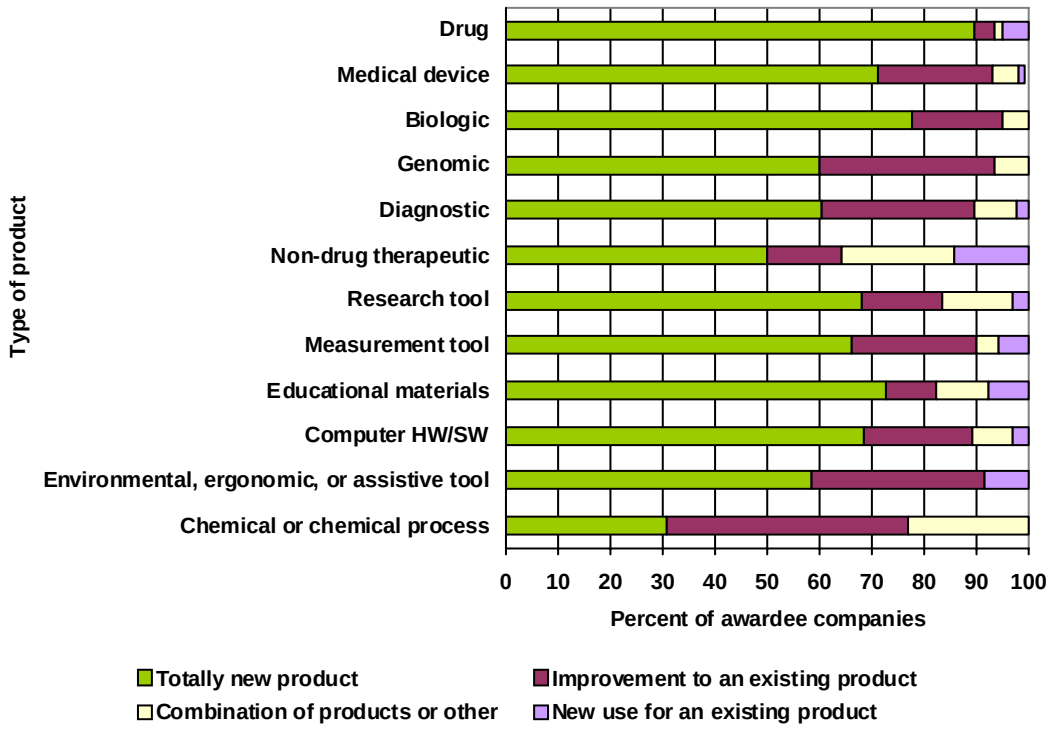


Note. These percentages are based on a total of 716 awardees who provided information on type of product. Percentages may not sum to 100 percent due to rounding. In addition, a very small percentage (0.1 percent) of the awards planned a product other than the ones identified.

Phase II awards sponsored a diverse group of products. The most common were medical devices. Five types of products—medical devices, computer hardware and software, research tools, diagnostic materials/devices, and drugs—accounted for nearly three-quarters (73 percent) of all planned products.

Among the different types of planned products, there were differences in whether the project sought to develop one or more new products or improve an existing product. As Exhibit 2-7 shows (on the next page) projects that focused on drugs most often described their goal as developing a "totally new" product (90 percent). This also was the case for companies working on biologics (77 percent), educational materials (73 percent), and medical devices (71 percent). In fact, regardless of the type of technological innovation, at least 50 percent or more of the companies labeled their product as "totally new," with one exception. Companies whose award was for a non-drug chemical or chemical process were more likely to see their intended product as an improvement to an already existing product.

EXHIBIT 2-7
Technological Innovations by Type of Planned Product



Note. The total number of awardee businesses that provided this information was 715. For each type of product, the percentages may not sum to 100 percent due to rounding. The relationship between the type of technological innovation and the planned product was statistically significant (chi-square statistic=69.8, $df = 33$, $p < 0.0002$).

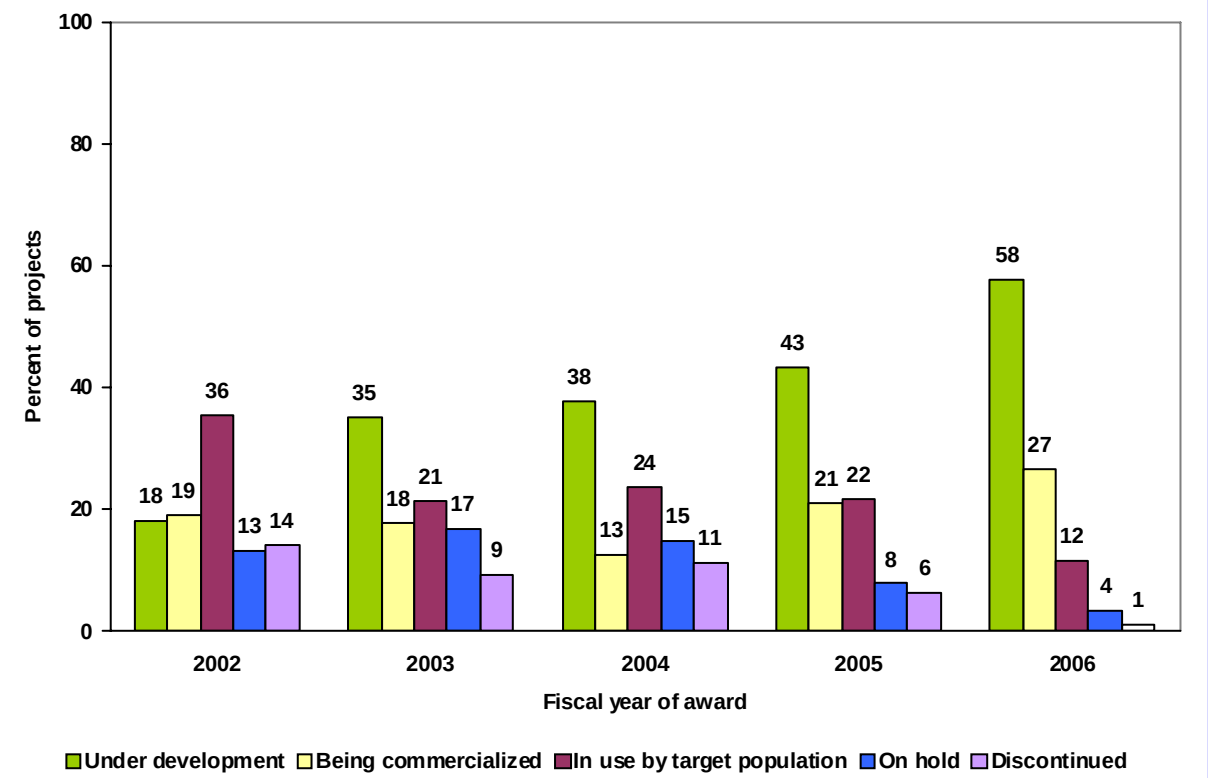
Most product types were described as "totally new" at least 50 percent of the time. The one exception was products involving chemicals or chemical processes, which were most frequently described (46 percent) as supporting improvements to an existing product.

Overall, 41 percent of the companies reported that their SBIR-funded product was currently in the development phase at the time of the survey. Another 20 percent indicated that it was being commercialized, and 22 percent stated that it was being used by the target population(s). Ten percent said that the product was "on hold," awaiting the receipt of additional funding or inactive for another reason. Eight percent of the companies had actually discontinued work on the project. (Numbers total more than 100 percent due to rounding).

Not surprisingly, the time that had elapsed since initial receipt of SBIR Phase II funding was significantly related to the current status of the project (see Exhibit 2-8 on the next page). Projects funded in FY 2006, having been underway for only about two years, were most likely to still be in the development stage (58 percent) and least likely to be discontinued (1 percent). However, only 18 percent of the projects funded in FY 2002, six years after the start of the award, were still under development, and 14 percent had been discontinued. Similarly, the percentage of projects whose products were currently in use by the target

population was reasonably small for FY 2006 awards (12 percent). This figure tripled for projects that were first funded in FY 2002 (36 percent).

EXHIBIT 2-8
Current Project Status by Fiscal Year of Award



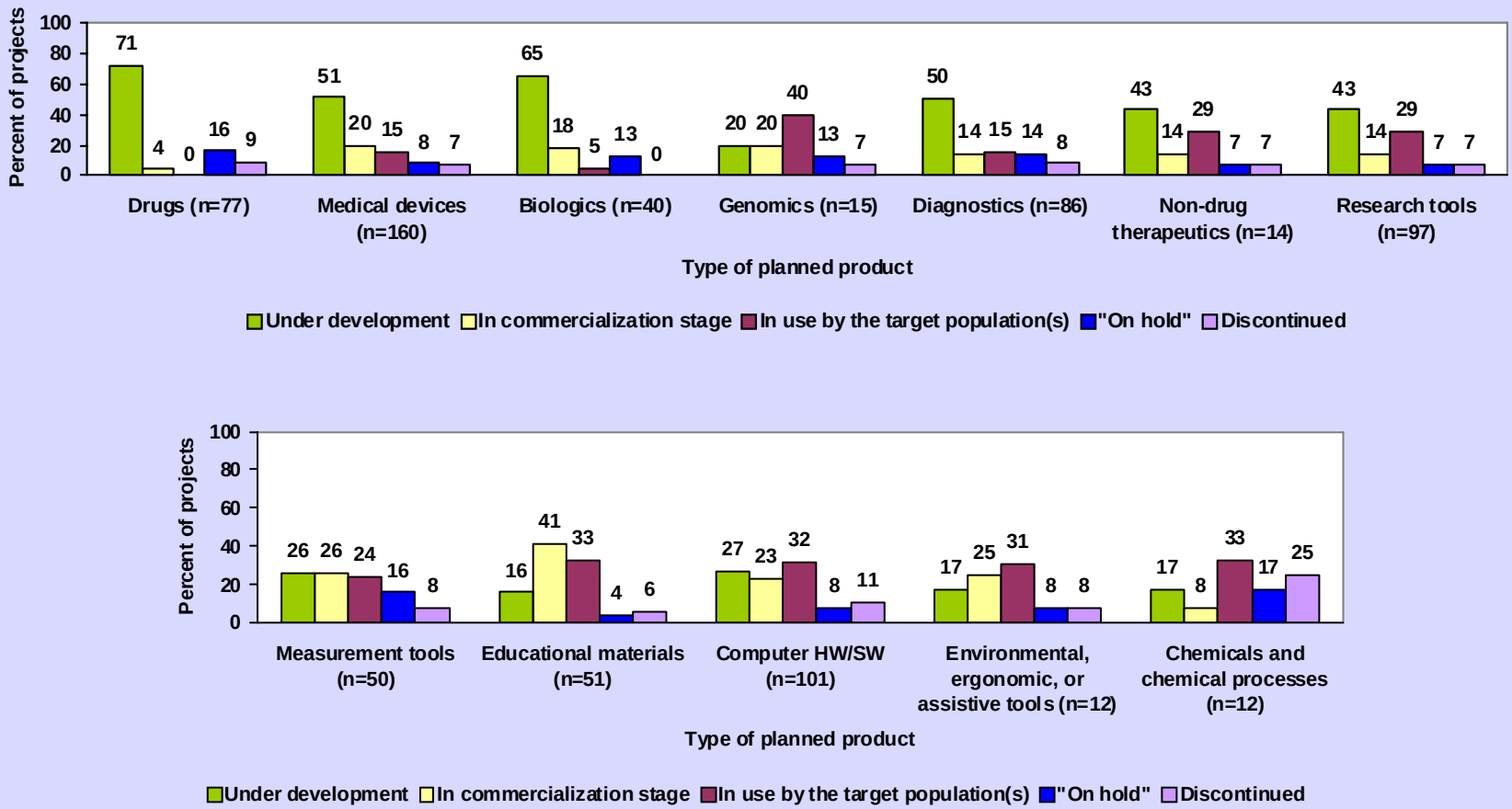
Note. The total *N* of respondents was 716. For each fiscal year of the award, percentages may not sum to 100 percent due to rounding. Fiscal year of the award and current project status were significantly related (chi-square statistic=99.4, *df* =16, $p < 0.001$).

The longer the elapsed time since the start date of the award, the more likely it was that projects were under development. Projects with relatively longer elapsed time, since the start date of the award were more likely to be in use by the target population(s) than were projects funded in FY 2006.

Another factor affecting project status was the type of product being developed. As shown in Exhibit 2-9, on the next page, awardees reported that the status of their SBIR product was either (1) under development, (2) in the commercialization stage, (3) in use by the target population; (4) "on hold," or (5) discontinued. Environmental, ergonomic, and assistive tools, along with genomics, were significantly more likely than other product types to be in use at the time of the survey. Drugs and medical devices were significantly more likely to be under development.

Educational materials were most likely to be in the commercialization stage (41 percent) at the time of the survey. Drugs (4 percent) and chemicals (8 percent) were least likely to be in the commercialization stage. Chemical products were said to have been discontinued more often (25 percent) than other types of products.

EXHIBIT 2-9
Current Project Status by Type of Planned Product



Note. A total of 715 companies provided this information. For each type of product, percentages may not sum to 100 percent due to rounding. Current project status and type of planned product were significantly associated (chi-square statistic=145, df = 27, $p < 0.0001$).

The type of product was significantly related to current project status. Environmental, ergonomic, and assistive tools, along with genomics, were significantly more likely to be already in use at the time of the survey. Drugs and medical devices were significantly more likely to be under development.

Finally, differences in current project status surfaced, depending on the IC that sponsored the Phase II award (see Exhibit 2-10 on the next page). The National Institute of Mental Health (NIMH), the NICHD, and the cluster of ICs that included the NIAAA, the National Institute on Drug Abuse (NIDA), NINR, and NCMHD were the most likely to have their products in use at the time of the survey. Nearly one-third of these ICs' awardees reported that their SBIR-funded project had been completed and their product made available to the respective target population(s). These percentages were significantly larger than were those for projects sponsored by the NCI, NHLBI, NIAID, NIGMS, and NIDDK, which ranged from 14 to 17 percent. Such differences might be expected: the ICs with lower percentages are more likely to support projects to develop drugs and medical devices—two product types that take the longest to reach the market because of such factors as the need for FDA approval.

The discontinued rates for Phase II projects were typically between 8 and 10 percent. A significantly lower rate occurred for the NIGMS when compared with that for all other ICs, excluding the NIMH, combined (chi-square statistic=5.33, df=1, $p < 0.03$). Although the NIMH also experienced a visibly lower rate (3 percent), this difference was not significantly different.

Although the percentage discontinued SBIR-funded projects was only 8 percent overall, it is useful to explore the extent to which these projects shared any distinctive characteristics from those of projects that were still ongoing. Exhibit 2-11 on page 2-15 shows the various reasons for abandoning work on the project for the 54 discontinued projects. As shown, 59 percent of the awardees reported that there was insufficient funding for the planned work. The second most frequent reason cited by 44 percent of awardees was that the business itself had shifted priorities. Between 24 and 30 percent cited problems involving too high a level of risk, the non-competitive nature of the product, and a market demand that was too small. Smaller percentages believed that the project was abandoned at least in part because of the PI's departure from the company, the inability to obtain FDA approval, or that products were licensed to another company.

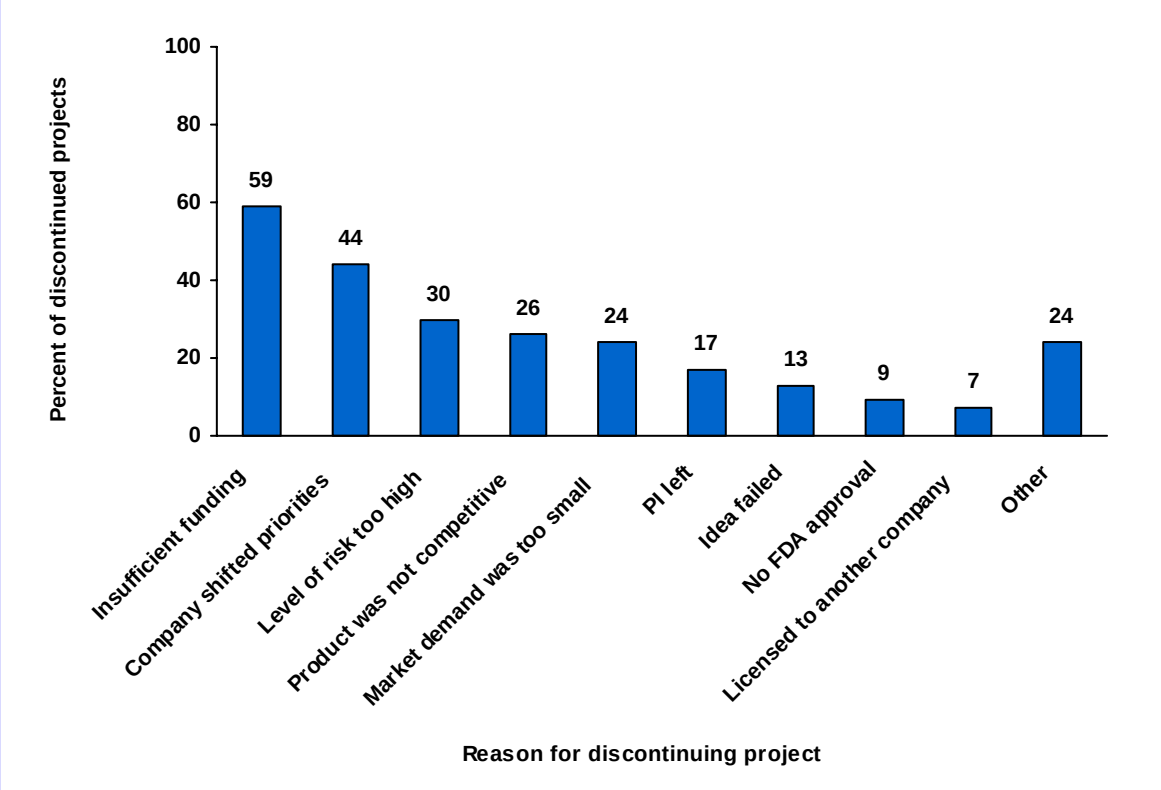
EXHIBIT 2-10
Current Project Status by NIH IC Sponsor

NIH IC Sponsor	Total N	Current Project Status									
		Under development		Under commercialization		In use		"On hold"		Discontinued	
		N	%	*N*	%	*N*	%	*N*	%	*N*	%
NBIB, NCRR, NHGRI, NIAMS, NIDCD, NIDCR, NIEHS, NCCAM and NLM	154	59	38	34	22	34	22	16	10	11	7
NCI	109	36	33	29	27	17	16	16	15	11	10
NHLBI	95	53	56	15	16	13	14	6	6	8	8
NIAID	59	32	54	3	5	10	17	9	15	5	8
NIGMS	58	20	35	18	31	14	24	6	10	0	0
NIDDK	48	22	46	10	21	8	17	4	8	4	8
NICHD	47	15	32	9	19	15	32	4	9	4	9
NIA	40	17	43	8	20	10	25	2	5	3	8
NINDS	40	16	40	4	10	11	28	6	15	3	8
NIMH	33	9	27	9	27	11	33	3	9	1	3
NIAAA, NIDA, NINR, and NCMHD	33	11	33	4	12	11	33	3	9	4	12

Note. The total number of respondents was 716. Percentages are row percentages and may not sum to 100 percent due to rounding. Sponsoring IC and project status (under development, under commercialization, in use, and "on hold" or discontinued) were significantly associated (chi-square statistic= 57.6, $df = 33$, $p < 0.005$). The full titles of the sponsoring ICs are shown in Exhibit 1-1 on page 1-6.

There were significant differences in the current project status of awardee companies, depending on the IC that funded the project. The NIMH, the NICHD, and the cluster of ICs that included the NIAAA, NIDA, NINR, and NCMHD were the most likely to have their products in use at the time of the survey. Compared to all other ICs, the NIGMS, NIMH, and NIA were significantly less likely to have any discontinued or "on hold" projects.

EXHIBIT 2-11
Reasons for Discontinued Projects



Note. These percentages are based on a total of 54 respondents who provided reasons as to why their SBIR-funded project was discontinued. Percentages do not sum to 100 percent, given that individuals could indicate multiple reasons.

The most common reported reason for discontinuing work on an SBIR-funded project was insufficient funding (59 percent). A shift in the priorities of the company also was mentioned as a contributing factor by 44 percent of respondents). Thirty percent indicated that the level of risk was too high and about one-quarter (24 and 26 percent) believed the demand was too small or the product was not competitive.

