



National Survey to Evaluate the NIH SBIR Program

Final Report

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EXECUTIVE SUMMARY

In 2002, the National Institutes of Health (NIH) conducted a comprehensive evaluation of its Small Business Innovation Research (SBIR) program. Companies that received Phase II awards between 1992 and 2001 were surveyed to determine if the goals of the program were being met. The results of the *National Survey to Evaluate the NIH SBIR Program* are described in this report, which is accompanied by recommendations on how to monitor and evaluate the program in the future.

SBIR Program Overview

Small businesses are a national resource for technological innovation and a mainstay of the national economy. The SBIR Program was established in 1982 by Congress under the Small Business Innovation Development Act of 1982 (P.L. 97-219) to strengthen the role of small, innovative firms in federally-supported research and development (R&D). The Program was reauthorized in 1992 (P.L. 102-564) and again in 2000 (P.L. 106-554). The most recent reauthorization extended the Program through September 30, 2008. The four major congressional goals of the program are to:

- Stimulate technological innovation
- Use small business to meet federal research and development needs
- Foster and encourage participation by minority and disadvantaged persons in technological innovation
- Increase private-sector commercialization of innovations derived from federal research and development

Under the Act, agencies with substantial extramural R&D budgets must direct a portion of their R&D funds to small businesses. Since 1983, NIH has invested over \$3 billion in SBIR research to support the NIH goal of improving human health. At the time of this survey, 21 NIH Institutes/Centers (ICs) participated in the SBIR Program. Coordination of this NIH-wide program is provided by the Office of Extramural Programs and resides within the Office of Extramural Research.

Purpose and Method of Evaluation

NIH sponsored this study for three purposes. One purpose, in concert with recommendations made by the Office of the Inspector General (OIG), is to evaluate the extent to which NIH SBIR awardees stimulate technological innovation, meet federal R&D needs, and commercialize innovations supported through SBIR awards (see Appendix A1). The second is to comply with statutes and regulations requiring assessments of Federal programs (e.g., Government Performance and Results Act of 1993) to demonstrate their contribution to the Nation's economic well-being. A third purpose is to test the feasibility of using the evaluation framework described in Appendix A2 as the analytic basis for a dynamic project monitoring system.

The NIH designed and implemented the *National Survey to Evaluate the NIH SBIR Program*, and NIH SBIR program managers identified metrics for the survey, potential data sources, and methods for data collection. The survey was a census of all 1,052 recipients of NIH SBIR Phase II awards from 1992 through 2001. The survey included an initial contact, extensive telephone follow-up, and online, paper or telephone response options—all aimed at maximizing the survey response rate. These efforts achieved an 85 percent response rate during the September through November 2002 survey field period. Such a high response rate alleviates concerns about possible non-response bias.

Summary of Findings

The survey data from the 768 awardee respondents support the following findings.

- *NIH SBIR awardees stimulate technological innovation.*

Eighty-seven percent of the awardee respondents reported producing 670 new or improved products, processes, usages, and/or services in support of the NIH mission.

Technological achievements also included 2,203 technical articles, 666 patents, 2,850 conference presentations, 453 copyrights, 252 awards, and 322 trademarks.

Fifty-two percent of awardees received 1,465 additional Phase I or Phase II awards related to continued development and exploitation of their core technology. Of the 399 awardees who won additional SBIR awards, 40 percent also received non-SBIR funding.

- *SBIR contributions toward NIH's mission of uncovering new knowledge that will lead to better health for everyone are significant.*

Seventy-four percent of awardee respondents reported making more than 567 SBIR contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and ameliorations and cure of disease.

Eighty-six percent reported success in disseminating SBIR supported technology and information among populations using and receiving health and health care resources.

- *SBIR technologies generate substantial commercial activity.*

Seventy-three percent of awardee respondents reported commercializing new or improved products, processes, usages, and/or services in health-related fields. A minimum of 224 sales producing products/processes/services and 164 licenses were generated by the program, as were approximately \$821 million in cumulative sales. NIH's total investment for the 768 respondents is approximately \$551 million. (Many of the respondents are more recent awardees and are in the pre-revenue generation phase of their business development trajectory.)

Other evidences of commercialization include 48 drugs and medical devices receiving FDA approval, 281 awardees receiving additional funding from non-SBIR sources, and 436 having ongoing or completed marketing activities.

- *The value of the SBIR Program to small businesses is significant.*

Ninety-eight percent of the respondents said that SBIR support had been or will be “very important” or “important” in the research and development of the product, process, or service developed under the funded project.

Sixty-four percent said their projects would not have been pursued without SBIR support. Respondents believe that SBIR awards had an impact on pursuing a high-risk idea or action (87%), hiring additional personnel (80%), raising additional capital (44%), and credibility or visibility for finding partners (70%).

Conclusion

For the first time, NIH has conducted a comprehensive evaluation of its Phase II SBIR awardees. NIH now has the basis for a systematic approach to collecting and analyzing NIH SBIR Program outcomes that are relevant to the ICs that participate in the Program. The survey collected a standard data set about products, processes, and services that resulted from NIH SBIR funding. It also collected data about inventions, patents, copyrights, technical papers, and presentations. It assessed the commercialization and economic impact of research products, as well as various other research outcomes that improve medical care, increase intellectual property and the knowledge base, and foster research and research tools.

The findings are significant. Through the SBIR Program, small businesses have contributed to the NIH mission of improving human health through biomedical and behavioral research, while enhancing the commercial potential and societal import of their technological innovations. The SBIR Program serves as an important catalyst for a cascade of events—technology verification, recognition, and visibility—which, in turn, can be leveraged to attract Phase III partners, alliances, and investors. The survey results support the conclusion that the NIH SBIR Program advances national priorities for health improvement, technological innovation, and economic growth, while fostering small business enterprise.

Recommendations

The survey results form a performance baseline that NIH SBIR Program managers can use. Analysis of survey results will assist SBIR managers in assessing program status in a systematic manner. The information will be useful in highlighting areas of relative success—areas where retaining current program management practices appear to be warranted. Study information will also be useful in highlighting areas of relative weakness—areas where fresh approaches to improving overall program performance are required.

NIH can use baseline information stored in the survey database to respond to OIG requests to: 1) understand if innovative projects supported through the NIH SBIR Program are being reported and patented, and if so, to classify the types of products, processes or services that are derived through SBIR funding, and; 2) develop an ongoing system to evaluate the performance of the SBIR Program that includes measuring the success of award recipients in commercializing products resulting from their research. The results can also be used to determine if other measures of success defined within the NIH mission are being achieved.

Regular collection of data on relevant performance measures in the evaluation framework would keep the NIH SBIR Program managers more current about program performance.

Recommendations from the survey are:

- Review the evaluation framework and its metrics, together with survey outcomes, to consider the need for refinements
- Collect at least a minimum standard data set using performance parameters in the evaluation framework
- Assess awardee performance on a more regular and frequent basis

Doing so would offer the benefits of constant readiness to evaluate results and reduced costs for subsequent performance assessments and evaluations.

1. INTRODUCTION

The Small Business Innovation Research (SBIR) Program, first authorized in 1982, plays an important role in the nation's scientific research and development (R&D) arena. 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 specific research and R&D needs of the federal government. The Program encourages small business awardees to explore their technological potential and provides the incentive to profit from its commercialization. By including qualified small business concerns in the nation's R&D arena, high-tech innovation is stimulated and the United States gains entrepreneurial spirit as it meets its specific R&D needs.¹

Ten federal agencies participate in the SBIR Program. The National Institutes of Health (NIH) is the largest SBIR civilian agency and the second largest participating federal agency overall. Since the inception of the program, NIH has invested over \$3 billion in research support to small business concerns under the SBIR Program. The NIH SBIR Program is of particular importance to the nation. The NIH SBIR Program focus—supporting the agency's mission to “uncover new knowledge that will lead to better health for everyone”²—is a high public policy priority.

NIH SBIR Program focus and prominence prompt keen public interest in NIH SBIR Program results. To document results from 1992-2001, the Office of Extramural Research (OER) sponsored the *National Survey to Evaluate the NIH SBIR Program*. Humanitas, Inc., was the survey contractor for both the evaluation design and the survey. This report describes the survey methodology, respondents, and results.

- Chapter 1 explains relevant background issues, survey objectives, and survey methodology.
- Chapter 2 describes the characteristics of survey respondents.
- Chapter 3 presents summary findings and detailed analyses about all key evaluation issues explored by the survey questionnaire.
- Chapter 4 summarizes lessons learned from the survey and recommends related program performance monitoring and assessment initiatives.

Appendices provide details about the survey methodology and findings.

¹ Web site (03/19/03): <http://www.sba.gov/sbir/indexsbir-sttr.html>

² Web site (11/4/02): <http://www.nih.gov/about/NIHoverview.html>

1.1 Background and Objectives

Despite its size and continued growth, there has been little systematic analysis of the NIH SBIR Program. Although the General Accounting Office (GAO), the Office of the Inspector General (OIG), and the Small Business Administration (SBA), have undertaken studies of the SBIR Program, these have become outdated.

The *National Survey to Evaluate the NIH SBIR Program* is the first trans-NIH assessment of the SBIR Program. NIH planned and conducted the survey to accomplish the following aims.

- Assess whether the legislated goals of the SBIR Program especially pertinent to NIH's mission are being met:
 - Stimulate technological innovation
 - Use small business concerns to meet Federal research and development needs
 - Increase private sector commercialization of innovations derived from Federal research and development funding
- Address recommendations from a November 1999 OIG study that “[NIH should]...develop a system to evaluate the performance of the SBIR Program that will include measuring the success of SBIR award recipients in commercializing products resulting from their research projects.”³

NIH SBIR Program administrators and awardees believe that the metrics used to evaluate Program success must reflect the full spectrum of the divergent needs and missions of the NIH Institutes and Centers (ICs) participating in the Program. (See Appendix A1 for a list of the 21 NIH ICs participating in the Program at the time of the survey.) Because cumulative sales (the metric used in most prior studies) is not the *sole* metric of success for all agencies, NIH program participants from a cross-section of ICs developed consensus about how to determine and assess attainment of *all relevant* SBIR program goals. This survey focused on how well both commercialization and non-commercialization goals are being met. The latter goals include medical and societal benefits and contributions to the intellectual property and knowledge base that result from technological innovation.

1.2 Methodology

NIH planned and implemented this survey in 2002 to meet the major objectives of: 1) assessing whether the SBIR Program goals are being met, and 2) addressing OIG recommendations to measure the success of SBIR award recipients in commercializing research products. The following guidelines directed the development of the survey methodology:

³ Office of Inspector General, *Review of the Effectiveness of the National Institutes of Health's Administration of the Small Business Innovation Research Program* (CIN: A-15-98-00031).

- Use an evaluation framework in developing the survey to ensure that the data includes metrics for answering all study questions.
- Conduct a census of awardees rather than a survey, if the sample universe for the 10-year (1992-2001) study period is not too large.
- Update the contact information, some of which dated from up to 10 years ago, before fielding the survey.
- 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 any nonresponse bias.
- Clean and code the survey data to produce an accurate data file for analysis.

The following sections discuss these survey guidelines and refer to appendices that contain additional information.

1.2.1 Evaluation Framework Guides Survey Development

The feasibility study for this assessment developed an evaluation framework based on Congressionally mandated goals for the SBIR Program. The framework stated the SBIR Program goals and the NIH-specific objective for each goal. It defined standards, indices, and measures for assessing each objective. In the absence of concrete data on performance, indices were set at minimal levels as a place holder until survey results could inform future development of this metric.

The framework guided development of the preliminary survey instrument. The measures for assessing the objectives map to specific questions in the survey. Please see Appendix A2, *Evaluation Framework*. It contains A2.1, *Evaluation Framework for the NIH SBIR Program Assessment*, and A2.2, *Map of Survey Items to NIH SBIR Program Objectives*.

A focus group of nine principal investigators (PIs) who had won Phase I and Phase II SBIR awards provided feedback about the preliminary survey and information about the most appropriate respondent, the response burden, the best metrics for measuring successful award outcomes, and motivations for participating in the survey. An online pretest of the preliminary survey and subsequent telephone debriefing with nine PIs whose small business concerns had won Phase II awards further evaluated the survey instrument. The final survey questionnaire incorporates changes and clarifications suggested by the focus group, the online pretest results, and the participants in the pretest and debriefing interviews.

1.2.2 Sampling Approach

The *National Survey to Evaluate the NIH SBIR Program* is a census of all Phase II NIH SBIR award recipients during the period from 1992 through 2001. We conducted a *census* of all awardees rather than a survey of a *random sample* of awardees because there were 1,052 awardees, which was about the size of the desired sample. For those approximately 30 percent of awardees who have received more than one Phase II award, we randomly selected a single award as the focus of the survey. This sampling approach helped minimize respondent burden and provided a single, consistent focus for respondents' assessment.

The following definitions give an overview of the sampling approach.

- *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 during the period from 1992 through 2001.
- *Awardee.* The awardee is the small business concern that received the grant.
- *Project.* The project is the research and development undertaken and supported by the award.
- *Respondents.* The eligible survey respondents for each awardee, in order of desirability, are: 1) the principal investigator (PI) on the SBIR 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 application, if there was no replacement PI.⁴
- *Study Period.* The period included in this evaluation is from 1992 through 2001 inclusive.
- *Stratification.* There was no stratification of the sample by funding IC, an initial plan, because OMB officials urged us to conduct a census rather than a survey. Post-sample stratification using various criteria is part of the data analysis.
- *Usable Sample Units.* Usable sample units are existing, nonduplicate awardees located within the U.S.A.
- *Eligible Respondents.* Eligible respondents for the awardees (described above) are people who are employed by the awardee small business concern and reside within the U.S.A.

⁴ Although we screened all respondents in terms of their eligibility, 20 “technically ineligible” respondents did participate in the survey. Five were board members or option holders, four were consultants, and eleven were the original PIs but no longer at the awardee businesses. We believe that strong motivation to respond to the survey prompted these individuals to respond as “the initial PI” or “business contact.”

1.2.3 Database Update

Because the contact information in the NIH databases for awardees and respondents was from 1 to 11 years old, we included an initial database update phase in the survey implementation. The purposes of this phase were to: 1) confirm that the small business concern still existed, 2) learn the status of the business and resolve any name changes resulting from mergers and acquisitions, 3) update the business's mailing address and telephone number, 4) determine the eligible respondent, and 5) update the respondent's business email address and telephone number.

We contacted each awardee using an *initial contact letter* addressed to the PI on the SBIR application. We asked the PI to update the status of the awardee business and its contact information, using an enclosed paper form or an online form. We endorsed the outgoing mailing envelopes *Address Service Requested* to ask for forwarding service and notification of change of address from the U.S. Postal Service. We used the services of a professional telephone center to supplement our efforts to follow up with nonresponders to the update request. The telephone center attempted to contact each nonresponder and obtain: 1) updated contact information for the awardee business, 2) the name and contact information for the eligible respondent, and 3) when appropriate, information that the awardee business was no longer in existence (was unusable). Appendix 6, *Mail and Email Messages and Telephone Scripts*, contains copies of these materials—A6.1, *Contact Update Letter and Form*, and A6.2, *Script for Telephone Follow-Up About Update*.

The result of the update phase was a database of 1,052 unique awardee small business concerns with current (or presumed current) contact information for the 82 percent (866) of the awardees deemed usable sample units. We were not able to contact all awardees in the database within the allocated period. We presumed some awardees to be usable small business concerns when their mailings were not returned and their telephones appeared to be working.

Please see Appendix A3, *Survey Sample*, for additional information on the SBIR awardee database. A3.1, *SBIR Awardee Database*, describes the activities and results of the database update phase in more detail. During the actual survey field period, we were able to further confirm or update the usability status of additional awardee small business concerns. A3.2, *Limitations of the Awardee Database*, discusses some possible limitations in the database serving as the sample for the survey. These limitations conceivably could result from the random procedure used to select the single award that was the focus of the survey for each awardee. Comparisons of the random selection of awards with the universe of awards confirm that the random selection is indeed representative of the universe. A3.3, *Respondent Selection Procedures and Limitations*, describes the procedures for selecting the eligible respondent for the awardee small business concern.

1.2.4 Survey Instrument

We constructed the survey questionnaire so that it was as precise as possible, used consistent terminology, and continually referenced the randomly selected award that was the focus of the survey. Our goal 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.” We used close-ended response categories as often as we could, though we made provision for “Other (please specify)” open-ended responses where we thought they were necessary. Selecting a response makes it easier for most respondents to answer a question.

Providing for a unique response assures those who might feel “boxed in” by response selections that do not meet their special needs.

We limited the length of the survey so that most respondents could answer all the items within 15 to 30 minutes, including any time needed to retrieve information or consult other sources. The opening screen for the online survey and the cover of the paper questionnaire contained this reporting burden, the control number, and other additional information required by OMB (Office of Management and Budget).

We produced versions of the survey for the online implementation, for a paper questionnaire for those who specifically requested this mode of response, and for a telephone survey that interviewers administered to nonresponders requesting this method during the telephone follow-up. We strove to keep all versions of the survey as similar as possible. For this reason, as an example, we minimized the use of “select all that apply” items, which are not recommended for use in online surveys.⁵ Instead, we asked respondents to answer positively or negatively to each response choice. This approach also kept the telephone survey very similar to the self-administered online and paper surveys. (In a telephone survey, a respondent cannot “select all that apply.” Interviewers must read each response choice, and respondents must answer “yes” or “no.”)

Appendix A5, *Survey Instrument*, contains copies of the paper and telephone surveys: A5.1, *Paper Survey*, and A5.2, *Telephone Survey*.

1.2.5 Online Survey Implementation

We implemented the *National Survey to Evaluate the NIH SBIR Program* on the Internet to make maximal use of information technology. The online implementation minimized respondent burden—it is easier and less time consuming for most respondents to “click” on the appropriate answer than to “check” it on paper, or to type in an open-ended response than write it out. Additionally, 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 SSL (Secure Socket Layer) encryption technology. The access process required respondents to input their user name and unique password before they could begin the survey. Although respondents could leave and return to the online survey, the implementation allowed each to complete only a single survey. “Submitting” the survey, typically upon completion, stored the survey responses in a secure database.

After the paper advance letter advising respondents of the upcoming survey, all subsequent 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. Subsequent electronic communications (after the paper advance letter) included the following.

⁵ Dillman, Don A. *Mail and Internet Surveys: The Tailored Design Method*. New York: John Wiley & Sons, Inc., 398-99.

- Initial “cover letter” email
- Reminder/thank you email
- Second “cover letter” email
- “Thank-you for promising to respond” email
- “Incomplete” email (to those who started the online survey, but did not submit it)
- “Last call” email from JoAnne Goodnight, NIH SBIR/STTR Program Coordinator

All of the 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.

Appendix A6, *Mail and Email Messages and Telephone Scripts*, contains copies of all communications and scripts used during the fielding of the survey and the follow-up with nonresponders:

- A6.3 *Advance Letter*
- A6.4 *First Cover Mail and Email Messages*
- A6.5 *Thank You/Reminder Mail and Email Messages*
- A6.6 *Second Cover Mail and Email Messages*
- A6.7 *Personal Final Request Email Message*
- A6.8 *Script for Telephone Follow-Up About Survey*
- A6.9 *Promisers’ Mail and Email Messages*
- A6.10 *Incomplete Email Message*

1.2.6 Maximizing Survey Response

The survey response goal was to achieve participation from 80 percent of the usable and eligible awardees. This is an extremely high response rate that is typically achieved only when respondents believe the survey has high interest and importance, or when they receive valued incentives to participate. Pretest results indicated that respondents who received SBIR awards would view this survey as important and worthy of participation. Nonetheless, we planned and implemented a strategy focused on maximizing response to the survey.

This approach included the multiple communications itemized above and the ability to accommodate requests for alternative modes of survey administration. We provided a paper version of the survey to those respondents who requested one and to those for whom we were not able to secure an email address. This self-administered paper questionnaire was nearly identical in format and content to the online version of the survey. We also sent subsequent communications to this group of respondents using the U.S. Postal Service.

After sending these multiple communications, we followed up with nonresponders to the survey using a professional telephone center. We briefed the telephone interviewers and supervisor about the background and goals of this assessment, and we trained the interviewers to administer a telephone version of the survey, should one be requested. The interviewers attempted to contact all nonresponders, update awardee and respondent contact information, and offer a choice of an online, paper, or telephone survey. They made a minimum of nine calls that were staggered across days and time periods in their attempts to reach each nonresponder. Appendix A5, *Survey*

Instrument, contains the booklet used in briefing and training the interviewers: A5.3, *Interviewer Briefing*.

As part of the follow-up with non-responders, we sent email messages containing the survey link, user name, and password to all those who “promised” to complete an online survey. We mailed letters containing the paper questionnaire to all who “promised” to complete a paper survey. The interviewers administered the telephone survey on the spot or at a convenient appointment time to all who preferred this approach.

An online response rate calculator, accessible at any time by both personnel within OER and Humanitas, 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.

As a result of these extensive efforts at maximizing response, this survey achieved an 85 percent response rate, surpassing expectations. A total of 768 awardees participated in the survey. With such a high response rate, we need not be concerned about possible nonresponse bias. For additional information, please see Appendix A4. It contains A4.1; *Online Survey Response Rate Calculator*, A4.2; *Final Disposition of Sample*, A4.3; *Daily and Cumulative Completes*, and A4.4; *CASRO Response Rate Formula*.

The NIH SBIR Survey Response Rate Calculator (A4.1) shows the “in-the-field” response rate calculations. After the survey field period ended, we computed the final sample disposition, carefully reviewing and assigning each sample piece to the most accurate category. The Final Disposition of Sample (A4.2) groups the sample by usability and eligibility, and it shows the calculation of the Usability Rate, Eligibility Rate, and Response Rate. The response rate is 1% lower here than in the online calculator because, in the finalization process, a small amount of sample was reclassified. We wanted to be as accurate as possible in distinguishing between unusable and ineligible sample because these classifications provide important information about the awardees. *Unusable* awardee businesses are no longer in existence. *Ineligible* awardee businesses exist, but they have no eligible respondent to “speak” for them—that is, neither the original PI, his or her replacement, nor the business official who signed the SBIR application was still employed by the awardee business.

The bar charts of the Daily and Cumulative Completes (A4.3) show the effects of the multiple contacts in boosting response to the survey. We can note that the numbers of completed surveys exhibit “spikes” just after the first cover email, the thank you email, the second cover email, and the personalized email from JoAnne Goodnight, the NIH SBIR/STTR Program Coordinator. In comparison, the effects of the telephone follow-up, begun on October 8, 2002 (“FolUp” on the chart), were slow building, as the interviewers repetitively attempted to contact each nonresponder.

The CASRO Response Rate Formula (A4.4) shows the accepted procedure for calculating response rate. This relatively conservative formula includes the assumptions that any sample of unknown usability or unknown eligibility is usable or eligible at the same rate that the sample of known usability and known eligibility is.

1.2.7 Cleaning and Coding the Data

There is minimal cleaning 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. However, the manual input of data from paper questionnaires and the coding of open-ended responses can introduce errors. To minimize errors of this type, we used the following procedures.

- Double keying of all data from paper surveys and computer comparison of the double data records
- Resolution of any discrepancies between the two records by visual inspection of the paper questionnaire
- Double keying into a special implementation of the online survey to make use of the program controls for skipping, code input, and range checks
- Development and review of codes for the open-ended responses
- Training coders in the use of the codes
- Independent checking of all coded values
- Careful review of frequency distributions of all survey data, merged background data (from NIH SBIR databases), and newly-coded data

We also did some quality control checks of the follow-up telephone interviews conducted by the interviewers in the commercial telephone center. The supervisor of the interviewers on this job and a Humanitas researcher listened to some of the interviews, periodically we reviewed proper technique with the supervisor, and we called some random respondents to make sure that they did indeed complete the interviews that the interviewers conducted. These activities provided positive feedback on the interviewing.

Appendix A7, *Data Cleaning and Coding*, describes these processes. A7.1, *Cleaning and Coding Processes*, provides more detail about cleaning and coding the data. A7.2, *Limitations of Categorization and Coding*, discusses the inherent limitations of coding. A7.3, *Telephone Interview Validation Script*, shows the brief script used by the researcher who called some of the telephone responders.

2. RESPONDENTS

To provide an accurate context for interpreting the survey results that are reported in Chapter 3, this chapter describes the survey respondents. We begin by discussing the usability and eligibility of the awardee sample. Next, we focus on the characteristics of the respondent spokespersons who reported information on behalf of the awardees. The last section of this chapter reports on the status of the funded projects described by the spokespersons.

The information in this chapter suggests that survey results should be interpreted keeping these key respondent characteristics in mind:

- Most (74%) of the 768 SBIR awards described by 768 survey respondents were received from 1997 through 2001, the second half of the study period, so the survey results are particularly relevant to projects funded within 1 to 5 years of the time of measurement.
- The number of Phase II awards in each IC included in the survey was proportional to the number of Phase II awards made by each IC during the study period, so the respondents are representative of all awardees in terms of their IC affiliation.
- Most survey respondents (75%) are the initial PIs, the respondent category that reported the highest level of recall of information about the referenced SBIR awards. This suggests that the survey results are based on the best available information.

2.1 Unusable Awardees

An important goal in survey research is achieving participation in the survey from nearly all potential respondents. This greatly reduces any possible response bias—that is, differences between the people who participated in the survey and those who did not. Reducing the possibility of response bias makes it possible to generalize survey results from the participants to the entire survey population. In the NIH SBIR survey, 11 percent of the 1,052 awardee sample pieces were unusable, and 1 percent was of unknown usability. To determine whether the unusable sample introduced any possible response bias, we compared respondents and nonrespondents as best we could, granted that we had only limited or no contact with nonrespondents.

2.1.1 Characterizing Unusable Sample

Prior to conducting the survey, we defined usable sampling units as existing, nonduplicate small businesses located within the U.S.A. After completing the initial data update and the survey fielding, we were able to categorize the unusable sample into these groups:

<u>Unusable Sample</u>	<u>Number</u>	<u>Percent of Total Sample</u>
Awardee small business no longer exists	47	4%
No contact information exists after extensive tracking	69	7%
Duplicate sample	2	0%

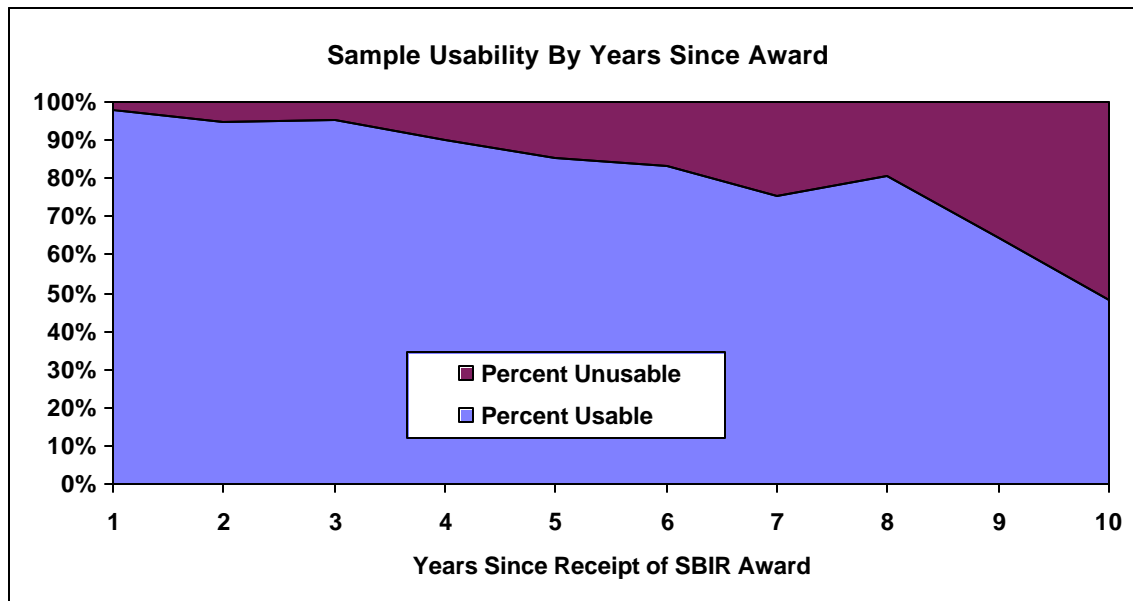
For the first group, we were able to confirm that the awardee small business was no longer in existence by speaking with the PI or a replacement researcher, company business officials, or other individuals, or by finding information on the Internet in articles or online company publications. For the second group, we were not able to get confirmation that the awardee small business no longer exists. However, after extensive tracking efforts, we concluded that this was likely the case.

