



Report on the 2007 Outcome Measures Update

NIH SBIR Performance Outcomes Data System (PODS)

Contract Number: GS-00F-0024M
Purchase Order Number 467-FZ-302093-1

April 16, 2007

EXECUTIVE SUMMARY

The NIH Office of Extramural Programs continued expansion of the Performance Outcomes and Data System (PODS) in FY07. NIH initiated development of this comprehensive data system to facilitate monitoring and evaluating the performance of the Small Business Innovation Research (SBIR) Program. The initial database comprised contact and outcome data reported by 768 Phase II SBIR awardee respondents to the 2002 *National Survey to Evaluate the NIH SBIR Program*.

In March 2007, NIH conducted an electronic update of contact information and selected outcome measures, supplementing four similar updates conducted in 2004 and 2005. The purpose of these updates was to monitor and summarize the progress made by SBIR awardees in commercializing their SBIR-supported projects in the years since the 2002 survey. This report discusses the findings from the March 2007 outcome measures update.

Successive updates reach different subsets of awardees, thus resulting in contact with a relatively large number of unique awardees. Combined, the five electronic updates since the 2002 survey reached 568 or 74% of the 768 original survey respondents. This excellent response was achieved economically and efficiently—it used only email contacts and required no telephone follow up. Considering that about 280 of the original awardee companies have either discontinued their supported projects or are no longer in business, the response is especially impressive.

Regular updates document the continued achievements of SBIR awardees over time:

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

Conclusions from the most recent update support those from past updates:

- Successive updates reach different subsets of awardees, thus reaching a relatively large number of unique awardees.
- Email updates are cost and time efficient and produce fairly good response rates without any telephone follow up.
- Regular updates document the continued achievements of SBIR awardees over time.

- Ongoing updating of contact information in PODS is critical in maintaining contact with awardees and getting latest outcome measures for ongoing projects.

The March 2007 update also yielded information about the follow-up process in general, which suggests that after five years' worth of updates, subsequent updates collect useful information from fewer and fewer respondents. Although the updates yield interesting findings about individual award outcomes, collecting information from decreasing numbers of respondents means that summary statistics can not be generalized accurately to the population because they are based on small samples.

The baseline information from the 2002 survey is becoming dated and larger numbers of the original awardees are becoming ineligible as their projects are discontinued or their companies cease to exist. Generalizing results of the project outcome data typically needs consistent bases. However, combining data from awardees obtained at different times from different but overlapping subgroups who received their awards at different times does not yield clear, easily understood findings.

The declining usefulness of the current update approach for generalizing results suggests these additional conclusions:

- It would be advantageous to establish another cohort of awardees, collect baseline data, and track important outcome measures over time. Many of the SBIR-supported projects have reached endpoints—they have been successfully commercialized, they have been discontinued, or the awardee company is no longer in business. It may soon be time to restart the cycle—measuring the success in commercializing their SBIR-supported projects since the receipt of their awards for a new group of awardees.
- Awardees submitting online final progress reports within the same year may constitute a good cohort for follow up, and ideally, an ongoing series of annual cohorts. Their final reports can serve as baseline measures, in much the manner that the 2002 survey served as the baseline measure for the current PODS cohort. Tracking each cohort that received its Phase II SBIR awards in the same year will yield useful statistics about outcomes. Because there is an association between time since award and successful outcome measures, summaries and comparisons among awardees with common award dates are most meaningful. Additionally, using the online report data leverages the products of the movement from paper to electronic submission of such reports.
- If SBIR chooses to identify and track a new cohort, strategies will be needed for handling multiple SBIR awards per awardee and their possible impact on single or multiple projects. The 2002 survey randomly selected a single SBIR award and its project as the focus of the survey, an idealized situation created to minimize respondent burden. Using a cohort of awardees means that a subset of awardees will likely have multiple awards. Rational ways to handle these situations, analyze the resultant data, and draw useful and easily understood conclusions will be needed.

2007 OUTCOME MEASURES UPDATE

The NIH Office of Extramural Programs continued expansion of the Performance Outcomes and Data System (PODS) in FY07. NIH initiated development of this comprehensive data system to facilitate monitoring and evaluating the performance of the Small Business Innovation Research (SBIR) Program. The initial database comprised contact and outcome data reported by 768 Phase II SBIR awardee respondents to the 2002 *National Survey to Evaluate the NIH SBIR Program*.