Exhibit 2-12, on the next page shows that the relationship between product characteristics and discontinuing work was only marginally significant ($p < 0.06$). Whereas 7 percent of companies developing new products reported discontinuing work on the SBIR-funded project, this was true of 11 percent of companies that were working on improvements to or new uses for existing products.

The decision to discontinue a project was significantly related to receipt of additional SBIR awards. As shown by Exhibit 2-12, companies that had no related SBIR awards were nearly twice as likely as those that had competed successfully for these awards to have discontinued their project (10 versus 6 percent).

EXHIBIT 2-12
Discontinued Projects by Product Characteristic and Awardee's Receipt of Additional SBIR Awards

	Project was discontinued			
	Yes		No	
	N	%	*N*	%
Product characteristic				
Developing one or more new products	36	7	510	93
Improving or finding new use for an existing product	18	11	146	89
Receipt of additional SBIR awards				
Yes	23	6	385	94
No	30	10	261	90

Note. A total of 710 awardees provided information on both current project status and product characteristic. The corresponding number for receipt of additional SBIR awards and project status was 699. Percentages are row percentages. The relationship between product characteristic and project status was only marginally significant (chi-square statistic=3.45, *df*=1, $p < 0.06$) whereas the relationship between receipt of additional SBIR awards and project status was statistically significant (chi-square statistic=5.29, *df*=1, $p < 0.02$).

Companies that received additional SBIR Phase I or Phase II awards were significantly less likely to have abandoned work on their Phase II project then were small businesses that had not competed successfully for such additional awards.

Seldom did awardees attribute only one reason to their decision to abandon work on their product. Only 24 percent of this group cited only one factor, 33 percent identified two reasons, and 43 percent listed three or more motivations. Certain rationales also tended to occur jointly. The belief that a product was not sufficiently competitive was significantly related to also viewing the level of risk as too high (the correlation between these two variables was 0.36, $p < 0.008$). Having insufficient funding also was significantly correlated with the departure of the PI (the correlation was 0.27, $p < 0.04$). In both cases, although these correlations were statistically significant, they were fairly modest in size.

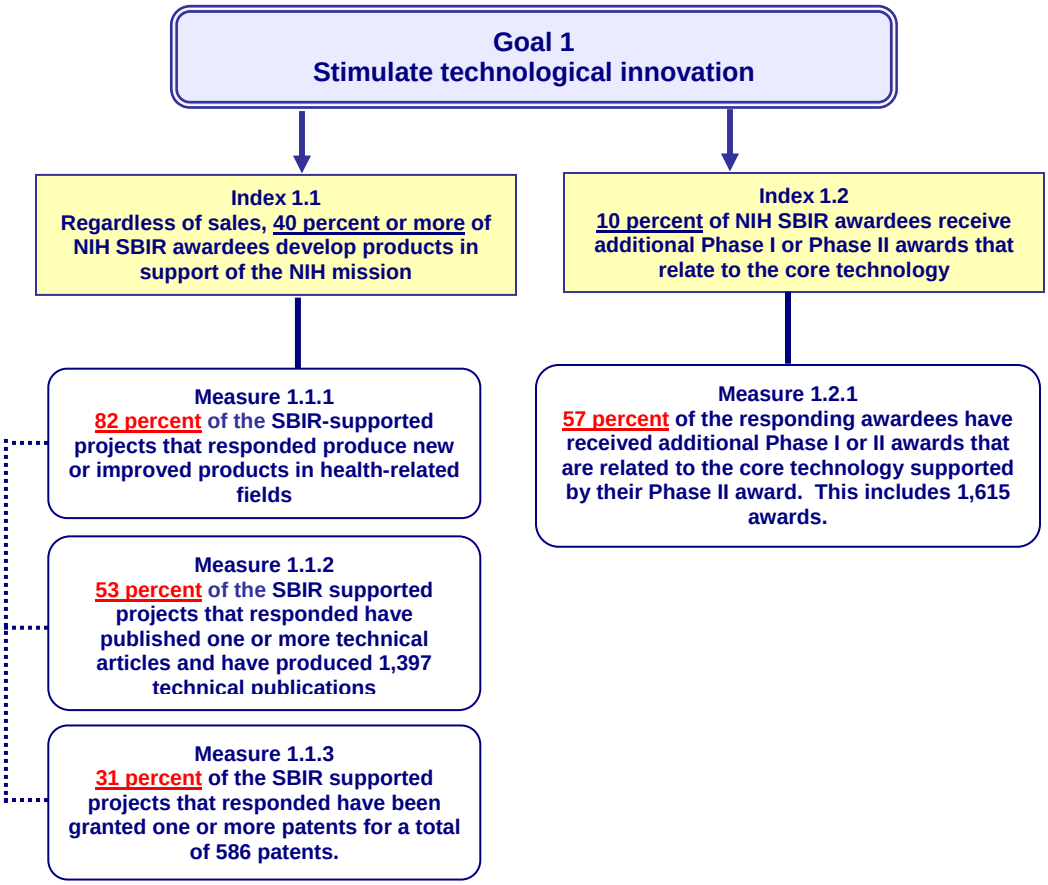
3. STIMULATING TECHNOLOGICAL INNOVATION

This chapter presents findings about attainment of the first NIH SBIR program goal, stimulating technological innovation. It begins with a summary of findings about goal attainment. Then it presents analyses of each related index and overall performance of SBIR awardees over time.

3.1 NIH SBIR Awardees Stimulated Technological Innovation

Exhibit 3-1 summarizes the survey findings about awardee outcomes for stimulating technological innovation. Phase II awardees reported exceeding specified levels for both indices in the Evaluation Framework—developing products in support of the NIH mission and receiving additional awards that relate to the core technology.

EXHIBIT 3-1
Summary of Outcomes Associated with Stimulating Technological Innovation



The next sections describe awardees' reported performance in attaining each performance index benchmark *at the time of survey measurement*.

3.2 Performance on NIH SBIR Product Development Targets

Survey respondents exceeded the NIH SBIR performance target expressed by Index 1.1, which is "Regardless of sales, 40 percent or more of NIH SBIR awardees develop products in support of the NIH mission." This section describes performance on the three related measures from the NIH SBIR program Evaluation Framework.

3.2.1 New or Improved Products in Health-Related Fields

Measure 1.1.1 describes the number of SBIR-supported projects that produce new or improved products in health-related fields, which is one indicator of alignment with the NIH mission. The number of respondents who said they are developing and commercializing new or improved products in health-related fields is 587 (82 percent of 719 respondents). These included 290 projects with products under development, 143 projects in the midst of the commercialization stage, and 154 projects that have made their products available for commercial use.

3.2.2 Technical Articles and Related Activities in Support of the NIH Mission

Measure 1.1.2 describes the number of technical articles generated by NIH SBIR projects. This measure provides important information about mission support because progress toward stimulating technological innovation is accomplished when contributions are made to the body of scientific and technological knowledge. These contributions include publishing articles in peer-reviewed scientific journals and authoring or co-authoring articles that appear in industry or technical publications.

In addition to querying survey respondents about publications, the questionnaire also asked about other indicators of contribution to the body of scientific and technological knowledge in support of the NIH mission: conference presentations and honorary awards. Conference presentations can be precursors to formal publications; they promote public awareness of the SBIR-supported product, and in turn increase the product's visibility and possibly its quality. Visibility and quality benefits also can accrue when project personnel receive honorary awards that relate to their SBIR project activities.

As shown by Exhibit 3-2 (on the next page), slightly more than half (53 percent) of awardee respondents indicated that they had generated one or more publications that were associated with the project, and nearly three-quarters (73 percent) made one or more conference presentations. Thirteen percent received at least one award.

EXHIBIT 3-2
Summary of Presentations, Publications, and Awards Associated with SBIR-Supported Projects

	Conference Presentations	Publications	Awards
Awardee companies			
Number	519	375	95
Percent	73	53	13
Items			
Total	2,771	1,397	148
Mean	0.9	2.0	0.2
Standard deviation	7.4	4.9	0.7
Median	2.0	1.0	0.0

Note. The total number of awardees who responded to survey queries about these items was 709.

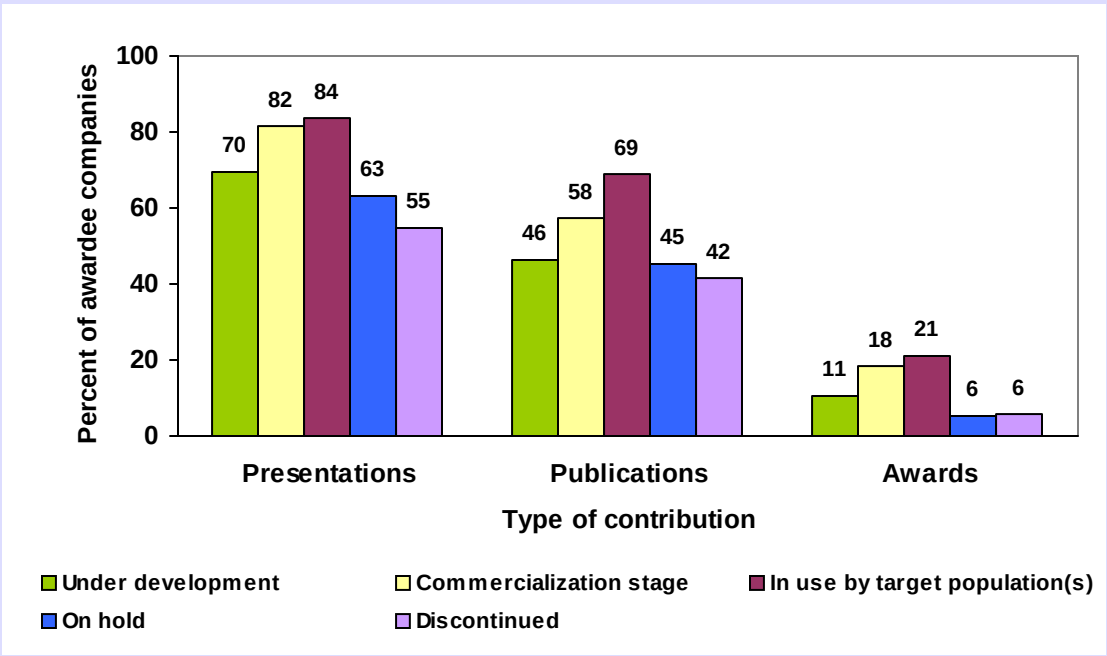
Nearly three-quarters (73 percent) of all awardees reported giving one or more conference presentations. Fifty-three percent reported producing one or more publications. Approximately 13 percent reported receiving at least one award.

The NIH SBIR program awards generated 1,397 publications, 2,771 conference presentations, and 148 awards. Median numbers per reporting awardee were 1, 2, and 0, respectively.

Whether awardees reported publications, presentations, and awards related to the SBIR-funded project was significantly related to the current status of the project. Exhibit 3-3 on the following page shows that larger percentages of companies whose products were being commercialized or in use by the target population(s) indicated having one or more publications, presentations, and awards. Fifty-eight percent of awardees who were in the midst of commercializing their product had published at least one technical article. Sixty-nine percent of awardees whose product was commercially available and in use published at least one technical article. The corresponding percentage was 46 percent for awardees who were still involved in product development.

Regardless of project status, a sizable percentage of SBIR projects make contributions to the scientific knowledge base. Noticeable levels of activity in authoring technical articles occurred even for projects that were “on hold” or discontinued (45 and 42 percent, respectively).

EXHIBIT 3-3
Awardees with Presentations, Publications, and Awards by the Current Status of their SBIR-Supported Project



Note. Current project status was significantly related to all three ways of contributing to the knowledge base. For publications, the chi-square was 26.3 ($df = 4$, $p < 0.001$). For presentations, the chi-square statistic was 28.8 ($df = 4$, $p < 0.0001$), and for awards, it was 19.1 ($df = 4$, $p < 0.0007$). The total number of awardees who responded to survey queries about these outcomes was 709.

Awardees that were commercializing their product or had made it already available were significantly more likely to have published one or more technical articles and to have received one or more awards than were awardees whose projects were "on hold" or discontinued. Awardees whose projects were "on hold" or discontinued had published at least one technical article (45 and 42 percent, respectively). Even higher percentages of these more "inactive" projects reported making one or more conference presentations.

As also shown by Exhibit 3-3, a pattern similar to that observed for publications occurred with regard to conference presentations and awards. The strongest performance was exhibited by awardees who had moved past the product development stage and had ongoing or completed projects.

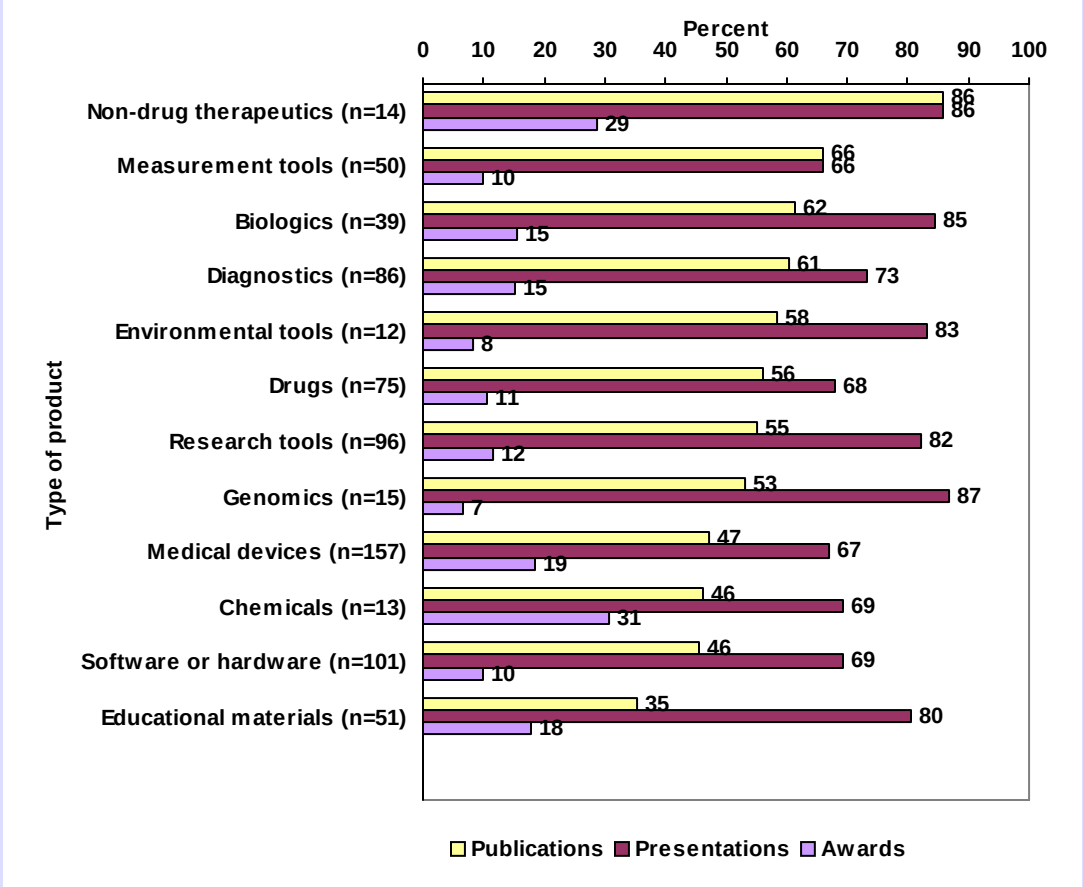
Overall, when compared to publications, the percent of awardees with at least one product-related conference presentation was noticeably higher, and the percent with one or more awards was dramatically smaller, regardless of the current status of the SBIR-funded project.

The elapsed time between the receipt of SBIR Phase II funds was significantly related to publications (chi-square statistic = 27.2, $df = 4$, $p < 0.0001$). Essentially, the more time that had elapsed, the more likely it was for a company to have published one or more scientific articles. Whereas 68 percent of FY 2002 awardees indicated one or more publications, the corresponding percentages for FYs 2003-2006 awardees were 60, 57, 44, and 42 percent, respectively. In contrast, there was no relationship between when the small business received the SBIR Phase II award and whether it had since presented at a conference or received an honorary award that was project-related.

Having one or more publications, presentations, or awards was not significantly related to the Institute/Center (IC) groupings. Conference presentations and awards were not associated with the type of product being sponsored by the Phase II award.

Publications and type of product were related. Exhibit 3-4 shows awardees that were working on non-drug therapeutics were the most likely to have one or more publications (86 percent). Between 61 and 66 percent of companies working on measurement and assessment tools, diagnostic materials and devices, and biologics, and 53 to 58 percent of awardees developing new or improved drugs, genomics, research tools, and environmental tools reported that they had produced one or more publications. Nearly half of the awardees receiving SBIR support for medical devices, software and hardware, and chemical products reported having one or more publications. Awardees planning on creating educational materials were the least likely to have published, with 35 percent reporting having one or more publications related to the award.

EXHIBIT 3-4
Awardees with Publications, Presentations, and Awards by Type of SBIR-Supported Product



Note. Type of product and publication activity were significantly related (chi-square statistic=24.1, $df = 11$, $p < 0.01$). For presentations, the relationship with product type was only marginally significant (chi-square statistic=17.6, $df = 11$, $p < 0.09$). The total number of awardees who responded to survey queries about these outcomes was 709.

Awardees with projects developing new or improving existing non-drug therapeutics were significantly more likely to have published one or more technical articles that were related to their Phase II project than were awardees working on other types of products. Awardees developing non-drug therapeutic products, chemicals or chemical processes also were significantly more likely to have received recognition in terms of an award. Regardless of the type of product, large majorities of awardees (between 66 and 87 percent) had presented at one or more scientific conferences.

3.2.3 Patents and Other Indicators of Stimulating Technological Innovation

Measure 1.1.3 quantifies patents, another indicator of the degree to which NIH SBIR projects stimulate technological innovation in support of the agency's mission. The survey provided information on other indicators of technological innovation stimulus as well—copyrights and trademarks.

As shown by Exhibit 3-5, 31 percent of survey respondents received one or more patents associated with their SBIR Phase II project. This figure is consistent with the earlier findings of the National Research Council (NRC) (33 percent).[11] Another 41 percent had a pending patent application; 18 percent reported having at least one copyright; and 27 percent reported having obtained at least one trademark.

EXHIBIT 3-5
Awardees' Patents, Copyrights, and Trademarks

	Patents	Pending Patent Applications	Copyrights	Trademarks	Total
Awardee companies					
Number	217	289	127	191	491
Percent	31%	41%	18%	27%	69%
Items					
Total	586	614	517	306	2,023
Mean	0.8	0.9	0.7	0.4	2.9
Standard deviation	3.1	1.7	5.6	0.9	7.2
Median	0.0	0.0	0.0	0.0	1.0

Note. The Total column on the far right of this table reports the number and percent of awardees with one or more patents, pending patent applications, copyrights, and trademarks. It also reports the sum of these four items and the mean and median number per project. The number of awardees who responded to survey queries about these outcomes was 709.