2.1.2 Comparing Usable and Unusable Awardees

We compared the usable and unusable awardees by characteristics available for both groups. These were U.S. census region, IC sponsoring the award, and years since receipt of the SBIR Phase II award. We found that there were no statistically significant differences between the usable and the unusable awardees by census region or sponsoring IC. That is, approximately the same percentages of usable and unusable awardees existed within each census region and for each sponsoring IC—88 percent usable and 12 percent unusable (unusable plus usability unknown).

When we examine the distribution of usable and unusable awardee sample by years since receipt of the SBIR award, we find that the percent of usable sample is not constant. It gradually decreases as the years since the award increase, going from 98 percent usable one year since the award to 48 percent usable ten years since the award. This difference between the distribution of usable sample by years since award is statistically significant at the .0001 level (chi-square=105.83; $p < 0.0001$). The following exhibit illustrates this.

Exhibit 2-1 Usable and Unusable Awardee Sample by Years Since Award



Usable and unusable awardee sample are not distributed evenly across the years elapsed since receipt of the SBIR Phase II award. The sample decreases in percent usable over time, going from 98 percent usable in year one to 48 percent usable in year ten. Overall, 88 percent of the 1,052 awardee sample pieces were usable.

Thus, the achieved sample of respondents contains proportionately fewer awardees who received their awards in the earlier years. There were also far fewer SBIR awards given during the initial five years of the study period. Only 34 percent of the 1,052 awardees (357) received their awards

from 1992 to 1996. Thus, even with 100 percent response from all awardees, the survey data would be dominated by the 66 percent of the awardees (695) who received their awards from 1997 to 2001. Overall, 24 percent of the awardee sample dating from the five-year period from 1992 through 1996 was unusable, compared with 6.6 percent of the sample from 1997 through 2001.

2.2 Ineligible Awardees

The ineligibility of some awardees could also introduce response bias. In the NIH SBIR survey, only 3 percent of the usable awardees were ineligible to participate in the survey. Ninety-seven percent were eligible. Because of this very high eligibility rate, it is unlikely that differences between eligible and ineligible awardees could affect the survey data. Nonetheless, it is interesting to compare the eligible and ineligible awardees. (The ineligible ones include two of unknown eligibility).

2.2.1 Characterizing Ineligible Sample

Prior to the survey, we defined eligible sampling units as usable awardee small businesses, in which a qualified respondent was employed by the awardee business and resided within the U.S.A. In order of desirability, qualified respondents were: 1) the original PI on the SBIR 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 application, if there was no replacement PI. After completing the initial data update and the survey fielding, we were able to categorize the ineligible awardees into these groups:

<u>Ineligible Sample</u>	<u>Number</u>	<u>Percent of Total Sample</u>
Respondent permanently incapacitated; no replacement	2	0%
Respondent no longer with awardee; no replacement	24	2%
Respondent not residing in U.S.A.; no replacement	1	0%

The first group comprised a recently deceased PI and a PI out on maternity leave. The second group included the bulk of the ineligible potential respondents. They were primarily PIs no longer employed by the awardee small business because of job changes and retirement. There were no replacement PIs, often because the SBIR supported project was discontinued, and there were no business officials who were still employed by the small business. In the final group was one PI who was transferred abroad for five years, who had no replacement.

2.2.2 Comparing Eligible and Ineligible Awardees

As we did with the usable and unusable awardees, we compared the eligible and ineligible potential respondents by U.S. census region, NIH sponsoring IC, and years since receipt of the SBIR award. There were no statistically significant differences between the percents of eligible and ineligible respondents by census region or sponsoring IC. Approximately 3 percent of the potential respondents in each region and IC were ineligible.

Within the years since receipt of the SBIR award, there were statistically significant differences among the percentages of respondents (chi-square=41.82; p<0.0001). The percent of eligible

sample decreases as the years since award increase, going from 99 percent eligible one year since award to 75 percent eligible ten years since award. Overall, 7.5 percent of the usable awardees who received their awards during the initial five years of the study period (1992 to 1996) had ineligible respondents, compared with 1.6 percent of the awardees from the most recent five years (1997 to 2001).

However, as is the case with the usable and unusable awardees, differences between the eligible and ineligible respondents can have only minimal effect on the survey data, primarily because such small numbers of respondents are involved. There are only 29 ineligible potential respondents (including the two of unknown eligibility)—ten with awards from 1 to 5 years ago and 19 with awards from 6 to 10 years ago.

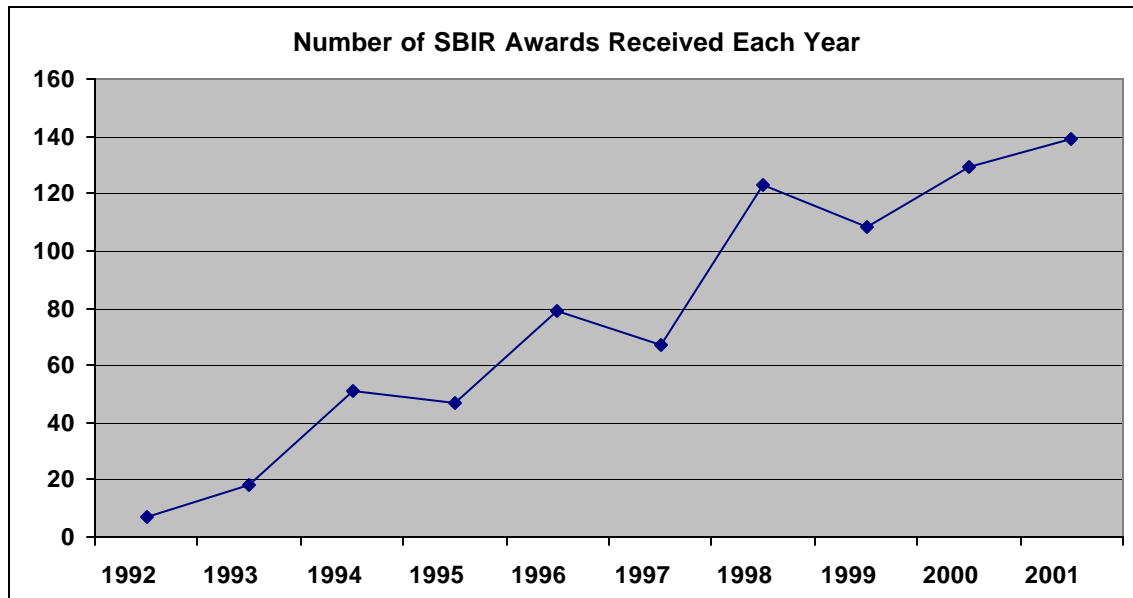
2.3 Award and Awardee Characteristics

In this section, we describe the *survey respondents* in terms of the years in which the awardee small businesses received their awards, the NIH ICs sponsoring the awards, the geographical locations of the awardees, and the founding years of these small business concerns.

2.3.1 Year of SBIR Award

Increasing numbers of Phase II NIH SBIR awards were funded during the successive years of the survey study period (1992 through 2001).

Exhibit 2-2 NIH SBIR Phase II Awards by Year of Receipt for Survey Respondents



NIH funded nearly three times as many awards during the second five-year period (1997 to 2001) than during the first five-year period (1992 to 1996)—566 as compared with 202.

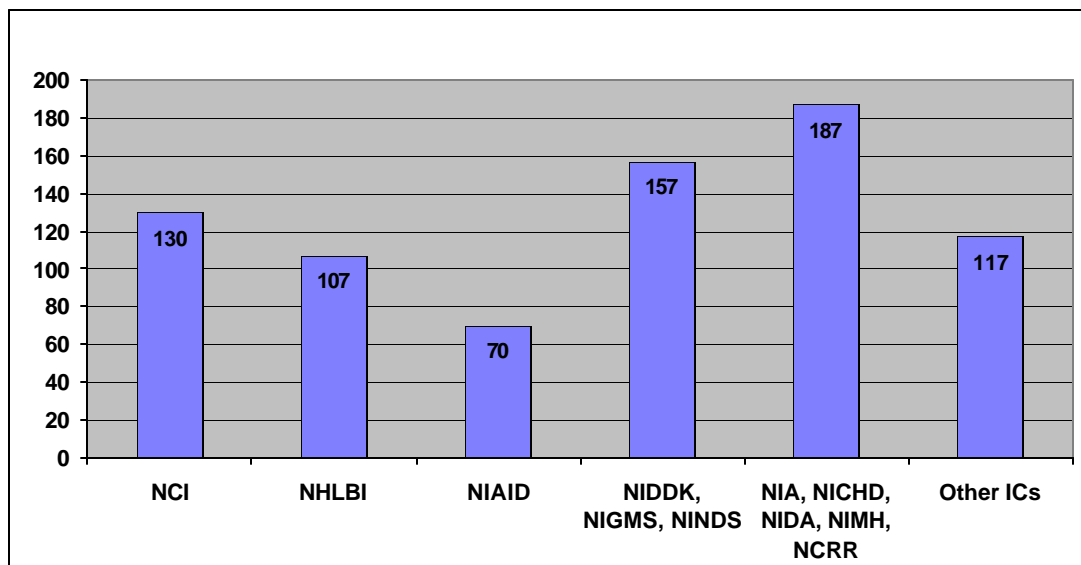
Of the 768 awards received by survey respondents, 26 percent were awarded during the initial five years of the study period and 74 percent were awarded during the final five years. This skewing of the awards to the more recent funding years is primarily a function of increased

federal funding for the SBIR Program, although slightly lower usability and eligibility rates for the earliest years of the study period contribute to this to a very small degree. To some extent, the scewing of awards to the most recent year of the study period affects those award outcomes that depend on the length of elapsed time since receipt of award.

2.3.2 IC Funding Award

The 768 Phase II SBIR awards received by awardee respondents are distributed among the IC Groups funding the awards, as shown in the following exhibit. (The ICs are grouped, based on their commonalities and relative funding amounts, so that there are a reasonable number of comparison groups).

Exhibit 2-3 NIH SBIR Phase II Awards by IC Group

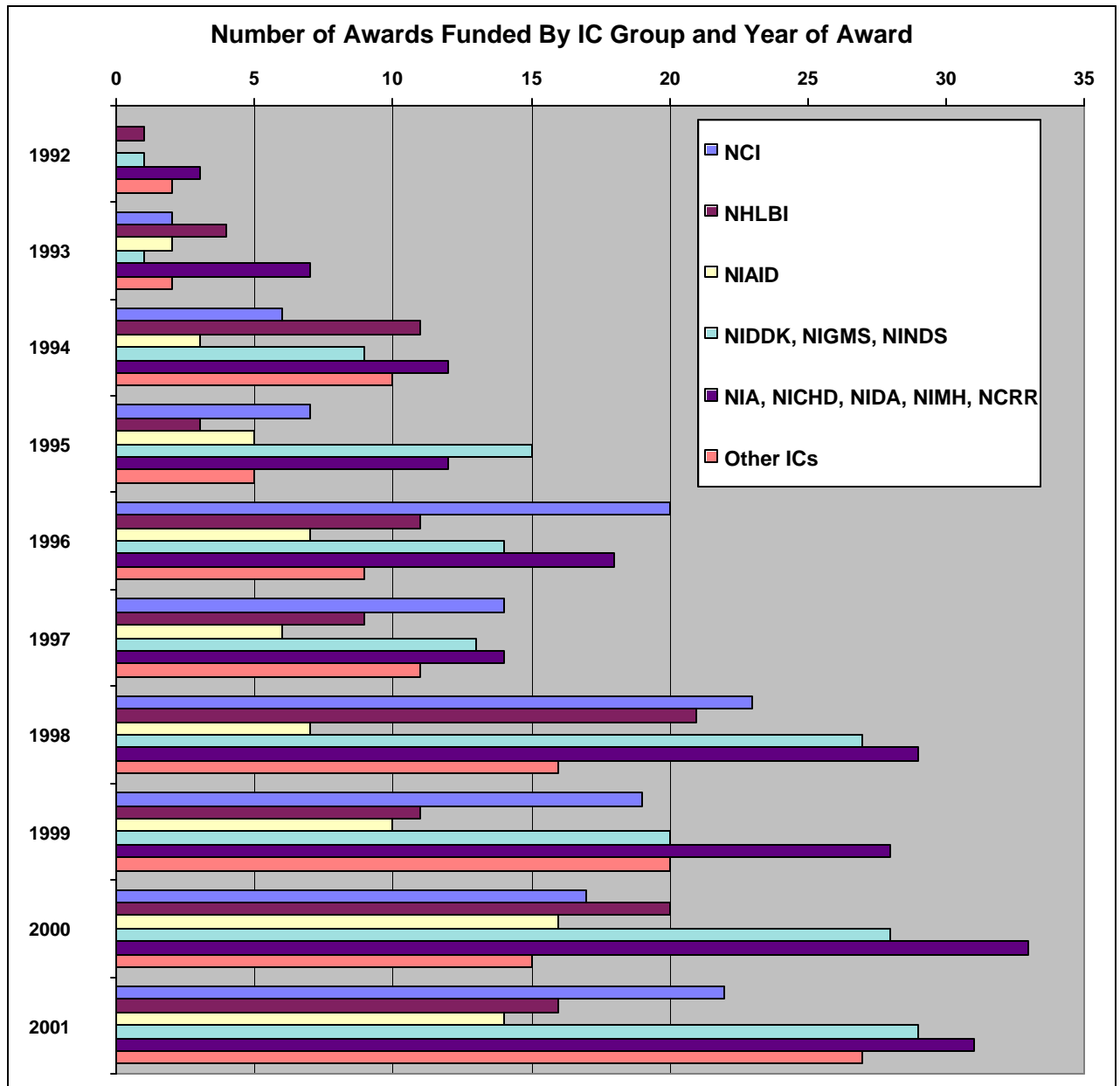


The IC Groups funded the 768 NIH SBIR Phase II awards received by the awardee respondents during the study period from 1992 through 2001 that are the focus awards in this survey. ("Other ICs" include: NCCAM, NIAAA, NIAMS, NIDCD, NIDCR, NEI, NHGRI, NIEHS, and NINR.)

The numbers of Phase II awards for each of the IC Groups are proportional to the total numbers of Phase II awards funded by the IC Groups during the study period. The *random* selection of a single focus award for each awardee accomplished this. (Please see Appendix A3.2, *Limitations of Awardee Database*, for further discussion of the selection procedure and comparisons of the randomly selected awards with all the awards.)

The next exhibit shows the numbers of Phase II SBIR awards funded by each NIH IC Group by the year of the award. The funding IC Group and year of award are independent of each other.

Exhibit 2-4 Phase II Awards by IC Group and Year of Award for Survey Respondents

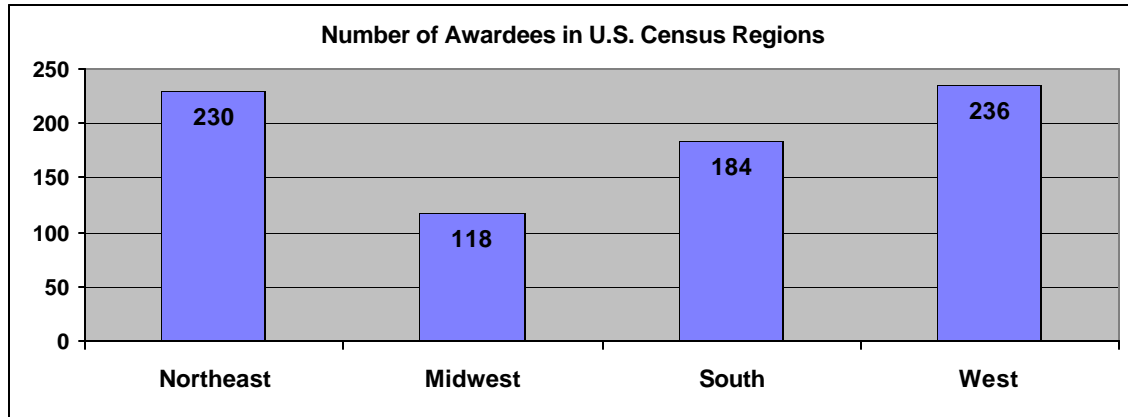


The NIH ICs funded increasing numbers of Phase II SBIR awards during the successive years of the ten-year study period included in the survey. ("Other ICs" include: NCCAM, NIAAA, NIA MS, NIDCD, NIDCR, NEI, NHGRI, NIEHS, and NINR.)

2.3.3 Awardee Locations

The awardee respondents are distributed across the four U.S. Census Regions in the same proportions in which the initial sample units are distributed across these regions. In terms of absolute numbers, however, more awardee small business concerns are located in the Northeast and West regions. The following exhibit illustrates this.

Exhibit 2-5 Awardee Small Business Concerns by U.S. Census Region

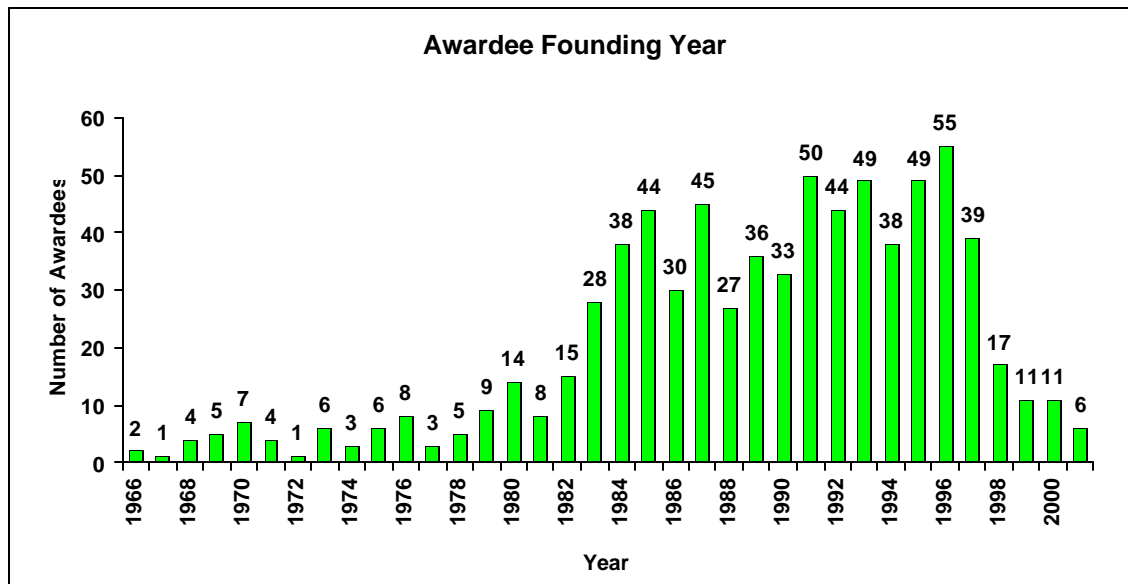


More of the 768 awardees are located in the Northeast and West than Midwest and South regions.

2.3.4 Awardee Founding Year

Over 75 percent of the awardee businesses were founded in the period from 1985 through 2001. Half were founded in 1990 or later. The range of founding years goes from 1960 to 2001, with the exception of one business founded in 1886 (whose surprisingly early founding date we confirmed by recontacting the respondent). The next exhibit shows the distribution of founding dates for the awardee small business concerns.

Exhibit 2-6 Founding Year of Awardee Small Business Concerns



The median founding year is 1990—half of the small business concerns were founded between 1990 and 2001. (This chart does not include eight awardees who did not supply their founding year and nine awardees founded before 1966.)

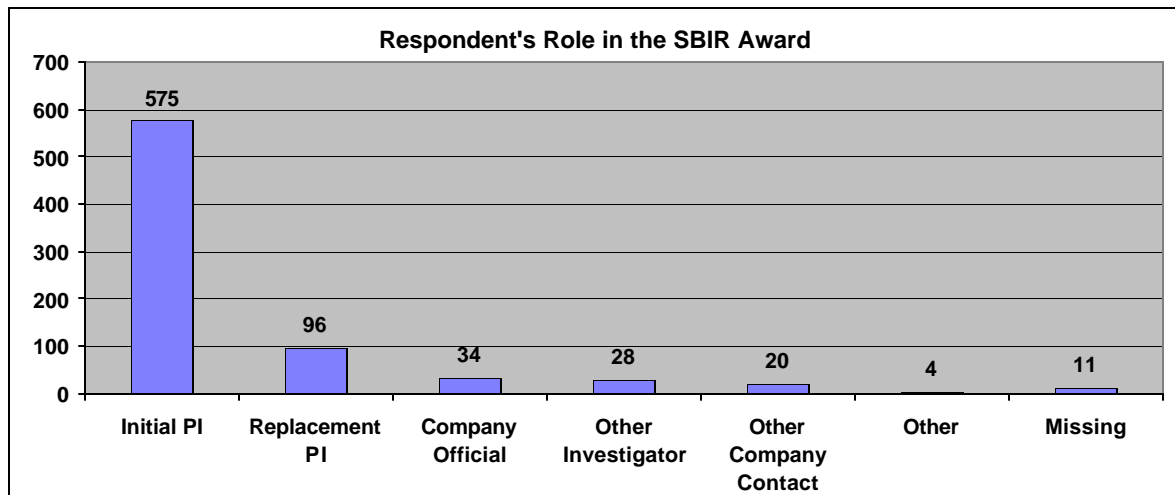
2.4 Respondent Demographics

This section characterizes the respondent spokespersons for the awardees—that is, the people who literally responded to the survey. We characterize the respondents in terms of their roles in the SBIR awards, their relationships to the awardee businesses, their knowledge about the award, and their mode of response to the survey.

2.4.1 Respondent Role in Award

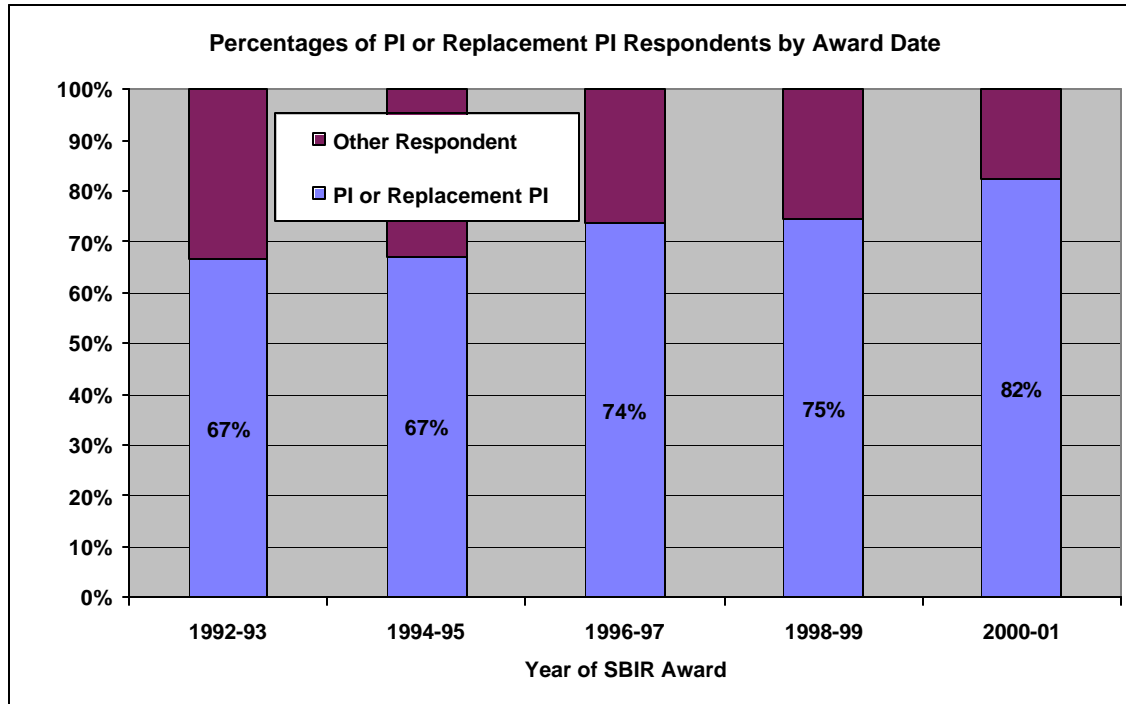
Of the 768 survey respondents, 575 (75%) are the initial PIs listed on the SBIR award application. The next exhibit shows the distribution of respondents by their role in the SBIR Phase II award. When we group replacement PIs and other investigators with the initial PIs, we find that 699 (91%) of the respondents are individuals involved with research on the supported project. A total of 54 (7%), are business officials—either the company official who signed the SBIR application on behalf of the small business or another company contact at the awardee business.

Exhibit 2-7 Respondent Spokespersons by Role in SBIR Award



Seventy-five percent (575) of the 768 survey respondents are the initial PIs listed on the SBIR award application.

We were able to locate and contact the PI or replacement PI who was still employed by the awardee small business for 82 percent of the awards funded during 2000 to 2001. This percentage decreased to 67 percent of the awards funded during 1992 to 1993. The following exhibit shows the decreasing availability of the PI or replacement PI for awards funded in the earlier years of the study period. This relationship between PI availability and funding year is significant at the 5% level (chi-square=11.78; p=.0191).

Exhibit 2-8 Respondent Spokespersons by Date of SBIR Award

The percentages of respondent spokespersons who were the initial or replacement PI for the SBIR award decreased as the award date went back in time.

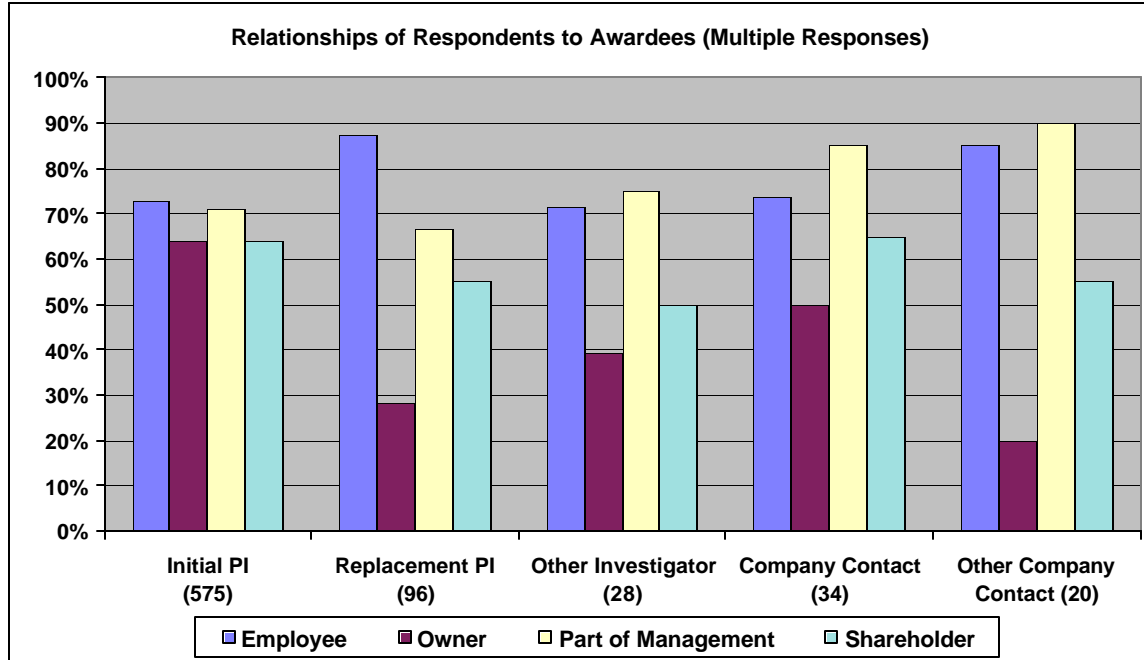
2.4.2 Relationship to Awardee

The respondent spokespersons had multiple relationships with their awardee small businesses. Sixty-four percent of the 575 initial PIs (who are 75 percent of all respondents) stated that they were employees, owners, part of management, *and* shareholders of their awardee businesses. This “wearing of four hats” was true for fewer percentages of the other respondents. Generally, less than 50 percent stated that they were also owners of the awardee businesses.

The next exhibit shows the multiple relationships of each of the different types of respondents to their awardee small businesses. In the survey, the respondents could indicate multiple current relationships. Thus, the percentages shown on this exhibit are of the number of each type of respondent, not of the total responses.