The initial version of PODS allowed NIH to view and update individual awardee contact data, to specify lists of subsets of award and awardee information, and to define tables of award and awardee outcome measures collected during the 2002 survey. In 2005, enhancements to PODS allowed NIH to (1) view detailed information about the awards and awardees contained in specific table cells, (2) pilot an evaluation of the online collection of final SBIR progress reports, and (3) conduct two online updates of selected outcome measures. In 2007, NIH conducted another online update of awardee contact information and selected outcome measures. Also scheduled in 2007 are (1) an expanded pilot test of the online collection of Phase II SBIR final progress reports, and (2) the integration of the update and final progress report data into PODS.

The purpose of the 2007 update was to monitor and summarize the progress made by SBIR awardees in commercializing their supported projects. This report discusses the response to this update, conducted in March 2007, and summarizes the progress of SBIR awardees to date. The appendices contain copies of the relevant materials.

1. Response to Update

On February 13, 2007, Humanitas, Inc. sent out personalized email messages to 521 of the 768 original awardee respondents to the 2002 survey.¹ The remaining 247 awardee respondents were ineligible for subsequent follow-up because their SBIR-projects had been discontinued, their awardee businesses had been sold or were no longer in business, or their emails had “bounced” (returned as undeliverable) in each of three prior updates.

The email messages referenced the Phase II SBIR award that had been the focus of the 2002 survey and asked the recipients to update their contact information and several outcome measures assessing the commercialization of their SBIR-funded projects. The emails provided a password and link to a secure (SSL technology) online site containing the update form.

Humanitas sent 338 follow-up email messages to nonresponders to the initial request on February 20² and 251 final reminders on March 5, 2007. The online site closed on March 6.

¹ Four of the 521 initial emails were sent in the following week because of erroneous email addresses. Forty-six of the initial emails were resent during the next two weeks because of out-of-office responses, spam filters, mailbox full replies, and other similar messages.

² Thirty additional follow-up email messages were sent during the subsequent two weeks to maintain the appropriate time interval between the initial and follow-up emails.

Appendix A contains a paper version of the online update form. Appendix B1-3 contains copies of the email communications.

During the course of this update, 34 additional awardee businesses were identified as ineligible for further follow-up. Reasons for ineligibility included those mentioned earlier, as well as additional bounced emails for which tracking failed to locate good email addresses. Typically, working email addresses cannot be located for companies no longer in existence.

A total of 487 awardee businesses, 63% of the original 768 survey respondents, remained eligible for the update. Of these 487, 275 participated in updating outcome measures. This yields a response rate of 56%. The group of 275 respondents is 36% of the original 768 survey respondents who first provided data in 2002.

The following figures summarize the response to this update.

Initial email messages sent	521
Follow-up email messages	338
Final reminder email messages	251
Ineligible awardees	34
Eligible awardees	<u>487</u>
	521
Respondents	275
Response rate (275/487)	56%

The responses to this update identified an additional 26 awardee businesses that have become ineligible for further follow up. Twenty-three of the awardee respondents reported that they have discontinued their SBIR-funded projects and three have sold their technology or gone out of business. Thus, currently, a total of 461 (or 60%) of the original 768 survey respondents remain eligible.

The prior four updates since the 2002 survey—the product name update in April 2004, the outcome measures update in June 2004, and the two outcome measures updates in January and August of 2005—reached a combined total of 552 of the original 768 respondents to the 2002 survey. This update reached an additional 16 awardees who had responded to the survey, but who did not respond to any of the prior updates. Thus, a total of 568 of the original 768 respondents to the 2002 survey have participated in one or more of the five updates since 2002.

This is an impressive response—568 is 74% of the original 768 survey respondents. It is especially impressive when we consider that 281 of the 768 survey respondents were ineligible for this update because of discontinued projects, sold companies, or companies no longer in business. (Please note that some of the awardees reached by the earlier updates may no longer be eligible and thus are not part of the current group of 275 respondents.)

Especially interesting is the fact that 123 awardees have responded to each and every one of the five updates since the 2002 survey. Two hundred awardees have not responded to a single

update since the survey. It is likely that many of these awardees comprise the awardee companies that have gone out of business or discontinued their projects in the interval since the 2002 survey.

The table in the following exhibit summarizes awardee response to the five updates since the 2002 survey. As more awardee companies become ineligible for follow up because their projects are discontinued or they go out of business, the absolute number of respondents to the updates declines.