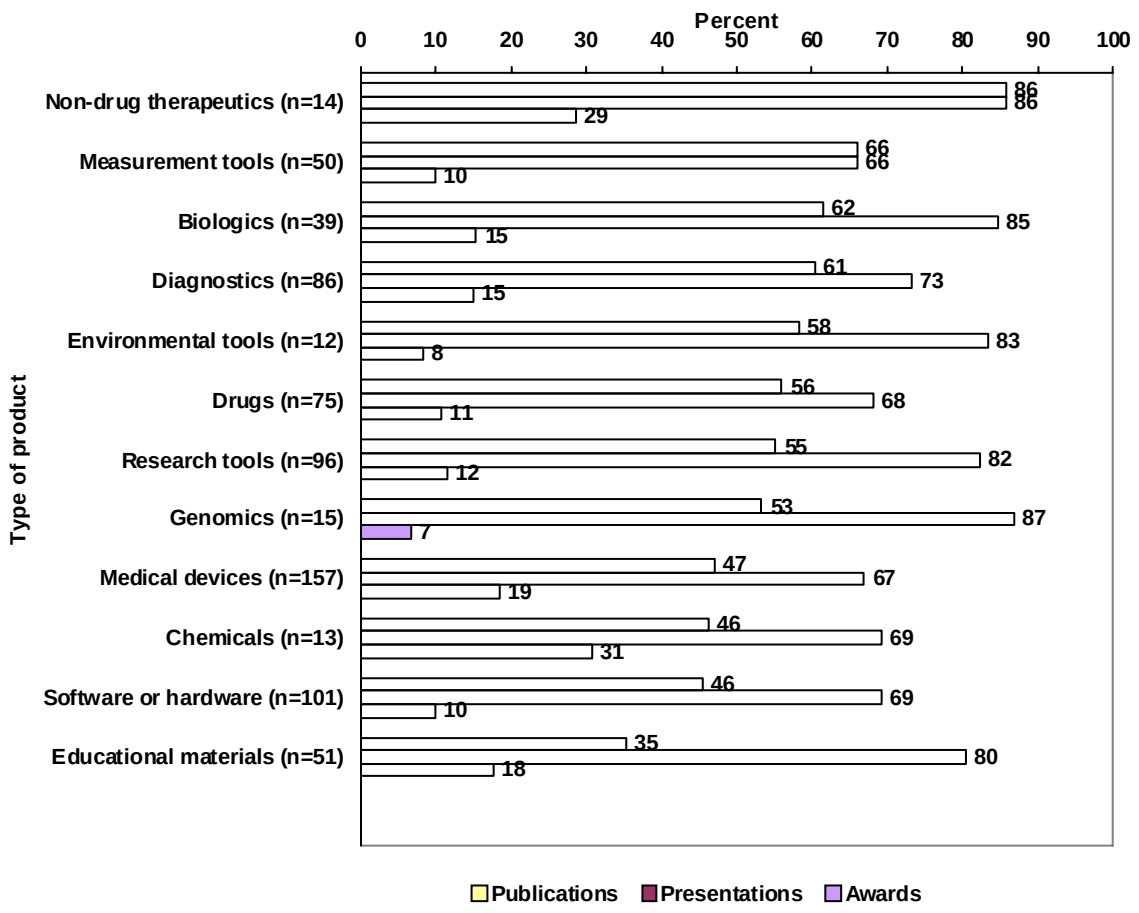
Nearly one-third of awardees reported having obtained one or more patents for their SBIR-supported project. Whether holding a patent or not, 41 percent had a patent application pending. Eighteen percent of the projects reported having one or more copyrights, and 27 percent reported at least one trademark associated with their SBIR product. The majority (69 percent) had at least one patent, pending patent application, copyright, or trademark related to their SBIR project.

Across all 709 responding awardees, SBIR-funded work resulted in 586 patents, 614 pending patent applications, 517 copyrights, and 306 trademarks. Although the average and median numbers of these items per awardee are either 0 or less than 1, it is important to keep mind that patents, copyrights, and trademarks are not relevant outcomes for all awardees. Failure to generate these outcomes may be due partly to the current status of the project, or to the fact that some types of products may have no patent, copyright, or trademark potential.

[11] National Research Council, 2007. *An Assessment of the Small Business Innovation Research Program.* Charles W. Wessner, ed. Washington, DC: National Academy Press.

Exhibit 3-6 shows that the type of SBIR-funded product and receipt of one or more patents, copyrights, and trademarks are related. For example, whereas patents were granted to 48 percent of projects that involved the development and improvement of drugs, very few such projects reported having obtained trademarks (12 percent), and none had obtained a copyright. In contrast, no educational materials products were given patents, but 69 percent had one or more copyrights—the largest percentage among different product types for this outcome.

EXHIBIT 3-6
Awardees with One or More Patents, Copyrights, and Trademarks by Type of SBIR-Supported Product

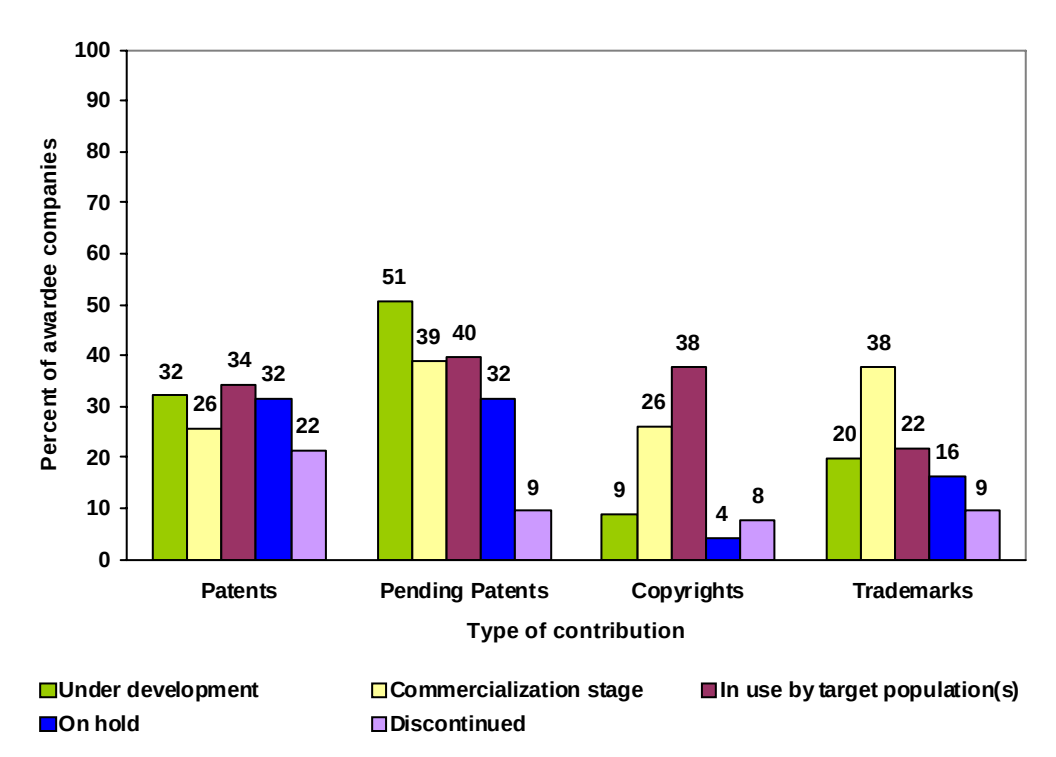


Note. Type of product and having one or more SBIR project-related patents were significantly associated (chi-square statistic=76.4, df = 11, p < 0.0001). This also was true for copyrights and product type (chi-square statistic=180.9, df = 11, p < 0.0001) as well as trademarks and product type (chi-square statistic=24.3, df = 11, p < 0.02. The total number of awardees who responded to survey queries about each of these outcomes was 709.

The extent to which awardees had obtained at least one patent, copyright, or trademark was highly dependent on the type of product supported by the award. Between 48 and 58 percent of environmental tools, biologics, and medical devices had received at least one patent. Educational materials (69 percent) were most likely to have received copyrights. Non-drug therapeutics (57 percent) were most likely to have received trademarks.

As Exhibit 3-7 illustrates, the current status of the Phase II project was significantly related to all intellectual property outcomes, with the exception of patents. The patterns of differences for pending patent applications, copyrights, and trademarks were different. Copyrights were significantly more likely for projects where the product was being commercialized or was actually available for use. Thirty-eight percent of these projects reported receiving one or more copyrights related to the SBIR award, as compared to 9 percent of projects where the product was still being developed, 4 percent of projects that were "on hold," and 8 percent of discontinued projects. The same was true for projects that had reached the commercialization stage; here, 26 percent indicated receipt of at least one copyright. The largest percentage of projects that possessed related trademarks (38 percent) were those in the commercialization stage. The corresponding figures for products under development, in use, "on hold", or discontinued were 20, 22, 16, and 9 percent, respectively.

EXHIBIT 3-7
Reported Patents, Pending Patent Applications, Copyrights, and Trademarks by Status of SBIR-Funded Project



Note. A total of 708 awardee small businesses provided this information. Current project status and having at least one pending patent application were significantly related (chi square statistic=35.7, df=4, p < .0001, p < 0.03). The same was true for current project status and both copyrights (chi square statistic=77.3, df=4, p < .0001) and trademarks (chi square statistic=44.5, df=4, p < .0001)

The current status of the project and having been granted at least one patent were unrelated. Projects whose products were under development were significantly more likely to have at least one pending patent application. Copyrights were significantly more likely for projects that were in the commercialization stage or whose products were in use by the target population. Projects in the commercialization stage were significantly more likely to have one or more trademarks.

Current status of project and receipt of one or more patents were unrelated. Fifty-one percent of projects that were in the midst of product development reported pending patent applications. This percentage is significantly higher than those for all other status categories.

The receipt of one or more patents was significantly related to the fiscal year of the award (chi-square statistic=11.3, df=4, $p < 0.03$). Whereas 38 percent of awardees who received their Phase II award in FYs 2002 or 2003 reported having obtained one or more patents, this was true for 30 percent of FY 2004 awards, 24 percent of FY 2005 awards, and 25 percent of FY 2006 awards. Such results are not unexpected, given that less time had elapsed for the more recently funded projects to have developed their product to the point where a patent application is appropriate. In fact, the start date of the Phase II award and having one or more pending patent applications also were significantly related (chi-square statistic=10.8, df=4, $p < 0.03$); here, the percentage of pending applications was higher for more recently awarded projects (e.g., 48 percent of 2006 awardees versus 30 percent of FY 2002 awardees). In contrast, obtaining a copyright or getting a trademark was not related to fiscal year of the award.

3.3 Performance on Receipt of Additional SBIR Awards

The second major index of degree of technological innovation identified by the Evaluation Framework quantifies the number of awardees who received additional Phase I or Phase II SBIR awards related to the core technology or product referenced in the survey. Exhibit 3-8 shows that 408 awardees (58 percent) who responded to survey questions about this matter reported having competed successfully for one or more additional Phase I or Phase II awards for products related to the supported project.

As also shown by Exhibit 3-8, a larger percentage of awardee companies obtained Phase I awards (58 percent) than Phase II awards (40 percent). This differential success is to be expected. Companies are likely to have more than one idea or product under development at any given time, not all Phase I awardees request Phase II funding, and not all Phase II funding requests are granted.

EXHIBIT 3-8
Additional Related Phase I and Phase II SBIR Awards

	Phase I Award	Phase II Award	Either Phase I or Phase II Award
Awardee Companies			
Number with at least one award	405	283	408
Percent	58	40	58
	Phase I Awards	**Phase II Awards**	**All Awards**
Awards			
Total	1,408	567	1,615
Mean	1.5	0.8	2.3
Standard deviation	1.4	1.4	3.4
Median	1.0	0.0	1.0

Note. A total of 699 awardee small businesses provided information on whether they had received a Phase I or Phase II award, and 604 provided data on the actual number of awards received.

Most awardees had successfully competed for one or more Phase I or Phase II awards related to their SBIR-supported project.

Forty-two percent of awardee companies that competed successfully for additional SBIR awards also reported success in obtaining non SBIR awards for their Phase II funded project. In contrast, only 28 percent of awardees who had not competed successfully for additional SBIR awards reported successfully obtaining non SBIR awards. This difference in performance was statistically significant (chi-square=14.1, df=1, $p < 0.0002$).

3.4 Comparison with 1997-2001 Phase II Awardees

Exhibit 3-9, on the next page, summarizes the performance of FYs 2002-2006 Phase II awardees on the two indices for the goal of stimulating technological innovation. It also compares their performance with that of the FYs 1997-2001 Phase II awardees who responded to the 2002 survey.

The FYs 2002-2006 Phase II awardees met or exceeded each of the two numerical indices identified by the SBIR program. This also was true for FYs 1997-2001 awardees for the one index that could be compared—receipt of additional SBIR Phase I or Phase II awards.[12]

Further study is needed to determine reasons for the significant differences in performance that were observed between the two cohorts:

- A decrease in the total number of technical articles authored by FYs 2002-2006 awardees as compared to their FYs 1997-2001 counterparts (t-test statistic=2.69, df=544, $p < 0.005$).
- A decline for recent awardees in the percentage who obtained at least one patent for their SBIR funded product (chi square statistic=9.7, df=1, $p < 0.002$).
- A decline in the percentage of FYs 2002-2006 awardees who published (chi square statistic=28.0, df=1, $p < 0.0001$).
- A decline in the percentage of recent awardees with scientific conference presentations (chi square statistic=5.4, df=1, $p < 0.02$), which also may be related to the lower percentage who published.

As Ruhm and Link found for a sample of 1992-2001 Phase II awardees, involvement by faculty, graduate students, and other academic personnel did distinguish awardees who commercialized their product from those who did not.[13] This also may be true with regard to publications, given that academic institutions are more likely to emphasize such outcomes. These types of variables could be explored in future studies.

[12]As noted in Chapter 1, the question used to assess performance on the index involving the development of new or improved products was not identical in the 2002 and 2008 surveys, preventing comparison between 1997-2001 and 2002-2006 awardees.

[13]Albert N. Link and Christopher J. Ruhm. *Bringing Science to Market: Commercializing from NIH SBIR Awards. (Working Paper 14057).* (Cambridge, MA: National Bureau of Economic Research, June 2008).

EXHIBIT 3-9
Comparison of NIH SBIR Awardees' Performance in Stimulating Technological Innovation

Performance Index Performance Measure		**Phase II Award Start**					
		FYs 1997- 2001			**FYs 2002- 2006**		
		N	**Percent**	**Total *N***	***N***	**Percent**	**Total *N***
1.1	**Whether or not sales have occurred, 40% or more of NIH SBIR awardees produce new or improved products, processes, usages, and/or services in support of the NIH mission**						
1.1.1	Number of new or improved SBIR supported products in health-related fields	--	--	--	587	82	719
1.1.2	Number of technical articles on new or improved SBIR-supported products	369	68	545	375	53	709
1.1.3	Number of patents for new or improved SBIR-supported products	213	39	546	217	31	709
1.2	**10% or more of NIH SBIR awardees receive additional Phase I or Phase II awards that relate to the core technology**						
1.2.1	Number and percent of awardees who received additional related Phase I or Phase II awards	298	56	535	408	58	699

Note. Performance indices and measures are posited by the Evaluation Framework (Appendix A). The FY 1997-2001 results are based on analyses of this subset of NIH SBIR program 2002 survey data to allow comparisons for this report. Further study is needed to determine reasons for apparent differences in performance. Differences in question wording between the 2002 and 2008 surveys did not allow comparison of performance for Performance Index 1.1.1.

Comparisons of performance for awardees that received SBIR awards between FYs 1997-2001 and those that received awards between FYs 2002-2006 showed both similarities and differences in performance for performance indices 1.1 and 1.2 and associated measures. For technical articles and patents, performance levels did differ. Significantly larger percentages of awardees in the earlier cohort had published at least one technical article (68 percent) and obtained one or more patents (39 percent). The corresponding percentages for FY 2002-2006 awardees were 53 and 31 percent, respectively. Both cohorts far exceeded the stated benchmark of 10 percent for receiving additional SBIR funding that was related to the core technology supported by the Phase II award. Their level of performance also was quite similar—56 percent of FY 1997-2001 awardees and 58 percent of FY 2002-2006 awardees.

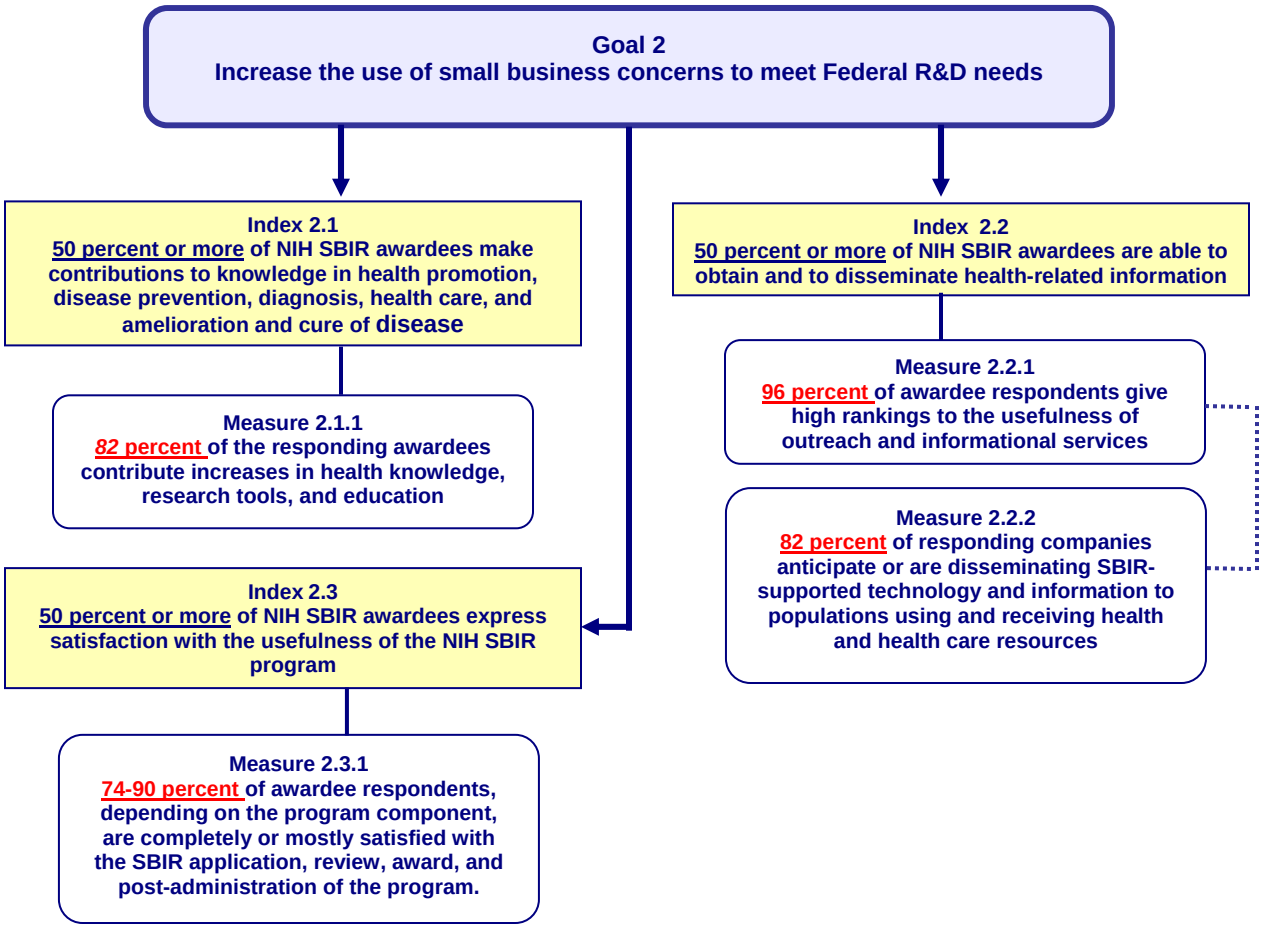
4. INCREASED USE OF SMALL BUSINESS CONCERNS

This chapter presents findings about attainment of the second NIH SBIR program goal addressed by the survey, *using small business concerns to meet Federal research and development (R&D) needs*. It opens with a summary of findings about goal attainment. Then it presents analyses of each related index and overall performance of SBIR awardees over time.

4.1 NIH SBIR Awardees Met Federal Research and Development Needs

Exhibit 4-1 displays the survey findings about awardee outcomes related to using small business concerns to meet Federal R&D needs. Phase II awardees reported exceeding specified benchmarks for all three related indices in the Evaluation Framework—contributing specified types of knowledge, obtaining and disseminating health-related information, and expressing satisfaction with the usefulness of the NIH SBIR program.