Twenty respondents indicated “other” relationships with their small businesses. Five were board members or option holders, and four were consultants. Eleven indicated that they were currently no longer with their awardee businesses—seven were no longer employed by the existing awardee businesses, and four of the businesses no longer existed. According to the eligibility requirements for the survey, these 11 respondents should not have participated. However, all of them were the initial or replacement PI for their Phase II awards. We suspect that relatively strong motivation (likely, appreciation for their awards) prompted these individuals to respond to the survey when they received the initial contact update request and the subsequent link to the survey. Additionally, 19 respondents did not indicate their relationships to the awardee businesses.

Exhibit 2-9 Multiple Relationships of Respondents to the Awardee Small Businesses



Nearly three-quarters of the 575 respondents, who were the initial PIs, “wore four hats”—those of employee, owner, part of management, and shareholder. Smaller percentages of the other respondents were also owners of their small businesses. (Fifteen respondents are not included—11 gave no data and four responded “other.”)

2.4.3 Knowledge About Award

Survey respondents report that they were able to recall the information that this survey requested about the referenced SBIR award from “well” to “very well.” The overall average is 1.5. The ratings provided as the responses for this survey item went from 1 (“very well”) to 5 (“not very well”). Looking at the respondents broken out by their role in the award, we see that self-reported recall ranges from 1.4 for the initial PIs to 2.6 for other company contacts.

Exhibit 2-10 Self-Reported Recall of Information Requested by Survey About SBIR Award

Initial PI	Replacement PI	Other Investigator	Company Contact on SBIR Application	Other Company Contact
1.4	1.7	1.8	1.6	2.6

Self-reported recall was higher for initial PIs than for other types of survey respondents.

This statistically significant difference in knowledge ($F=20.7$; $p<.0001$) confirms the decision we made prior to fielding the survey to seek the PI on the SBIR award application as the most knowledgeable respondent about the award and its outcomes. Because 75 percent of the survey respondents are the initial PIs on their award applications, it is likely that the information they supplied is accurate as best they can recall.

2.4.4 Mode of Response

Eighty-six percent of respondents (658) answered the survey online. Three percent (25) responded using a paper questionnaire that was returned by mail (22) or by fax (3). These two modes of response—online survey or paper questionnaire—are very similar, in that they are self-administered surveys. Both types of respondents considered questions that they read themselves and answered by selecting among supplied response categories that they also read themselves.

This is not the same situation that existed for respondents who elected to complete a telephone interview during the follow-up with nonrespondents. There, the interviewer mediated the questions and responses to some degree. Despite using an identical questionnaire and following specific instructions on conducting the interview, the interviewer affected the response situation by reading the questions and response categories and by his or her presence during the response process. Thus, we typically want to learn if there are differences between the respondents who completed a self-administered interview and those who completed an interviewer-administered one. Conceivably, such differences could affect the survey data.

Eleven percent of respondents (85) completed telephone interviews. These individuals were all initial nonresponders who elected to complete the survey by telephone during the follow-up process. (Some respondents, who completed the survey on line or using a paper questionnaire, also responded because they received a follow-up call from a telephone interviewer. These individuals “promised” to complete the survey online or via mail, rather than complete a telephone interview. Some did, and some did not).

There are no statistically significant differences among online, telephone, and mail/fax respondents when we compare them in terms of their role in the SBIR award as initial PI, subsequent PI, other investigator, company contact on the SBIR application, or other company contact. There are no such differences when we compare them in terms of their awardee small businesses’ major fields of business.

In conclusion, it is not likely that response mode differences affect the survey data. Eighty-six percent completed the survey online and, for the most part, this percentage is consistent across important subgroups.

2.5 Project Status

In this section, we report on the status of the funded project. We describe the ages of the small businesses at the time they received their awards and their ages and the statuses of their projects at the time of the survey. The relative ages of the businesses and different stages of project development likely affect measures of success of the awards.

2.5.1 Years in Business Relative to Award and Survey

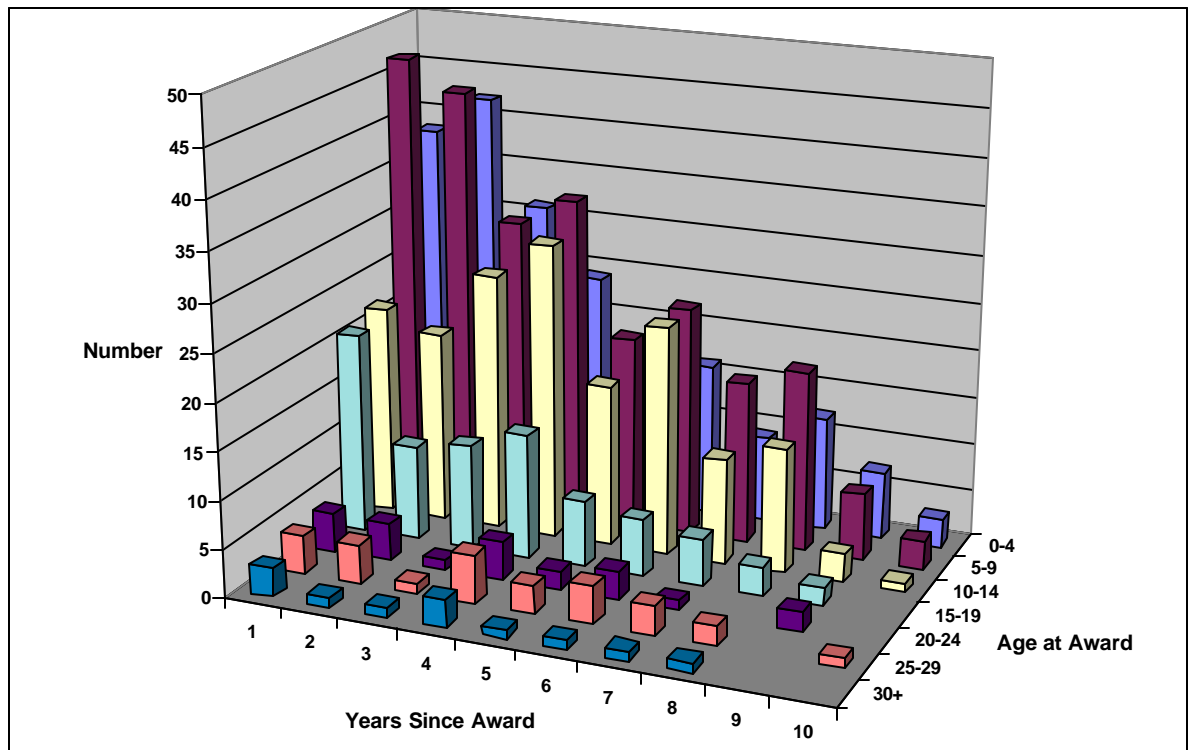
Fifty-nine percent of the awardee businesses were less than 10 years old at the time that they received their Phase II awards. At the time of the survey, less than five years had elapsed since receipt of their awards for 64 percent of the awardees. Thus, for the most part, the awardee

businesses were relatively young companies at the time they received their awards and at the time of this evaluation.

The comparatively small number of years elapsed since receipt of their awards for 64 percent of the awardee businesses is a function of several factors. The most important is that NIH funded nearly three times as many awards during the second five-year period (1997 to 2001) than during the first (1992 to 1996). In addition, slightly higher percentages of the older sample—that is, businesses that had received SBIR awards in the 1992 to 1996 period—were unusable or ineligible.

Small businesses that receive SBIR awards are generally recently established (young) businesses. The next exhibit shows the dual distributions of: 1) years in business at receipt of the SBIR award, and 2) years since receipt of the award and the fielding of the survey. These two variables are independent (no association between them).

Exhibit 2-11 Awardees Age at Time of Award and Years Since Receipt of Award



The large majority of awardees were relatively young businesses when they received their Phase II awards (59 percent were less than 10 years old). At the time of the survey, not that many years had elapsed since receipt of their awards (less than five years had elapsed for 64 percent).

2.5.2 Status of Funded Project

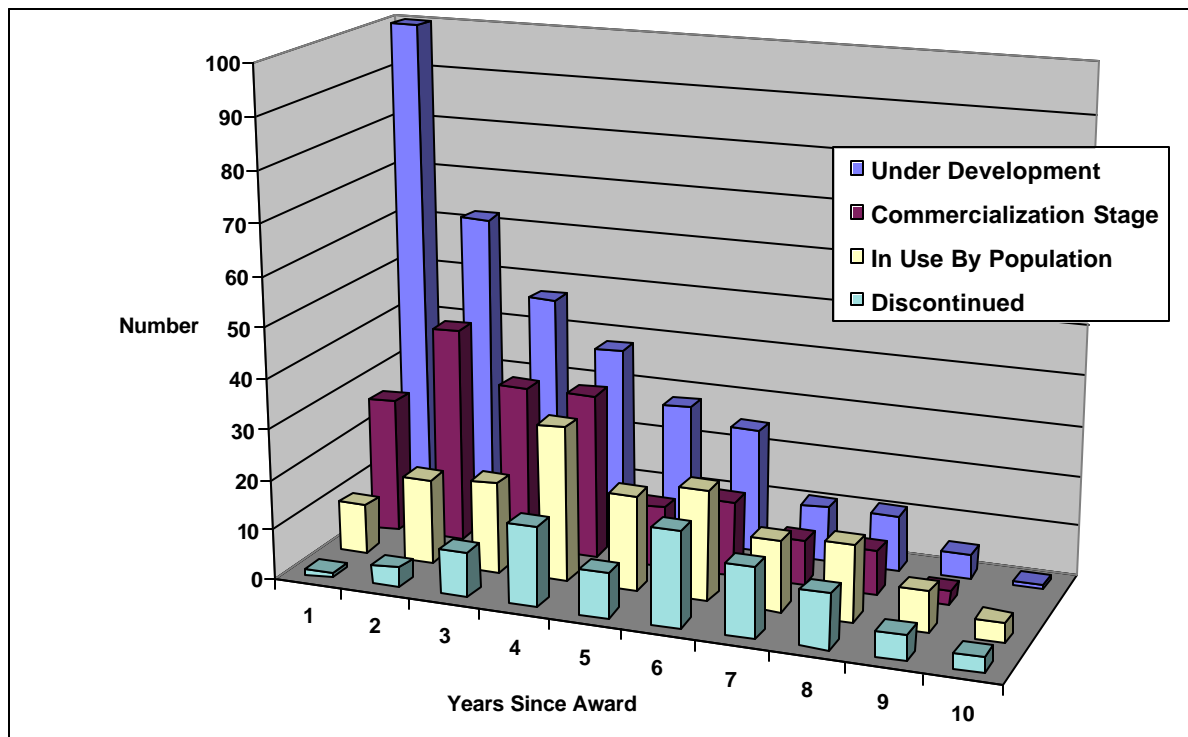
Survey respondents indicated the current status of the project funded by the SBIR Phase II award:

<u>Project Status</u>	<u>Number of Awardees</u>	<u>Percent of Total Respondents</u>
Under development	328	43%
Commercialization stage	184	24%
In use by target population	158	21%
Discontinued	91	12%
Other	7	1%

The explanations provided for “Other” were primarily related to dormancy or ending of the project for reasons other than discontinuance.

When we examine the status of the funded project by years elapsed since the receipt of the Phase II award, we observe several patterns of relationships. These differences are significant at the 1% level (chi-square=151.51; p<.0001). The following exhibit displays these relationships.

Exhibit 2-12 Current Status of Funded Project and Years Since Receipt of Phase II Award



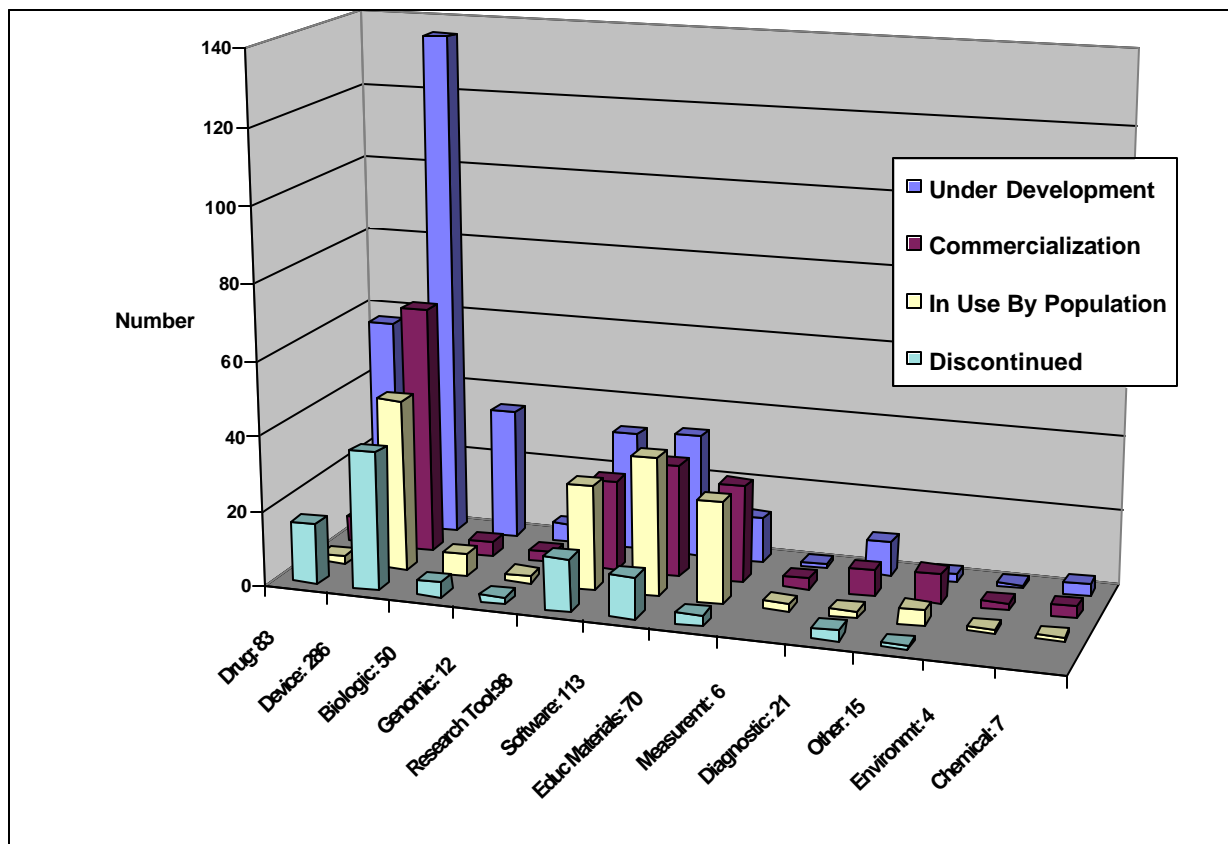
The current status of the SBIR-funded project is associated with the number of years elapsed since receipt of the award. The distribution of projects in each of the status stages peaks in successively further years since the receipt of the SBIR award—proportionately more projects are under development in the first year, in commercialization the second through the fourth year, in use by populations in the fourth year, and, if discontinued, discontinued in the sixth year.

The number of projects under development is highest the initial year after the award and declines gradually as the number of years since the award increases. The number of projects in the commercialization stage peaks the second through fourth years after the receipt of the award and declines more dramatically after that. The number of projects in use by the target population peaks the fourth year after receipt of the award and declines gradually thereafter. The number of discontinued projects slowly rises and then gradually declines, with the most projects discontinued in the sixth year since receipt of the award.

These relationship patterns appear consistent and logical. They likely reflect funding realities—projects can undergo development only for a reasonable amount of time. After that, they need to move into commercialization and subsequent use by the target population or be discontinued. There are larger numbers of projects under development or in the commercialization stage because NIH funded three times as many awards during the most recent five years (566), as compared with the prior five (202).

When we examine the statuses of the funded projects by the different types of projects planned for commercialization by the awardee businesses, we note variations between the project types. These differences are statistically significant at the 1% level (chi-square=129.5; $p < .0001$). The following exhibit illustrates these variations between the types of projects.

Exhibit 2-13 Current Status of Funded Project and Project Planned for Commercialization



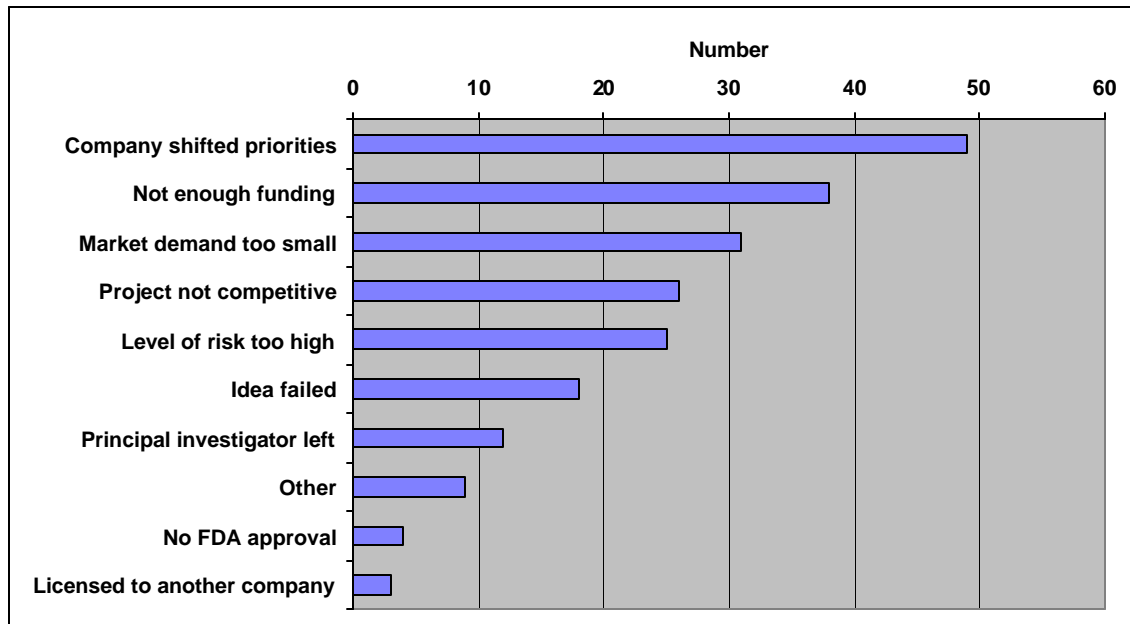
The current status of funded projects is associated with the type of project planned for commercialization. Higher proportions of drugs and devices are under development than are biologics, research tools, software, and educational materials.

We should ignore those project types with very small numbers of awardees. When we look at the projects with larger numbers of awardee businesses, we see that drugs and devices, for example, have a different pattern of development than biologics, research tools, software, and educational materials. Greater proportions of awardees with drug and device projects are in the under development stage than are awardees with biologics, research tools, software, or educational materials. This may likely reflect varying development requirements for different projects, such

as needs for testing and securing FDA approval. These requirements may tend to lengthen the development stage for drugs and devices.

Ninety-one respondents (12%) reported that the funded projects had been discontinued. The next exhibit shows the reasons they gave for discontinuing the projects. Multiple responses per respondent were permitted.

Exhibit 2-14 Reasons for Discontinuing the Funded Project (Multiple Responses)



The 91 respondents who reported that their SBIR-funded projects had been discontinued gave 215 reasons for the discontinuances. Most often cited reasons were a shift in company priorities and not enough funding.

In general, the most numerous reasons for discontinuing projects appear to relate to funding. Keeping in mind that respondents selected multiple reasons why the product, process, or service was discontinued, it is likely that the reasons are related. Companies probably “shifted priorities” because the project did not get “enough funding” or did not generate enough sales (“market demand too small” and/or “project not competitive”). It may not have appeared that project success and sales were imminent (“level of risk too high”). Relatively smaller numbers of respondents cited other reasons related to the project itself or the PI.

When we look for additional supporting information about why projects were discontinued, we find that discontinuing projects is associated with receipt/non-receipt of non-SBIR funding. Proportionately less small business awardees that discontinued the funded projects received additional non-SBIR funding. The next exhibit illustrates this association, which is statistically significant at the 1% level (chi-square=34.92; $p < .0001$). On average, 40 percent of those awardees with ongoing projects (those under development, in the commercialization stage, or in use by the target population) received additional non-SBIR funding, versus only 11 percent of awardees with discontinued projects.

We cannot state that lack of additional non-SBIR funding is responsible for discontinuing projects, only that these two variables are associated. It is likely that receipt of additional

funding—either non-SBIR funding and/or additional SBIR awards, which are related to each other (see the discussion in Section 3.1.4, *Additional SBIR Support of Core Technology*)—is associated with the merit and sales prospects of the project itself. Confirming this is beyond the scope of this survey, which could not and did not attempt to assess the value of awardee projects directly. On the other hand, the fact that proportionately more awardees with ongoing projects (those that were not discontinued) did receive additional funding from either SBIR or non-SBIR sources is an indirect measure of their merit and sales potential.

Exhibit 2-15 Association Between Current Project Status to Receiving Additional Non-SBIR Funding

Q25. Has your company received any additional <u>non-SBIR</u> funding or capital for this project?			
Q18. What is the current status of the project funded by the referenced SBIR award?			
	Yes	No	Total
Under development	117 36%	211 64%	328 100%
Commercialization stage	81 44%	103 56%	184 100%
In use by target population	71 45%	87 55%	158 100%
Discontinued	10 11%	81 89%	91 100%
Total	279 37%	482 63%	761 100%
X² statistic	34.92		
P	<0.0001		

Higher proportions of those awardees who have ongoing projects (not discontinued) have received additional non-SBIR funding. This finding is statistically significant at the 1% level.

3. SURVEY FINDINGS

This chapter reports survey findings about attainment of three legislated goals of the SBIR Program that were studied:

- Stimulate technological innovation
- Use small business concerns to meet federal research and development needs
- Increase private sector commercialization of innovations derived from federal research and development

We organize survey findings sections to discuss each goal in turn. Within each section, we present a summary chart that describes findings in this manner:

- We list performance indices and related measures posited for this goal in the evaluation framework (Appendix A2).
- For each index, we show the percentage of awardee respondents attaining it.
- For each measure, we itemize the number of specific achievements.

Then we present detailed narrative and graphic analyses that support the findings described in the chart.

3.1 Technological Innovation

This section discusses the survey findings that relate to the first goal of the SBIR Program—to *stimulate technological innovation*. We evaluated the survey findings specifically in terms of assessing the NIH objective for the SBIR Program—to *stimulate technological innovation in support of the NIH mission, from the date of the SBIR award to the date of measurement*. As shown by the following summary exhibit, survey findings indicate that SBIR awardees achieved high rates of success in attaining both related indices.

Exhibit 3-1 Summary of Awardee Performance: Technological Innovations

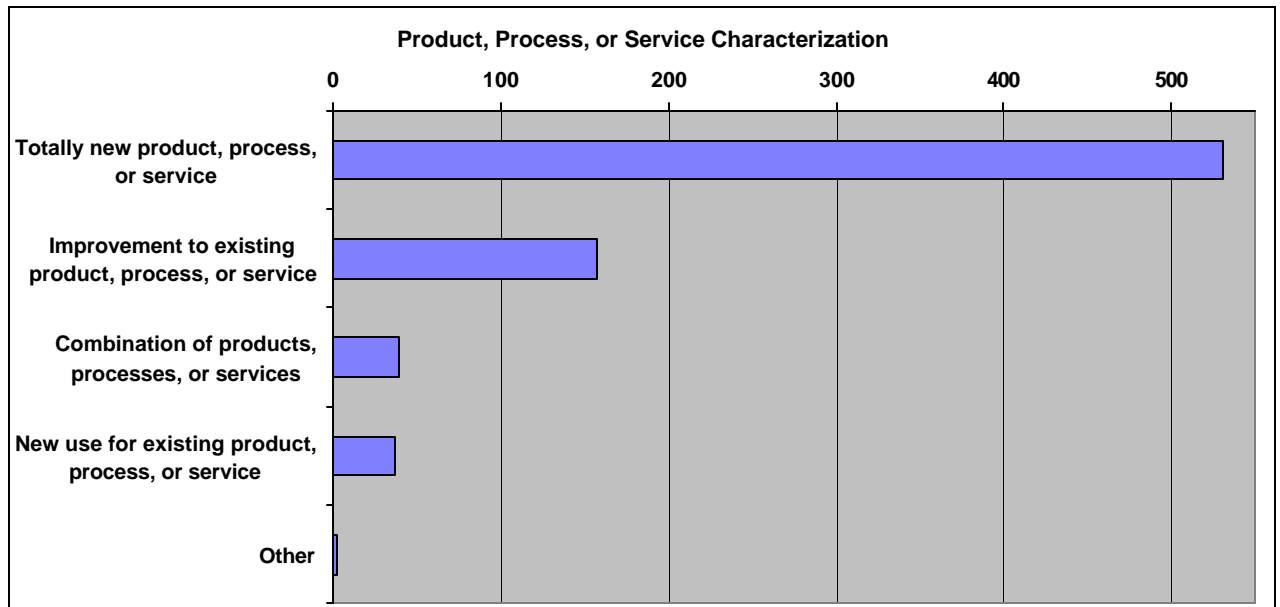
Stimulate Technological Innovation	Findings	
	Indices	Measures
1.1 Whether or not sales have occurred, a percentage of the NIH SBIR awardees produce new or improved products, processes, usages, and/or services in support of the NIH mission.	87%	
1.1.1 Number of new or improved products, processes, usages, and/or services		670
1.1.2 Number of technical articles		2,203
1.1.3 Number of patents		666
1.2 A percentage of the NIH SBIR awardees receive additional Phase I or Phase II awards that relate to the core technology.	52%	
1.2.1 Number of additional Phase I or Phase II awards that are based on the core technology		1,465

The rest of this section provides detail about these findings and related relevant issues.

3.1.1 New Products, Processes, and Services

We asked survey respondents to select the single description that most characterized the product, process, or service that was planned under the SBIR-supported project. The next exhibit shows their responses.

Exhibit 3-2 Type of Technological Innovation Planned Under the SBIR-Supported Project

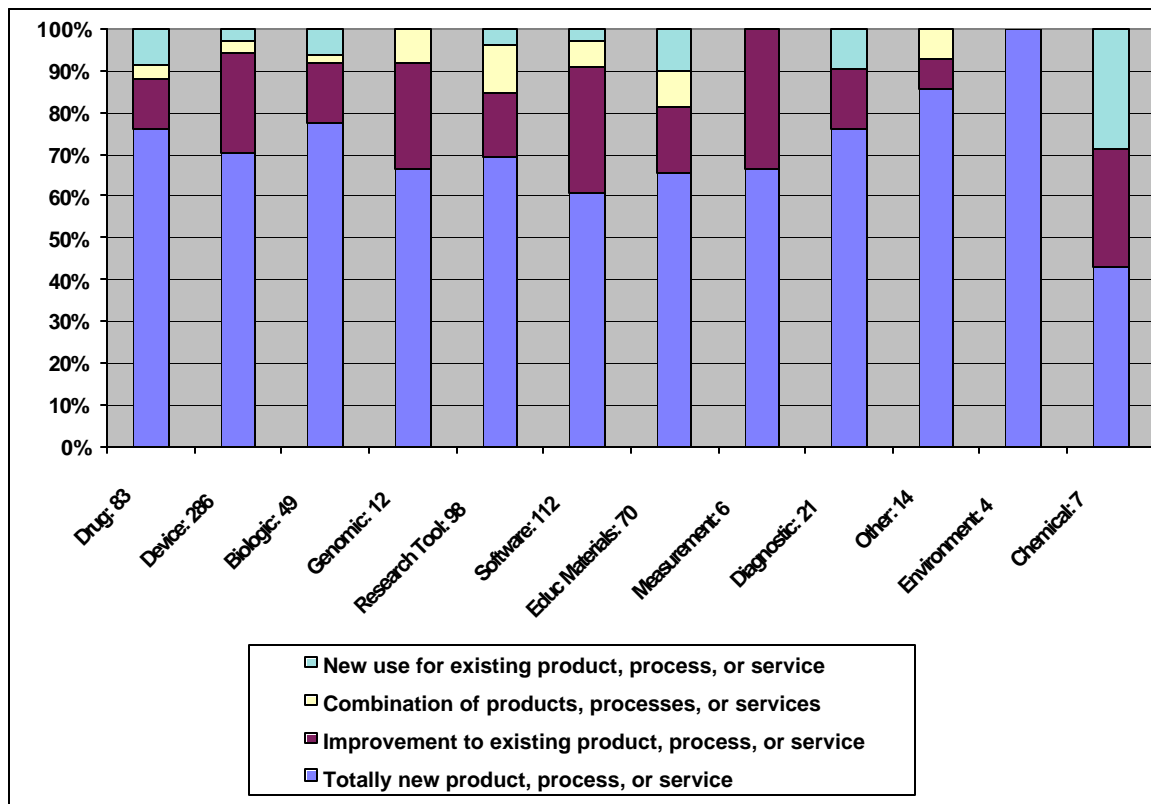


This exhibit shows the numbers of each type of technological innovation planned by the 768 respondents. The overwhelming majority of awardees planned a totally new product, process, or service for the supported project.