Exhibit 1: Summary of Awardees' Response to All Updates since the Initial 2002 Survey

	2002 Survey	April 2004 Product Name Update	June 2004 Outcome Measures Update	January 2005 Outcome Measures Update	August 2005 Outcome Measures Update	March 2007 Outcome Measures Update
Total Respondents	768	348	341	415	314	275
Awardees Eligible to Respond		714	713	587	521	487
Response Rate (Respondents/Eligible Awardees)		49%	48%	71%	60%	56%
Percentage of Initial Survey Respondents		45%	44%	54%	41%	36%

This table summarizes the response to each of the five updates conducted since the 2002 survey. In the two 2004 updates, we attempted to reach nearly all of the initial respondents to the 2002 survey. Beginning in 2005, we no longer attempted to reach those awardees who had discontinued their projects or whose companies were no longer in business. Thus, the response rates to the updates (third row of table) increase. (With the number of eligible awardees reduced, the respondents to the updates are a larger proportion of the eligible awardees.)

The last row of the table shows the percentage that each group of respondents is of the initial 2002 survey respondents. These percentages are decreasing slowly over time as both the number of eligible awardees decreases (ineligible awardees are not contacted) and the time since the original survey increases (saliency of the update lessens).

2. Project Status

The latest outcome measures update asked about the current status of the SBIR-funded project. Based on verbatim responses supplied in the earlier updates as explanations for a status of "Other," the response categories for the status item in the August 2005 update were revised so that they would be more inclusive. The new wording, used also in this update for the status responses, is:

- Under development (project being improved, refocused, evaluated, or in clinical trials)
- Commercialization stage
- In use by target population (project completed, commercially available, or in use)
- Discontinued (project ended without commercialization or without significant sales)
- On hold (project currently inactive or awaiting funding)
- Other (please specify)

Exhibit 2, below, summarizes the current status of SBIR-funded projects for the 275 awardee respondents that participated in this outcome measures update. It also compares the current status of the projects with their earlier status in the 2002 survey and the previous January and August 2005 updates.

Exhibit 2: Responders to 2002 Survey and 2005 and 2007 Updates by Current Status of Project

	<u>2002 Survey:</u> What is the current status of the project funded by the referenced SBIR award?	<u>2005 and 2007 Updates:</u> What is the <u>current status</u> of this project?		
	All 2002 Responders	All Jan 2005 Responders	All Aug 2005 Responders	All Mar 2007 Responders
Under Development	328 43%	96 23%	82 26%	62 23%
Commercialization Stage	184 24%	91 22%	62 20%	43 16%
In Use by Population	158 21%	112 27%	110 35%	116 42%
Discontinued	91 12%	62 15%	14 4%	23 8%
Other; On Hold	7 1%	18 4%	35 11%	27 10%
Missing		36 9%	11 4%	4 1%
Total	768 100%	415 100%	314 100%	275 100%

The distribution of the 768 respondents to the 2002 survey by the current status of their SBIR-funded project in 2002 is shown in the first column of this table. The distribution of the *subsets* of 415, 314, and 275 respondents to the 2005 and 2007 updates are shown in three rightmost columns. (The respondents with missing data declared themselves ineligible because they no longer were employed by the awardee business or the business had been sold.)

During the elapsed five years since the 2002 survey, there has been some redistribution of the status of funded projects from the initial stages to later stages. Higher percentages of projects are now in use by the targeted populations. (Note that there are different though overlapping subsets of respondents to the three updates, and that those awardees with discontinued projects in earlier updates were not included in the subsequent updates.)

In this table, you can see the general trend of projects moving from earlier statuses—under development and in commercialization stage, into the successful end status—in use by target population. In 2002, 21% of projects were in use by targeted populations; in January 2005, 27%; in August 2005, 35%; and in March 2007, 42%. (These percentages are of the number of awardees responding to the survey and each of the updates. They are *not* the same group of awardees, however, but different though overlapping subsets of respondents.)

Exhibits 3, 4, and 5, which follow, track the *same* group of awardees over time. The first of these exhibits, Exhibit 3, tracks the 328 survey respondents who reported that their projects were under development at the time of the 2002 survey. The *rows* of this table show August 2005 findings; the *columns* show March 2007 findings. In August 2005, 60 of the 328 projects were still under development (rightmost cell in row one of the table). Some of the projects, however, had moved into later statuses—21 were in the commercialization stage and 17 were in use by the target population (rightmost cells of rows two and three).