EXHIBIT 4-1
Summary of Outcomes Associated with
Using Small Business Concerns to Meet Federal Research and Development Needs



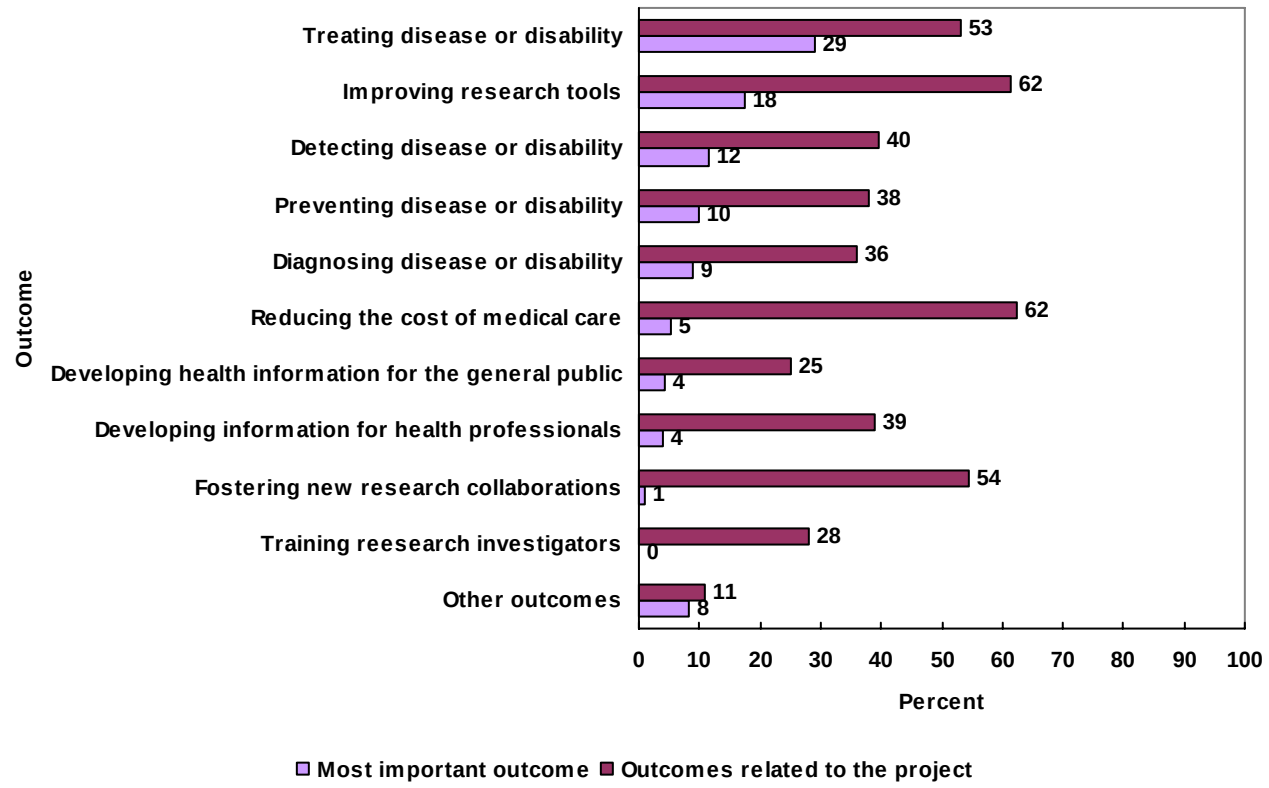
Awardees' reported performance in attaining each performance index *at the time of survey measurement* is described in the following sections.

4.2 Performance on Contributions to Knowledge

Survey respondents reported having far exceeded the Index 2.1 benchmark that 50 percent or more of awardees contribute to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease. They provided strong evidence of having provided the increases in health knowledge, research tools, and education specified by Measure 2.1.1.

To identify these contributions, the survey asked the awardees themselves to select which of 11 specific medical, societal, and technological outcomes were associated with their funded project. This list was developed by NIH personnel as those contributions most relevant to health promotion as well as prevention, diagnosis, treatment, and cure of disease. Awardees were first asked to choose the outcomes most relevant to their product; they were then to identify the one outcome that was most important. Exhibit 4-2 lists the specific outcomes included in the 2008 survey instrument. As shown by the exhibit, projects typically had multiple outcomes. In fact, only 11 percent of respondents identified only one of the 11 outcomes listed; the median number of outcomes was four.

EXHIBIT 4-2
Medical, Societal, or Technological Outcomes of SBIR-Funded Projects



Note. A total of 714 awardee small businesses provided information about whether each specific outcome applied to their SBIR-funded project. Data on the most important outcome were provided by 712 awardees.

SBIR-supported projects, in general, had multiple outcomes. Most outcomes were associated with health care, enhancing the quality of research, or both. Respondents cited treating disease and disability and improving research tools as the most important outcomes.

Most common were two outcomes associated with providing health care—reducing the cost of medical care (62 percent) and treating disease or disability (53 percent)—and two aimed at enhancing the quality of research—improving research tools (62 percent) and fostering new research collaborations (54 percent). The next most frequent outcomes all were targeted at health care issues; between 30 and 40 percent of awardee companies viewed disease prevention, detection, diagnosis and developing information for health professionals as outcomes of their projects. Another research outcome—training new investigators—was viewed as relevant by 28 percent of awardees.

When awardees were asked to identify the *most important* outcome, addressing healthcare and research needs remained top priorities. Twenty-nine percent of SBIR-funded small businesses indicated that treating disease and disability was the most important outcome associated with their project, and another 18 percent attached the same level of importance to improving research tools. Other outcomes were deemed most important by smaller percentages of awardees. For example, reducing the cost of medical care, although chosen as one outcome by 62 percent of respondents, was viewed as the most important outcome by only 5 percent of the projects. Similarly, more than one half (54 percent) believed that fostering research collaborations was an outcome of their SBIR award, but only a very small minority (1 percent) believed it to be the most important outcome. Overall, 92 percent believed that the most important outcome for their SBIR-funded project was one of these healthcare or research outcomes.

It is interesting to note that significant differences repeatedly appeared in the relationship between the current project status and both (1) whether a specific outcome was attributed to an SBIR-funded project, and (2) which outcome was identified as most important. Projects still in the developmental stage were more than twice as likely to identify treating disease as the most important outcome (45 percent) than were completed projects and those being commercialized (20 percent for each) When compared to completed projects, projects that were developing their products also were significantly less likely to believe their most important outcome was the improvement of research tools (chi-square statistic=80.8, df=10, $p < 0.001$). Whereas only 11 percent chose this as their primary outcome, this was true for 24 percent of products that already had been made available for use by the target population(s).

Such differences in perspectives might be expected, given that different types of products have different timelines for product development. As reported in Chapter 2, current project status was related to type of product, and certain types of products (e.g., specific types of research tools) may require less time to develop and thus be available more quickly. In addition, views of outcomes most likely change as products move further along the product development pathway. During the product development phase, goals are broad, a host of ideas are continuously tested, and modifications are made. By the time a product is ready for commercialization, however, developers have a much clearer idea about the product's capabilities and expected outcomes.

Performance assessment for this index focused on awardees that are still in the development phase, commercializing their product, or completed their project and making it available to consumers. This was the method used in assessing performance in the 2002 survey. A total of 587 projects (82 percent) fell into these categories.

Technical articles and conference presentations also represent contributions to health-related knowledge. However, the Evaluation Framework includes these types of contributions as a measure of the extent to which SBIR awardees develop new and improved products consistent with the NIH mission (Goal 1) rather than as a measure of contributions to knowledge (Goal 2). As reported in Chapter 1, sizable percentages of awardees have published one or more technical articles and presented at scientific conferences. This includes both projects in the developmental and commercialization stages, those that have made their product available for use by the target populations(s), and projects that have been

discontinued. Given that publications and presentations are not included as a measure for Goal 2, both estimates of the percentage of projects that make contributions to health-related knowledge most likely would increase if publications, presentations, and patents also were defined as relevant to include under Measure 2.1.1.

4.3 Performance on Dissemination of Information

The second index for assessing performance on the overall goal of using small business concerns to meet Federal R&D needs focuses on the dissemination of health-related information. The Evaluation Framework describes dissemination as having two distinct aspects. First, the NIH should disseminate information to their awardee companies. Second, Phase II awardees are responsible for disseminating health-related information to populations using and receiving health care resources.

4.3.1 NIH Dissemination to SBIR Phase II Awardees

Measure 2.2.1 quantifies and describes awardee perception of the usefulness of the NIH SBIR/STTR program office's outreach and informational services. When asked if they were aware that they could contact NIH staff for more information about the program or assistance with the application, review, award, and award management, an overwhelming 96 percent of awardees responded affirmatively. There were no significant differences in these perceptions among awardees with different award start dates, different sponsoring Institutes/Centers (ICs), or whether they had received other related SBIR awards.

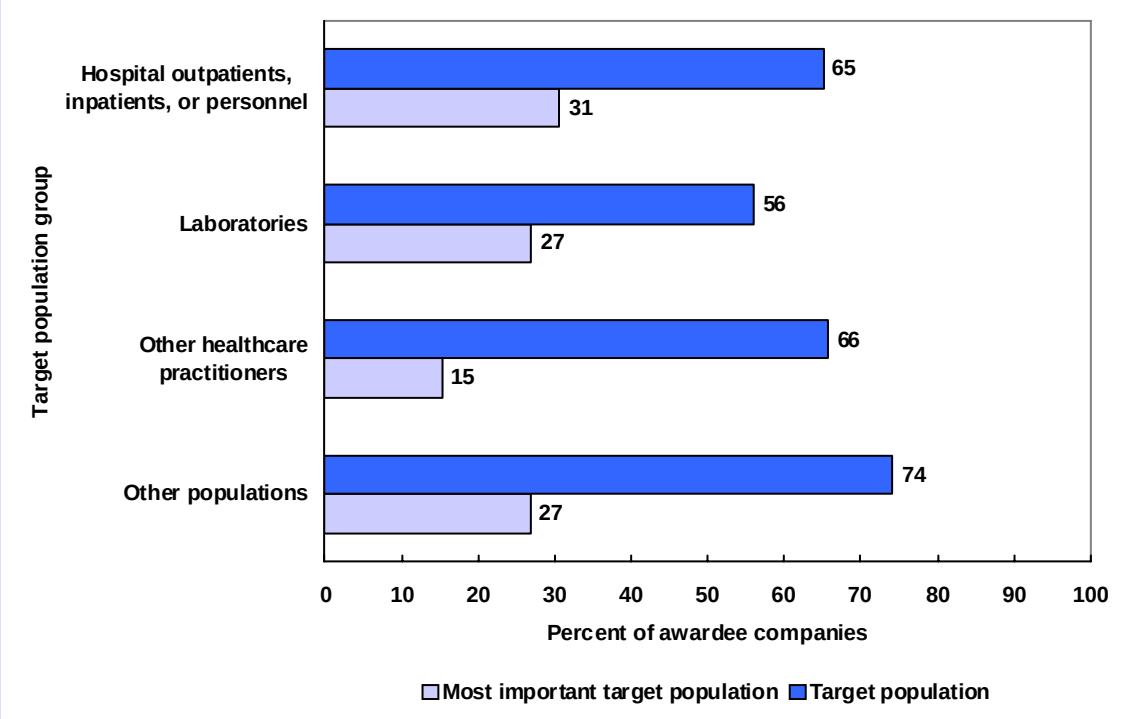
4.3.2 Awardee Dissemination of Health-Related Information

Measure 2.2.2 quantifies and describes the awardees who anticipate or are disseminating SBIR-supported technology and information to populations using and receiving health and health care resources. The 2008 survey asked awardees to identify the potential or actual target populations for their product as well as which target population was most important. Similar to the measure for contributions to knowledge, the 17 specific target populations, as well as the four broader target groups under which these target populations fell, were identified by NIH personnel.

The four broad target groups of key interest were: (1) hospital inpatients, outpatients, or staff; (2) other healthcare practitioners, such as physicians, nurses, home care providers and emergency medical technicians; (3) laboratories, and (4) other populations, including the general public, worksites, municipal workers, and educational institutions. Awardees typically reported that their SBIR-supported product was likely to be used by one or more major target population group.

Exhibit 4-3 on the next page shows which major target population groups were cited as using or likely to use the SBIR-supported product. Sixty-five percent said that hospital inpatients, outpatients, or staff were using or likely to use their product. Nearly two-thirds (66 percent) said SBIR-supported products were used or likely to be used by other healthcare practitioners. Fifty-six percent were intended for use by research and/or diagnostic laboratories. Nearly three-quarters (74 percent) were targeted to other populations. As also shown by Exhibit 4-3, awardees reported that the most important target population was least frequently other healthcare practitioners (15 percent) and most often the other three categories (27 to 31 percent).

EXHIBIT 4-3
Target Population Groups that Use or Are Likely to Use the SBIR-Supported Product



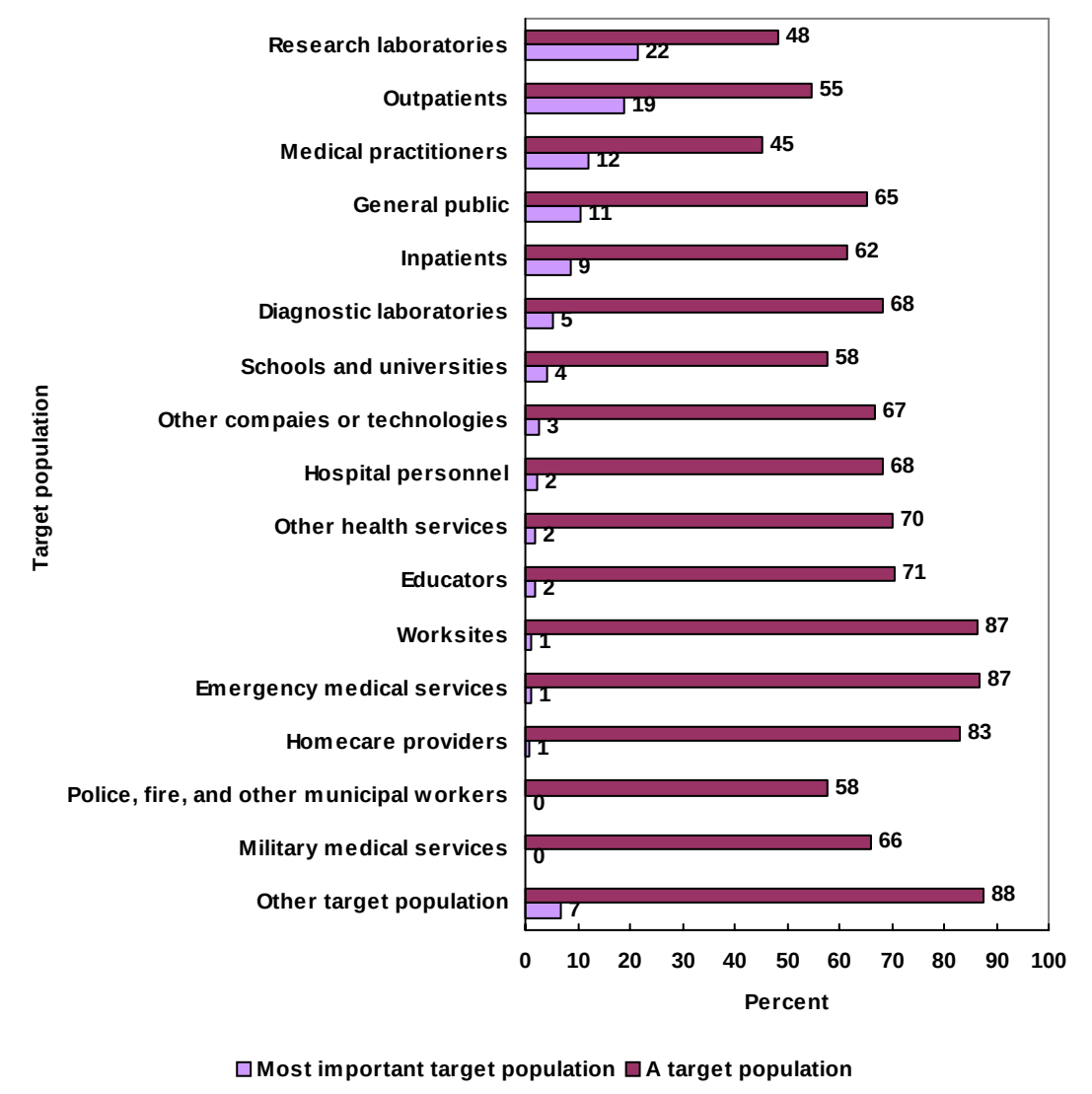
Note. A total of 658 awardee small businesses provided information about whether their SBIR-funded project was directed at each of the four target population groups. Data on the most important target population group were reported by 651 awardees.

SBIR-supported products are directed at four broad target population groups: hospital outpatients, inpatients, or personnel; laboratories; other healthcare practitioners; and other populations. Between 56 and 74 percent of awardees stated that their product focused on each of these four different target population groups. When asked about their product's most important target population, 31 percent of awardees identified one in the hospital outpatients, inpatients, or personnel target group. The corresponding percentages for laboratories, other healthcare practitioners, and other populations were 27, 15, and 27 percent, respectively.

As shown by Exhibit 4-4 (on the next page), many awardees said that their SBIR projects target several specific populations within the target population groups. The median number of specific populations selected was five. Eight percent of awardees identified only one specific target population for their SBIR-supported project.

Of the 16 specific target populations listed in the survey, all but five (research laboratories, outpatients, medical practitioners, schools and universities, and municipal workers) were identified as targets by nearly two-thirds or more of awardees. Worksites, emergency medical services, and homecare providers were cited as a target population most frequently, and more than 80 percent of the time. Medical practitioners and research laboratories were cited as a target population least frequently, and less than 50 percent of the time.

EXHIBIT 4-4
Target Populations Currently Using or Likely to Use SBIR-Funded Products



Note. A total of 658 awardee small businesses provided information about whether each specific target population applied to their SBIR-funded project. Data on the most important outcome was reported by 651 awardees.

Of the 16 specific target populations listed in the survey, all but five were identified as a target population by nearly two-thirds or more of awardees. The two specific target populations that were identified as the most important by the largest percentages of respondents were research laboratories and outpatients.

For the hospital populations, outpatients, inpatients, or personnel category, awardees most frequently identified outpatients as their most important target population (19 percent). For laboratories, awardees most often stated that their most important population was research laboratories (22 percent). For other healthcare practitioners, medical practitioners emerged as the key target population (12 percent). Finally, when considering other populations, the general public was the key group, chosen by 11 percent of respondents. Other specific populations were the most important target for smaller groups of awardee businesses (1 to 9 percent).

Current project status was related to both whether awardees identified a target population group for their SBIR-funded project and which segment was most important. Although no differences surfaced with regard to research and diagnostic laboratories, they did appear for the other target population groups. The primary disparities occurred between "on hold" projects and those at more active stages. Whereas 31 percent of the products in development, 25 percent of projects in the commercialization stage, and 30 percent of completed projects saw hospitals as a target population, this was true for only 14 percent of projects that were "on hold." Only with regard to other target populations did a different pattern emerge. Here, 50 percent of projects in the midst of developing their products identified a specific target population such as the general public, worksites, or schools and universities, compared to between 16 and 18 percent of projects at other stages.

When one considers only the most important specific target population, 41 percent of projects in the developmental stage viewed hospitals as their most important consumers. However, only 17 percent of completed projects, 23 percent of projects in the commercialization stage, and 34 percent of projects "on hold" held similar opinions.

Exhibit 4-5, on the following page, presents SBIR awardees' estimates of the anticipated size of the primary target population for their products. All awardees estimate that the largest target population is the general public; 72 percent of the companies that are gearing their product toward this group judge its size as equal to or exceeding 500,000. The same percentage of companies whose most important target population is other health service practitioners also estimate these groups to be of similar size, as do the 69 percent of projects with medical practitioners as their key constituency. Between 52 and 56 percent of awardees who identified diagnostic labs, outpatients, and other populations also expect these groups to be relatively large.

Multiplying the number of respondents in each size category by the midpoint of each category yields a rough estimate of the size of the total population being served, for most size categories. Estimates for the category of 500,000 or more used the start point of 500,000 because the category's upper limit was not specified. This yields 145.2 million as the approximate total size of all populations using and receiving products relevant to health prevention, detection, diagnosis, and treatment as well as biomedical research. This is clearly a "guesstimate" for several reasons. In addition to using the midpoint of each size category, this figure does not take into account that several SBIR projects can have products that are aimed at the same group(s) of individuals, and it relies on the information provided by respondents, whose actual knowledge of the size of the target population may vary.

EXHIBIT 4-5
Anticipated Size of Most Important Target Populations for Ongoing Projects

Target Population Group	Total	Anticipated Size of Population									
		Under 10,000		10,000 – 49,999		50,000 – 199,999		200,000 – 499,999		500,000 or more	
		N	%	*N*	%	*N*	%	*N*	%	*N*	%
Hospitals											
Outpatients	108	10	9	8	8	19	18	9	8	61	56
Inpatients	53	10	19	9	17	8	15	4	8	22	42
Hospital personnel	13	3	22	2	15	2	15	0	0	6	46
Laboratories											
Research laboratories	99	55	56	18	18	10	10	3	3	13	13
Diagnostic laboratories	23	3	13	1	4	2	9	5	22	12	52
Other healthcare practitioners											
Medical practitioners	69	7	10	10	14	8	12	6	9	38	69
Other health services	18	0	0	2	11	2	11	1	6	13	72
Other populations											
General public	60	4	7	6	10	3	5	4	7	43	72
Educators	10	1	10	5	50	1	10	2	20	1	10
Schools and universities	19	5	26	4	21	1	5	2	11	7	37
Other companies or technologies	48	8	17	7	15	3	6	3		27	56
Total	520	106	20	73	14	59	11	39	8	243	47

Note. Due to small sample sizes, home care providers and emergency medical services were combined with other health services populations. For the same reason, worksites, police and other municipal workers, and other companies also were included under Other Populations that are not the general public, educators, or educational institutions.