Sixty-nine percent of the 768 awardees (531) planned a totally new product, process, or service. Twenty percent (157) planned an improvement to an existing product, process, or service; 5 percent (39) planned a combination of products, processes, or services; and 5 percent (37) planned a new use for an existing product, process, or service. Three respondents indicated something else (“other”), and one did not respond to this item.

When we examine the type of technological innovation planned under the SBIR-supported project in terms of other key survey variables, we find that there are variations by the type of product, process, or service planned for commercialization. This finding is significant at the 1% level (chi-square=58.17; p=.0072). Overall, 69 percent of the awardees planned a totally new product, process, or service. However, somewhat larger proportions of those planning drugs and biologics and smaller proportions of those planning devices, software, and educational materials planned totally new items. (We ignore those items planned by relatively few numbers of respondents.) The following exhibit shows the type of technological innovations by the planned product, process, or service.

Exhibit 3-3 Type of Technological Innovation by Planned Product, Process, or Service



The types of technological innovations are associated with the type of project planned for commercialization. Proportionately more awardees planning drugs and biologics consider their projects totally new than do awardees planning software and educational materials.

It is likely that common practices and definitions vary by the type of planned technological innovation, and that may affect whether the item is characterized as totally new, an improvement, a combination, or a new use. Innovators of drugs and biologics, for example, may characterize more of their products as totally new because improvements in processing or changes in

combinations of ingredients may yield new products. The ability to patent the product may also contribute to characterizing it as new.

When we examine the type of technological innovation planned under the SBIR-supported project in terms of other key survey variables, we find no statistically significant differences in the proportions of each type of innovation. There are no significant differences: 1) among the IC Groups, 2) between the groups requiring and not requiring FDA approval, or 3) between the groups that did or did not receive additional non-SBIR funding.

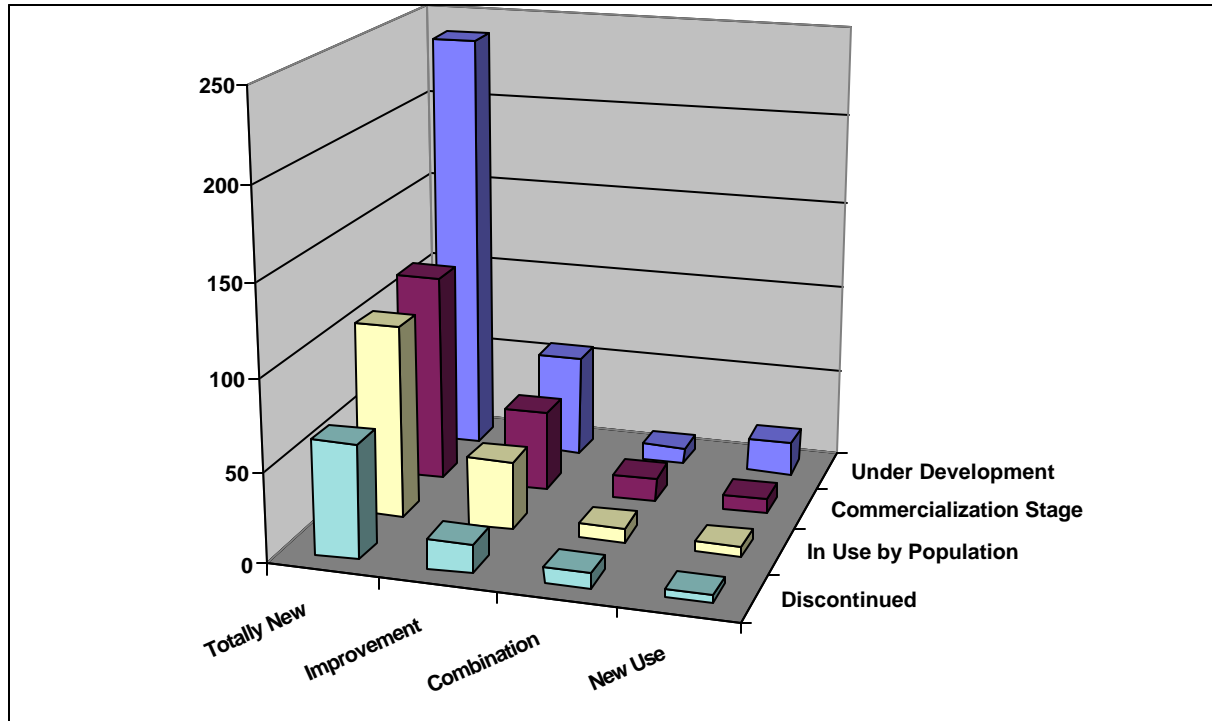
To assess awardees' success in terms of the indices and measures related to technological innovation (see Exhibit 3-1), we need to learn how many of the innovations are ongoing—that is, not discontinued. A total of 91 products, processes or services were discontinued, and seven others have statuses relating to project dormancy. This leaves 670 ongoing innovations.

Stated in terms of Measure 1.1.1, the awardee respondents produced 670 technological innovations that are currently ongoing projects.

To summarize this in terms of Index 1.1, 87 percent of NIH SBIR awardees produce new or improved products, processes, usages, and/or services in support of the NIH mission.

The next exhibit shows the type of technological innovation by current project status. There is no statistically significant association between the two variables. The preponderance of responses in the rear corner of the graph reflects the dual facts that 69 percent of awardees characterize their supported project as totally new, and 43 percent report the current status of the project as under development.

Exhibit 3-4 Type of Technological Innovation and Current Project Status



This exhibit displays data from 758 survey respondents: 10 respondents provided no data. Sixty-nine percent of the technological innovations are totally new products, processes, or services. Forty-three percent are currently under development.

Awardee respondents supplied applicable trade or commercial names, generic names, and model numbers for the product, process, or service produced by the SBIR-supported project. After removing “Not Applicable” and other similar “non-names”, we found the following numbers of names.

- Trade or commercial names 458
- Generic names 375
- Model numbers 63
- Trade or commercial + generic names 256
- Trade or commercial + generic + mode 43

3.1.2 Publications, Presentations, and Awards

Eighty-three percent of all awardees (634) reported one or more publications in press or journals, conference presentations, awards (such as Tibbetts or state), or other meritorious achievements associated with the SBIR-supported product, process, or service. Together, these 634 awardees reported 5,374 of these items. The following exhibit summarizes these achievements individually and overall.

Exhibit 3-5 Summary Statistics for Publications, Presentations, and Awards

Publications, Presentations, and Awards Associated With the SBIR-Supported Product, Process, or Service					
	Publications in Press or Journal	Conference Presentations	Awards	Other	Total
Number of awardees	512	583	119	23	634
Percent of all awardees	67%	76%	15%	3%	83%
Sum of All Items	2,203	2,850	252	69	5,374
Mean Number	4.3	4.9	2.1	3	8.5
Median Number	2	3	1	2	--

The Total column gives the number and percent of awardees with one or more of all these items, the sum of all items, and the mean number of items per awardee. Eighty-three percent of all awardees (634) reported one or more publications, presentations, awards, or other meritorious achievements. Together, these awardees reported 5,374 items.

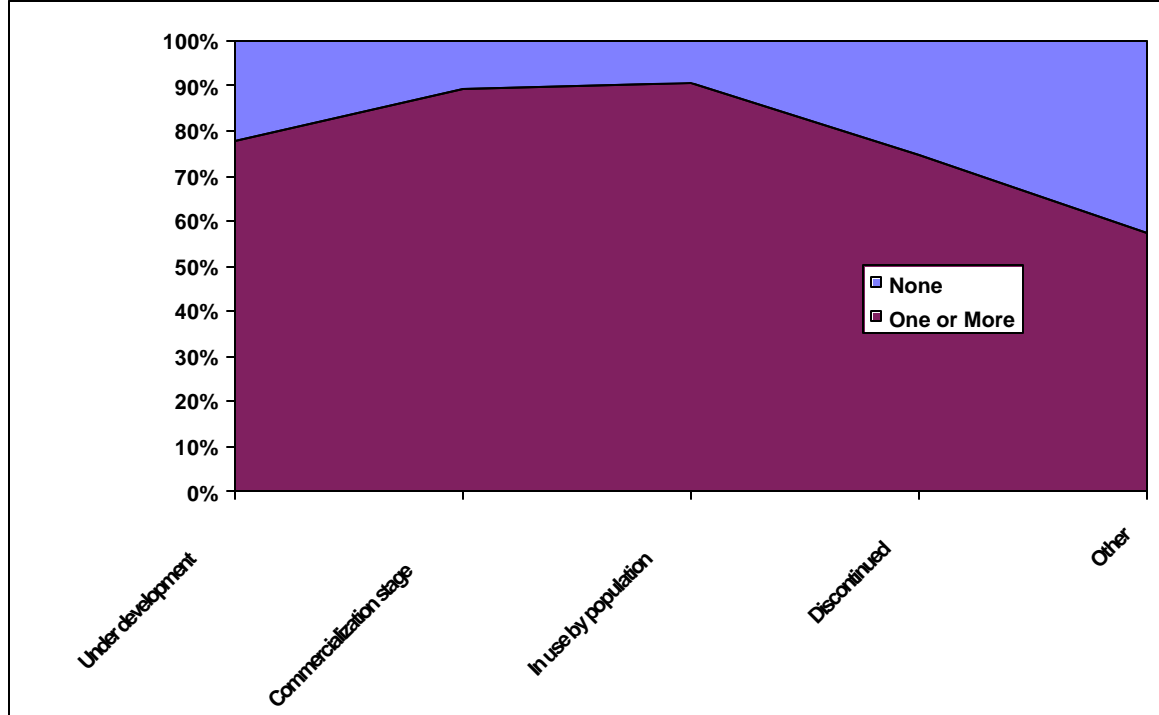
Stated in terms of Measure 1.1.2, the awardee respondents' technical achievements include a total of 2,203 publications in press or journal, 2,850 conference presentations, 252 awards, and 69 other meritorious achievements.

When we examine these achievements in terms of other key survey variables, we learn that having one or more publications, presentations, awards, or other meritorious achievements is associated with the current status of the SBIR-funded project. The next two exhibits show this.

Exhibit 3-6 Project Status Relates to Having 1+ Publications, Presentations, or Awards

Q31. Awardee has one or more publications, presentations, awards or other meritorious achievements			
Q18. What is the current status of the project funded by the referenced SBIR award?	Yes	No	Total
Under development	255 78%	73 22%	328 100%
Commercialization stage	164 89%	20 11%	184 100%
In use by target population	143 91%	15 10%	158 100%
Discontinued	68 75%	23 25%	91 100%
Other	4 57%	3 43%	7 100%
Total	634 83%	134 17%	768 100%
X² statistic	24.74		
P	<0.0001		

Higher proportions of those awardees who had projects in the commercialization stage or in use by the target populations, reported one or more publications, presentations, awards or other meritorious achievements, than did awardees whose projects are still under development or discontinued. This finding is statistically significant at the 1% level.

Exhibit 3-7 Awardees With 1+ Publications, Presentations, or Awards by Project Status

Higher proportions of awardees reporting one or more publications, presentations, awards, or other meritorious achievements had projects in the commercialization stage or in use by the target populations than did those awardees with projects still under development or discontinued. This is a graphic presentation of the tabular data in the prior exhibit.

As these exhibits show, higher proportions of awardees with projects in the commercialization stage or in use by the target populations had one or more publications, presentations, awards, or other achievements than did awardees with projects still under development or discontinued. This finding is significant at the 1% level (chi-square=24.74; $p < .0001$). Having projects in these stages is also associated with higher numbers of elapsed years since receipt of the SBIR award, which may also explain the higher proportions of awardees with one or more achievements.

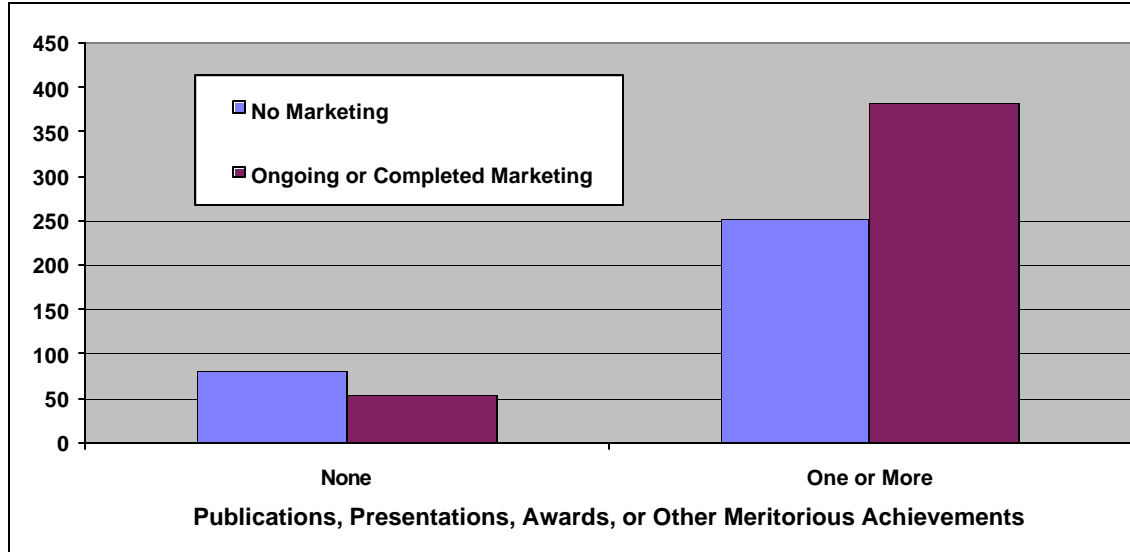
Having one or more publications, presentations, awards, or other meritorious achievements is associated with having ongoing or completed marketing activities. We asked respondents to describe the status of four marketing activities by their company or their licensee—1) preparation of marketing plan, 2) hiring of marketing staff, 3) publicity and advertising, and 4) test marketing. The response options were “not yet planned,” “planned,” “ongoing,” “complete,” “need assistance,” or “not applicable.” To summarize responses in terms of the existence of any marketing activities, we assigned respondents to either of two categories:

- Any marketing activities—One or more of the four activities is either ongoing or complete.
- No marketing activities—None of the four activities is either ongoing or complete.

The next exhibit illustrates the associations between publications and marketing activities. Higher proportions of awardees with one or more publications, presentations, awards, or other

meritorious achievements have ongoing or completed marketing activities. This finding is statistically significant at the 1% level (chi-square=17.14; $p < .0001$).

Exhibit 3-8 Awardees With 1+ Publications, Presentations, or Awards by Marketing Status



Higher proportions of awardees with one or more publications, presentations, awards, or other meritorious achievements have ongoing or completed marketing activities. This difference is statistically significant at the 1% level.

The production and publication of papers, conference presentations, and the receipt of awards and other meritorious achievements are associated with the success of the funded project—that is, success in terms of ongoing or completed marketing activities, commercialization, and migration to use by the target population. This helps confirm our selection of numbers of publications as a measure of the stimulation of technological innovation.

There were no statistically significant differences among the awardees by the NIH ICs funding the awards, the awardee major fields of business, or the product process, or service planned for commercialization, in terms of numbers of publications, presentations, awards, or other meritorious achievements.

3.1.3 Patents, Copyrights, and Trademarks

Fifty-nine percent of all awardees (450) reported one or more patents, copyrights, trademarks, or pending patents and other similar items. Together, these 450 awardees reported 1,460 of these items. The next exhibit summarizes these achievements individually and overall.

Exhibit 3-9 Summary Statistics for Patents, Copyrights, and Trademarks

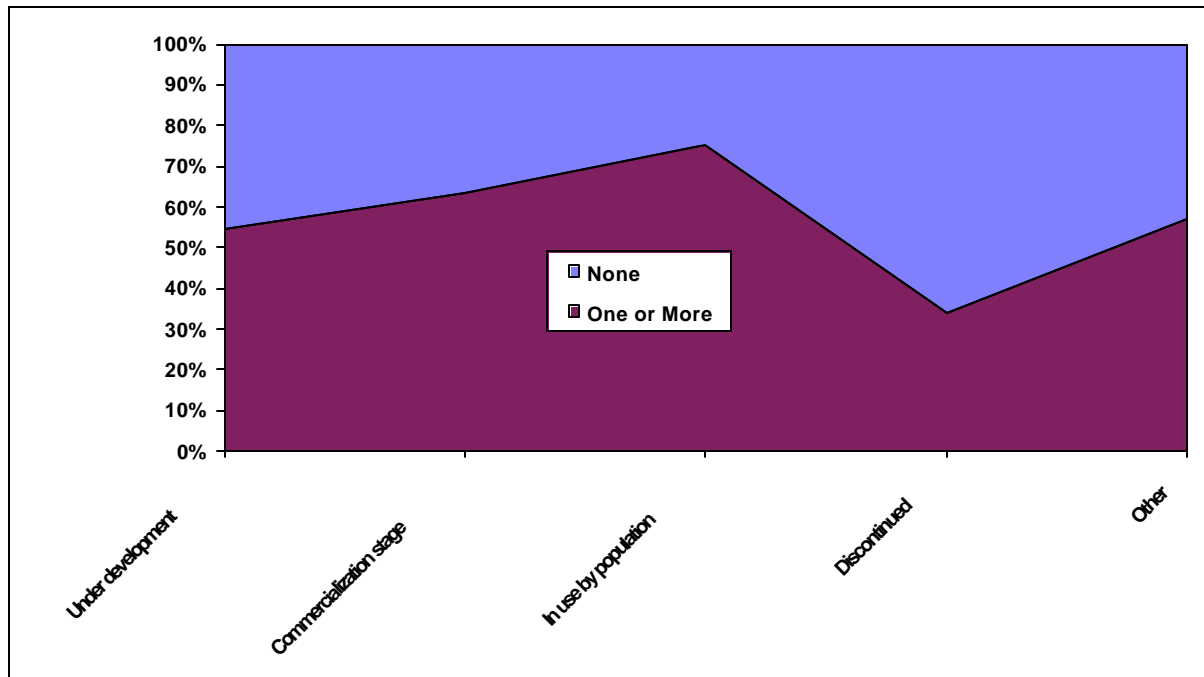
Patents, Copyrights, and Trademarks Associated With the SBIR-Supported Product, Process, or Service					
	Patents	Copyrights	Trademarks	Pending Items	Total
Number of awardees	287	149	199	14	450
Percent of all awardees	37%	19%	26%	2%	59%
Sum of All Items	666	453	322	19	1,460
Mean Number	2.3	3.0	1.7	1.4	3.2
Median Number	1	1	1	1	--

The Total column gives the number and percent of awardees with one or more of all these items, the sum of all items, and the mean number of items per awardee. Fifty-nine percent of all awardees (450) reported one or more patents, copyrights, trademarks, or pending patents and other similar items. Together, these awards reported 1,460 items.

Stated in terms of Measure 1.1.3, the awardee respondents' technical achievements include a total of 666 patents, 453 copyrights, 322 trademarks, and 19 pending patents or other similar items.

When we examine these achievements in terms of other key survey variables, as we did with numbers of publications, we learn that having one or more patents, copyrights, trademarks, or pending patents and other similar items also are associated with the current status of the SBIR-funded project. This finding is statistically significant at the 1% level (chi-square=44.86; p<.0001). The next exhibit shows this graphically.

Exhibit 3-10 Awardees With 1+ Patents, Copyrights, or Trademarks by Project Status

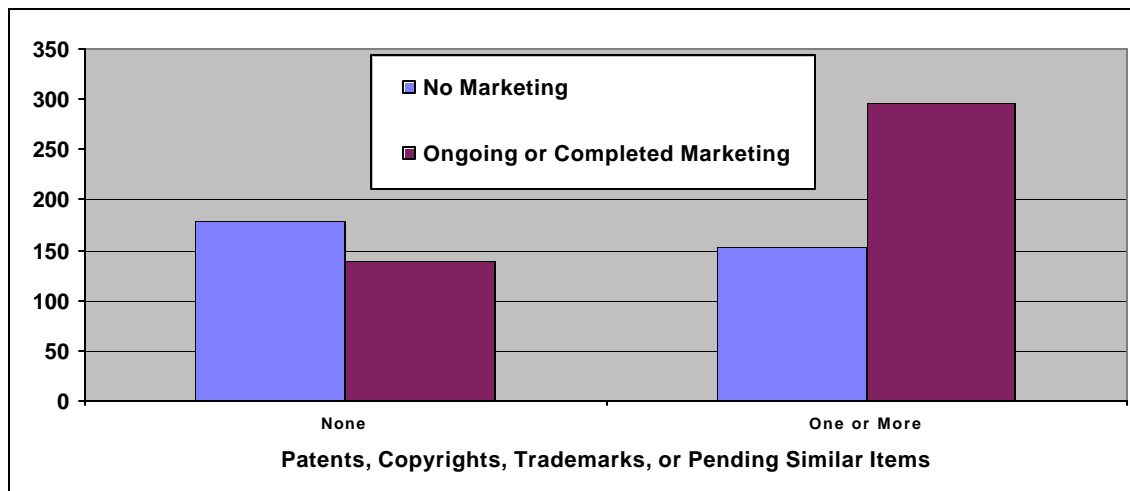


Proportions of awardees with one or more patents, copyrights, trademarks, or pending patents and other similar items were highest for those that had projects in the commercialization stage or in use by the target populations. This finding is statistically significant at the 1% level.

This exhibit, a graph of awardees with one or more patents, copyrights, and trademarks, has a somewhat different shape than the earlier similar one for publications, presentations, and awards. As was the case with publications, higher proportions of awardees with projects in use by the target populations have one or more patents, copyrights, or trademarks than do awardees with other project statuses. However, the proportion of those having one or more patents for discontinued projects is lower than the proportion of those having one or more publications for discontinued products.

As was the case with publications, higher proportions of awardees with one or more patents, copyrights, trademarks, or pending similar items reported ongoing or completed marketing activities. This finding is statistically significant at the 1% level (chi-square=36.82; p<.0001).

Exhibit 3-11 Awardees With 1+ Patents, Copyrights, or Trademarks by Marketing Status

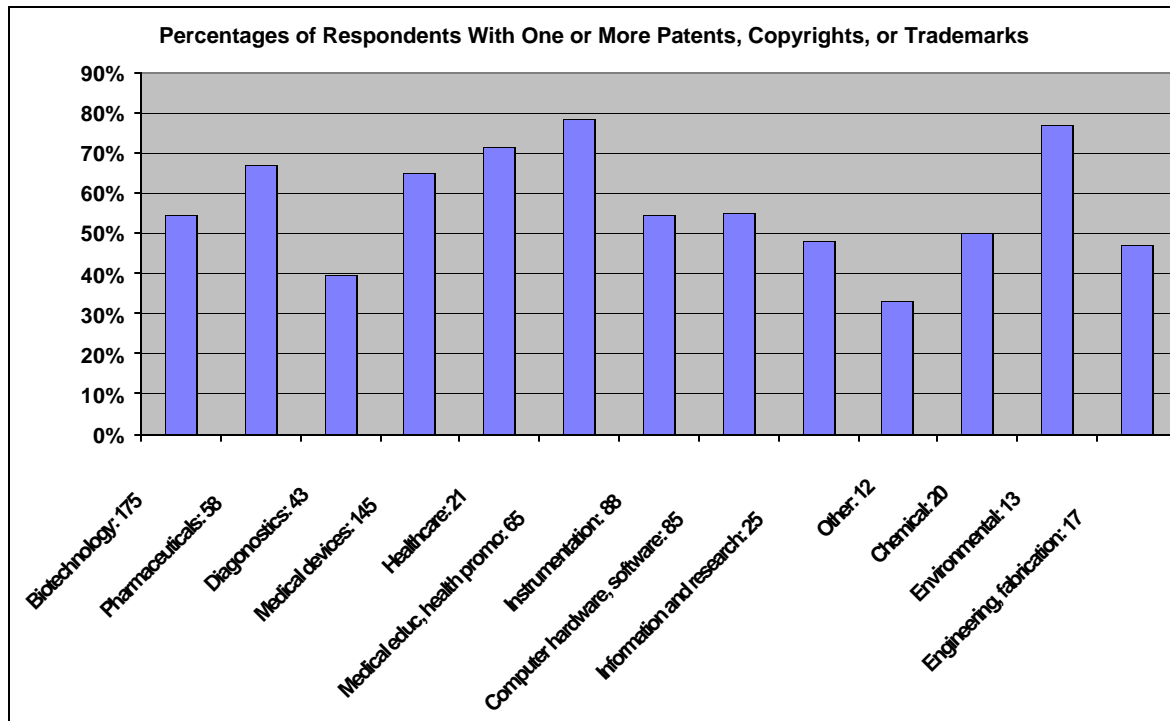


Proportions of awardees with one or more patents, copyrights, trademarks, or pending patents and other similar items were highest for those that had ongoing or completed marketing activities. This difference is statistically significant at the 1% level.

The proportion of awardee respondents with one or more patents, copyrights, trademarks, or pending patents and similar items varies by the awardees' major fields of business. Some fields of business have higher proportions of awardees with one or more patents, copyrights, or trademarks, than others. This finding is significant at the 1% level (chi-square=32.53; p=.0011).

The overall average number of awardees with one or more patents, copyrights, or trademarks is 59 percent (see the earlier exhibit, *Summary Statistics for Patents, Copyrights, and Trademarks*). Again, considering primarily the fields of business with reasonably large numbers of awardees in the next exhibit, we see that some fields are above average and some below. It may be that patents, copyrights, and trademarks are associated more with some specific fields of business than others.

Exhibit 3-12 Awardees With 1+ Patents, Copyrights, or Trademarks by Field of Business



Varying proportions of awardees in the different major fields of business have one or more patents, copyrights, trademarks, or pending patents and other similar pending items. This finding is significant at the 1% level. The average for all fields of business is 59 percent. (One awardee provided no data.)

As was the case with publications, there were no statistically significant differences among the awardees by the NIH ICs funding the awards or the product, process, or service planned for commercialization, in terms of patents, copyrights, trademarks, or pending similar items.

3.1.4 Additional SBIR Support of Core Technology

The second of the two indices for assessing the status of technological innovation is the percentage of NIH SBIR awardees receiving additional Phase I or Phase II awards related to the core technology associated with the reference award or focus of the survey.

In addition to the award that was the focus of the survey, 52 percent (399) of the 768 awardee small business concerns won other Phase I or Phase II SBIR awards for products, processes, or services related to the supported project. Of the remaining 48 percent of awardees, 42 percent did not win any other SBIR awards and 6 percent were not sure if they did or did not.

Besides the Phase II award that was the focus of each survey, the 399 awardees winning related SBIR awards won 1,005 additional Phase I and 460 additional Phase II awards. Thus, respondents reported that a total of 1,864 SBIR awards supported these 399 funded projects—the 399 referenced in the survey plus the additional 1,005 Phase I and 460 Phase II awards. The median numbers of additional related Phase I and Phase II awards per company are two and one, respectively. The following table gives more information about the numbers of additional awards in terms of summary descriptive statistics.

Exhibit 3-13 Additional Related Phase I and Phase II SBIR Awards Won by 399 Awardees

	Additional Phase I Awards	Additional Phase II Awards
Total	1,005	460
Mean	2.5	1.2
Range	0-24	0-12
Median	2	1
Mode	2	1
25th Percentile	1	0
75th Percentile	3	2

Fifty-two percent of the awardee small business concerns won additional Phase I awards and from Phase II awards related to the supported project.

Stated in terms of Measure 1.2.1, the awardee businesses received 1,005 additional Phase I and 460 additional Phase II SBIR awards that are based on the core technology.

To summarize this in terms of Index 1.2, 52 percent of NIH SBIR awardees receive additional Phase I or Phase II awards that relate to the core technology.

Higher proportions of those awardees who won additional Phase I or Phase II SBIR awards also received non-SBIR funding for their supported project than did those who had not won additional SBIR awards. Of the 399 awardees who won additional SBIR awards, 40 percent also received non-SBIR funding. Of the 369 awardees who did not win additional SBIR awards, only 33 percent also received non-SBIR funding. This finding is statistically significant at the 5% level (chi-square=4.1; p=.0428). The next exhibit shows this relationship.