In March 2007, 30 or 50% of the 60 projects under development in August 2005 remain under development. However, during that year-and-one-half interval, some of the projects have moved into the commercialization (top cell in the second column) or have been discontinued or put on hold (top cells in fourth and fifth columns).

Exhibit 3: Current Status of 328 Projects under Development at time of 2002 Survey

<u>August 2005 Update:</u> What is the <u>current status</u> of this project?	<u>March 2007 Update:</u> What is the <u>current status</u> of this project?						
	Under Development	Commercial-ization	In Use by Population	Discontinued	Other / On Hold	No response Mar 07	Total
Under Development	30 50%	4 7%		3 5%	9 15%	14 23%	60 100%
Commercialization		7 33%	5 24%	1 5%	1 5%	7 33%	21 100%
In Use by Population	1 6%	1 6%	8 47%	1 6%	1 6%	5 29%	17 100%
Discontinued						9 100%	9 100%
Other / On Hold	5 24%	1 5%		2 10%	7 34%	6 29%	21 100%
No response Aug 05	10 5%	4 2%	6 3%	2 1%	6 3%	172 86%	200 100%
Total	46 14%	17 5%	19 6%	9 3%	24 7%	213 65%	328 100%

This table shows the redistribution of the 328 SBIR-funded projects that were under development at the time of the 2002 survey. For example, in August 2005, 60 of the 328 projects were still under development, but 21 were in the commercialization stage and 17 were in use by the targeted populations. A total of 200 of the 328 awardees with projects under development in 2002 did not respond to the August 2005 update.

In March 2007, 30 or 50% of the 60 projects that were under development in August 2005 are still under development, but 4 or 7% are now in the commercialization stage. Three projects (5%) have been discontinued and 9 (15%) are on hold. Of the 21 projects that were in the commercialization stage in August 2005, 5 (24%) are now in use by their targeted populations. A total of 213 or 65% of the 328 awardees with projects under development in 2002 did not respond to the March 2007 update.

Exhibit 4, below, tracks the 184 survey respondents who reported that their projects were in the commercialization stage at the time of the 2002 survey. As before, with the passage of time we see similar redistributions of projects into later statuses. In August 2005, 32 of the 184 awardees remain in the commercialization stage, but 32 have moved into use by their target populations (rightmost cells of rows two and three). In March 2007, 8 or 25% of the 32 remain in the commercialization stage, but 8 or 25% are now in use by the target populations.

Exhibit 4: Current Status of 184 Projects in the Commercialization Stage at time of 2002 Survey

<u>August 2005 Update:</u> What is the <u>current status</u> of this project?	<u>March 2007 Update:</u> What is the <u>current status</u> of this project?						
	Under Development	Commercial-ization	In Use by Population	Discontinued	Other / On Hold	No response Mar 07	Total
Under Development	3 18%	3 18%	3 18%	2 12%	2 12%	4 24%	17 100%
Commercialization	1 3%	8 25%	8 25%		7 22%	8 25%	32 100%
In Use by Population		3 9%	19 59%	1 3%		9 28%	32 100%
Discontinued			1 50%			1 50%	2 100%
Other / On Hold			2 22%	3 33%	2 22%	3 33%	10 100%
No response Aug 05	3 3%	4 4%	3 3%	1 1%	2 2%	78 86%	91 100%
Total	7 4%	18 10%	36 20%	7 4%	13 7%	103 56%	184 100%

This table shows the redistribution of the 184 SBIR-funded projects that were in the commercialization stage at the time of the 2002 survey. For example, in August 2005, 32 of the 184 projects were still in the commercialization stage, but 32 were in use by their targeted populations. A total of 91 of the 184 awardees with projects in the commercialization stage did not respond to the August 2005 update.

In March 2007, 8 or 25% of the 32 projects that were in the commercialization stage in August 2005 are still in that stage, but 8 or 25% are now in use by the target population. A total of 103 or 56% of the 184 awardees with projects under development in 2002 did not respond to the March 2007 update.

Exhibit 5, which follows, tracks the 158 survey respondents who reported that their projects were in use by the target population at the time of the 2002 survey. In August 2005, 58 of the 158 projects remain in use by the target population, but 9 have moved back into the commercialization stage and 1 is under development. This is also the case in March 2007. A total of 38 or 66% of the 58 projects are still in use by the target population, but 4 have moved back to the commercialization stage. This movement to prior statuses may represent further refinement of products already or previously in the market place.