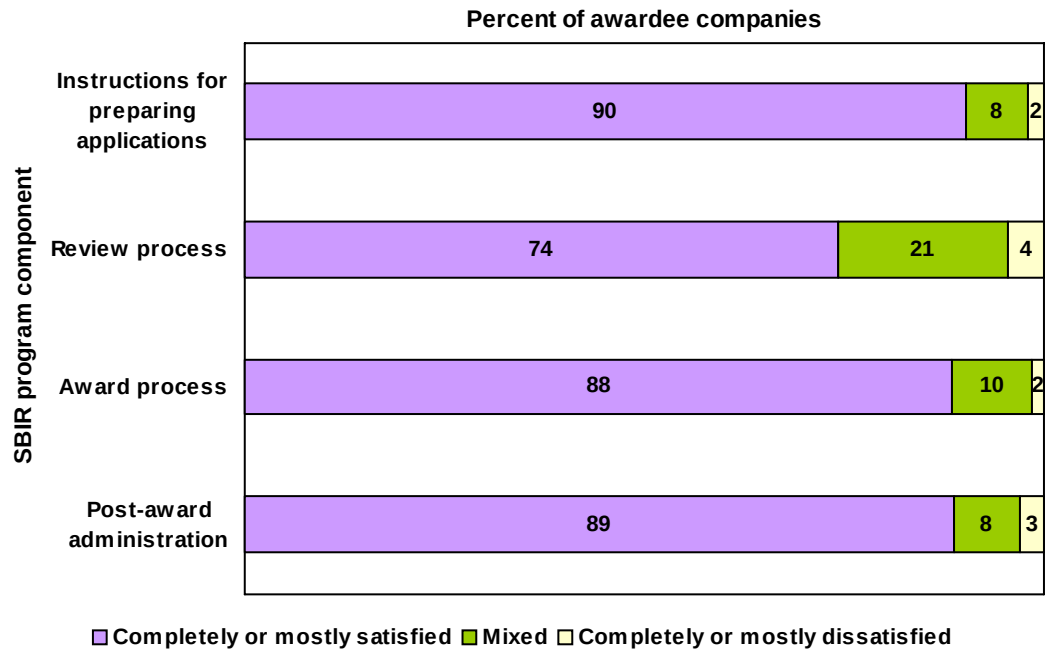
More than two-thirds of projects that identified the general public, medical practitioners or other health services professionals anticipated their target populations to total at least 500,000. This also was true for 52 percent of projects whose major target population was diagnostic laboratories and 56 percent of projects with products primarily aimed at outpatients. Nearly three-quarters (74 percent) of awardees working on core technologies for research laboratories, and 60 percent of awardees with projects aimed at educators, expected their most important target population to be less than 50,000.

4.4 Satisfaction with the SBIR Application, Review, Award, and Post-Award Processes

Index 2.3 describes awardees' satisfaction with selected aspects of the SBIR program. Measure 2.3.1 benchmarks degree of satisfaction with the NIH SBIR application, review, award, and post-administration processes.

Exhibit 4-6 summarizes awardees' judgments about the adequacy of the instructions for preparing applications, the review and award processes, and post-award administration. For each, levels of satisfaction were high. Between 88 and 90 percent were completely or mostly satisfied with the quality of the instructions for preparing applications, the award process, and the administration after their grant had been awarded.

EXHIBIT 4-6
Awardee Satisfaction with the NIH Application, Review, Award, and Post-Award Processes



Note. A total of 658 awardee small businesses provided information about whether each specific outcome applied to their SBIR-funded project. Data on the most important outcome was reported by 652 grantees. The total numbers of awardees who rated each aspect ranged from 704 to 708. Respondents used a 5-point rating scale where 1 was "completely satisfied", 2 was "mostly satisfied", 3 was "mixed", 4 was "mostly dissatisfied", and 5 was "completely dissatisfied." The numbers shown are percentages and may not sum to 100 percent due to rounding.

SBIR Phase II awardees expressed high levels of satisfaction with the application, review, award, and post-award administrative components of the program. Between 88 and 94 percent were completely or mostly satisfied with all components except the review process, which completely or mostly satisfied 74 percent.

The one component that generated a somewhat lower level of satisfaction was the review process, but even here 74 percent were completely or mostly satisfied and only 4 percent were completely or mostly dissatisfied. Twenty-one percent held more mixed views. This expression of ambivalence is not uncommon for the recipients of NIH funding in an environment that is increasingly competitive and where even successful awardees often have to revise and resubmit their applications one or more times before securing funding.

Satisfaction levels did not differ significantly by fiscal year of award or by IC grouping. Although overall satisfaction levels remained high, they did depend somewhat, however, on whether awardees had won other related SBIR awards. Whereas 92 percent of small businesses that had no additional SBIR funding were satisfied with the award process, this was true for 86 percent of awardees who had won other SBIR grants (*chi-square statistic*=7.5, *df*=2, $p < 0.03$).

Averaging the satisfaction ratings across the four components for each respondent yielded an index of satisfaction for each respondent. The average rating was 1.75 (standard deviation = 0.60). Using a 5-point rating scale that was used where 1 = "completely satisfied" and 2 = "mostly satisfied", indicates that awardees' overall satisfaction level is slightly higher than "mostly satisfied." This represents a very positive assessment.

Awardees were asked whether the project funded by the award would have been pursued if SBIR support had been unavailable. Only 12 percent of companies believed that the project would still have been undertaken, and 67 percent thought that it never would have been initiated. Twenty percent were uncertain about what would have happened. Again, no significant differences in responses were found, depending on the fiscal year of the award, the receipt of other related SBIR awards, IC grouping, or type of product sponsored by the award.

Finally, respondents indicated how important SBIR support was or will be in the R&D of the planned product. Again, the overwhelming majority (89 percent) believed it was very important, and 9 percent judged it as important. Only 1 percent said that it was somewhat important, and less than 1 percent each deemed SBIR support as not important or not very important. Again, there were no significant differences in responses by type of product, fiscal year, IC grouping, or receipt of other SBIR awards.

4.5 Comparison of Two Awardee Cohorts' Performance in Increasing the Use of Small Business to Meet Federal R&D Needs

Exhibit 4-7, on the following page, presents data about awardees performance in increasing the use of small business to meet Federal R&D needs. The exhibit describes performance for three indices and their associated measures for the Phase II awardees in FYs 1997-2001 and FYs 2002-2006.

As shown by the exhibit, the FY 2002-2006 awardees exceeded the 50 percent benchmark for index 2.1—making contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease. As was noted in Chapter 1, comparisons of these awardees' performance with those of the earlier survey cohort could not be made for this index due to a difference in question wording between the two survey instruments.

EXHIBIT 4-7
Comparison of NIH SBIR Awardees' Performance in Increasing Use of Small Business to Meet Federal R&D Needs

Performance Index Performance Measure		Phase II Award Start					
		FYs 1997-2001			FYs 2002-2006		
		N	Percent	Total *N*	*N*	Percent	Total *N*
2.1	**50 percent or more of NIH SBIR awardees make contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease**						
2.1.1	Number and percent of SBIR-supported contributions from ongoing projects that yield increases in health knowledge, research tools, and education	--	--	--	567	82	719
2.2	**50 percent or more of NIH SBIR awardees are able to obtain and disseminate health-related information**						
2.2.1	Number and percent of awardee companies that gave high rankings to the usefulness of outreach and informational services	528	94	559	674	96	705
	Number of disseminations of SBIR-supported technology and information among populations using and receiving health and health care resources	--	--	--	587	82	719
2.2.2	Number and percent of awardees who have or anticipate disseminations of SBIR-supported technology and information among populations using and receiving health and health care resources	--	--	--	587	82	719
2.3	**50 percent or more of NIH awardees express satisfaction with the usefulness of the NIH SBIR program**						
2.3.1	Numbers and percents of awardee companies experiencing high levels of satisfaction with the SBIR application, review, award, and post-award administration of the NIH SBIR program	414-498	74-89	554-560	526-637	74-90	704-708

Note. The FYs 1997-2001 results are based on analyses of this subset of NIH SBIR program 2002 survey data to allow comparisons for this report. Further study is needed to determine reasons for apparent differences in performance. The 2008 survey added a response option that affected more than one outcome measure; therefore, it was not possible to compare performance in terms of the percents of awardees that make health-related contributions or who have or anticipate making disseminations of SBIR-supported technology and information.

Comparisons of performance between awardees for FYs 1997-2001 and FYs 2002-2006 were limited to two measures. For both measures, the percentages were very similar. Between 94 and 96 percent of awardees gave high rankings to outreach and informational service for measure 2.2.1. Between 74 and 90 percent of the two cohorts expressed high levels of satisfaction with the SBIR application, review, award, and post-award administration of the program for measure 2.3.1.

The SBIR program consistently outperformed the index for disseminating information to its awardees. Ninety-six percent of FYs 2002-2006 awardees gave high marks to these efforts, similar to the 94 percent obtained for the earlier cohort of respondents.

FYs 2002-2006 awardees also exceeded the third index regarding awardee satisfaction with the SBIR program. From 74 to 90 percent expressed high levels of satisfaction with the application, review, award, and post-award administration processes. These results were consistent with those for the earlier cohort.

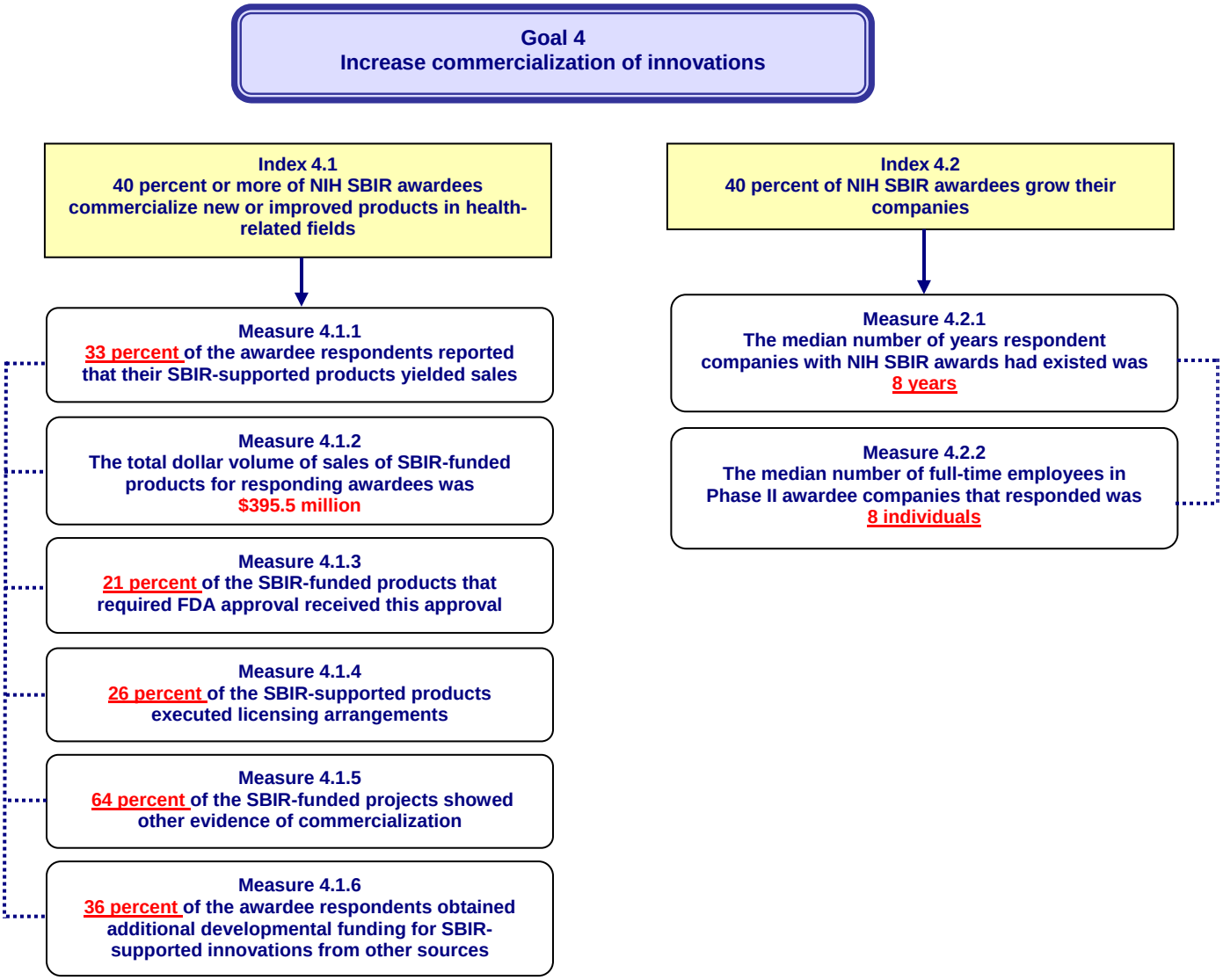
5. COMMERCIALIZATION OF INNOVATIONS

This chapter presents findings about attainment of the third NIH SBIR program goal addressed by the survey and the fourth goal in the Evaluation Framework, *commercializing innovations.* It opens with a summary of findings about goal attainment. Then it presents analyses of each related index and overall performance of SBIR awardees over time.

5.1 NIH SBIR Awardees Commercialized Innovations

Exhibit 5-1 displays the survey findings about awardee outcomes related to commercializing innovations. Phase II awardees reported attainment of benchmarks that bode well for success.

EXHIBIT 5-1
Summary of Outcomes Associated with Commercializing Innovations



Awardees' reported performance in attaining each performance index *at the time of survey measurement* is described in the following sections.

5.2 Performance in Commercializing SBIR-Funded Products

This section reports on reported awardee attainment of six related measures in the realms of sales, FDA approval, licensing arrangements, other evidence of commercialization, and additional developmental funding. In assessing performance for Index 4.1, commercialization is defined as accomplishing one or more of these outcomes. By this definition, 76 percent of the FYs 2002-2006 awardees that provided the necessary information commercialized new or improved products in health-related fields.

5.2.1 Product Sales

Overall, 581 (88 percent) of the awardees with ongoing projects anticipated sales upon completion of their projects. This is roughly the same percentage as for the 2002 survey, when 85 percent of awardees expected sales.

As shown by Exhibit 5-2 on the next page, large majorities of awardees, regardless of the type of SBIR funded product, expected or had achieved sales. With only a few exceptions, whether sales were expected did not dramatically differ among companies working on different types of products; the percentage foreseeing sales ranged between 88 and 94 percent for all but three types of products. The percentages expecting sales for companies working on drugs and those developing diagnostic materials or devices were, however, significantly lower than companies with other types of projects. Here, 80 to 81 percent of these awardees expected sales (chi-square statistic = 16.0, df=1, $p < 0.001$). In addition, 67 percent of companies whose SBIR-supported project involved biologics foresaw sales, and this percentage was significantly lower than those mentioned for any other type of product ($p < 0.0001$).

The survey asked awardees who anticipated sales upon completion of their projects whether their expectations had been realized. When project status is not taken into account, 33 percent or 189 SBIR-supported new or improved products yielded sales; 59 percent stated that sales were still anticipated; and 8 percent described other situations, in which sales were uncertain because the project was "on hold."

EXHIBIT 5-2
Number and Percent of Awardees that Expected Sales by Type of Product

Type of product	Total *N*	Expectations for Sales	
		N	Percent
Drugs	70	57	81
Medical devices	149	138	93
Biologics	40	27	68
Genomics	14	13	93
Research tools	91	84	92
Software or hardware	90	83	92
Educational materials	48	45	94
Diagnostic materials or devices	80	63	79
Measurement or assessment tools	46	40	87
Environmental tools	11	10	91
Chemicals	10	9	90
Non-drug therapeutics	13	11	85
Total	662	581	88

Note. Data are for projects that are under development, being commercialized, already in use by the target population or on hold. No projects that had been discontinued expected sales.

Overall, large majorities of awardees expected sales at the start of their SBIR-supported projects. Awardees developing drugs, biologics, and diagnostics expected significantly lower sales (68 to 81 percent) than did awardees working on other types of products (85 to 94 percent).

When the elapsed time between the start date of the Phase II award is considered, one gains more insight regarding the potential of awardees' sales expectations being fulfilled. As Exhibit 5-3 on the next page shows, between 36 and 46 percent of awardees whose Phase II award began in FYs 2002-2005 reported that sales had been realized, compared with 24 percent for awardees whose award began in FY 2006.

EXHIBIT 5-3
Current Status of Sales by Fiscal Year of Phase II Award

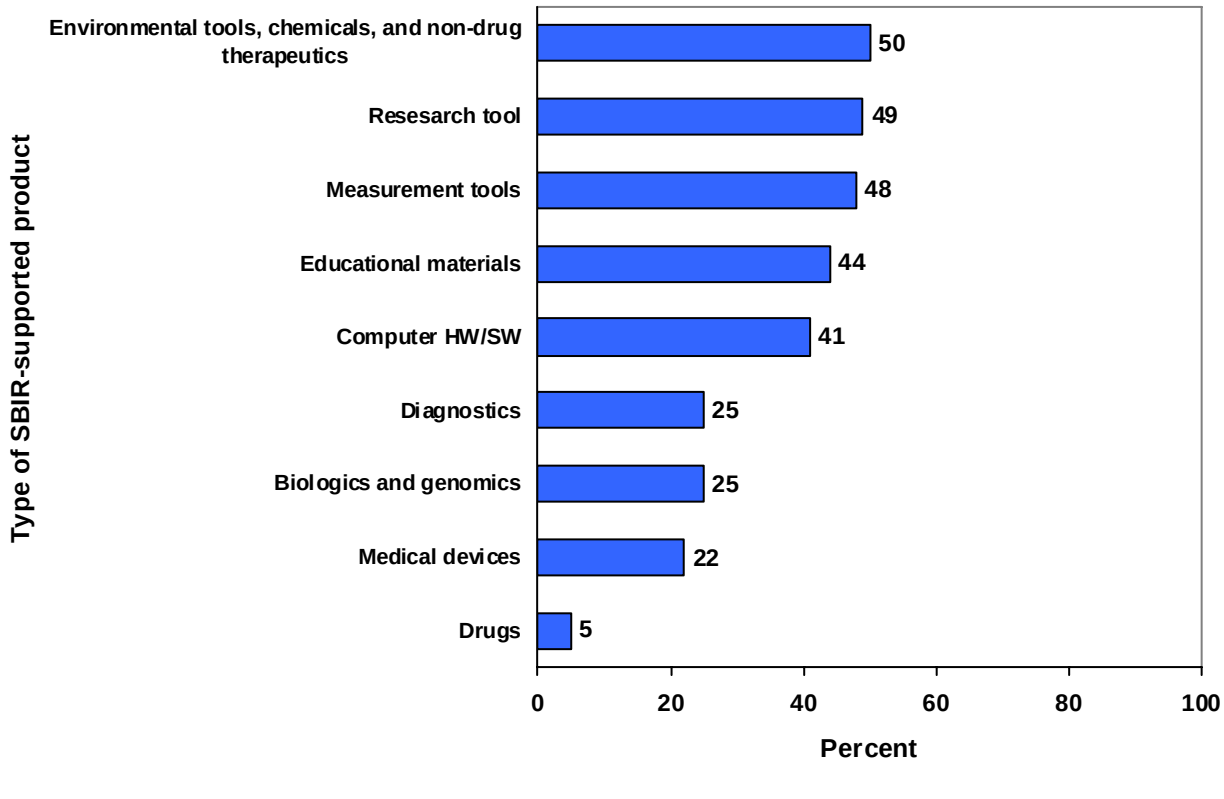
Start date of Phase II award (fiscal year)	Total *N*	Status of Expected Sales	
		Realized	Anticipated
		N (%)	*N (%)*
2002	92	42 (46)	50 (54)
2003	107	33 (31)	74 (69)
2004	103	35 (34)	68 (66)
2005	107	38 (36)	69 (64)
2006	171	41 (24)	130 (76)

Note. Data are for 580 ongoing projects that reported expected sales. Award date and status of sales were significantly related (chi-square = 13.6, $df = 4$, $p < 0.009$).

Among awardee companies that anticipated sales, the elapsed time from the start date of the Phase II award to survey administration was significantly related to whether sales were realized. Awardees that received the Phase II SBIR award in FY 2002 were the most likely to have realized their sales expectations; those that received the award in FY 2006 were least likely to have realized sales.

The characteristics of SBIR-funded products were examined more closely for the ongoing projects that started between FYs 2002-2006 that expected sales (see Exhibit 5-4 on the next page). The type of product was significantly related to current sales status. Half or nearly half of the projects that produced chemicals, environmental tools, or non-drug therapeutics, research tools, and measurement tool products had already realized sales. However, this was true for only 22 to 25 percent of projects with medical device, biologic, genomic, and diagnostic products. Only 5 percent of projects working on drug products had achieved expected sales. These differences may well be a function of several factors that can increase the time required to make a product commercially available, such as requiring FDA approval.