This finding suggests that comparable assessments of the value or potential value of awardees' projects were made by SBIR and non-SBIR funding sources. That is, projects worthy of multiple SBIR awards are also more likely to be worthy of additional outside (non-SBIR) funding.

Exhibit 3-14 Winning Additional SBIR Awards Relates to Receiving Additional Non-SBIR \$

Q25. Has your company received any additional <u>non-SBIR</u> funding or capital for this project?			
Q5. Has the <u>company</u> won any other SBIR Phase I or Phase II awards, in addition to the reference award, for products, processes, or services that are <u>related to this project</u> ?			
	Yes	No	Total
Yes	160 40%	239 60%	399 100%
No	121 33%	248 67%	369 100%
Total	281 37%	487 63%	768 100%
X² statistic	4.10		
P	0.0428 (corrected for continuity)		

Higher proportions of those awardees who won additional Phase I or Phase II SBIR awards related to the Phase II award that is the focus of the survey also received additional non-SBIR funding. This finding is statistically significant at the 5% level.

3.2 Increased Use of Small Business Concerns

This section of the final report discusses the survey findings that relate to the second goal of the SBIR Program—to use small business concerns to meet federal research and development needs. We evaluated the survey findings specifically in terms of assessing the NIH objective for the SBIR Program—to increase the use of small business concerns to meet federal research and development needs in support of the NIH mission from the date of the SBIR award to the date of measurement.

As shown by the following summary exhibit, survey results indicate that the SBIR awardees achieved high rates of success for all related indices.

Exhibit 3-15 Summary of Awardees Performance: Use of Small Business Concerns

Use of Small Business Concerns to Meet Federal R&D Needs	Findings	
	Indices	Measures
<p>2.1 NIH awardees make contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and amelioration and cure of disease</p> <p>2.1.1 Number of SBIR supported contributions yielding increases in health knowledge, research tools, and education</p>	74%	567+
<p>2.2 NIH awardees are able to obtain and disseminate health-related information</p> <p>2.2.1 Number of awardee companies giving high rankings to the usefulness of outreach and informational services</p> <p>2.2.2 Number of disseminations of SBIR supported technology and information among populations using and receiving health and health care resources</p>	86%	714 660
<p>2.3 NIH awardees express satisfaction with the usefulness of the NIH SBIR Program</p> <p>2.3.1 Number of awardee companies experiencing high levels of satisfaction with the NIH SBIR Program</p>	73-93%	560-714

The rest of this section of the report provides detail about these findings and related issues.

3.2.1 Contributions to Health Knowledge

Each awardee respondent selected from among a list of health-related categories the one that best described their company's major field of business. Together, their selections present a picture of the health-related areas to which the SBIR-supported projects contribute.

In descending order, these are the awardees' major fields of business, the number of awardees in each field, and the percentage each group is of all 768 awardee respondents. (One respondent did not provide the field of business.)

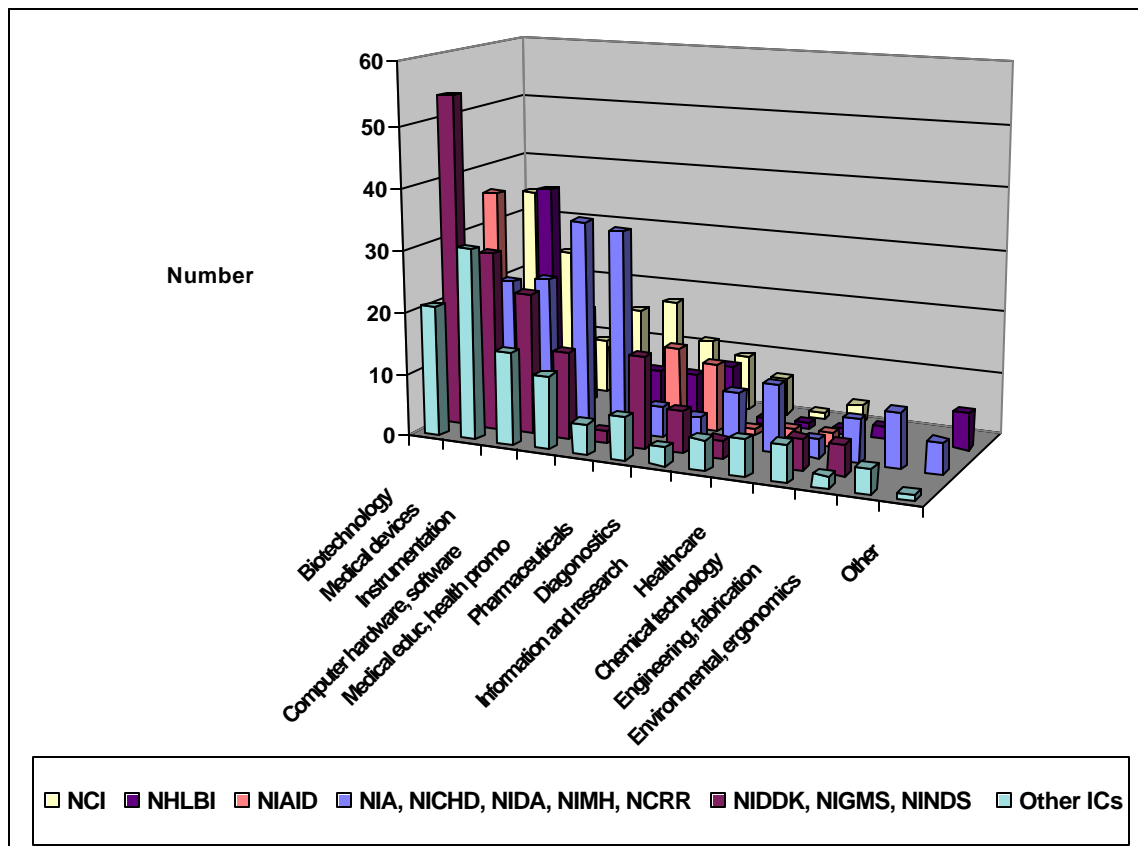
Final Report

<u>Field of Business</u>	<u>Number of Awardees</u>	<u>Percent of Total Respondents</u>
Biotechnology	175	23%
Medical devices	145	19%
Instrumentation	88	11%
Computer hardware, software	85	11%
Medical education, health promotion	65	8%
Pharmaceuticals	58	8%
Diagnostics	43	6%
Information and research	25	3%
Health care	21	3%
Chemical technology	20	3%
Engineering, fabrication	17	2%
Environment, ergonomics	13	2%
Other	12	2%

The "Other" field of business includes items such as robotics, aerospace, batteries, and consulting/support for various military organizations.

The next exhibit presents a pictorial overview of the awardee major fields of business by the IC groups funding the SBIR Phase II award.

Exhibit 3-16 Awardee Major Fields of Business by NIH IC Group



The bars in this exhibit show the numbers of awardees within each grouping defined by the companies' major fields of business and the IC Group funding the reference award. There is an association between major field of business and IC Group that is statistically significant at the 1% level. (Other ICs includes: NCCAM, NEI, NHGRI, NIAAA, NIAMS, NIDCD, NIDCR, NIEHS, and NINR).

Final Report

There is an association between field of business and funding IC group that is statistically significant at the 1% level (chi-square=266.99; p<.0001). To a large degree, this is as expected, since the ICs fund research and development in support of their specific areas of interest. Nonetheless, this is an interesting issue because some of the major fields of business appear reasonably broad enough to elicit funding from multiple ICs, and we can see that this is indeed the case. NIAID, for example, funds research primarily in the field of biotechnology, but some funding goes also to the fields of pharmaceuticals and diagnostics. NHLBI funds research primarily in the field of medical devices, but some funding goes also to a variety of other fields.

The next exhibit is a tabular presentation of the same data. Although it is more difficult to gain an overview of the associations from the table, it is possible to see the exact numbers and percentages within each category. The percentages are *column* percents—that is, the percent that each cell count is of the column total. The column percents allow us to compare the relative proportions of each IC Group’s awards that are in the various fields of business.

Exhibit 3-17 Awardees’ Major Field of Business by NIH IC Group in Tabular Format

Major Field of Business	NIH IC Group						Total
	NCI	NIAID	NHLBI	NIA, NICHD, NIDA, NIMH, NCRR	NIDDK, NIGMS, NINDS	Other ICs	
Biotechnology	34 26%	36 52%	11 10%	19 10%	54 34%	21 18%	175 23%
	24 18%	2 3%	36 34%	23 12%	29 18%	31 26%	145 19%
	9 7%	1 1%	16 15%	24 13%	23 15%	15 13%	88 11%
	15 12%		10 9%	34 18%	14 9%	12 10%	85 11%
	17 13%	1 1%	7 7%	33 18%	2 1%	5 4%	65 8%
	11 8%	13 19%	7 7%	5 3%	15 10%	7 6%	58 8%
	9 7%	11 16%	9 8%	4 2%	7 4%	3 3%	43 6%
	6 5%	1 1%	1 1%	9 5%	3 2%	5 4%	25 3%
	1 1%	2 3%	1 1%	11 6%		6 5%	21 3%
	3 2%	2 3%	1 1%	3 2%	5 3%	6 5%	20 3%
	1 1%		2 2%	7 4%	5 3%	2 2%	17 2%
				9 5%		4 3%	13 2%
			6 6%	5 3%		1 1%	12 2%
	130 100%	69 100%	107 100%	186 100%	157 100%	118 100%	767 100%

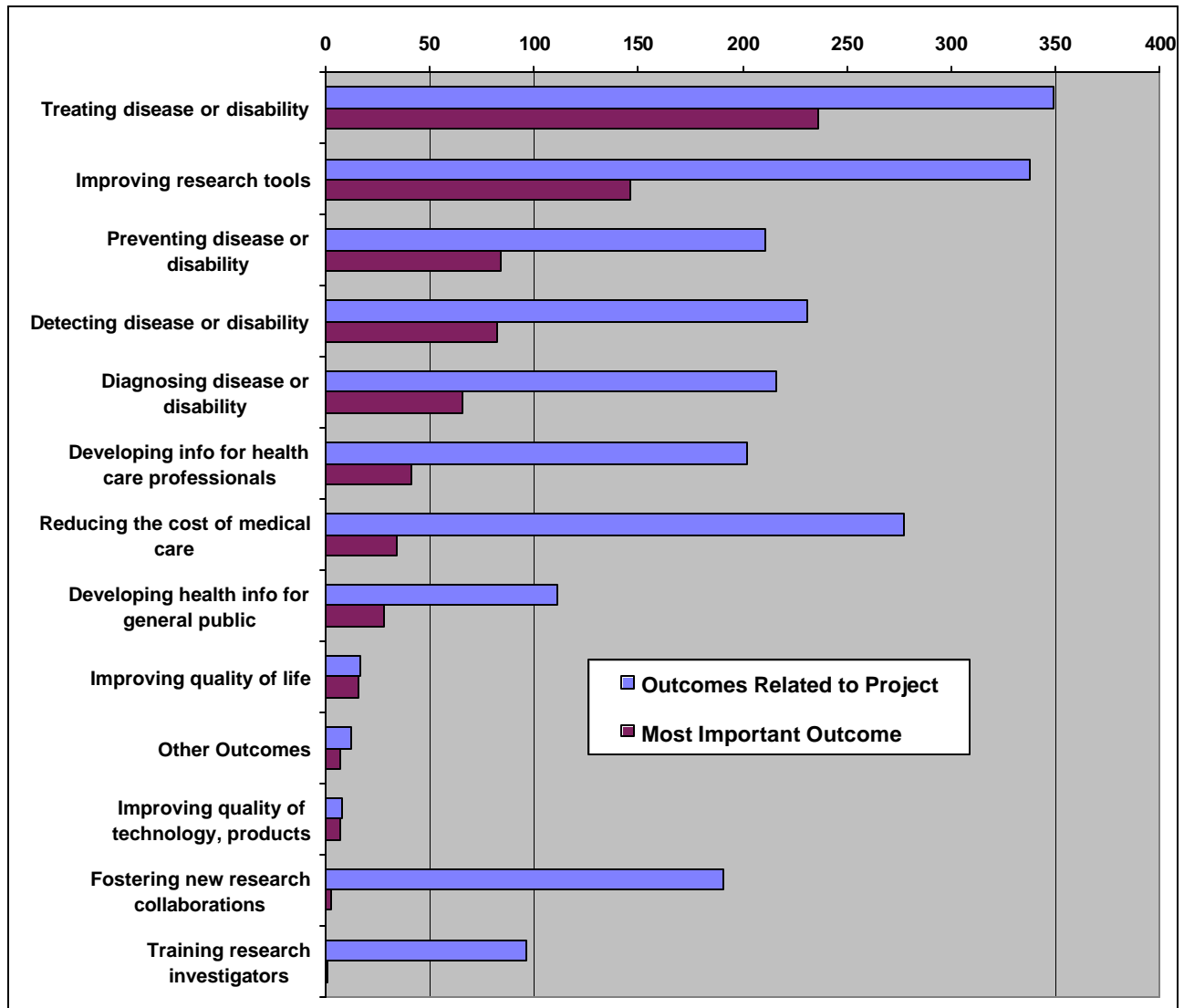
Overall, 23 percent of all awardees’ major field of business is biotechnology. However, proportionately more awardees funded by NIAID are in biotechnology (52%) than in other fields of business. (Other ICs include: NCCAM, NIAAA, NIAMS, NIDCD, NIDCR, NEI, NHGRI, NIEHS, and NINR.) (One awardee provided no data.)

Using the same examples that we used earlier for the three-dimensional bar chart to discuss this next exhibit, we can see that more than half of NIAID's SBIR funding (52%) is in the field of biotechnology; 19 percent and 16 percent are in the fields of pharmaceuticals and diagnostics, respectively. A third of NHLBI's SBIR funding (34%) is in the field of medical devices, 15 percent is in instrumentation, 10 percent in biotechnology, and 9 percent in computer hardware and software. In absolute numbers, NIDDK, NINDS, and NIGMS together fund the most SBIR awards in biotechnology (54). This represents 34 percent of their funding during the study time period.

To better pinpoint the specific areas to which the SBIR-supported projects contribute, the survey asked the awardees about project outcomes. The awardees were asked to select the categories that best describe the medical, societal, or technological outcomes that relate to the product, process, or service supported by the referenced SBIR award. The awardee respondents first selected *all* relevant outcomes (multiple responses permitted), and then they selected the single *most important* outcome (single response only). The next exhibit shows both *all* outcomes related to the SBIR project and the single *most important* outcomes. The response bars are ordered by the *most important* outcomes.

It is interesting to note that, overall, treating disease or disability, improving research tools, and reducing the cost of medical care are the top three outcomes. However, when respondents are limited to selecting the single most important outcome, treating disease or disability and improving research tools are the top two most important outcomes. Reducing the cost of medical care is now the seventh most important outcome. A reasonable interpretation of this is that the supported projects have multiple medical, societal, and technological outcomes, in addition to the specific ones at which they are targeted.

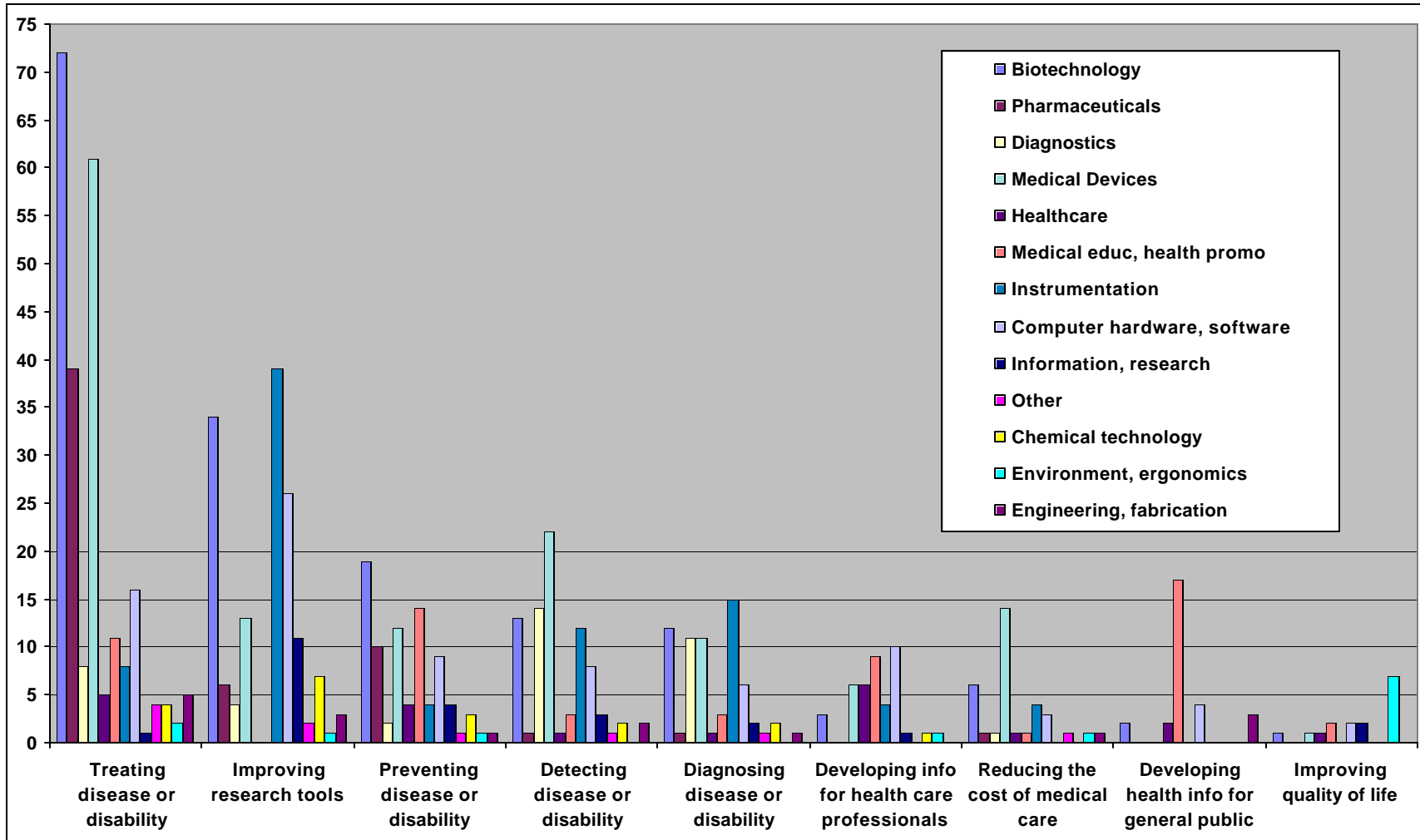
Exhibit 3-18 Medical, Societal, or Technological Outcomes Related to the SBIR Project



This bar graph shows all outcomes related to the SBIR-supported product, process, or service (multiple responses permitted) and the single most important outcome. The outcomes are ordered by the most important outcome. Note, for example, that although relatively large numbers of awardees cite “reducing the cost of medical care” as an outcome related to the SBIR-supported project, relatively smaller numbers cite it as the most important outcome. (Seventeen awardees provided no data for both all outcomes and the single most important outcome.)

To better understand the contributions that the awardee small business concerns make, we looked at the awardees’ major fields of business by their most important project outcomes. These two variables have a strong association, which is significant at the 1 percent level (chi-square=697.69; $p < .0001$). This is as expected, because *field of business* and *medical, societal, or technological outcome* are overlapping ways of describing the contributions that the awardee businesses make. The next exhibit shows the numbers of awardee businesses in each major field of business within each of the most important outcomes.

Exhibit 3-19 Most Important Project Outcomes by Awardees Major Fields of Business



This exhibit shows the numbers of awardees in each major field of business within each of the most important project outcomes. Note, for example, that relatively high numbers of awardees report that the most important outcomes for biotechnology businesses are “treating disease or disability” and “improving research tools.” (Five small groups, including “other and “missing,” are omitted).

In this exhibit, we see that biotechnology businesses contribute most to treating disease or disability and improving research tools. Pharmaceutical businesses contribute most to treating disease or disability. Diagnostic businesses contribute most to detecting and diagnosing disease or disability. Medical device businesses contribute most to treating disease or disability. Medical education/health promotion businesses contribute most to developing health information for the general public. Computer hardware/software businesses contribute most to improving research tools.

To measure awardees' success at meeting our index for assessing the use of small business concerns (see Section 3.2, *Increased Use of Small Business Concerns*), we need to learn how many of the contributions we just examined are ongoing—that is, not discontinued. The next exhibit is a table of ongoing SBIR-supported projects. Discontinued projects are not included. Additionally, to simplify the table, we have excluded the “other” and “missing” categories, as well as those few categories with very small cell counts.

Within each table cell, ongoing projects are broken out as follows.

<u>Row Number</u>	<u>Color</u>	<u>Project Stage</u>
1	Blue	Under development
2	Green	In commercialization
3	Yellow	In use by target populations

Looking at this table, we can see the contributions that ongoing SBIR-supported projects make in terms of both their most important medical, societal, or technological outcomes and the awardee companies' major fields of business.

Stated in terms of Measure 2.1.1, the awardee respondents produced 567+ contributions, which are currently ongoing projects that yield increases in health knowledge, research tools, and education.

To summarize this in terms of Index 2.1, 74 percent or more of NIH awardees make contributions to knowledge in health promotion, disease prevention, diagnosis, health care, and ameliorations and cure of disease.

To break out the 567 awardee contributions by specific categories, we can consult the row and column totals of the next tabular exhibit. For example, companies whose major field of business is medical education/health promotion made 53 contributions. Alternatively, 34 companies report that their most important outcome is developing information for health care professionals, and 24 report that theirs is developing health information for the general public.

Exhibit 3-20 Most Important Outcomes by Major Fields of Business for Ongoing Projects

Most Important Medical, Societal, Technological Outcome	Awardee Major Fields of Business								
	Biotechnology	Pharmaceuticals	Diagnostics	Medical Devices	Health Care	Medical Educ, Health Promo	Instrumentation	Computer Hardware Software	TOTALS
	143	46	33	124	20	53	77	71	567
Treating disease or disability 193	52	28	3	28	4	4	3	6	128
	9	2	2	13		2	2	5	35
	4		2	13	1	4	1	5	30
Improving research tools 109	9	2	1	5			15	7	39
	7	2		4			11	5	29
	14	1	2	3			11	10	41
Preventing disease or disability 67	11	7		5	1		2	1	27
	6	2	2	2	1	10	2	4	29
				4	2	3		2	11
Detecting disease or disability 65	5	1	5	16		1	5	5	38
	2		3	3	1	1	1		11
	5		3	2		1	3	2	16
Diagnosing disease or disability 49	7		5	3		2	8	2	27
	3		3	3			2	3	14
			1	2	1		3	1	8
Developing info for health professionals 34				2		2	1	5	10
	1			1	3	2	1	2	10
	1			3	3	3	2	2	14
Reducing the cost of medical care 26	1	1		5	1		1		9
	2		1	7		1	3		14
	2							1	3
Developing info for general public 24	2					3			5
					1	7		1	9
					1	7		2	10
TOTALS 567	87	39	14	64	6	12	35	26	283
	30	6	1	33	6	23	22	20	151
	26	1	8	27	8	18	20	25	133

This table shows the most important medical, societal, or technological project outcomes by the awardee companies' major fields of business for ongoing projects only (discontinued projects omitted).

- The first row in each cell (blue) shows the number of awardees with projects under development.
- The second row in each cell (green) shows the number of awardees with projects in the commercialization stage.
- The third row in each cell (yellow) shows the number of awardees with projects in use by the target populations.

Row and column totals are in bold. The lower right box, outlined with double lines, shows the totals for each project stage. (Categories with relatively small counts or missing data are omitted from this table.)

3.2.3 Dissemination of Health Information

This section describes the dissemination of health information from two perspectives. The first is in terms of the satisfaction of small business awardees with NIH SBIR Program outreach and informational services. The second, and most important, is in terms of the dissemination of SBIR-supported technology and information among populations using and receiving health and health care resources.

Ninety-two percent of awardee respondents were aware that they could contact NIH SBIR Program staff for additional information or assistance about any aspects of the SBIR grant review, award, and management process. Six percent were not. One percent did not supply this information.

Awardees rate their satisfaction with their experiences obtaining information about the SBIR Program very highly:

<u>Satisfaction level</u>	<u>Number</u>	<u>Percent of Total</u>
Completely satisfied	446	59%
Mostly satisfied	268	35%
Mixed satisfaction	37	5%
Mostly dissatisfied	2	.3%

Summary statistics for these satisfaction ratings are: 1.4 is the mean, 1 is the median, 1 is the mode. We calculated these statistics using 1= “completely satisfied,” 2= “mostly satisfied,” 3= “mixed,” 4= “mostly dissatisfied,” and 5= “completely dissatisfied.”

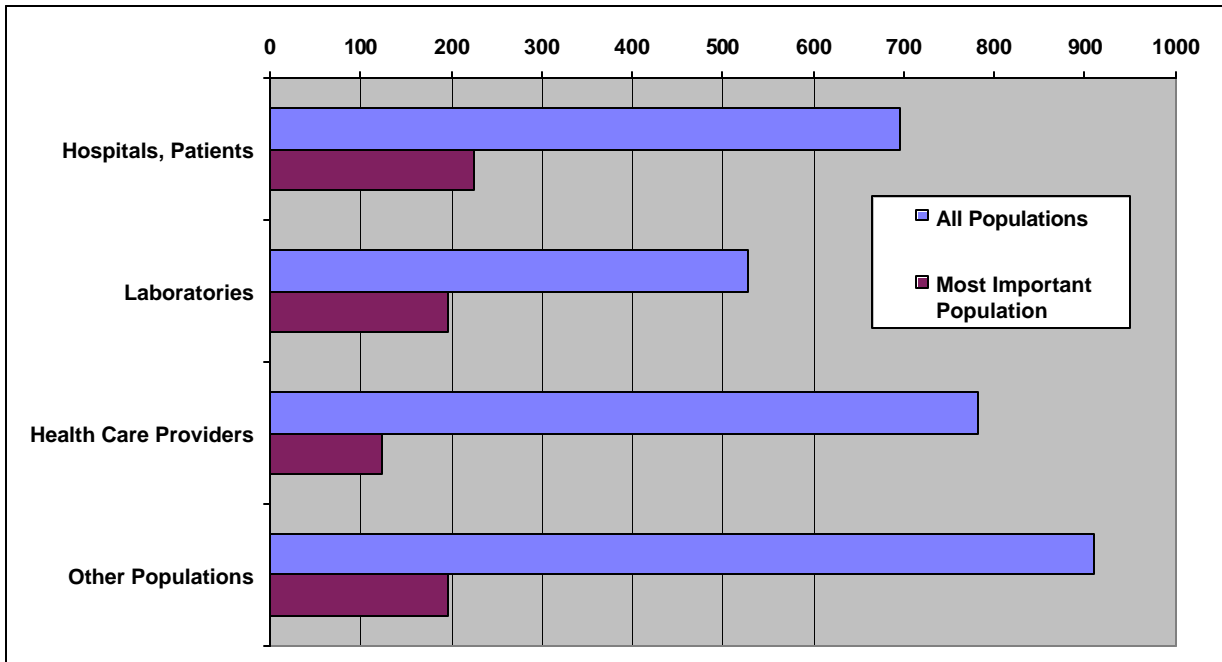
Stated in terms of Measure 2.2.1, 92 percent of awardee companies were aware that they could contact NIH staff for information or assistance, and 714 (93%) give high rankings (“completely satisfied” or “mostly satisfied”) to their experiences obtaining information about the SBIR Program.

To assess the dissemination of SBIR-supported technology and information among populations using and receiving health and health care resources, the survey asked respondents to select all populations who were currently using, or likely to use, the product, process, or service developed under the SBIR-supported project. The next exhibit shows their responses grouped into four broad summary categories. The summary categories are:

Hospitals, patients:	Outpatients Inpatients Hospital personnel	Healthcare providers:	Medical practitioners Homecare providers Emergency medical services Military medical services Other health services
Laboratories:	Research laboratories Diagnostic laboratories	Other populations:	General public Educators Worksites Schools, universities Police, fire, other municipal workers Other companies, other technologies

As was the case with project outcomes, the ordering of *all* populations differs from the ordering of the *most important* populations. For example, although hospitals and patients are the third largest category when ordered by numbers of respondents selecting it as part of all populations using or likely to use the SIR project, it is the single most important population.