Exhibit 5: Current Status of 158 Projects in Use by the Target Population at time of 2002 Survey

<u>August 2005 Update:</u> What is the <u>current status</u> of this project?	<u>March 2007 Update:</u> What is the <u>current status</u> of this project?						
	Under Development	Commercial-ization	In Use by Population	Discontinued	Other / On Hold	No response Mar 07	Total
Under Development					1 100%		1 100%
Commercialization			5 56%			4 44%	9 100%
In Use by Population		4 7%	38 66%	1 2%	1 2%	14 24%	58 100%
Discontinued						2 100%	2 100%
Other / On Hold	1 50%					1 50%	2 100%
No response Aug 05	2 2%	3 3%	10 12%		2 2%	69 80%	86 100%
Total	3 2%	7 4%	53 34%	1 1%	4 3%	90 57%	158 100%

This table shows the redistribution of the 158 SBIR-funded projects that were in use by the target population at the time of the 2002 survey. For example, in August 2005, 58 of the 158 projects were still in use by the target population, but 9 were back in the commercialization stage. A total of 86 of the 158 awardees with projects in use by the target population did not respond to the August 2005 update.

In March 2007, 38 or 66% of the 58 projects that were in use by the target population in August 2005 are still in that stage, but 4 or 7% are now back in the commercialization stage. A total of 90 or 57% of the 158 awardees with projects in use by the target population did not respond to the March 2007 update.

At all stages, there are also small numbers of SBIR-supported projects becoming discontinued. This is shown on each of the three prior tables. Awardees with discontinued projects or at other “end points” (awardee company out of business or sold) are not included in subsequent follow-ups³. Thus, as of the March 2007 update, the 23 awardees reporting discontinued projects and the three reporting the demise of their companies or otherwise lost to follow up will be defined as ineligible for further follow-up. Additionally, three respondents reporting that they are not valid spokespersons for the awardee businesses will require tracking to locate appropriate spokespersons and, depending upon the outcome of the tracking efforts, may or may not be eligible for further follow-up.

³ In the current update, 14 awardees who reported discontinued projects in August 2005 inadvertently received update emails. Only one of these awardees responded, confirming the discontinuation of the project and, coincidentally, confirming our hypothesis that those awardees with discontinued projects tend not to respond to update requests.

3. FDA Status

The March 2007 outcome measures update asked if FDA approval was required and (as applicable) if it was received for the product, process, or service supported by the SBIR Phase II award. The August 2005 update incorporated expanded and more precise response categories for this item to forestall having to recode many verbatim responses supplied in explanation of “Other” responses. This update added one additional response category (sixth on the list below). The response options for this question on FDA status are:

- Not yet submitted for review
- Applied for *clinical trial* approval (IND, IDE, HUD)
- Applied for *marketing* approval (NDA, PMA, 510(k), HDE)
- Review ongoing
- Obtained approval to use in clinical trials (IND, IDE, HUD, granted an exemption from IND or deemed nonsignificant risk)
- Obtained approval for marketing (NDA, PMA, 510(k), HDE)
- Given orphan drug status
- Not approved
- Other (please specify)

The new categories reduced the numbers of “Other” responses that needed recoding to existing categories. However, an additional minor refinement is still needed. No respondents selected the “Review ongoing” response. This response category, originally included in the 2002 survey, is no longer necessary because of the addition of the two “Applied for...” categories (second and third above). We can now distinguish between the types of FDA approval sought and obtained, and unless the *obtaining* of approval is reported, it is obvious that review is ongoing for those who *applied* for approval.

The next table, Exhibit 6, shows additional projects receiving FDA approval since the 2002 survey that were reported by SBIR awardees in the 2004, 2005, and 2007 updates. When this information was provided, projects with approval for clinical trials/IND and for marketing are shown separately.⁴ Only additional (not previously reported) projects with approval are included in the counts for the updates. A total of 87 SBIR-funded projects have received FDA approval.