EXHIBIT 5-4
Realization of Sales upon Project Completion by Type of SBIR-Supported Product



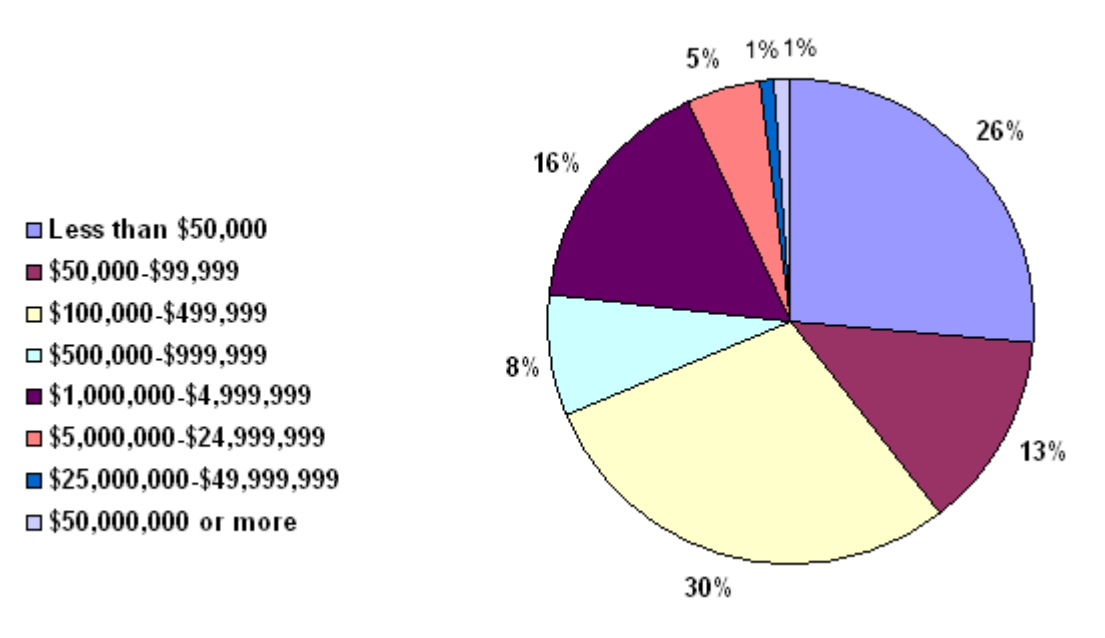
Note. Data are for 579 ongoing projects that reported whether expected sales had been realized. Status of sales was significantly related to type of product (chi-square statistic=52.4, *df*=8, $p < 0.0001$)

As would be expected, there were significant differences between whether sales had been realized and the type of product supported by the Phase II award. Projects involving the development or improvement of environmental tools, measurement tools, and non-drug therapeutics; research tools; educational materials; and computer hardware and software were most likely to have realized sales.

5.2.2 Cumulative Sales

Measure 4.1.2 indicates commercialization attainment levels by quantifying the total dollar volume of sales of SBIR-supported products. Of the 189 awardees who realized sales, 184 provided information about the amount of total cumulative sales through December 2007. As shown in Exhibit 5-5 on the next page, 66 percent of awardees reported cumulative sales totaling less than $1 million. Sixteen percent indicated sales of at least $1 million but less than $5 million. Seven percent reported sales of $5 million or more; typically, these sales did not quite reach $25 million.

EXHIBIT 5-5
Amount of Cumulative Sales for Completed SBIR-Funded Projects



Note. Data are for the 184 ongoing projects that reported realizing sales and provided information on the amount of cumulative sales as of December 2007. Percents may not total 100 percent due to rounding.

The large majority (66 percent) of awardees indicated that their cumulative sales totaled less than $1 million. Sixteen percent reported cumulative sales of at least $1 million but less than $5 million. Seven percent generated sales of $5 million or more.

An estimate of cumulative total sales can be obtained by using the midpoint of each sales category and the start point of the final unbounded category ($50 million or more). This yields an estimate of cumulative total sales through December 2007 is $395.5 million, with an average amount per project of approximately $2.15 million.

Certain types of products generated more sales dollars than others (see Exhibit 5-6 on the next page). The total cumulative sales across all projects that focused on research tools nearly reached $100 million. For medical devices, the corresponding figure was approximately $73 million. In contrast, educational materials generated the lowest sales figures; 20 products produced a total of $4.8 million.

EXHIBIT 5-6
Percent of Companies that Achieved Cumulative Sales by Type of Product

Type of product	Total *N*	Amount of cumulative sales through December 2007 (in thousands)								
		$50 or less	$50-$99	$100-$499	$500-$999	$1,000-$4,499	$5,000-$24,999	$25,000-$49,999	$50,000 or More	Estimated total across all products
		Percent of Projects								
		%	%	%	%	%	%	%	%	
Drugs	3	0	0	0	33	33	33	0	0	$18,750
Medical devices	29	24	14	24	14	17	3	3	0	$73,075
Biologics and genomics	10	30	0	30	10	10	10	10	0	$57,225
Research tools	40	10	10	38	5	28	10	0	0	$99,400
Software or hardware	33	21	15	33	6	18	6	0	0	$53,350
Educational materials	20	75	5	10	5	5	0	0	0	$4,800
Diagnostic materials or devices	15	20	40	20	7	13	6	0	0	$8,175
Measurement or assessment tools	19	26	16	37	5	11	5	0	0	$24,200
Other	15	27	7	40	13	7	0	0	0	$56,475
Total, all products	184	48	13	29	8	16	5	1	0	$395,450

Note. Data are for the 184 ongoing projects that reported realizing sales and provided information on the amount of cumulative sales as of December 2007. Percentages are row percentages and may not total to 100 percent due to rounding. The estimated total sales across each product type was calculated, using the midpoint of each sales category; for the category "50,000 or more", the bottom limit ($50 million) was used.

Certain types of products generated more sales dollars than others. Most awardees reported estimated sales of $50,000 or less. The highest estimated cumulative sales total was $99.4 million for companies that developed research tools. The next highest estimate—for projects that were developing medical devices—was $73 million. Across all products, the cumulative sales totaled an estimated $395.5 million.

Exhibit 5-7 presents sales for each Institute/Center (IC) that reported sales figures. Comparing cumulative sales among (1) different IC groupings and (2) new products and those improving or identifying another use for an existing product indicated that there is no statistically significant relationship between the two variables.

EXHIBIT 5-7
Estimated Cumulative Sales for Awardees Realizing Sales by Awarding NIH Institute or Center

Awarding NIH Institute or Center		Awardees realizing sales		Total Sales (in thousands of dollars)	Mean sales (in thousands of dollars)
		N	% of all awardees funded by this IC		
NCI	National Cancer Institute	21	26	50,725[b]	2,536.3[b]
NCRR	National Center for Research Resources	17	41	39,725[d]	2,482.8[d]
NCCAM	National Center on Complementary and Alternative Medicine	2	40	825	412.5
NEI	National Eye Institute	4	33	3,775[c]	1,258.3[c]
NHGRI	National Human Genome Research Institute	5	45	90,825	18,165.0
NHLBI	National Heart, Lung, and Blood Institute	13	17	7,900	607.7
NIA	National Institute on Aging	13	38	6,900[a]	575.0[a]
NIAAA	National Institute on Alcohol Abuse and Alcoholism	5	56	400	80.0
NIAID	National Institute of Allergy and Infectious Diseases	13	30	20,900[a]	1,741.7[a]
NIAMS	National Institute of Arthritis, Musculoskeletal and Skin Disease	1	7	75	--
NIBIB	National Institute of Biomedical Imaging and Bioengineering	3	33	625	208.3
NICHD	National Institute of Child Health and Human Development	16	38	8,325	520.3
NIDA	National Institute on Drug Abuse	3	21	3,100	1033.3
NIDCD	National Institute on Deafness and Communication Disorders	5	28	3,825	765.0
NIDCR	National Institute of Dental and Craniofacial Research	4	40	1,650	412.5
NIDDK	National Institute on Diabetes, Digestive, and Kidney Diseases	13	37	56,425	4,340.4
NIEHD	National Institute of Environmental and Health Sciences	5	36	675	135.0
NIGMS	National Institute of General Medical Sciences	21	40	41,425	1,972.6
NIMHI	National Institute of Mental Health	13	46	13,650	1,050.0
NINDS	National Institute of Neurological Disorders and Stroke	12	35	43,700	3,641.7
Total		189	33	395,450	2,092.3

Note. Data on realizing sales are for the 189 ongoing projects that provided this information. Information on cumulative sales as of December 2007 was provided by 184 of these respondents. Total sales and mean sales were estimated by using the midpoint of the categories shown in Exhibit 5-6 (the start point was used for the final, unbounded category). None of the Phase II projects funded by the National Institute of Nursing Research (NINR) and the National Center on Minority Health and Health Disparities (NCMHD) had yet realized sales.

[a]Based on 12 respondents [b]Based on 20 respondents [c]Based on 3 respondents [d]Based on 16 respondents

The percent of awardees that realized sales, the estimated total cumulative sales, and the average sales for SBIR-funded projects varied among ICs. NHGRI had the highest mean sales, an estimated $18 million. The four ICS with the next highest mean sales were NIDDK ($4.3 million), NINDS ($3.6 million, NCI ($2.5 million), and NCRR ($2.5 million).

Exhibit 5-8 summarizes the extent to which FYs 2002-2006 projects achieved sales.

EXHIBIT 5-8
Summary of SBIR Projects' Sales Performance for FYs 2002-2006
as of December 2007

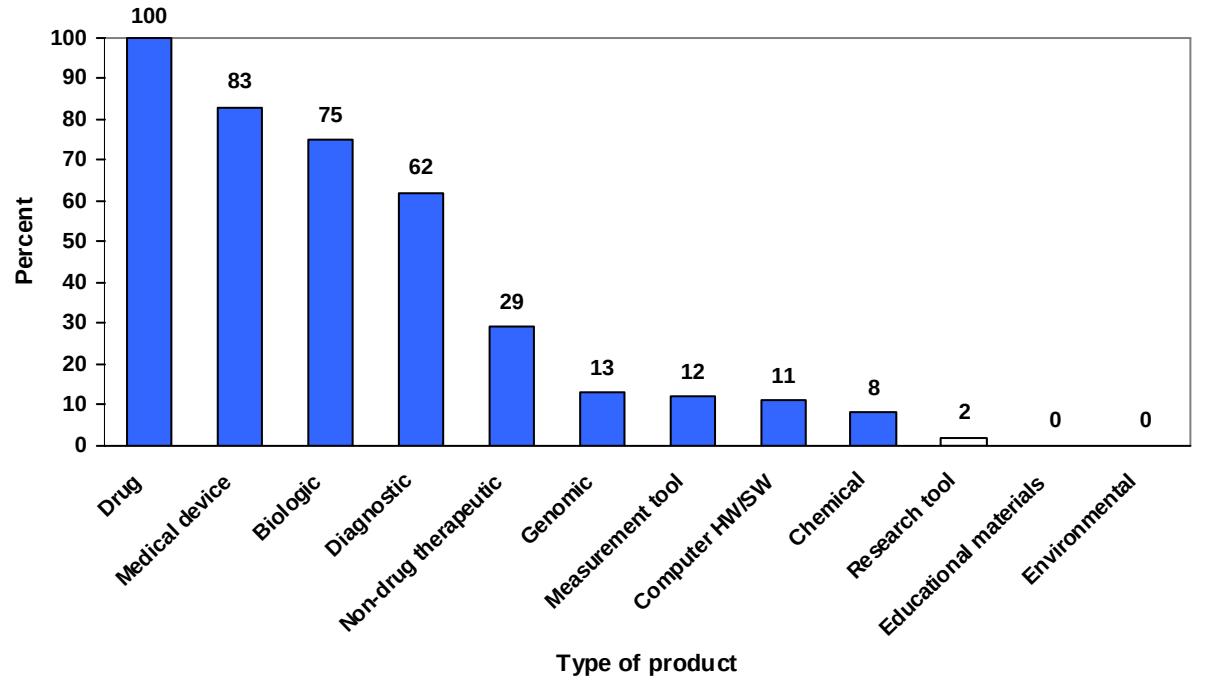
	N of projects	**Percent**	**Total *N***
Ongoing projects that expected sales	581	82	719
Ongoing projects that expected and had realized sales	189	33	581
	***N* of awardees**	**Estimated total**	**Average per awardee**
Estimated total cumulative sales to date	184	$395,450,000	$2,092.300

Among the 719 respondents, 581, or 82, percent were ongoing and expected sales. Of this group, 189, or 33 percent, stated that sales already had been realized. As of December 2007, 184 of the awardees who had realized sales estimated total cumulative sales at $395.5 million, resulting in an average total of slightly more than $2 million in sales per awardee.

5.2.3 FDA Approval of SBIR-Funded Products

Measure 4.1.3 quantifies the number of SBIR-funded products that have received FDA approval, a paperwork intensive "must" for certain product types that delays the awardee's ability to commercialize in other ways, such as sales and marketing. Three hundred and nineteen respondents indicated that their products required FDA approval. Exhibit 5-9, on the next page, shows that all projects that involved drug development required FDA approval, as did substantial majorities of projects whose product was a medical device (83 percent), a biologic (75 percent), or diagnostic material or device (62 percent). For the remainder of products, FDA approval was less likely to be applicable.

EXHIBIT 5-9
Percent of SBIR-Funded Products Requiring FDA Approval by Type of Product



Note. The number of awardees that indicated whether FDA approval was required and also identified the type of SBIR product totaled 716. As would be expected, the type of product and the need for FDA approval were significantly related (chi-square statistic=421.2, *df*=11, $p < 0.0001$).

All drug development products required FDA approval, as did 83 percent of medical device products, 75 percent of biologic products, and 62 percent of diagnostic products.

As shown by Exhibit 5-10 (on the next page), among the 716 awardees, 319 (45 percent) indicated that their projects needed FDA approval. Among the 319 respondents whose SBIR-funded projects required FDA approval, slightly less than one-third (31 percent) had been submitted for FDA review. Of the 98 products that had been submitted, 68 percent had been approved. Most likely to receive approval were diagnostics, measurement tools, non-drug therapeutics, and computer hardware and software, all of which had approval rates of 75 percent or higher. Approval rates were somewhat lower (between 57 and 68 percent) for drugs, medical devices and biologics.

EXHIBIT 5-10
FDA Approval Status by Type of SBIR-Funded Product

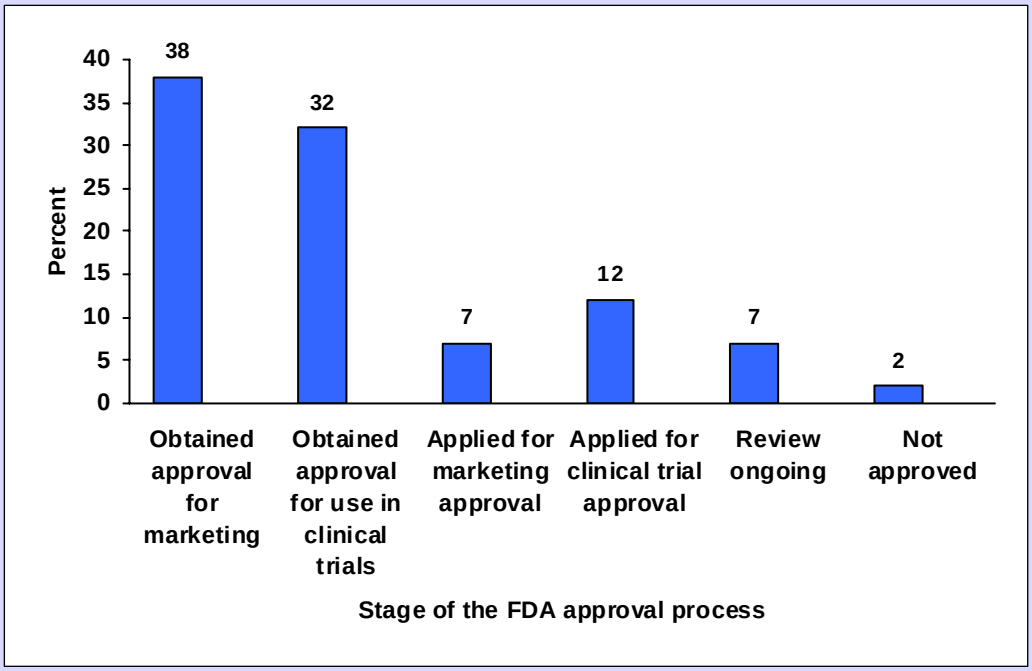
Type of product	Total *N*	Required FDA approval		Status of FDA Approval Process: Submitted for FDA review		Status of FDA Approval Process: Received FDA approval	
		N	%	*N*	%	*N*	%
Drug	77	77	100	22	29	13	59
Medical device	160	133	83	50	38	34	68
Biologic	40	30	75	7	23	4	57
Diagnostic	86	53	62	11	21	9	82
Non-drug therapeutic	14	4	29	1	25	1	100
Measurement tool	50	6	12	3	50	3	100
Genomic	15	2	13				
Computer HW/SW	101	11	11	4	36	3	75
Chemical (non-drug)	13	1	8	0	0		
Research tool	97	2	2	0	0		
Educational materials	51	0	0				
Environmental, ergonomic, or assistive tool	12	0	0				
All product types	716	319	45%	98	31%	67	68%

Note. Three respondents provided no data on whether their product required FDA approval. The results are ordered from highest to lowest in terms of the percent of SBIR-funded projects requiring FDA approval.

At least 75 percent of diagnostics, non-drug therapeutics, measurement tools, and software or hardware products that required FDA approval had been approved.

As Exhibit 5-11 on the following page shows, 38 percent of the projects that had begun the FDA review process had received approval for marketing. Another 32 percent had received approval for use in clinical trials and had (1) Investigational New Drug (IND) status, (2) been granted an exemption from IND, or (3) been judged a non significant risk. Only a small minority (2 percent) had completed the process but not been approved.

EXHIBIT 5-11
Stage of the FDA Approval Process for SBIR-Funded Projects that Submitted Applications to the FDA



Note. Data are for 98 projects that reported having submitted applications to the FDA.

For awardees that submitted applications to the FDA, 38 percent received approval for marketing, and 32 percent received approval for use in clinical trials. Only a small minority (2 percent) were not approved.

5.2.4 Licensing of SBIR-Funded Projects

Measure 4.1.4 quantifies the number of SBIR-supported products that executed licensing arrangements, another indicator of commercialization. Among all projects, 26 percent (173 projects) reported that they had done so. This percentage did not differ significantly by the start date of the Phase II award or by the type of product, but significant differences did appear in terms of current project status (chi-square statistic=40.4, df=8, $p < 0.0001$). As would be expected, discontinued projects and those that had been placed "on hold" were the least likely to have licensed their products (13 and 14 percent, respectively). In some cases, the failure to obtain a license was one of the reasons for not further pursuing commercialization.

Awardee small businesses that were still developing their products also were less likely to have successfully completed licensing negotiations (19 percent). Significantly larger percentages of projects that were involved in commercialization (36 percent) or had made their products commercially available (40 percent) had secured licenses for their products.

5.2.5 Other Evidence of Commercialization

Measure 4.1.5 describes and quantifies other evidence of commercialization—various types of marketing activities, public stock offerings, and giving trade or commercial names to the SBIR-funded product.

Approximately 88 percent of companies (488) reported at least one ongoing or completed marketing activity. Overall, about 23 percent of companies had completed their marketing plan, 20 percent had completed hiring marketing staff, and 20 percent had completed test marketing activities. Eleven percent reported that their publicity and advertising campaigns had been completed.

Exhibit 5-12 on the next page shows the status of marketing activities for awardees with ongoing projects by current status of project. The shaded percentages identify their most typical level of involvement in marketing activities, depending on the current status of their project. Between 64 and 66 percent of awardees who were still developing their products had not yet become involved in most marketing efforts, with the exception of preparing a marketing plan. In contrast, companies that were commercializing their SBIR-funded projects were more likely to be in the midst of preparing marketing plans (60 percent), publicizing and advertising their product (54 percent), and carrying out test marketing (50 percent). For awardees who had already made their product available for use, the majority had completed all marketing activities except ongoing publicity and advertising. When projects were "on hold," little attention was being paid to marketing activities.