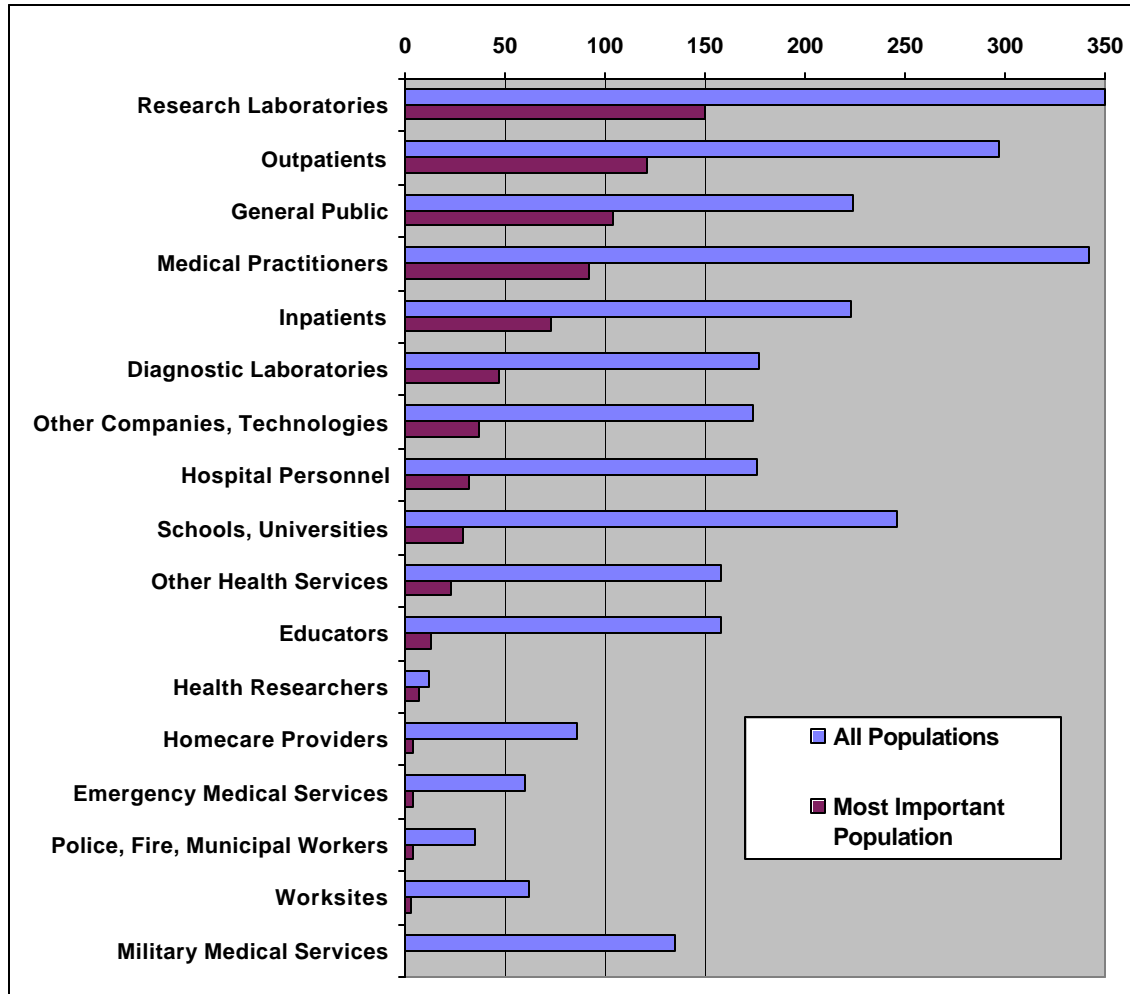
Exhibit 3-21 Summary Populations Using or Likely to Use SBIR-Supported Project



This exhibit shows the numbers of all populations (multiple responses) and the single most important populations (single responses) who are currently using, or are likely to use, the product, process, or service developed under the SBIR-supported project. The population categories are summaries of all relevant populations. Hospitals and patients are the single most important population to use or be likely to use SBIR-supported projects' technologies and information. (Twenty awardees provided no data).

When we examine the individual population categories (not the summary categories), we again note the different orderings among all populations using or likely to use the SBIR-funded project and the single most important specific population. The next exhibit illustrates this. The categories in the bar chart are ordered by the single most important population.

Exhibit 3-22 Specific Populations Currently Using or Likely to Use SBIR-Supported Project



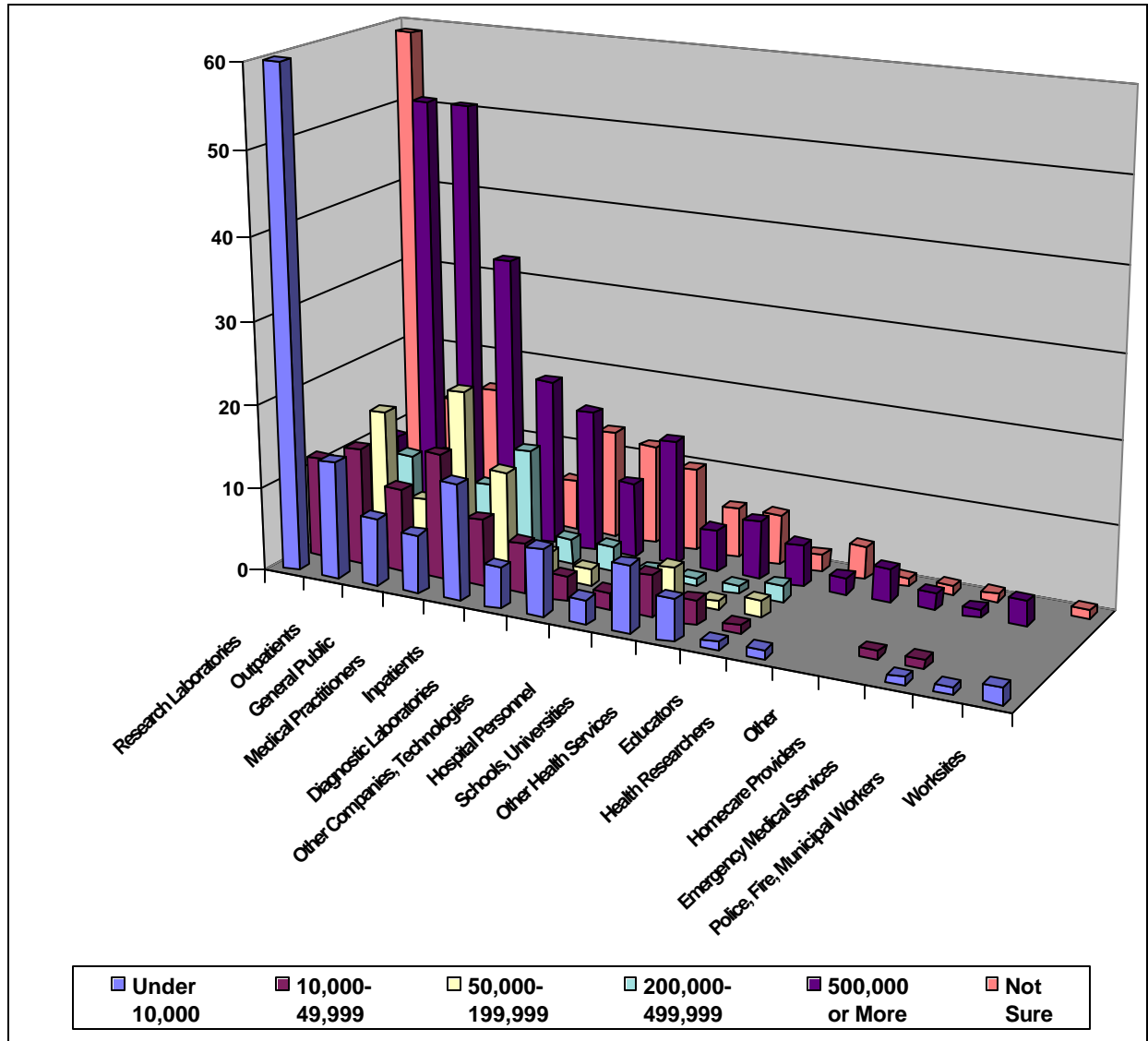
This bar graph shows all populations (multiple responses) who are currently using, or are likely to use, the product, process, or service developed under the SBIR-supported project and the single most important population (single responses). The populations are ordered by the most important population. Research laboratories are the single most important specific population currently using and likely to use the SBIR-supported project. (Twenty awardees provided no data).

Overall, research laboratories, medical practitioners, outpatients, and schools/universities are the top four populations. The general public and inpatients are the fifth and sixth populations. However, when respondents are limited to selecting the single most important population, research laboratories, outpatients, the general public, medical practitioners, and inpatients are the top five populations.

Supported projects affect multiple populations, both those that use and those that receive health and health care resources. Although medical practitioners, for example, constitute a large population using or likely to use SBIR projects, research laboratories, outpatients, and the general public are likely the most important populations for these projects.

The next exhibit shows the most important target populations by the anticipated sizes of those populations. This three-dimensional bar chart gives an *overview* of what most awardee respondents believe will be the approximate sizes of the different populations.

Exhibit 3-23 Anticipated Size of Most Important Target Populations in Next Few Years



This three-dimensional bar chart gives an overview of the single most important populations, who are currently using or likely to use the SBIR-supported project, by the anticipated size of the total target populations. The populations are ordered by the single most important populations. The height of a bar is the number of respondents selecting that particular single most important population and size category combination. For example, relatively large numbers of respondents cited “under 10,000” and “not sure” as the sizes of the anticipated population for research laboratories and “500,000 or more” as the size of the anticipated population for outpatients and the general public.

For example, the anticipated populations outpatients and the general public are relatively large—“500,000 or more.” It is less clear, however, what the anticipated population for research laboratories is—comparable numbers of awardees cite “under 10,000” and “not sure.”

This exhibit, as well as the next one, should be viewed only as an *overview of the anticipated population sizes*. This is because we can tabulate the population size categories by just a single variable—the *most important* population. However, the survey asked respondents to select the anticipated size of the *total* target populations that would benefit from or use the product, process,

or service being developed under the SBIR project. Thus, the categories respondents selected likely represent the size of all populations using or likely to use the SBIR project. Nonetheless, the exhibits do give a sense of the relative sizes of the target populations.

To measure awardees' success in terms of our index about disseminating health-related information, we need to look at the anticipated sizes of the target populations for just ongoing (not discontinued) SBIR-funded projects. The next exhibit gives this information.

Exhibit 3-24 Anticipated Size of Most Important Populations for Ongoing Projects

Q16B. Please select the single most important population who is currently using, or is likely to use, the product, process, or service developed under this project?	Q17. Within the next few years, what is the anticipated size of the total target populations that would benefit from or use the product, process, or service being developed under this project?						Total
	Under 10,000	10,000-49,999	50,000-199,999	200,000-499,999	500,000 or More	Not Sure	
Research Laboratories	50	11	4	4	9	48	126
Outpatients	12	13	17	10	47	9	108
General Public	5	10	7	10	51	13	96
Medical Practitioners	6	14	21	7	32	4	84
Inpatients	9	7	9	12	18	4	59
Diagnostic Laboratories	2	6	2	1	17	10	38
Other Companies, Technologies	8	3	2	3	8	12	36
Hospital Personnel	3	2	1	1	14	10	31
Schools, Universities	7	5	4	1	5	5	27
Other Health Services	4	3	1	1	7	4	20
Educators	1	1	2	2	5	1	12
Homecare Providers		1			2	1	4
Emergency Medical Services	1	1			1	1	4
Other					4		4
Police, Fire, Municipal Workers	1				3		4
Health Researchers					2	2	4
Worksites	2					1	3
Total	111	77	70	52	225	125	660

This table shows the single most important populations tabulated by the anticipated size of the target populations. Only ongoing SBIR projects are included; 91 discontinued ones and seven "others" are omitted. (Ten awardees with ongoing projects supplied no size data.)

This table uses the same data as the previous three-dimensional bar chart, but includes only those awardees with projects under development, in the commercialization stage, or in use by the target populations. As is the case with the prior exhibit, this table should be viewed only within the context of providing an overview of anticipated population sizes.

If we want a rough estimate of the size of the total population (all specific target populations lumped together), we can multiply the number of respondents in each size category by the midpoint of each category (using the start point of 500,000 instead of the midpoint for the largest and unlimited category). This gives us 142.3 million persons as the approximate total size of all

populations using and receiving health and health care resources from the SBIR-funded projects. This total does not include 125 populations of unknown size.

Stated in terms of Measure 2.2.2, the awardee respondents are disseminating or will be disseminating SBIR-supported technology and information to at least 660 populations that use and receive health and health care resources. Together, these populations comprise approximately 142.3 million persons.

To summarize the two measures (2.2.1 and 2.2.2) relating to Index 2.2:

- *92 percent of awardee companies are aware that they can obtain information and assistance from NIH staff, and 93 percent give high rankings to their experiences obtaining information.*
- *86 percent of awardee companies have ongoing projects that disseminate technology and health-related information to populations that use and receive health and healthcare resources. The approximate size of the combined populations is 142.3 million.*

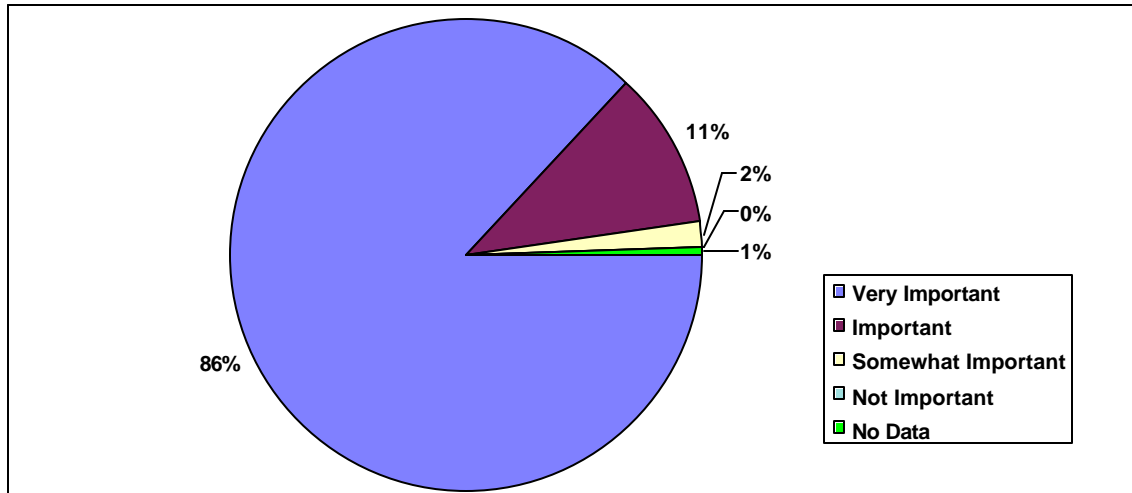
3.2.3 Satisfaction With NIH SBIR Program

The survey asked awardees if the project funded by the referenced SBIR award would still have been pursued if the SBIR Program were not available. Sixty-four percent of the awardees responded “no,” 15 percent “yes”, and 21 percent were “not sure” or “did not know”. There were *no* statistically significant differences among any groupings formed by key survey variables, such as IC Group, companies’ major fields of business, product/process/service planned for commercialization, current project status, or receipt of additional non-SBIR funding.

It appears that SBIR funding was crucial for pursuing their projects for nearly two-thirds of the awardees. The type of product, process, or service, the major field of business, and even the receipt of non-SBIR funding were not associated with the ability to pursue the funded project.

The survey also asked awardees how important overall SBIR support had been, or how important it will be, in research and development of the product, process, or service. Nearly all (98 percent) of the awardees answered “very important” or “important.” Two percent said “somewhat important. Only a single respondent answered “not important.” Four awardees did not answer this survey item. The next exhibit illustrates these findings.

Exhibit 3-25 Importance of SBIR Support Cited by Awardees



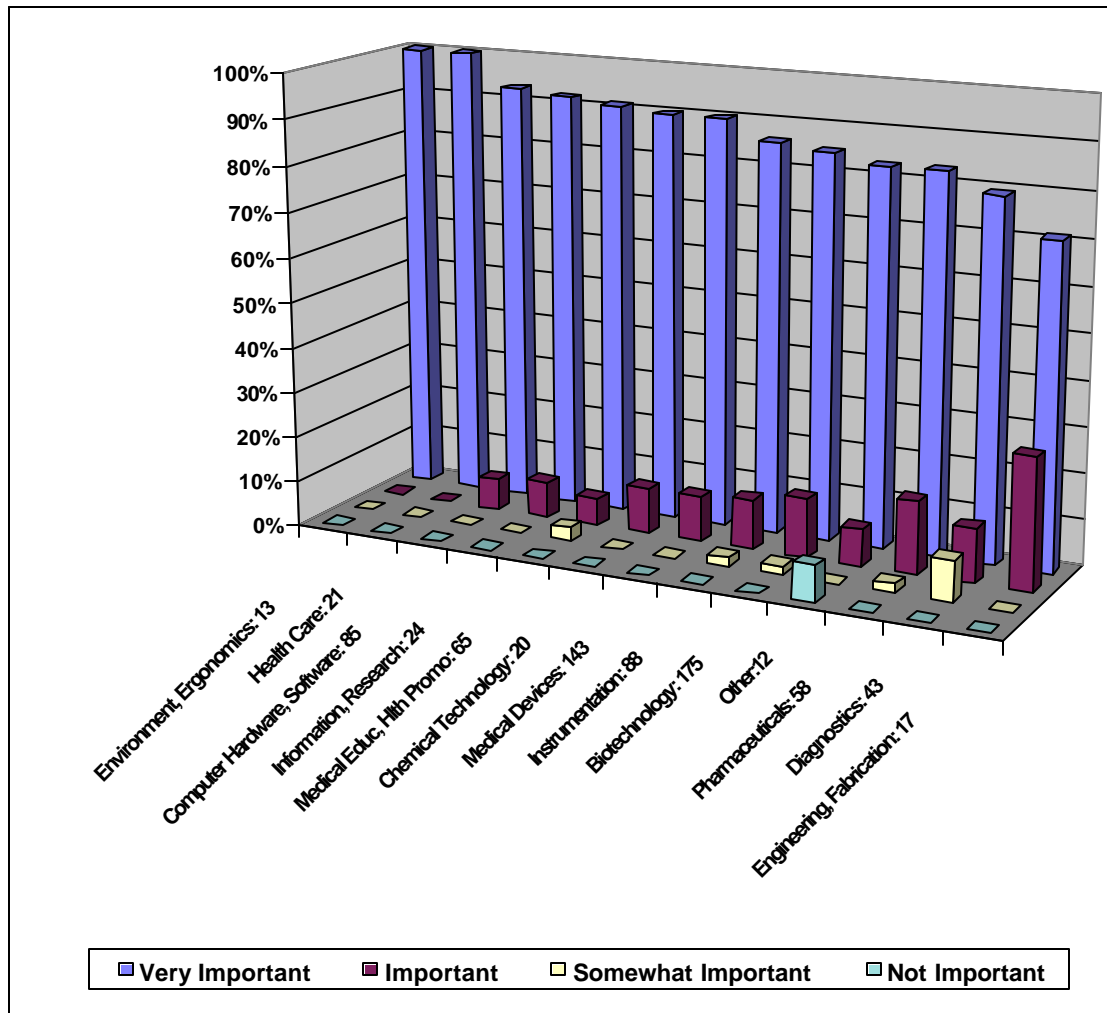
Ninety-eight percent of awardees responded that SBIR support was “very important” or “important.” Only a single respondent said that SBIR support was “not important” (0% above). Four awardees did not answer this item.

When we examine the importance of SBIR support by the current status of the funded project, we find that proportionately fewer awardees with discontinued projects rate SBIR support “very important.” Instead, proportionately more of those with discontinued projects rate it “important.”

The association between the importance of SBIR support and the current status of the funded project is statistically significant at the 1% level (chi-square=56.94; $p < .0001$). One possible interpretation of this finding may be that the SBIR funding was not sufficient to prevent discontinuing the project. Other factors may have played a role in the project’s demise. Or it may merely be that those awardees with discontinued projects view SBIR and its support with a little less enthusiasm. It should be noted, though, that even though this difference exists, the large majority of those with discontinued projects still rated SBIR support “very important.”

When we look at the importance of SBIR support by the awardee companies’ major fields of business, we also find that there is an association that is statistically significant at the 1% level (chi-square=100.55; $p < .0001$). There are some relatively small variations in the proportions of awardees rating SBIR support “very important” by the major fields of business. The next exhibit shows this. It is ordered by the percentages of “very important” ratings.

Exhibit 3-26 Importance of SBIR Support by Awardees Major Fields of Business



The bars in this exhibit show the percentages of awardees within each grouping defined by importance rating of SBIR support and awardee companies' major fields of business. The association between these two variables is statistically significant at the 1% level. The bars are ordered by the percentage of "very important" ratings, so that we can note the fields of business that give proportionately more "very important" ratings to SBIR support (leftmost bars) from those that give proportionately fewer "very important" ratings (rightmost bars). (Four awardees provided no data.)

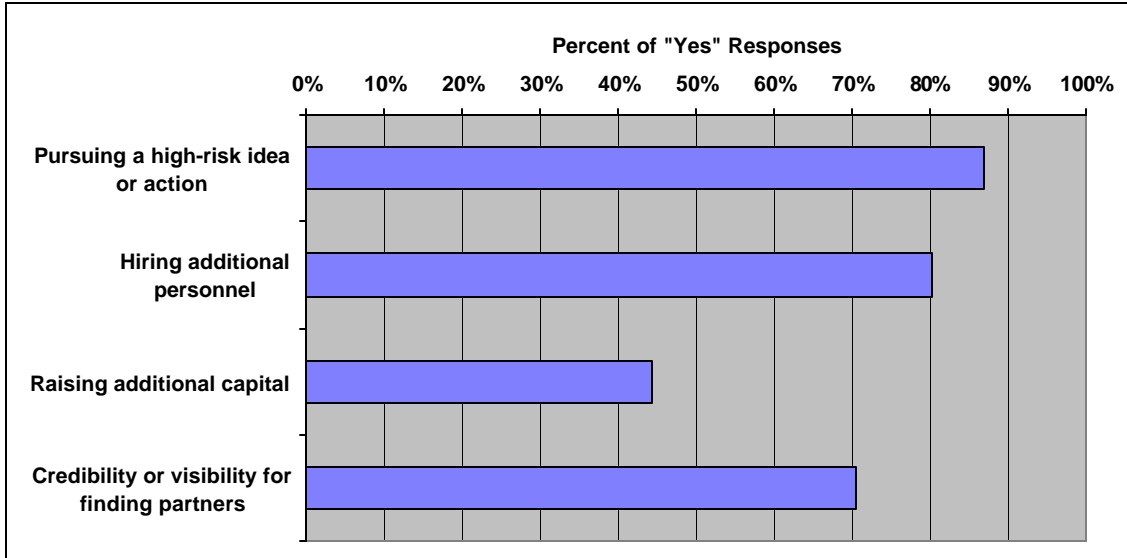
Note that the differences in percentages of awardees rating SBIR support "very important" are between fields of business at the left and right edges of this chart. These bars represent relatively small numbers of awardees. The percentages in the large majority of the fields of business in the center of the chart are equivalent. These bars represent relatively large numbers of awardees. Thus, while these differences are significant and perhaps of interest, they are minor.

There are no statistically significant differences in the importance of SBIR support among any other groupings formed by key survey variables. There are no differences by type of product, process, or service planned for commercialization, or by IC Group.

To further assess the effects of the SBIR support, the survey asked awardees if the granting of one or more SBIR awards for the product, process, or service had an impact on four important

activities. The next exhibit shows these activities and the percentages of awardee respondents responding “yes.” Those answering “no” or “not sure” are not included.

Exhibit 3-27 Activities Affected by the Granting of One or More SBIR Awards



This exhibit shows the percentages of awardees responding “yes”—the granting of one or more SBIR awards for the product, process, or service had an impact on the specified activity. “No” and “not sure” responses are not shown. Multiple responses (one for each activity) are included.

We can see that, for 80 percent or more of awardees, SBIR support had an impact on pursuing a high-risk idea or action that might not otherwise be undertaken and hiring additional personnel. SBIR support also gave credibility or visibility for finding partners for 70 percent of awardees and affected the raising of additional capital for over 40 percent.

The survey assessed awardee satisfaction with their experiences going through the SBIR application, review, and award process. Overall, the awardee respondents gave very high satisfaction ratings to nearly all items. There are no statistically significant differences in any of the satisfaction ratings among the IC Groups.

To measure awardees’ success in terms of the index about expressing satisfaction with the NIH SBIR Program, it is appropriate that we include all awardees—that is, those with ongoing projects and those with discontinued projects. The following exhibit tabulates the numbers of awardees giving high satisfaction and importance ratings to SBIR activities and support.

Exhibit 3-28 Awardees Giving High Satisfaction and Importance Ratings to SBIR

Q33. Thinking <u>now just about the referenced award</u> , how satisfied were you with your experiences going through the SBIR application, review, and award process?	Completely or Mostly Satisfied		Completely Satisfied	Mostly Satisfied
	Obtaining information about the SBIR Program	714	93%	446
Instructions for preparing applications	673	88%	368	305
Review process	560	73%	240	320
Award process	635	83%	316	319
Post-award administration	646	84%	377	269
Q3. If the SBIR program were <u>not</u> available, would the project funded by the referenced award still have been pursued?	No			
	489	64%		
Q8. How important overall has SBIR support been, or how important will it be, in research and development of this product, process, or service?	Very Important or Important		Very Important	Important
	750	98%	668	82

This table shows the numbers of awardees giving high satisfaction ratings to their experiences with the SBIR Program, stating that the SBIR Program was necessary for the pursuit of their project, and giving high importance ratings to the SBIR support for the research and development of their project.

Stated in terms of Measure 2.3.1, from 560 to 714 awardee companies experienced high levels of satisfaction with the NIH SBIR Program, 489 believe that they could not have pursued their project if the SBIR Program were not available, and 750 give SBIR support high importance ratings.

To summarize this in terms of Index 2.3 defining SBIR Program expectations:

- *73 percent to 93 percent of awardee companies express high levels of satisfaction with their experiences going through the NIH SBIR Program.*
- *64 percent believe that they could not have pursued their project if the SBIR Program were not available.*
- *98 percent state that SBIR support has or will be very important or important in the research and development of their project.*

3.3 Commercialization of Innovations

This section of the final report discusses the survey findings that relate to the goal of the SBIR Program *to increase the commercialization of innovations*. We evaluated the survey findings specifically in terms of assessing the NIH objective for the SBIR Program—*to increase private-sector commercialization of innovations resulting from federal research and development in support of the NIH mission, from the date of award to the date of measurement*.

As shown by the following summary exhibit, SBIR survey results indicated that SBIR awardees achieved high rates of success in attaining both related indices.

Exhibit 3-29 Summary of Awardee Performance: Commercialization of Innovations

Increase the Commercialization of Innovations	Findings	
	Indices	Measures
<p>4.1 Companies with NIH SBIR awards commercialize new or improved products, processes, usages, and/or services in health-related fields.</p> <p>4.1.1 Number of SBIR-supported products, processes, usages, and/or services that yield sales</p> <p>4.1.2 Dollar volume of sales of SBIR-supported products, processes, usages, and/or services</p> <p>4.1.3 Number of SBIR-supported drugs and medical devices receiving FDA approval</p> <p>4.1.4 Number of licenses</p> <p>4.1.5 Other evidences of commercialization</p> <p>4.1.6 Number of awardees receiving additional funding from sources other than the SBIR Program</p>	73%	<p>224</p> <p>\$821 Million</p> <p>48</p> <p>164</p> <p>458</p> <p>281</p>
<p>4.2 Companies with NIH SBIR awards grow their companies</p> <p>4.2.1 Median number of years companies with NIH SBIR awards exist</p> <p>4.2.2 Median number of full-time employees</p>	80%	<p>11</p> <p>10</p>

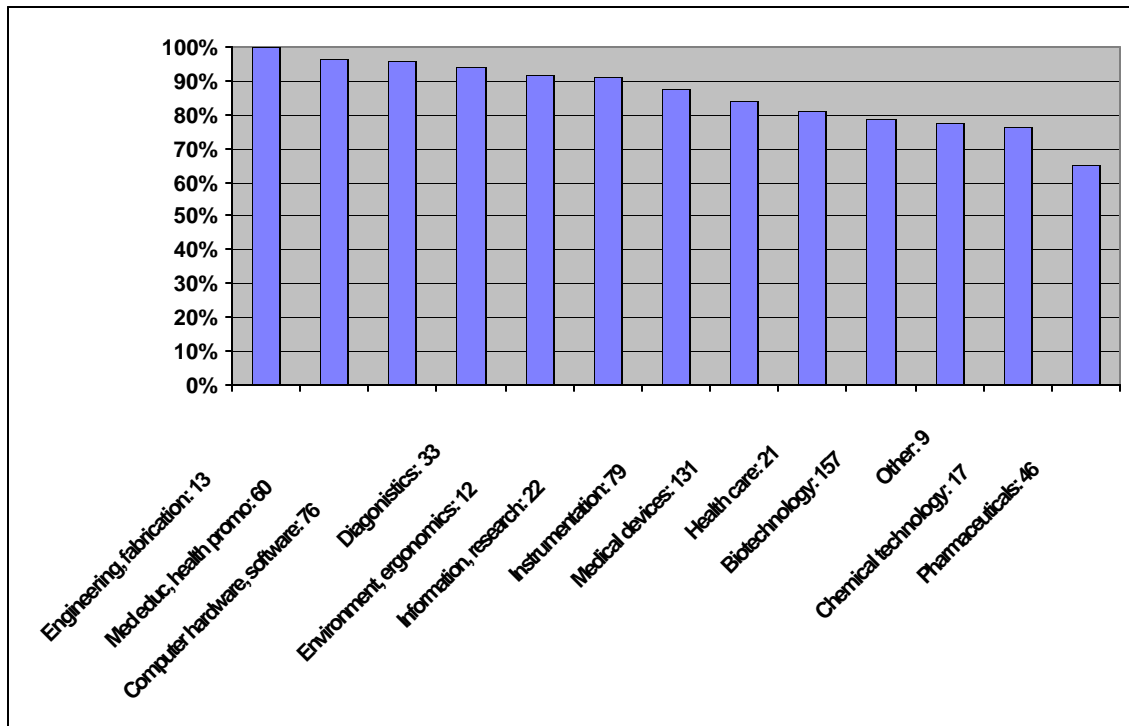
The rest of this section of the report provides detail about these findings and related issues.

3.3.1 Sales of Products, Processes, and Services

The survey asked awardees if sales were (or are) expected upon completion of the project. The awardees were to consider both sales and sales of licenses in answering this question, which was asked only of those 677 awardees with ongoing projects. Overall, 576 or 85 percent of the 677 awardees expected sales.

There were no differences among awardees by the IC groups or the individual ICs supporting their projects. There were, however, differences among awardees' sales expectations by their major fields of business and the type of product, process, or service planned for commercialization. The next two exhibits illustrate this.

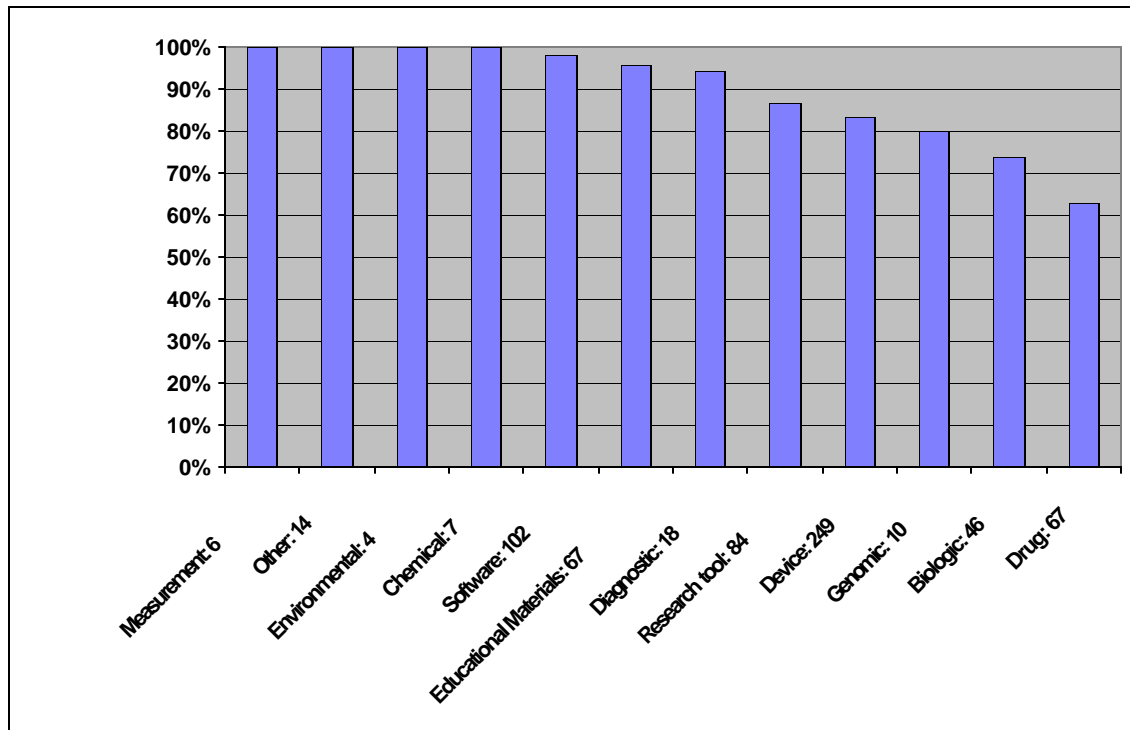
Exhibit 3-30 Expectation of Sales Upon Project Completion by Major Fields of Business



This exhibit shows the percentages of awardees expecting sales upon completion of their projects by the companies' major fields of business. There is an association between these two variables that is statistically significant at the 1% level. Companies in all fields of business expect sales, but levels of expectation vary. Companies' whose fields of business are at the left and right sides of the bar graph differ most in their expectations of sales. (Only the 677 awardees with ongoing projects are included in this chart. The 91 awardees with discontinued projects were not asked this question and are not included. One awardee provided no data.)

The differences are between awardees in businesses or with products that are at the leftmost and rightmost sides of the bar graphs (Exhibit 3-30 and Exhibit 3-31). Summarizing this information, it appears that awardee businesses in the fields of biotechnology, chemical technology, and pharmaceuticals and whose products are drugs, and biologics have proportionately lower expectations of sales upon completion of their projects than do awardee businesses in the fields of engineering, medical education, computer hardware/software, and diagnostics and whose products are measurement, software, educational materials, and diagnostics. These findings are statistically significant at the 1% level ($\chi^2=40.14$; $p<.0001$ and $\chi^2=59.26$; $p<.0001$ for fields of business and types of projects, respectively).

Exhibit 3-31 Expectation of Sales Upon Project Completion by Product Types



This exhibit shows the percentages of awardees expecting sales upon completion of their projects by the companies' product, process, or service. There is an association between these two variables that is statistically significant at the 1% level. Companies' project types at the left and right sides of the bar graph differ in their expectations of sales. Companies with all categories of product, process or service expect sales, but levels of expectation vary. (Only the 677 awardees with ongoing projects are included in this chart. The 91 awardees with discontinued projects were not asked this question and are not included. Three awardees provided no data).

As is apparent, the major-field-of-business and type-of-product variables are redundant expressions of the same or similar information. One interpretation of this finding is that *some* small business concerns, whose commercialized products require clinical trials and FDA approval, may not have expectations of sales upon completion of the product research and development. We should keep in mind, however, that over 60 percent of these businesses (the ones at the rightmost sides of the bar charts) did expect sales upon project completion.

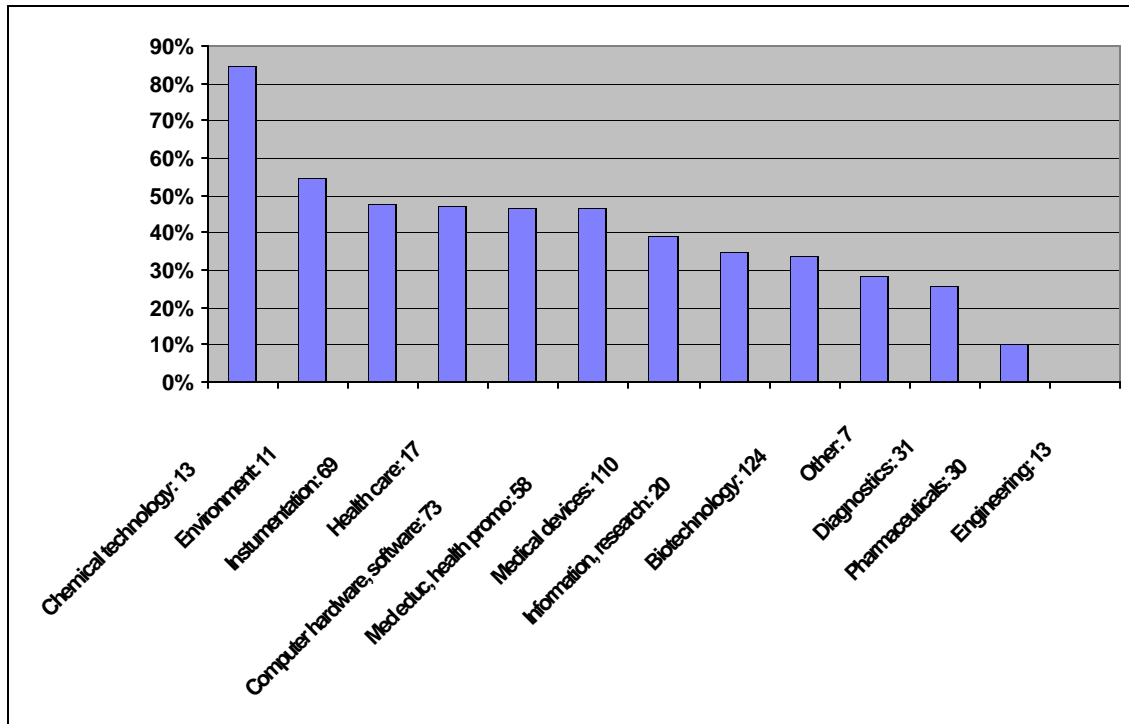
The survey asked those 576 awardees who expected sales upon the completion of their projects if sales were realized. They reported:

<u>Result</u>	<u>Number of Awardees Reporting</u>	<u>Percent of Total Reporting</u>
Sales were realized	224	39%
Sales are anticipated	340	59%
Other	12	2%

We can conclude that, overall, of the awardees expecting sales upon project completion, 224 or 39 percent realized sales and 340 or 59 percent anticipate sales. Twelve awardees or 2 percent gave various other reasons why there were no sales, the gist of which were that there was no longer anticipation of any sales.

There were no statistically significant differences among awardees *realization and anticipation* of sales by individual ICs or IC groups. As was the case with the expectation of sales, however, there were differences among the awardees by major fields of business and product types. The differences were statistically significant at the 1% level (chi-square=68.60; p=.0009 and chi-square=62.78; p=.0013 for fields of business and types of projects, respectively). The next two exhibits illustrate these findings.

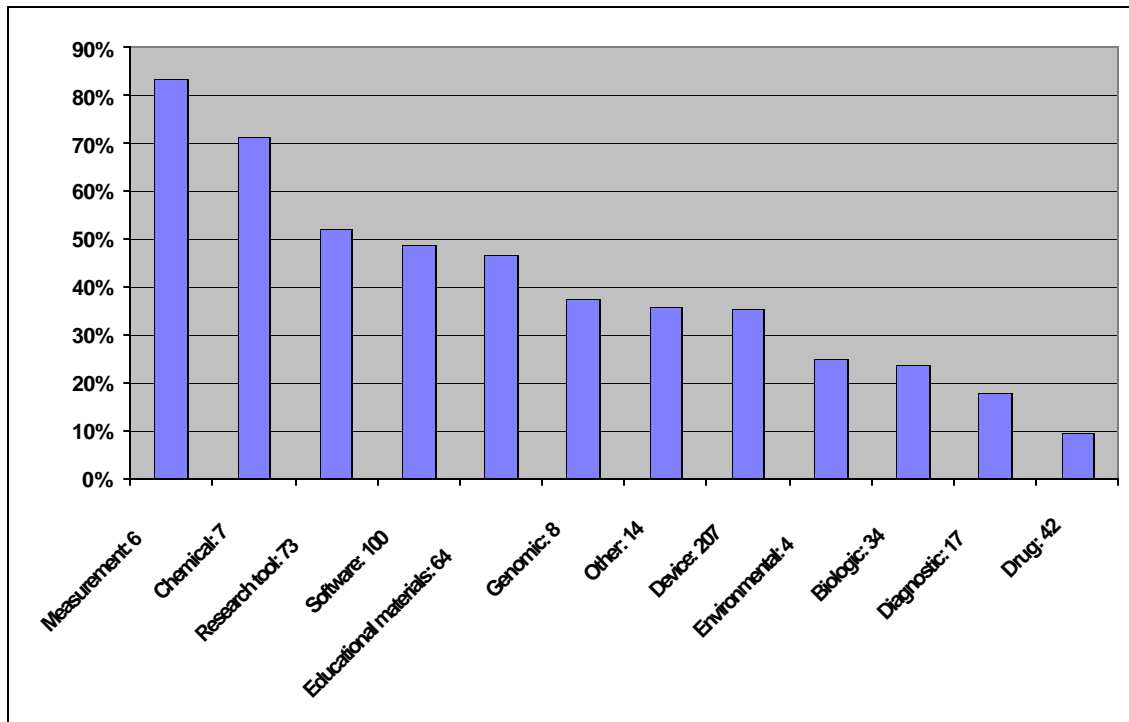
Exhibit 3-32 Realization of Sales Upon Project Completion by Major Fields of Business



There are relatively large variations between the fields of business at the left and right sides of the bar graph in their realization of sales. Looking at the fields of business with larger numbers of awardees, we see that lower proportions of medical device, biotechnology, diagnostics, and pharmaceuticals firms have realized sales at the time of assessment. (Only the 576 awardees who expected sales upon completion of their projects are included.)

The apparent variations in realization of sales among the fields of business and the product types (Exhibit 3-32 and Exhibit 3-33) are greater than the variations in expectation of sales. However, for the most part, the same fields of business and products types that have proportionately lower expectations of sales also have proportionately lower realization of sales. Again, the awardee businesses in the fields of pharmaceuticals, other, and biotechnology, and whose products are drugs, diagnostics, and biologics have proportionately lower realization of sales upon completion of their projects.

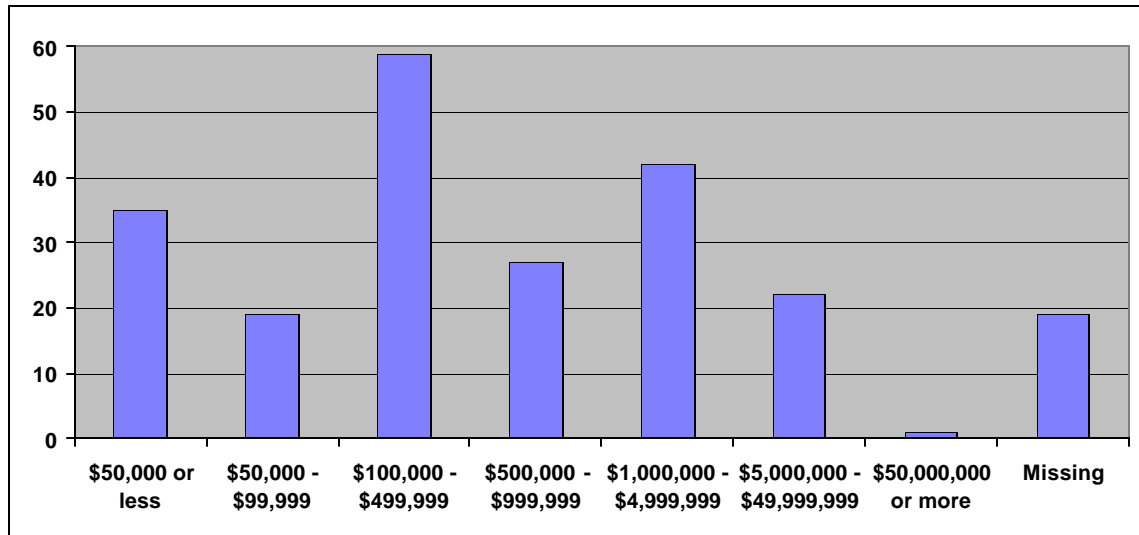
Exhibit 3-33 Realization of Sales Upon Project Completion by Product Types



There are relatively large variations between the types of products at the left and right sides of the bar graph in realization of sales. Looking at the product types with larger numbers of awardees, we see that lower proportions of awardees with device, biologic, diagnostic, and drug products realized sales at the time of assessment. (Only the 576 awardees who expected sales upon completion of their projects are included.)

The survey asked those 224 awardees who realized sales to select the dollar range of cumulative sales related to the product, process, or service developed under the SBIR-supported project. A total of 205 respondents provided this information; 19 who sold products did not. The next exhibit shows the distribution of cumulative sales. The median and mode sales category is \$100,000 to \$499,999.

Exhibit 3-34 Cumulative Sales for Those Awardees Realizing Sales



This bar chart shows the distribution of cumulative sales related to the SBIR supported product, process, or service for those awardees who realized sales. Nineteen awardees who sold products did not supply cumulative sales information.

We examined the distribution of sales amounts by the NIH ICs funding the SBIR projects because this is an area of interest to the individual ICs. There is *not* a statistically significant association between sales amount and IC. When we exclude those ICs with less than 5 awardees realizing sales, there are no statistically significant differences among individual ICs or among the IC groups.

Although surveys often ask for sales data using categorical response options as opposed to open-ended ones because respondents are more inclined to give sales figures this way, we are often interested in tallying total sales data. We can *estimate* total sales by using the midpoint of the bounded sales categories and the start point of the final unbounded category. The next exhibit tabulates the estimated cumulative sales by the different NIH ICs. Again, we present the cumulative sales by NIH IC because of the interest the ICs have in their particular sales data. *We should remember, however, that the cumulative sales figures are based on small numbers of awardees for many of the ICs, and that the sales amounts are estimates derived from categorical data.*

Exhibit 3-35 Estimated Cumulative Sales for Awardees Realizing Sales by NIH ICs

NIH Institute/Center		Number of Awardees Realizing Sales	Percent Of All Funded Awardees	Total Sales In \$1,000s	Mean Sales In \$1,000s
NIA	National Institute on Aging	9	24%	7,725	858
NIAAA	National Institute on Alcohol Abuse and Alcoholism	5	38%	4,200	840
NIAID	National Institute of Allergy and Infectious Disease	8	12%	61,700	7,713
NIAMS	National Institute of Arthritis, Musculoskeletal and Skin Diseases	3	17%	3,375	1,125
NCI	National Cancer Institute	35	27%	\$ 113,850	\$ 3,253
NICHHD	National Institute of Child Health and Human Development	19	38%	34,500	1,816
NIDCD	National Institute on Deafness and Communication Disorders	7	41%	7,575	1,082
NIDCR	National Institute of Dental and Craniofacial Research	3	30%	30,800	10,267
NIDA	National Institute on Drug Abuse	9	33%	32,275	3,586
NIDDK	National Institute of Diabetes, Digestive, and Kidney Diseases	3	7%	27,825	9,275
NIEHS	National Institute of Environmental Health Sciences	6	46%	7,425	1,238
NEI	National Eye Institute	3	10%	77,525	25,842
NIGMS	National Institute of General Medical Sciences	28	44%	111,350	3,977
NHLBI	National Heart, Lung, and Blood Institute	24	22%	71,925	2,997
NHGRI	National Human Genome Research Institute	2	18%	3,300	1,650
NIMH	National Institute of Mental Health	21	48%	101,475	4,832
NINDS	National Institute of Neurological Disorders and Stroke	8	16%	59,725	7,466
NINR	National Institute of Nursing Research	2	40%	1,500	750
NCRR	National Center for Research Resources	10	34%	63,200	6,320
TOTAL		205	27%	\$ 821,250	\$ 4,006

This table shows the NIH ICs funding those awardees realizing sales, the number of awardees per IC who realized sales from their funded projects, the percentage the awardees realizing sales are of all funded awardees by that IC, the total amount of cumulative sales in *thousands* of dollars per IC, and the mean amount of sales per awardee in *thousands* of dollars for that IC. The dollar figures are approximate amounts estimated by using the midpoint of the categories shown in the prior exhibit. (The start point is used instead of the midpoint for the final, unbounded category.) (Of the 224 realizing sales, 19 provided no sales data.)

What we can reasonably extract from this table is that 205 of the 768 awardee respondents (27%) realized total cumulative sales of approximately \$821 million. Mean cumulative sales per awardee with realized sales are about \$4 million. NCI, NHLBI, NICHHD, NIGMS, and NIMH funded larger *numbers* of awardee respondents with realized sales. These are five of the top eight ICs¹ in terms of the total *number* of respondents with SBIR awards funded during the study period. By and large, however, comparable proportions of awardees within each of the Institutes/Centers realized sales. (There are no statistically significant differences. Apparent differences are those that could be reasonably expected variations.)

¹ The top eight ICs in terms of total number of respondents with SBIR awards funded during 1992 through 2001 are: NCI 130, NHLBI 107, NIAID 69, NIGMS 64, NICHHD 50, NINDS 49, NIMH 44, and NIDDK 44. The other ICs have from one to 37 awardee respondents each during this period.

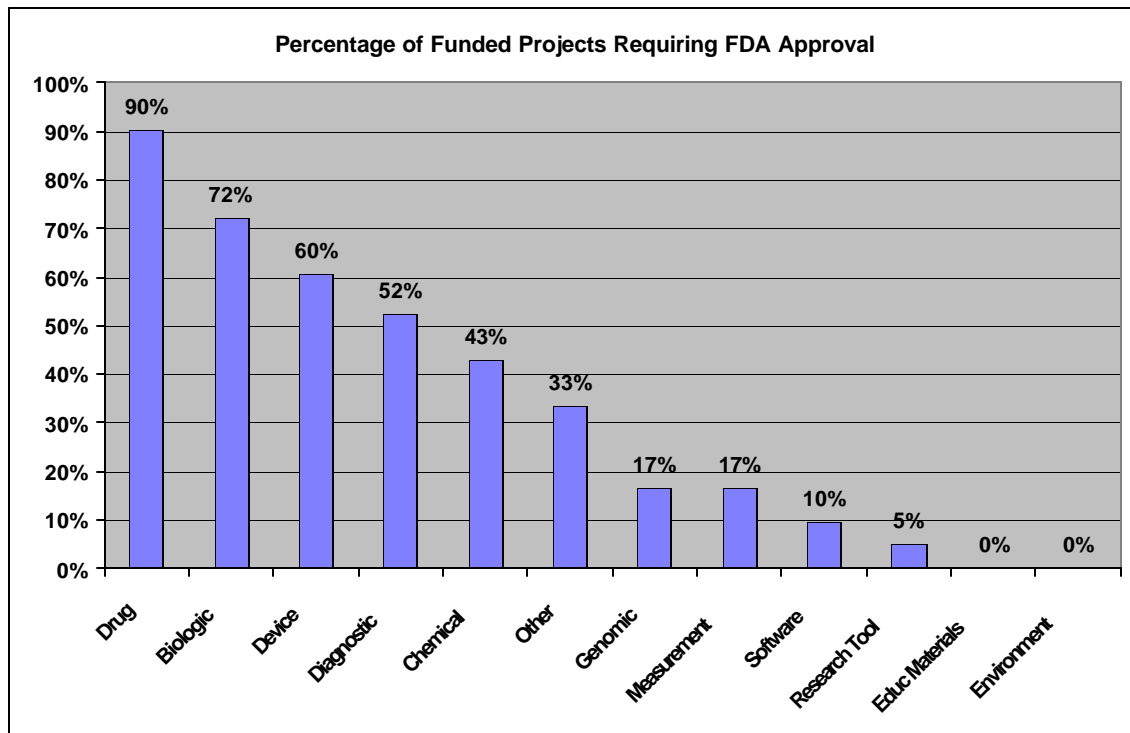
Stated in terms of Measure 4.1.1, 224 SBIR-supported products, processes, usages, and/or services yielded sales at the time of measurement. An additional 340 are anticipating sales.

Stated in terms of Measure 4.1.2, the dollar volume of sales of SBIR-supported products, processes, usages, and/or services at the time of measurement is approximately \$821 million.

3.3.2 Status of FDA Approval

Awardee respondents were asked if FDA approval was required for the product, process, or service funded under the SBIR award. Overall, 324 of the 768 awardees (42%) required FDA approval for their supported projects. The next exhibit shows the percentages of funded projects requiring FDA approval by the type of product, process, or service.

Exhibit 3-36 Percentage of Funded Projects Requiring FDA Approval by Product Type



Proportionately more drug, biologic, device, diagnostic, and chemical projects require FDA approval.

We see, as expected, that product type and requirement for FDA approval have a strong association, which is statistically significant at the 1% level (chi-square= 300.90; p<.0001). The percentages requiring FDA approval range from 90 percent of all drugs to 0 percent of educational materials and environmental products.

The next exhibit tabulates the status of the different product types by those requiring FDA approval, those submitted for approval, and those already approved. Overall, 42 percent of SBIR-supported projects require FDA approval, 28 percent of those requiring approval have been

submitted for FDA review, and 53 percent of those submitted for review have received FDA approval.

Exhibit 3-37 Status of FDA Approval by Type of Product, Process, or Service

Type of Product, Process, or Service	Status of FDA Approval						
	Total	Requires FDA Approval		Submitted for FDA Review		Received FDA Approval	
		Number	Percent	Number	Percent	Number	Percent
Drug	83	75	90%	16	21%	4	25%
Biologic	50	36	72%	12	33%	4	33%
Device	286	173	60%	48	28%	32	67%
Diagnostic	21	11	52%	3	27%	1	33%
Chemical	7	3	43%	2	67%		0%
Other	15	5	33%	3	60%	3	100%
Genomic	12	2	17%	1	50%		0%
Measurement	6	1	17%	0	0%		
Software	113	11	10%	4	36%	3	75%
Research Tool	98	5	5%	1	20%	1	100%
Educational Materials	70	0	0%	0			
Environment	4	0	0%	0			
TOTAL	765	322	42%	90	28%	48	53%

This table shows the total number of each type of product, process, or service, the number and percent of the total requiring FDA approval, the number and percent of those requiring approval that have been submitted for FDA review, and the number and percent of those submitted for review that have received FDA approval. (Three awardees provided no data.)

The status distribution of submitted projects that have *not* received FDA approval is:

<u>Status</u>	<u>Number</u>
Applied for review	8
Review ongoing	13
IND; clinical trials	11
Other	7
Not approved	2

An IND (Investigational New Drug) is approval to use an experimental drug, usually in a clinical trial. The “other” responses included discussion of 510(k) clearance, pre-clearance meetings, and general lack of knowledge about the status of the project.

Stated in terms of Measure 4.1.3, 48 SBIR-supported drugs, medical devices, and related products had received FDA approval at the time of measurement. An additional 32 products were currently undergoing FDA review and/or clinical trials.

With regard to licenses for SBIR-supported products, processes, and services, 164 awardees indicated that their companies executed license agreements. Seven of these 164 awardees reported that their funded projects were currently discontinued. For three of the awardees, licensing to another company was one of the reasons for discontinuing the project.

Stated in terms of Measure 4.1.4, 164 awardee companies have licensed the SBIR-supported products, processes, usages, and/or services. Seven of these projects are currently discontinued.

3.3.3 Other Evidence of Commercialization

In addition to the numbers of products, sales figures, FDA approvals, and licenses, there are other evidences of the commercialization of SBIR-supported innovations. These include various types of marketing activities, public stock offerings, and trade or commercial names for the funded products, processes, or services.

The next exhibit shows the status of marketing activities for the 677 ongoing awardee businesses (those not discontinued). The *percentages* in the table cells are of the 677 ongoing businesses.

Exhibit 3-38 Status of Marketing Activities for Ongoing Awardee Businesses

Respondents were asked to select one response for each activity.	Q20. Which of the following describes the status of marketing activities by your <u>company</u> and/or your licensee for this project....						
	Not Yet Planned	Planned	Ongoing	Complete	Need Assistance	Not Applicable	No Data
Preparation of marketing plan	129 19%	75 11%	256 38%	139 21%	33 5%	33 5%	12 2%
Hiring of marketing staff	220 32%	82 12%	96 14%	124 18%	46 7%	90 13%	19 3%
Publicity and advertising	214 32%	80 12%	196 29%	76 1%	48 7%	43 6%	20 3%
Test marketing	207 31%	73 11%	133 20%	123 18%	41 6%	77 11%	23 3%

This table shows the status of marketing activities at the time of the survey for 677 ongoing (not discontinued) awardee businesses. Percentages shown in each cell are of the 677 ongoing businesses. Note that some activities were not applicable for some awardees, and some respondents did not provide this information (“No Data”).