Only 11 companies (2 percent) with ongoing projects reported a pubic offering of their stock. Nine of these companies were listed on NASDAQ, one was on AMEX, and another was listed on another exchange. Six of these 11 companies reported biotechnology as their major field of business, three were pharmaceutical companies, one was primarily associated with diagnostic devices and materials, and one was a medical devices company. Over half (6) of these companies had more than 50 employees. Approximately 57 percent of awardees (366) provided a trade name for their SBIR-supported product.

5.2.6 Receipt of Additional Non-SBIR Funding

Measure 4.1.6 describes and quantifies awardees' performance in obtaining additional developmental funding for SBIR-supported innovations from non-SBIR funding sources. Approximately 36 percent of companies received additional non-SBIR funding for their project. As would be expected, companies whose projects were "on hold" or discontinued were significantly less likely to have obtained such non-SBIR support. Whereas 38 and 40 percent of products in the developmental and commercialization stages and 44 percent of products in use reported the receipt of additional non-SBIR funding, this was true for only 19 and 9 percent of "on hold" and discontinued projects, respectively (*chi square statistic*=34.9, df=4, $p < 0.0001$).

Supplemental financial support also was more likely for certain types of products. As Exhibit 5-13 on page 5-15 shows, between 47 and 55 percent of products that were biologics, environmental tools, drugs, and genomics received additional non-SBIR funding. As a group, the percentage was significantly higher than that for medical devices (43 percent had obtained additional non-SBIR funding). Between 31 and 34 percent of projects that involved diagnostic, research tool, and chemical products obtained such support as did 29 and 27 percent of projects focused on non-drug therapeutics and computer hardware and software. Again, the combined percentage for these products was significantly lower than for medical devices and the previously mentioned cluster of products. The least likely to get additional funding were measurement tools and educational materials.

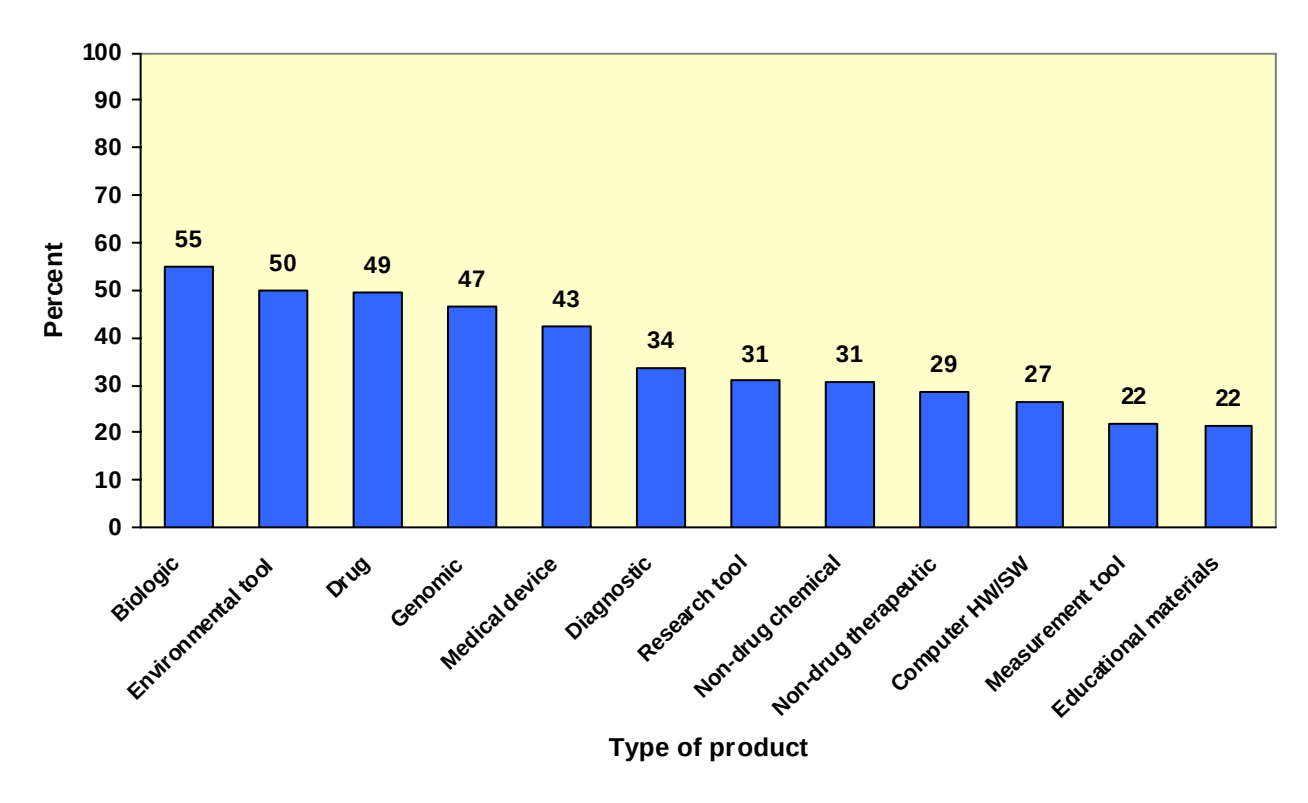
EXHIBIT 5-12
Percent of Awardees Engaged in Marketing Activities by Current Project Status

Project Status Marketing Activity	Total *N*	Status of involvement in marketing activities							
		Not yet planned		Planned		Ongoing		Complete	
		N	%	*N*	%	*N*	%	*N*	%
Under development									
Preparation of marketing plan	274	98	36	54	20	99	36	23	8
Hiring of marketing staff	237	155	65	45	19	23	10	14	6
Publicity and advertising	250	164	66	51	20	30	12	5	2
Test marketing	246	157	64	32	13	4	2	13	5
Commercialization stage									
Preparation of marketing plan	133	15	11	9	7	80	60	29	22
Hiring of marketing staff	113	31	27	29	26	27	24	26	23
Publicity and advertising	128	27	21	24	19	69	54	8	6
Test marketing	122	19	16	24	20	61	50	18	15
In use by target population(s)									
Preparation of marketing plan	140	8	6	5	4	42	30	85	61
Hiring of marketing staff	122	16	13	7	6	36	30	63	52
Publicity and advertising	141	10	7	2	1	79	56	50	36
Test marketing	123	7	6	2	2	31	25	83	68
"On hold"									
Preparation of marketing plan	57	32	56	7	12	13	23	5	9
Hiring of marketing staff	47	43	92	1	2	2	4	1	2
Publicity and advertising	52	40	77	4	8	7	14	1	2
Test marketing	49	39	80	3	6	5	10	2	4

Note. Percentages are row percentages and may not sum to 100 percent due to rounding. Shaded percentages refer to the current status of individual marketing activities for the majority of projects in the status category.

Awardees' involvement in marketing efforts depended on current project status. Awardees that were still developing their product or had placed efforts "on hold", typically had not yet planned marketing activities. In contrast, awardees that were in the commercialization stage tended to have ongoing marketing activities. Awardees that had made their product available for use typically were still running advertising and publicity campaigns, but had completed many other marketing activities.

EXHIBIT 5-13
Percent of Awardees that Received Additional Non-SBIR Funding by Type of SBIR-Supported Product



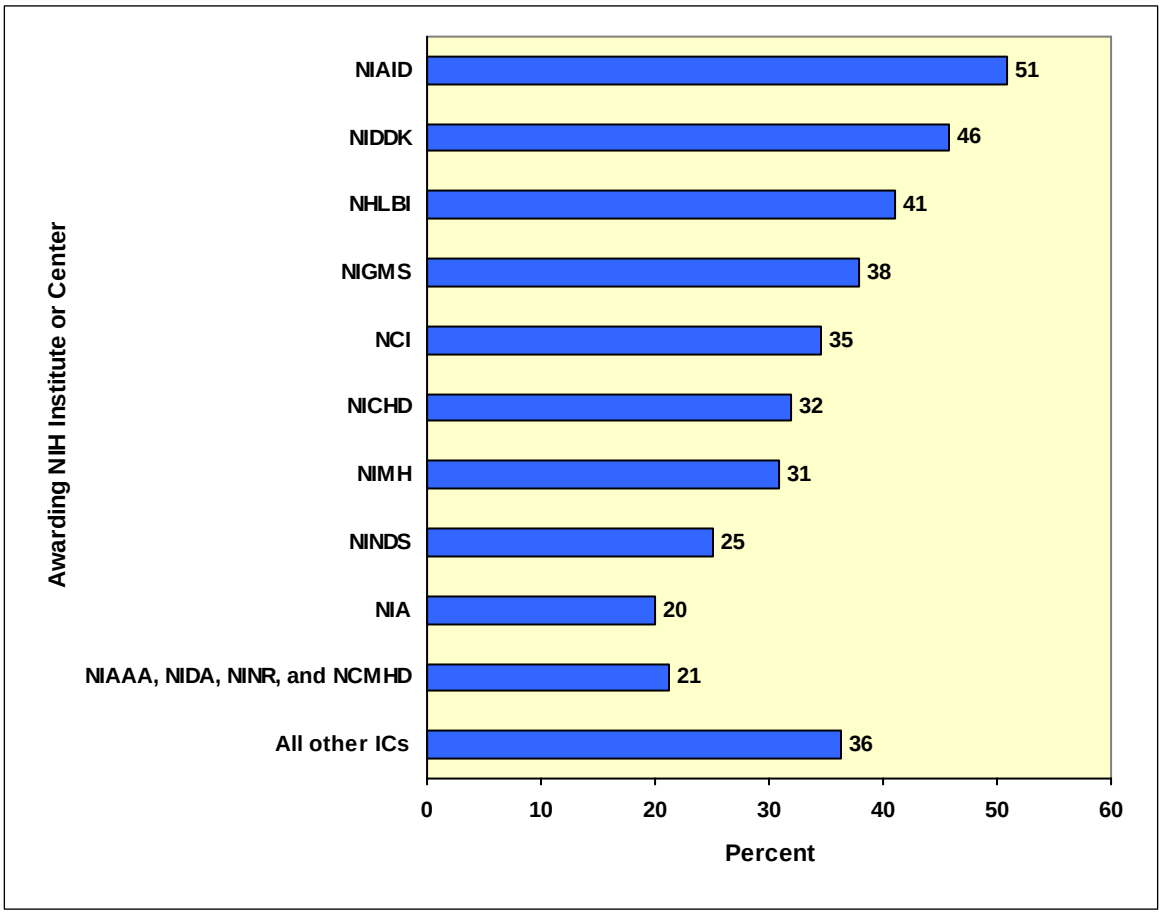
Note. Data are for 716 projects that provided information. Obtaining addition non-SBIR funding and type of product were significantly related (chi square statistic=31.4, $df = 11$, $p < 0.001$)

Between 47 and 55 percent of awardees that were working on biologics, environmental tools, drugs, and genomics had obtained additional non-SBIR funding for the core technology supported by the Phase II award. Slightly more than two-fifths (43 percent) of medical devices had been successful in securing this type of funding. For the remainder of product types, the percentages with additional support ranged from 22 to 34 percent.

Of the 259 projects receiving non-SBIR support, the large majority (83 percent) attributed such support partly to having received SBIR funding.

Significant differences also occurred among awarding NIH ICs (Exhibit 5-14). Awardees whose Phase II award was sponsored by the NIAID were significantly more likely to obtain additional non-SBIR support than all other Institutes or Centers except NIDDK. On the other hand, companies with awards from the NIA were significantly less likely to report obtaining additional monies, with only one-fifth of each indicating such support. This also was true for the cluster of ICs that included NIAAA, NIDA, NINR, and NCMHD.

EXHIBIT 5-14
Percent of Awardees that Reported Receipt of Additional Non-SBIR Funding by Awarding NIH Institute or Center

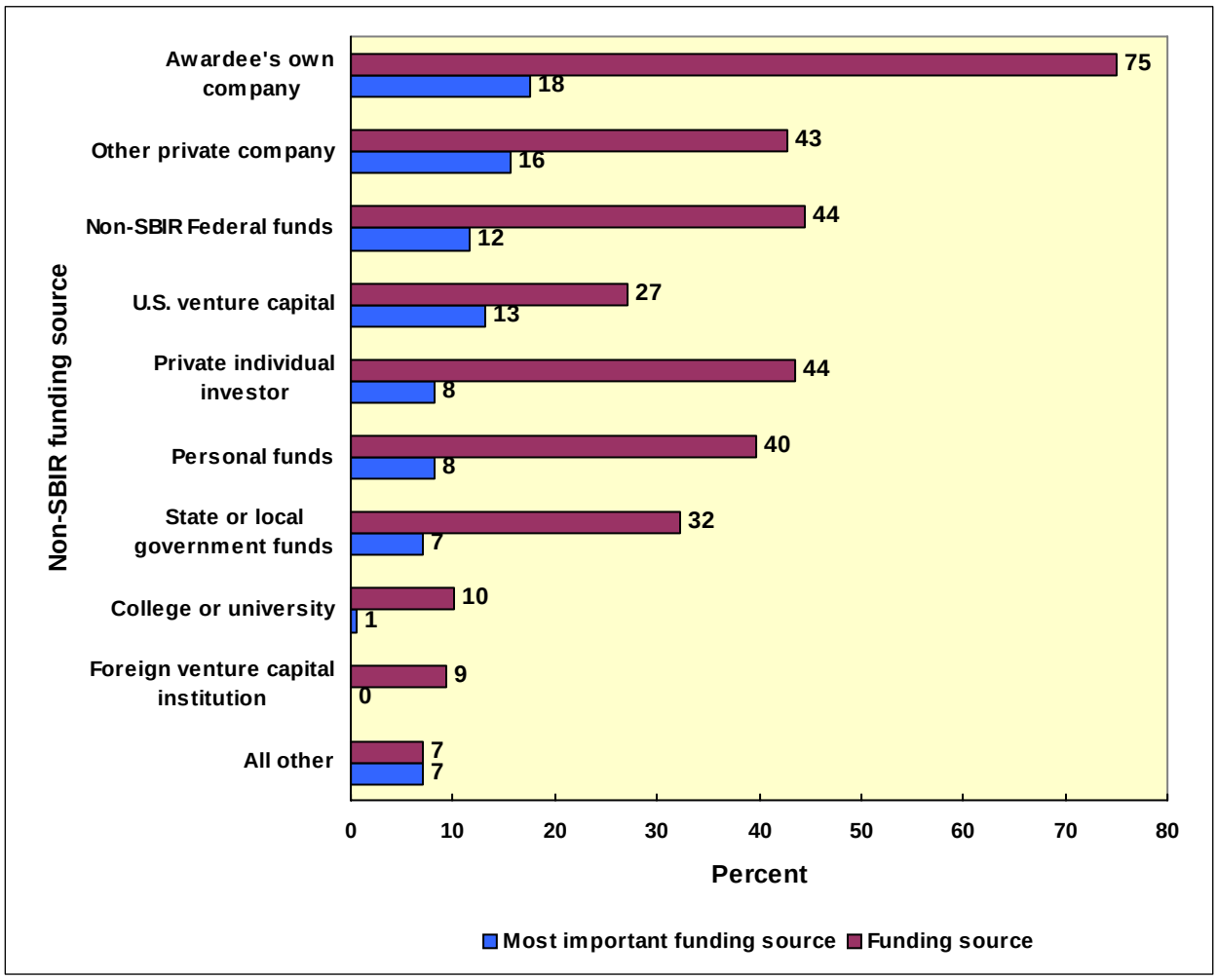


Note. Data are based on responses from 717 awardees. There were significant differences in the percentages of awardees who received additional non-SBIR funding by IC (chi square statistic=19.4, *df* = 10, p < 0.0352). See Appendix D for a full list of all other ICs and Exhibit 1-1 for the titles of all ICs.

Projects sponsored by different ICs differed significantly in terms of receipt of additional non-SBIR funding for their SBIR-supported project. Companies whose Phase II award was sponsored by the NIAID were significantly more likely to obtain additional non-SBIR support than were those funded by all other ICs, except for the NIDDK.

Awardees reported different opinions about the importance to these additional funding streams. When asked which source of funds had been most important, 18 percent identified monies from their own company, and another 16 percent identified another private company (Exhibit 5-15). Another program within the NIH or at another Federal agency was the most important additional source for 12 percent of awardees. Thirteen percent perceived the monies that they had obtained from U.S. venture capital companies as the most important additional funding source.

EXHIBIT 5-15
Percent of Awardees that Reported Receipt of Additional Non-SBIR Funding by Funding Source and Most Important Funding Source



Note. Percentages are based on responses from 257 awardees who received additional non-SBIR funding.

Awardees most often said that the most important non-SBIR funding source was their own company (18 percent), which also was the most frequently cited non-SBIR funding source (75 percent). Sixteen percent of awardees cited other private companies as the most important funding source, with 12 and 13 percent respectively citing non-SBIR Federal funds and U.S. venture capital most important.

Funding from the awardee company was least likely for projects "on hold" or discontinued (chi-square statistic=7.30, *df*=3, $p < 0.0629$). Between 78 and 81 percent of companies whose product was being developed, in the commercialization stage, or in use, reported investment by the business itself or additional non-SBIR funding. This was true for only about half of companies with discontinued or inactive projects. Although the percentages are much smaller, this pattern also occurred with regard to foreign venture capital funding. No discontinued or inactive projects had this type of additional funding. Only 3 percent of products in use had foreign venture capital monies, but 12 percent of companies that were still developing or commercializing their product reported this source (chi-square statistic=6.97, *df*=3, $p < 0.0729$). Additional investment from the individual PI was significantly more likely for projects in the commercialization stage or in use (45 and 54 percent, respectively) as compared to projects that were still in the developmental phase (33 percent) or inactive (11 percent) (chi-square statistic=15.1, *df*=3, $p < 0.0018$). No statistically significant differences were found for the other sources.

5.2.7 Summary of Commercialization Efforts

As shown by Exhibit 5-1 and discussed throughout this chapter, the Evaluation Framework includes five measures describing how NIH SBIR awardees commercialize their products—by realizing sales, obtaining FDA approval, executing licensing arrangements, having ongoing or completed marketing efforts, and obtaining additional non-SBIR funds for project support. Seventy-six percent of the FY 2002 through FY 2006 awardees reported commercializing new or improved products in health-related fields in one or more of these ways.

Identifying the numbers and types of commercialization outcomes reported by awardees can be useful in providing a deeper understanding of the nature of Phase II awardees' commercialization. Exhibit 5-16 on the next page provides this information for the 543 awardees who reported. Results should be interpreted by keeping in mind that the total number of measures that any awardee can achieve depends on the product being developed. For example, some products do not require FDA approval or may not need licensing agreements.

As shown by Exhibit 5-16, at the time of the survey, approximately 39 percent of the respondents reported having satisfied only one measure. The most frequently-cited accomplishment was marketing efforts (21 percent).

Twenty-nine percent of the awardees mentioned progress in two measures of commercialization. The most frequent mentions of two measures cited (1) realizing sales and marketing efforts (54 awardees, or 10 percent of the respondents), and (2) marketing activities and receipt of non-SBIR funds (9 percent).

Twenty-two percent reported progress on three measures. The most frequent mention of three measures cited realizing sales, marketing efforts, and obtaining additional non-SBIR funds (40 awardees, or 7 percent of the respondents). Much smaller percentages of awardees had achieved four measures (9 percent) and all five measures (1 percent).

EXHIBIT 5-16
Number and Type of Commercialization-Related Outcomes Achieved by Awardees

Commercialization Measures					*N*	%
Realized sales	**Obtained FDA approval**	**Executed licensing agreement(s)**	**Had ongoing or completed marketing efforts**	**Obtained additional non-SBIR funds**		
●					7	1
	●				9	2
		●			24	4
			●		115	21
				●	56	10
Achieved one of the five measures					211	39
●		●			1	< 1
●			●		54	10
●				●	2	< 1
	●	●			1	< 1
	●		●		6	1
	●			●	3	1
		●	●		24	4
		●		●	16	3
			●	●	50	9
Achieved two of the five measures					157	29
●	●	●			1	< 1
●	●		●		7	1
●		●	●		30	6
●		●		●	2	< 1
●			●	●	40	7
	●	●	●		3	1
	●	●		●	1	< 1
	●		●	●	9	2
		●	●	●	26	5
Achieved three of the five measures					119	22
●	●	●	●		2	< 1
●		●	●	●	27	5
●	●		●	●	10	2
●	●	●	●		2	< 1
	●	●	●	●	9	2
Achieved four of the five measures					50	9
●	●	●	●	●	6	1
Achieved all five measures					6	1

Note. Percentages are based on responses from 543 awardees. Percentages may not total to 100 percent or to the percent for the general category (e.g., achieved three measures) due to rounding.

Awardees were considered to have commercialized a new or improved product if they reported achieving at least one of the five commercialization measures. Thirty-nine percent of the responding awardees had satisfied at least one measure—most typically having ongoing or completed marketing efforts (21 percent). Twenty-nine percent of the responding awardees had achieved two of the five measures, with the highest percentage (10 percent) having realized sales and having ongoing or completed marketing efforts. Twenty-two percent of respondents realized three measures—the same two as the largest group in the two measure category, and also obtaining additional non-SBIR funds. The 9 percent who achieved four of the five measures most typically accomplished all but FDA approval (5 percent). Six awardees, or 1 percent of those reporting, achieved all five measures.

5.3 Growth of Awardee Small Businesses

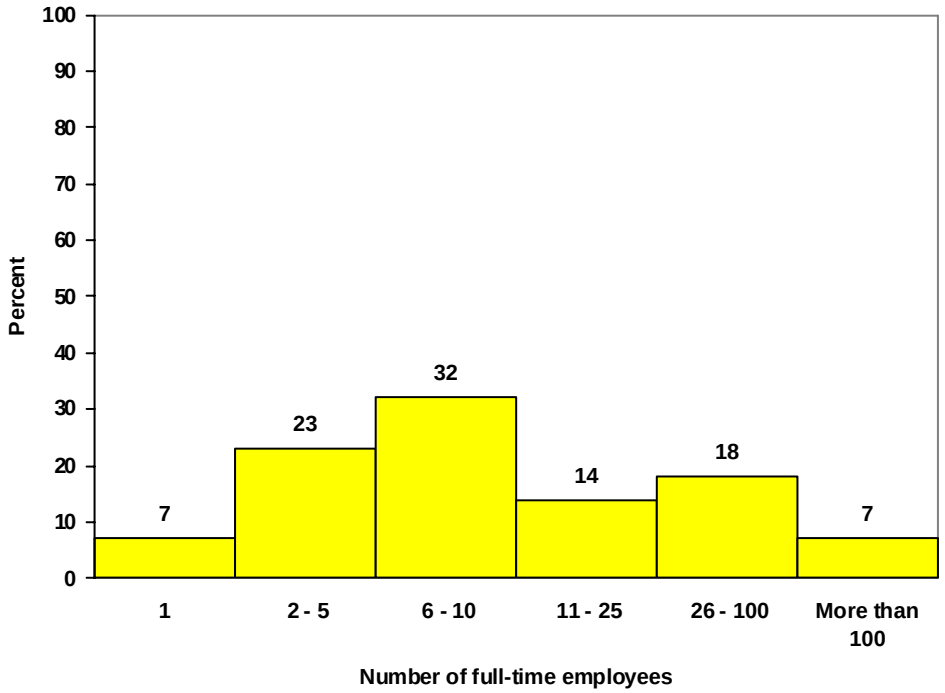
As described in Chapter 2, a significant percentage of awardee companies were in their early years of operation at the time of the award. Approximately 30 percent had been operating for five or fewer years. One-third (33 percent) had been in existence for 6-10 years, 16 percent for 11-15 years, and the remainder (21 percent) for more than 15 years. The distribution of years in operation was skewed to the right. The average years in existence was 10 years (standard deviation = 8), and the median was 8 years.

- One indicator of company size is the number of employees. As shown in Exhibit 5-17 on the next page, 62 percent of awardee companies had 10 or fewer full-time employees. Twenty-three percent employed 11 to 25 individuals, and 14 percent had between 26 and 100 employees. Only a small minority (7 percent) had more than 100 employees. The distribution of full-time employees was again skewed to the right, with a mean of 36 employees but a median that was much smaller (8 employees).

Eighty-one percent of the respondents reported that granting of the SBIR award had allowed them to hire additional personnel. Sixteen percent perceived the Phase II award to have no influence on staff hiring, and 3 percent were uncertain.

Awardees also were asked to indicate whether their companies experienced various growth-related activities because of the product developed with SBIR support. Exhibit 5-18, on page 5-22, shows the percentage of awardee companies that responded positively to these questions. The most frequent event was establishing a strategic partnership or alliance with another entity; nearly one-third (32 percent) of awardees reported that such relationships had been developed. The second most frequent activity involved executing a licensing agreement; here, slightly more than one-quarter (26 percent) of awardees had either licensed the SBIR-funded product themselves or sold the licensing rights to another company. In addition, about one-fifth (21 percent) of respondents reported private placement with angels, venture capitalists, or relatives. Joint ventures and debt financing occurred for 15 and 17 percent of awardee businesses, respectively.

EXHIBIT 5-17
Number of Full-Time Employees for Awardees



Note. Percentages are based on 711 awardees. For three companies that did not report this information; data were extracted from Dunn and Bradstreet profiles available on www.manta.com.

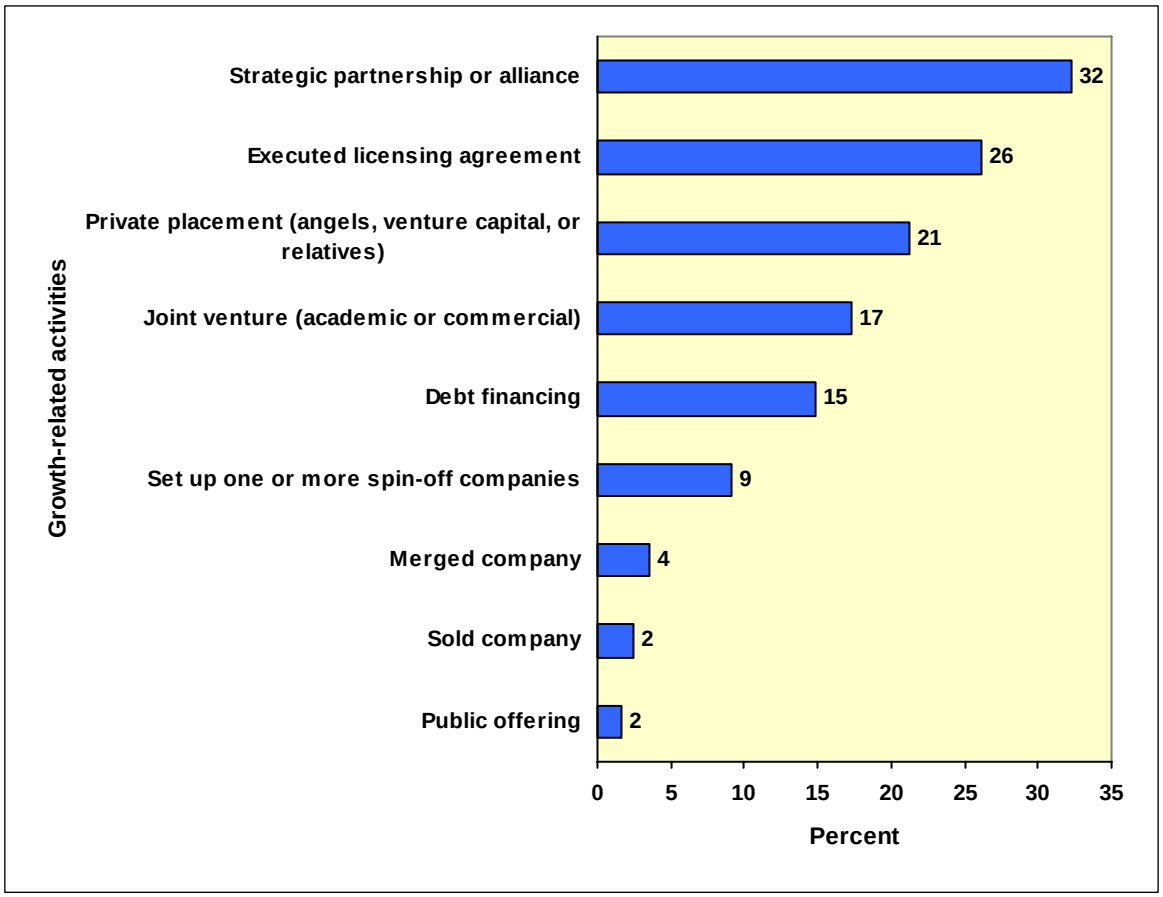
Slightly more than three-fifths (62 percent) of Phase II awardee companies had 10 or fewer full-time employees. The median number was eight.

Much lower percentages of awardees set up one or more spin-off companies (9 percent), merged their company with another business (4 percent), or sold their company (2 percent). These respondents could have been eliminated from the analysis because these outcomes made them technically ineligible to respond, given the criteria used for inclusion in the survey target population. However, in order to remain consistent with the analytic strategies used for the 2002 survey of Phase II awardees, these awardees were included in the analyses of survey responses.

Only 2 percent of awardee small businesses reported a public offering of their stock. The stock exchanges and ticker symbols for these 11 companies were:

- New York Stock Exchange: CLRA
- NASDAQ: BDSI, CASM, DCGN, IDIX, IMMC, MBRX, PANC, RPROS, RYND
- Other: MIIS.OB

EXHIBIT 5-18
Awardees' Reported Growth-Related Activities



Note. Depending on the specific activity, between 654 and 681 awardee companies provided information.

The most commonly reported growth-related activity was the development of strategic partnerships or alliances (32 percent). The next most frequently mentioned growth-related activities were successfully negotiating licensing arrangements (26 percent) and private placements (21 percent).

The questionnaire asked awardees about the extent to which receiving an SBIR award had an impact on other activities that are relevant to company growth. Eighty-six percent believed it had affected their credibility or visibility for finding partners. Fifty-three percent responded that it had an impact on raising additional capital.

Although less directly related to company growth, 94 percent said that the award had an effect on their ability to pursue a high-risk idea or action that might otherwise not have been undertaken. This is a strong testimonial to the role of the SBIR program in encouraging innovation.

5.4 Comparison of Two Awardee Cohorts' Performance in Commercializing Innovations

Exhibit 5-19 on the next page shows the outcomes of FYs 1997-2001 and FYs 2002-2006 awardees on the indices identified for commercialization. For the major index stating that companies with SBIR awards commercialize new or improved products, 67 percent of the earlier cohort of awardees had some involvement in commercialization as reported in 2002. The corresponding percentage for the later cohort of awardees was 61 percent as reported in 2008. This difference was not statistically significant.

With respect to the other measures reported in Exhibit 4-7, the performances of each cohort were nearly identical. The percentage of the later cohort of awardee companies that had executed licensing arrangements was somewhat higher than the earlier cohort—25 versus 20 percent—but again, this was not a significant difference.

In terms of growing their companies, the median numbers of years that awardees were in operation were both 8 years. The reported median number of employees in the later cohort was 10, versus 8 employees reported for the earlier survey cohort.

EXHIBIT 5-19
Comparison of SBIR Awardees' Performance in Commercializing Innovations

Performance Index / Performance Measure		Phase II Award Start					
		FYs 1997- 2001			FYs 2002- 2006		
		N	%	Total N	*N*	%	Total *N*
4.1	**40 percent of companies with NIH SBIR awards commercialize new or improved products, processes, and or services in health-related fields**[a]	377	67	566	541	74	717
4.1.1	Number and percent of SBIR-supported products that yield sales (of those that expect sales)	146	33	442	189	33	580
4.1.2	Estimated dollar volume of sales of SBIR-supported products (in millions)	--	--	--	$395.5	NA	189
4.1.3	Number and percent of SBIR-supported products receiving FDA approval (of those that required approval)	--	--	--	67	21	319
4.1.4	Number and percent of awardees executing licensing arrangements	116	23	509	173	26	664
4.1.5	Number and percent of awardees with other evidence of commercialization	341	65	527	391	64	607
4.1.6	Number and percent of awardees receiving additional non-SBIR funding	214	38	--	257	36	717
4.2	**40 percent of companies with NIH SBIR awards grow their companies**[b]	465	83	558	583	82	714
		Median		**Total N**	**Median**		**Total N**
4.2.1	Median number of years companies with NIH SBIR awards have existed (median)	7		557	8		711
4.2.2	Median number of full-time employees	10		557	8		711

Note. The FYs 1997-2001 results are based on analyses of a subset of the 2002 survey data. Total cumulative sales and the percent obtaining FDA approval were not compared for the two cohorts, given that the response categories for the questions in the 2008 survey were modified slightly from those listed in the 2002 questionnaire.

[a]This percentage refers to the percent of awardee respondents who did one or more of the following: realized sales; obtained FDA approval (if required); executed licensing arrangements; showed other evidence of commercialization (had ongoing/completed marketing activities or a public stock offering); or received additional non-SBIR funding for their core technology sponsored by the Phase II award.

[b]This percentage refers to the percent of awardee respondents who stated that one of the SBIR awards related to their product had on impact on their hiring of additional personnel.

Performance of the two cohorts was quite similar for measures related to both indices, Index 4.1, percent of companies that commercialized, and Index 4.2, percent of companies with NIH-SBIR awards who reported growing their companies. The one difference between the two cohorts was that a significantly higher percentage of FY 2002-2006 awardees reported some evidence of commercialization (74 percent) compared to the earlier cohort (67 percent).

6. CONCLUSIONS AND RECOMMENDATIONS

The 2008 national survey to assess the outcomes of the NIH SBIR program addresses three questions about performance by NIH SBIR Phase II awardees from FYs 2002-2006:

- To what degree do small businesses supported through the NIH SBIR program stimulate technological innovation?
- Has the NIH SBIR program's use of small business concerns satisfied Federal research and development (R&D) needs?
- Has the NIH SBIR program increased private sector commercialization of innovations derived from Federal R&D funding?

The questions focus on how well NIH has done in attaining Congressionally-mandated SBIR program goals 1, 2 and 4. Information from the 2008 survey supplements that obtained in the similar 2002 National Institutes of Health survey and the 2006 National Research Council assessment.

This chapter presents conclusions from the 2008 survey and offers recommendations for future NIH SBIR program evaluation.

6.1 NIH SBIR Awardees Met or Exceeded NIH Performance Targets

Respondents to the 2008 national survey to assess the outcomes of the NIH SBIR program reported exceeding all NIH targets related to the performance issues that were the study focus.

As shown by Exhibit 6-1 on the next page, at least 82 percent of awardees:

- Developed products that were consistent with the NIH mission
- Contributed to knowledge in fields of interest to NIH
- Demonstrated ability to obtain and disseminate health-related information to target populations
- Expressed satisfaction with the usefulness of the NIH SBIR program in terms of the application, award, and post-award administration program
- Grew their companies

For 74 percent, there is evidence that commercialization has been initiated at some level. Eighty-two percent of respondents reported that the SBIR program had had an impact on their hiring of additional personnel. Fifty-eight percent of awardees received additional Phase I or Phase II awards that relate to the core technology developed by the award described by their survey responses.

EXHIBIT 6-1
Summary of Performance for FYs 2002-2006 SBIR Phase II Awardees*

NIH SBIR Performance Goal NIH SBIR Performance Index	**NIH Performance Index Benchmark**	**Awardee Performance**
1. Stimulate Technological Innovation		
1.1 Regardless of sales SBIR awardees develop products in support of the NIH's mission	40%	82%
1.2 SBIR awardees received additional Phase I or Phase II awards that relate to the core technology	10%	58%
2. Use Small Business Concerns to Meet Federal R&D Needs		
2.1 SBIR awardees make contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease	50%	82%
2.2 SBIR awardees are able to obtain and disseminate health-related information	50%	82%
2.3 SBIR awardees express satisfaction with the usefulness of the NIH SBIR program	50%	74 – 90%
4. Increase Commercialization of Innovations		
4.1 SBIR awardees commercialize new or improved products in health-related fields	40%	74%
4.2 SBIR awardees grow their companies	40%	82%

The 2008 national survey to assess the outcomes of the NIH SBIR program assessed performance for three of the program's four goals. Awardee performance exceeded performance benchmarks for all of the performance indices that were examined.

******The survey assessed performance for Goals 1, 2, and 4 for the SBIR program.*

In addition to exceeding these numerical benchmarks, substantial percentages of SBIR awardees achieved several other related accomplishments of keen interest to Federal SBIR policy makers and practitioners. These accomplishments include:

- Fifty-three percent published one or more technical articles about new or improved SBIR-supported products, and 31 percent obtained one or more patents relevant to the core technology supported by the Phase II award.
- One-third (33 percent) of the projects realized sales, for a cumulative sales total of $395.5 million.
- One-quarter (25 percent) successfully executed licensing arrangements for their SBIR-supported product.
- Over one-third (36 percent) obtained additional non-SBIR funding related to their Phase II core technology.

6.2 Enhancements to NIH SBIR Program Monitoring and Evaluation Should be Considered

The NIH SBIR program has been in the vanguard of Federal programs in focusing scarce resources on monitoring and evaluation—two activities strongly endorsed by recent SBIR surveys and both legislative and executive branches of the Federal government. The 2008 survey implementation experience suggests that it may now be timely to consider two types of enhancements—updating the NIH SBIR program Evaluation Framework and expanding NIH SBIR program monitoring capabilities.

6.2.1 Update the SBIR Program Evaluation Framework

Evaluation frameworks can be valuable documents that accurately reflect up-to-date consensus about the attributes of program success and how and when they should be measured. Frameworks provide a guide about how to generate information that can be predicted to furnish credible evidence of program performance to program policy makers and managers alike.

The NIH SBIR program Evaluation Framework was developed in 2001 by an NIH-wide committee of SBIR administrators who wished to develop consensus on the attributes of a successful NIH SBIR program. In 2006, its suitability for use in structuring assessment of 2008 survey results was reaffirmed by a new NIH-wide committee. Revisiting the suitability of the NIH SBIR program Evaluation Framework would be beneficial to confirm current consensus about performance aims, given the new understanding of program performance generated by the NIH and NRC evaluations. At least these types of reviews should be conducted.

- **Performance measure suitability.** Some current measures may not be the most suitable ones for truly assessing attainment of a performance aim. Thus, this dimension of the measures should also be examined.

- **Performance measure focus.** Assessing program performance should focus on measuring those outcomes that indisputably relate to the effects of the SBIR award. Evaluation Framework measures should be reviewed to ensure that they all meet this criterion.

- **Performance benchmark level reasonableness.** There are large disparities between some stated performance index benchmark levels in the current Evaluation Framework and awardees' performance. This can be interpreted as quite positive—the program more than exceeded its expectations and selected the most talented and capable small businesses to support. However, review of performance index benchmarks is warranted, given the much higher than required levels of performance described by both the 2002 and 2008 surveys.

A committee of SBIR administrators from throughout the NIH could be convened to review the existing framework prior to instituting additional performance assessments and data collection efforts. To broaden the perspective of the group, it may be useful to ask professional evaluators—possibly including those from other Federal agencies—to review and comment on the draft NIH Framework. The review could address these issues:

- Does the current Evaluation Framework address all relevant performance questions? If not, what should be added? What variables *best measure* success in those areas of performance?

- Does the current Evaluation Framework address any performance questions that are no longer key issues for the NIH? Which should be deleted?

- Do Evaluation Framework performance standards and indices accurately reflect current NIH thinking about the degree of attainment that constitutes success? If not, how should they be revised?

- Could alternate measurement approaches be more accurate in describing results?

6.2.2 Expand Program Monitoring Capabilities

The NIH SBIR program's ability to evaluate and report on outcome attainment relies in part on its ability to continuously monitor program performance. Several expansions to the program's current monitoring capabilities may well be worthwhile investments for NIH to consider as ways to leverage the investment in the 2008 survey and other recent evaluations.

One priority issue is whether to continue the Program Outcomes Data System (PODS) beyond its current end date of March 2009. PODS development was funded primarily by NIH evaluation funds, but now the system must have other support for maintenance and ongoing operations. PODS provides ready access to automated contact and outcome data from the 2002 survey, voluntary 2002 survey updates, and the 2008 survey. The NIH SBIR program has found PODS useful for monitoring and disseminating up-to-date status and longitudinal data about awardees and award results. PODS is a system whose purpose and architecture matches the need for regular monitoring and data collection on outcomes for all types of Federal programs by providing up-to-date, usable, automated data.

If the decision is made to continue PODS, it may be useful to consider strategies for generating high levels of participation in updates by SBIR awardees. Participation rates to update requests have been lower than ideal, in part because Federal regulations dictate that participation must be voluntary. NIH SBIR administrators may wish to explore additional options for improving their ability to collect a standard data set for all awardees over time. They have already tested the option of having awardees submit Phase II final progress reports online in a format that facilitates storing the data in PODS. Initial attempts to do this indicate that awardees are enthusiastic about this submission method and that it may well be a solution to ensuring participation by all awardees over time.

If monitoring capabilities are expanded, early on NIH OER will need to develop procedures for handling multiple SBIR awards per awardee and analyzing their impact on product development. Both the 2002 and 2008 surveys randomly selected a single SBIR award and its product as the focus of each survey. The subsequent updates followed up on just this single award per awardee. This is an idealized situation, created to minimize respondent burden in the surveys.