As shown, about 20 percent of the ongoing businesses have completed preparation of their marketing plans, hiring of their marketing staff, and test marketing (column headed “Complete”). Only 1 percent had completed their publicity and advertising. About 30 percent of the ongoing businesses had not yet planned these activities (“Not Yet Planned”), and about 10 percent had (“Planned”). Many of the businesses have ongoing marketing activities—about 40 percent were preparing marketing plans, about 15 percent were hiring marketing staff, about 30 percent are publicizing and advertising their products, and about 20 percent were test marketing). Slightly more than 5 percent of the awardee respondents indicate specifically the need for assistance with the various marketing activities.

Overall, 436 (64%) of the 677 awardees with ongoing businesses had *ongoing or completed marketing activities*. We defined “ongoing or completed marketing activities” as *at least one of the four marketing activities was ongoing or completed*.

Twenty-one of the awardee businesses reported a public offering of their stock. The next exhibit lists the stock exchanges and gives the ticker symbols for those awardee businesses that have had public offerings.

Exhibit 3-39 Stock Exchanges and Ticker Symbols for Awardees With Public Offerings

Stock Exchanges	Ticker Symbols			
NASDAQ	BASI	BCRX	CERS	DDDP
	DPII	FUPG	IMGN	ISBC
	MAMH.OB	NEOTD	SRDX	TBIO
	TGEN	TRMS	TWT1	VION
AMEX	GEB	QSC	RVP	
Other	GLIA			

A total of 21 awardee companies reported public offerings—16 on NASDAQ, 3 on AMEX, and one on an unidentified other exchange. This table gives the stock exchanges and ticker symbols for 20 of those companies. (One company did not provide this information).

Sixty percent (458) of the 768 awardees provided the trade or commercial name for their SBIR-supported product, process, or service.

Stated in terms of Measure 4.1.5, other evidence of the commercialization of SBIR-supported innovations includes: 436 awardees with ongoing businesses have ongoing or completed marketing activities, 21 of the awardee businesses reported public offerings of their stock, and 458 awardee businesses have trade or commercial names for their innovations.

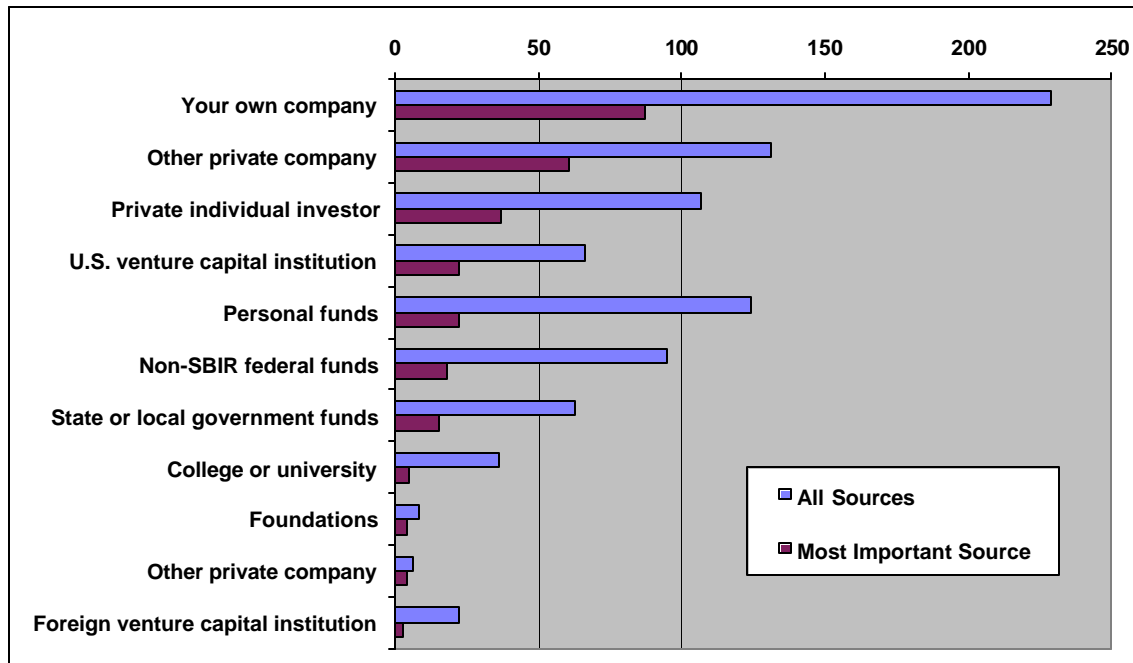
3.3.4 Additional Funding

Receiving additional developmental funding for SBIR-supported innovations from sources other than the SBIR Program is another indication of commercialization of these innovations. A total of 281 of the awardees (37%) have received additional non-SBIR funding or capital for their projects. Seventy-six percent of those receiving this funding (214 awardees) believe that it is a result of the initial NIH SBIR funding.

The survey asked the awardee respondents, who had received additional non-SBIR funding, to select all important sources of additional funding or capital for this project and its outcome (product, process, or service) and to indicate the most important source. All but two of the awardees provided data about their funding sources. The next exhibit shows both all sources and the single most important source.

The awardees' own company is both the single most important source of additional funding and the source cited by the largest number of respondents. Other private companies, personal funds, private individual investors, and non-SBIR federal funds are the next four most cited sources of additional funding. However, in terms of the most important sources, other private companies and private individual investors are the second and third most important.

Exhibit 3-40 Sources of Additional Funding or Capital for Awardee Projects



The sources of additional funding or capital are ordered by the single most important source. The awardees own company was both the single most important source and the source cited by the largest number of respondents. Other private companies and personal funds were next cited by relatively large numbers of awardees, although these sources are the second and fifth most important ones. (Two respondents provided no data.)

Stated in terms of Measure 4.1.6, 281 awardees have received additional developmental funding from sources other than the SBIR Program, and 214 of those receiving this funding believe that it is a result of the NIH SBIR funding.

The next exhibit summarizes Measures 4.1.1 to 4.1.6—evidences of commercialization relating to the realization of sales, FDA approval, licensing, marketing, public stock offering, and additional non-SBIR funding.

Exhibit 3-41 Summary of Evidence of Commercialization of SBIR-Funded Projects

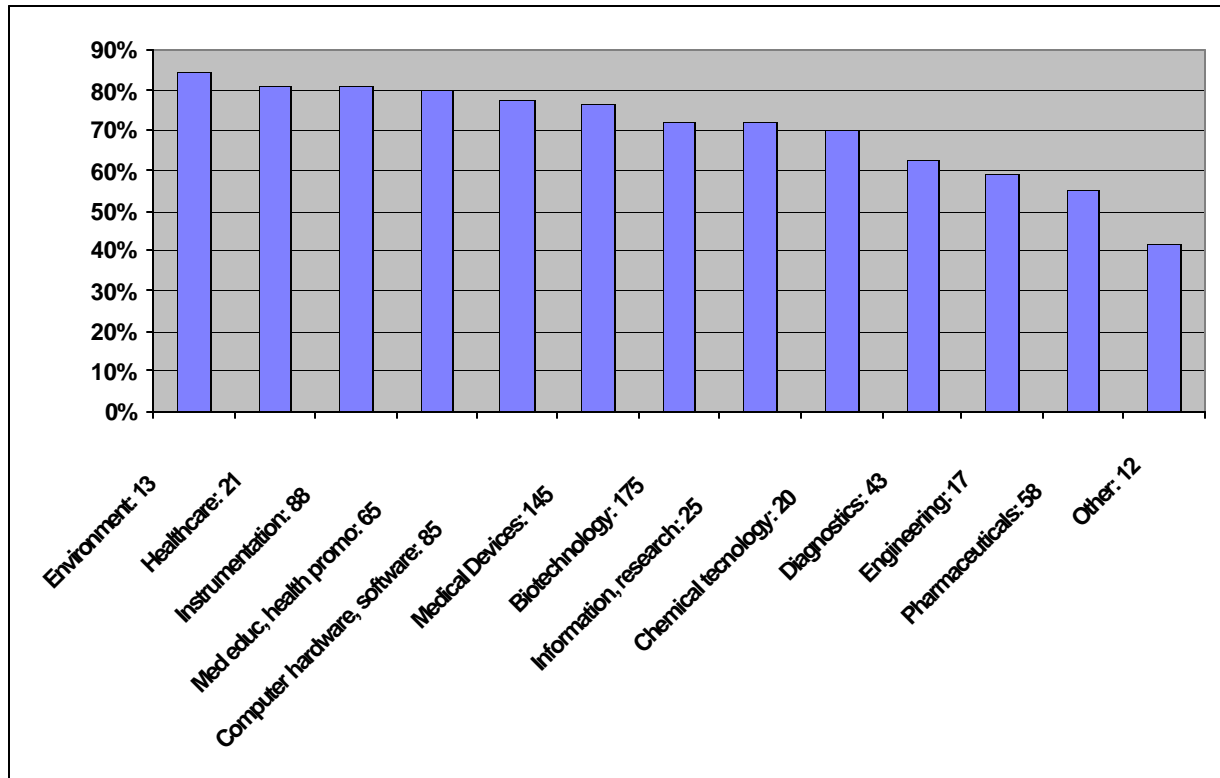
Measures of the Commercialization of New or Improved Products, Processes, Usages, and/or Services		
Q22. Sales were realized	224	29%
Q13. Product, process, or service had FDA approval	48	6%
Q29. Executed license agreement	164	21%
Q20. Marketing activities are ongoing or completed	436	57%
Q29. Public offering	21	3%
Q25. Company has received additional non-SBIR funding or capital	281	37%
Total number of evidences of commercialization	1,174	
Total number of awardees with one or more evidences of commercialization	564	73%

This table shows the numbers of awardees achieving each measure and their percentage of the 768 total awardees. Seventy-three percent of all awardees have achieved one or more of these measures.

Together, the 768 awardee respondents said they had achieved a total of 1,174 of the activities that we defined as evidences of the commercialization of the SBIR-funded products, processes, and services. Seventy-three percent of the 768 awardees (564) reported they had accomplished one or more of these commercialization activities.

There are no statistically significant differences among the NIH ICs or the IC groups in the achievement of one or more commercialization activities. There are, however, differences by the awardee companies' major fields of business. This association is statistically significant at the 1% level ($\chi^2=27.21$; $p=.0072$). The next exhibit shows this.

Exhibit 3-42 Evidence of Commercialization by Companies' Major Fields of Business



Awardee companies fields of business at the left and right sides of the chart differ in their achievement of one or more evidences of commercialization. (One awardee provided no data).

The ordering of the major fields of business by evidences of commercialization is similar to but not exactly the same as earlier orderings by realization of sales. In general (considering the fields with relatively large numbers of awardees and ignoring the others), some fields of business have a longer lead-time in the commercialization process than others. These are the fields that require clinical testing and/or FDA approval, such as pharmaceuticals. Also, note that the percentages in this exhibit are of *all* awardee companies in each field. Earlier percentages, for example, in the exhibits showing realization of sales, are of companies anticipating sales upon completion of their project. (The realization of sales question was asked only of those respondents who anticipated sales.)

To summarize the six measures about commercialization of innovations in terms of Index 4.1:

- *73 percent of companies with NIH SBIR awards commercialize new or improved products, processes, usages, and/or services in health-related fields.*
- *29 percent realized sales*
- *6 percent received FDA approval*
- *21 percent have executed license agreements*
- *57 percent have ongoing or completed marketing activities*
- *3 percent have reported a public offering*
- *37 percent have received additional non-SBIR funding*

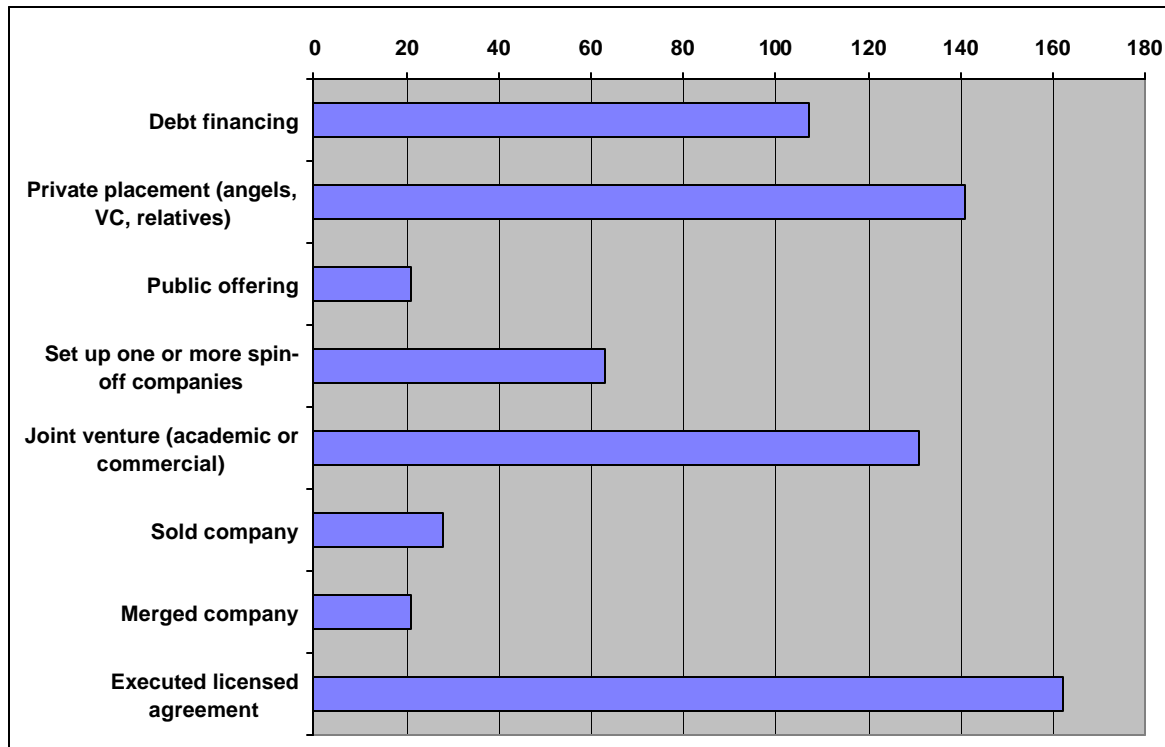
3.3.5 Growth of Small Business Concerns

In order to assess the extent to which awardees grow their companies, the survey asked for the founding year of their business, their total number of full-time employees or full-time equivalents, and indications of mergers and other growth-related activities.

We calculated awardee age as of 2001. Awardees founded in 2001 were considered 1 year old (as opposed to 0). The median age of the awardee businesses was 11 years. Fifty percent were between 7 and 16 years old. The oldest business was 115 years old. (This age was confirmed by calling the respondent.)

Awardees were asked to indicate whether their companies experienced various growth-related activities because of the product, process, or service developed under the SBIR-funded project. The next exhibit shows the number of awardee who reported experiencing each activity. A total of 391 awardees (51 percent of the 768 respondents) experienced at least one of these activities.

Exhibit 3-43 Growth-Related Activities Experienced by Awardee Businesses



A total of 391 awardees experienced at least one of these growth-related activities. Licensed agreement and private placement were most frequently -cited activities.

Stated in terms of Measure 4.2.1, the median number of years in existence of NIH SBIR awardee businesses is 11 years. Some of these businesses said they have financed debt, had private or public stock offerings, set up spin-offs or joint ventures, sold or merged their companies, and executed license agreements.

The median number of full-time employees in the awardee businesses is 10. Fifty percent of the awardees have from four to 35 employees. (We excluded one awardee business with 10,000 employees from the above calculations because it might be an erroneous outlier. We also excluded ten respondents who gave the number of current full-time employees as zero. Seventeen respondents did not provide data.)

Eighty percent of the awardee respondents (616) indicated that the granting of the SBIR award had an impact on the hiring of additional personnel. We can likely assume that the SBIR funding helped their businesses grow.

Stated in terms of Measure 4.2.2, the current median number of employees in NIH SBIR awardee companies is ten full-time employees. Eighty percent of the awardees were able to hire additional personnel because of the SBIR funding.

To summarize this in terms of Index 4.2:

- *Eighty percent of companies with NIH SBIR awards grow their companies—they indicated that they were able to hire additional personnel because of the granting of the SBIR award.*
- *The median age of an awardee business is 11 years.*
- *Fifty-one percent of all awardees experienced one or more growth-related activities, such as debt financing, private or public stock offerings, spin-offs or joint ventures, sold or merged companies, and executed license agreements.*
- *The median number of full-time employees is ten.*

4. CONCLUSIONS AND RECOMMENDATIONS

This chapter presents conclusions and recommendations derived from study findings and answers these questions:

- Has the SBIR Program fulfilled its goals?
- Has NIH developed a system to evaluate the performance of the SBIR Program that includes measuring the success of award recipients in commercializing products resulting from their funded projects?
- Are awardees meeting SBIR Program goals that are especially pertinent to the NIH mission?
- How should the NIH SBIR Program proceed with planning performance evaluation?

4.1 The SBIR Program Fulfills Its Goals

The *National Survey to Evaluate the NIH SBIR Program* collected abundant data that indicate that the NIH SBIR Program is fulfilling its goals. Collectively, the 768 respondents reported 224 products, processes, services, or licenses that yielded approximately \$821 million in cumulative sales revenues. While impressive, the \$821 million is merely a lower bound on the contribution of SBIR awardees to the commercialization of innovations that improve health and health care. It does not capture future sales anticipated by the additional respondents whose products are still under development or in the commercialization stage. Nor does it include the less tangible but very valuable contributions that the awardees make in stimulating technological innovation and increasing the use of small businesses.

The reports of anticipated sales are particularly significant. The total SBIR budget grew substantially in recent years, and 74 percent of the awards included in the survey were made during the last five years of the study period. These more recent awards account for a disproportionate share of the sample and magnify the percentage of anticipated but unrealized revenues. Many awardees simply require more than one to five years to complete development and commercialization activities before they can successfully move their products into the market. To date, a total of 576 (or 85%) of those respondents with ongoing (not discontinued) products report actual or anticipated sales. Only 12 percent of the respondents' projects have been discontinued.

Other indicators of commercialization and expected market success for the 677 ongoing awardee businesses include preparation of marketing plans (69 percent planned, ongoing, or complete); hiring of marketing staff (45 percent planned, ongoing, or complete); publicity and advertising (42 percent planned, ongoing, or complete); and test marketing (49 percent planned, ongoing, or complete). One hundred sixty-four respondents reported that their companies executed license agreements.

In addition to sales, the other less tangible contributions that SBIR awardees make help increase the technological knowledge base and disseminate information to the multiple populations that use and receive health and health care. Additionally, they indicate the extent of

commercialization activity and the promise of future application and generation of sales revenue. Respondents have received 666 patents, 453 copyrights, and 322 trademarks, with an additional 19 pending items. Forty-eight SBIR-supported drugs, medical devices, and related products had received FDA approval at the time of measurement. An additional 32 products were undergoing FDA review and/or clinical trials. Collectively, the 768 respondents published 2,203 technical articles, made 2,850 conference presentations, and received 252 awards and 69 other forms of acknowledgement for their contributions.

The stimulus of the SBIR program to small business activity is evident in the awardees' responses, which consistently affirmed the worth of the SBIR support for their activities. Ninety-eight percent of the respondents said that SBIR support had been or will be "very important" or "important" in the research and development of the product, process, or service developed under the funded project. Sixty-four percent said the project would not have been pursued without SBIR support. Respondents believe that SBIR awards had an impact on pursuing a high-risk idea or action (87%), hiring additional personnel (80%), raising additional capital (44%), and credibility or visibility for finding partners (70%).

The credibility provided by the SBIR award stimulated and facilitated raising funds from other sources. Thirty-seven percent (281) of the respondents reported receiving funds from non-SBIR sources. Seventy-six percent of those awardees (214) who received additional non-SBIR funding or capital for their project believed that the additional funding was a result of the NIH SBIR award. Fifty-one percent of all awardees (391) experienced one or more growth-related activities, such as debt financing, private or public stock offerings, spin-offs or joint ventures, sold or merged companies, or license agreements. Eighty percent of companies (616) believe that they were able to hire additional personnel because of the granting of the SBIR award.

These findings should be understood within the context of the sampling approach for the survey, not the overall magnitude of the SBIR program. The sample included all awards made from 1992 through 2001. Also, while the survey was a census of all recipients of NIH SBIR Phase II awards within this study period, it included only a single randomly selected Phase II award for each of the 32 percent of the awardees who received multiple Phase II awards. Thus, the 768 awards included in the respondent sample represent only \$551 million in total funding, which is a subset of the total SBIR funding of over \$3 billion since the inception of the SBIR program in 1983 and the \$2.1 billion awarded from 1992 through 2001.

4.2 NIH Evaluated SBIR Performance, Including Commercialization

NIH SBIR sponsorship of the *National Survey to Evaluate the NIH SBIR Program* demonstrates that NIH has developed a system to evaluate the SBIR program that includes measuring success in commercializing funded products. The online survey implementation, the comprehensive update phase, and the extensive telephone follow-up efforts resulted in achieving an 85 percent response rate during the September to November 2002 fielding period. Such a high response rate alleviates any concerns about possible nonresponse bias.

In preparation for the Survey, NIH SBIR developed an evaluation framework that posited NIH-specific SBIR Program goals, objectives, standards, indices, and measures. SBIR officials from a cross-section of ICs participated in preparing the framework. In the absence of performance data prior to the survey, SBIR officials defined place holder indices to state the minimum percentage

of awardees expected to succeed in attaining performance levels, intending that survey results would inform refinement of these performance benchmarks. The NIH Technical Merit Review Committee and the OMB approved use of the evaluation framework for structuring Survey questions to measure performance.

The Survey was designed to collect and analyze data according to the documented evaluation framework plan for assessing performance in terms of NIH SBIR Program goals. This included measuring the success of award recipients in commercializing products resulting from their SBIR research. Data about measures defined by the evaluation framework for indices of technological innovation, use of small businesses, and commercialization were collected for the survey.

4.3 NIH Awardees Report Success in Achieving SBIR Goals Studied

As shown in Exhibit 4-1, awardees reported success in achieving all SBIR goals studied—technological innovation, use of small business to meet federal R&D needs, and commercialization of innovations.

- **Technological Innovation.** Eighty-seven percent of awardee spokespersons reported producing new or improved products, processes, usages, and/or services in support of the NIH mission.
- **Use of Small Business.** Seventy-four percent of awardee spokespersons reported making more than 567 contributions to the knowledge base. Eighty-six percent reported success in meeting dissemination benchmarks.
- **Commercialization.** Seventy-three percent of awardee spokespersons reported commercializing new or improved products, processes, usages, and/or services in health-related fields.

Responses to survey items about related issues indicate that NIH SBIR awardees greatly value the support that the SBIR Program provides.

- *73 percent to 93 percent of awardee companies express high levels of satisfaction with their experiences going through the NIH SBIR Program.*
- *64 percent believe that they could not have pursued their project if the SBIR Program were not available.*
- *98 percent state that SBIR support has or will be very important or important in the research and development of their project.*

Exhibit 4-1 Consolidated Findings from the National Survey to Evaluate the NIH SBIR Program, 1992-2001*

	Findings	
	Indices	Measures
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.	87%	
1.1.1 Number of new or improved products, processes, usages, and/or services		670
1.1.2 Number of technical articles		2,203
1.1.3 Number of patents		666
1.2 NIH SBIR awardees receive additional Phase I or Phase II awards that relate to the core technology.	52%	
1.2.1 Number of additional Phase I or Phase II awards that relate to the core technology		1,465
Use of 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.	74%	
2.1.1 Number of SBIR supported contributions yielding increases in health knowledge, research tools, and education		567+
2.2 NIH awardees are able to obtain and disseminate health-related information	86%	
2.2.1 Number of awardee companies giving high rankings to the usefulness of outreach and informational services		714
2.2.2 Number of disseminations of SBIR supported technology and information among populations using and receiving health and health care resources		660
2.3 NIH awardees express satisfaction with the usefulness of the NIH SBIR Program	73% - 93%	
2.3.1 Number of awardee companies experiencing high levels of satisfaction with the NIH SBIR Program		560-714
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.	73%	
4.1.1 Number of SBIR-supported products, processes, usages, and/or services that yield sales		224
4.1.2 Dollar volume of sales of SBIR-supported products, processes, usages, and/or services		\$821 Million
4.1.3 Number of SBIR-supported drugs and medical devices receiving FDA approval		48
4.1.4 Number of licenses		164
4.1.5 Other evidences of commercialization		458
4.1.6 Number of awardees receiving additional funding from sources other than the SBIR Program		281
4.2 Companies with NIH SBIR awards grow their companies.	80%	
4.2.1 Median number of years companies with NIH SBIR awards exist (at time of measurement)		11
4.2.2 Median number of full-time employees		10

*Numbers match the numbering scheme shown in *Appendix A-2, Evaluation Framework*

4.4 NIH Should Consider Routine SBIR Program Monitoring and Assessment

This survey assessed SBIR awardees who won Phase II awards during the 10-year period, 1992 through 2001. The importance of the NIH SBIR Program to the small business community and good relations with the Program staff were extremely helpful in prompting awardee participation in the survey. These factors, along with the extensive contact tracking by SBIR Program staff and contractors before and during the survey implementation, led to the remarkably high 85 percent response rate. The survey obtained answers to all key evaluation questions. Analysis indicated that performance exceeds all index benchmarks addressed by the survey. These results establish new performance indicators that can serve as benchmarks for subsequent NIH SBIR Program monitoring and evaluation.

Regular collection of program data about at least some performance measures in the evaluation framework for all categories of awards would keep the NIH SBIR Program up to date on Program performance. We recommend that NIH SBIR officials review the evaluation framework and its metrics to consider whether modifications are in order, based on the survey outcome. After that, they should consider the feasibility of collecting at least a minimum standard data set using performance parameters in the evaluation framework. Doing so would offer the benefits of constant readiness to evaluate results and reduce costs for subsequent performance assessments and evaluations.

We recommend as well that NIH SBIR Program officials consider assessing awardee performance on a more regular and frequent basis. Doing so could have several important potential advantages.

- **Reach More Awardee Companies.** We learned from the survey that the most common year for discontinuing supported projects was the sixth year. Assessing the awardees more frequently—every three to five years, for example—could enable the SBIR Program to reach more companies that are in business. This would allow SBIR to collect data on various measures of success that cannot be obtained when the company is no longer in business.
- **Obtain Information from the Most Knowledgeable Respondents.** Assessing more frequently could enable SBIR to locate more of the original PIs (the most knowledgeable of the respondents) still at the awardee company.
- **Obtain More Accurate Information.** Assessing more frequently could enable SBIR to collect more accurate information. Respondents' memory for specific details and access to stored information declines over time. Interim data points, as opposed to end points, tend to be more accurate, and they permit analysis of key results over time. Total cumulative sales and number of patents, for example, could be evaluated in terms of number of years since receipt of award, if assessment was done more frequently.
- **Reduce the Cost of Data Collection.** Usability and eligibility rates for the respondent sample decreased as the date of the award became more distant from the time of assessment. Thus, older sample required more extensive tracking and contact attempts, incurring related costs to the survey project.

Regular assessment of the NIH SBIR Program would also allow Program staff to become cognizant of and address issues important to current and potential awardees. As the Program grows and develops, it could evaluate and possibly incorporate suggestions gathered in response to surveys and/or other assessments.

For example, a common concept in the responses to the open-ended survey item is that the SBIR Program should provide commercialization support and training. This need is also suggested by analysis of responses to closed-end survey questions that indicated that specific fields of business and product types—those requiring clinical or other testing and FDA approval—had proportionately lower expectations of sales and realizations of sales. SBIR awardees suggested that commercialization support include establishing SBIR grants funding Phase III commercialization; covering the costs of marketing, clinical trials, patents, and legal fees; and fostering partnerships and joint ventures.

Another common perception was that the SBIR review process takes too long and should be speeded up. Awardees felt that delays between grant submission and funding and between Phase I and Phase II funding can sidetrack projects or delay them so that they may no longer be innovative. Some awardees believe that the education or background of the reviewers is often poor, that the scores can be inconsistent, and that the focus of the review may be too academic.

Should the SBIR Program evaluate grantees' desire for more support in commercialization or for streamlining the review and funding process, it will be important to consider awardee suggestions in planning changes to the program. It would be useful to design programs with planning, monitoring, and evaluation components that build on survey findings and conform to evaluation framework specifications.