⁴ In the 2002 survey and in the earlier updates, FDA approval was not broken out into approval for clinical trial and approval for marketing. Initially, there was just an “Approved” category. In January 2005, the category “IND, clinical trials; IDE; 510(k)” was added, and “Approved” was modified to “Approved (certified, listed, or exempt; determined NSR; given orphan drug status.” In August 2005, the “Approved” category was modified to “Obtained approval to use in clinical trials (IND, IDE, HUD, granted an exemption from IND or deemed nonsignificant risk.” In March 2007, an additional “Approved” category was added for marketing approval (see list above).

Exhibit 6: Additional SBIR-Funded Projects Receiving FDA Approval

	2002 Survey	2004 Update	January 2005 Update	August 2005 Update	March 2007 Update	Total Unique Projects Approved
FDA approval received	48	9	2	0		60
FDA approval for clinical trials, IND	11	0	7	7	1	25
FDA approval for marketing					2	2
TOTAL	59	9	9	7	3	87

Awardee respondents report a total of 87 SBIR-funded projects with FDA approval. In 2002 at the time of the baseline survey, 59 projects had approval—either approval to market or approval for use in clinical trials/IND. In the 2004, 2005, and 2007 Outcome Measures Updates, 28 (9+9+7+3) *additional* projects reported FDA approval. (FDA approval was broken out into approval for clinical trials and approval for marketing only in the 2007 update.)

4. Cumulative Sales

The March 2007 outcome measures update asked about cumulative sales to date related to the product, process, or service developed under the referenced project. The wording for this item placed the stress on cumulative sales through December 2006:

What is the dollar range of cumulative sales to date—that is, total cumulative sales through December 2006, related to the product, process, or service developed under this project? (Please do not give incremental sales, but indicate total cumulative sales from the first sales through the most recent sales.)

For the current update, we also broke the next-to-largest response category into two categories. Following are the response options for this item in this update.

- No sales yet
- Less than \$50,000
- \$50,000 - \$99,999
- \$100,000 - \$499,999
- \$500,000 - \$999,999
- \$1,000,000 - \$4,999,999
- \$5,000,000 - \$24,999,999
- \$25,000,000 - \$49,999,999
- \$50,000,000 or more

The next table, Exhibit 7, shows the numbers of ongoing projects, the numbers of projects achieving sales, and the estimated cumulative sales to date for the 2002 survey and the most recent March 2007 update. As of this update, there are 461 ongoing projects, and approximately 390 projects have achieved sales. A total of 292 awardees have never reported sales or have specifically reported “No sales yet.” The estimated cumulative sales to date are \$1.95 billion.⁵

⁵ Because of the lack of a definitive “No sales yet” category and the use of the “Less than \$50,000” by some awardees without sales in the first two updates in June 2004 and January 2005, the number of projects achieving sales ranges from 311 to 469. The midpoint of that range, 390, can be used as a reasonable estimate of this figure. The cumulative sales to date, \$1.95 billion is not affected by the lack of the “No sales yet” category. This is because

Exhibit 7: SBIR-Funded Projects Achieving Sales and Cumulative Sales Increase Over Time

768 initial projects: 100%	2002 Survey	March 2007 Update
Ongoing projects	683 89%	461 60%
Projects achieving sales	224 29%	390 estimated; Range: 311-469 51% estimated; Range: 40%-61%
Estimated cumulative sales	\$821 Million	\$1.95 Billion

The number of ongoing projects and the percentage that they are of the *original 768 projects* in the 2002 survey are shown in the first row. The second row shows the number of projects achieving sales and the percentage that they are of the *original 768 projects* in the 2002 survey. The third row shows the estimated cumulative sales to date. As of the March 2007 update, 461 projects were ongoing. An estimated 390 achieved sales, with an estimated total cumulative sales to date of \$1.95 billion.

The total cumulative sales to date are computed from the response categories by using the midpoints of the category ranges. For the final unbounded category, “\$50,000,000 or more,” we used the start point of the category. The sales estimates are likely somewhat conservative because seven awardees reported sales without providing the amount, and there is some underestimation inherent in the use of the start point for the highest sales category.

A total of 461 of the 487 awardees initially eligible for inclusion in this update remain eligible—that is, their funded projects were not discontinued, the awardee companies were not sold or no longer in business, and we believe that the email addresses or other contact information for them are likely valid. Twenty-three of the initially eligible 487 awardees reported the discontinuation of their projects, and three reported the demise of their companies. This leaves 461 awardees presumed eligible. (We cannot be sure because only 275 awardees responded to this update. Nonresponse is often associated with the discontinuation of the funded project or end of the awardee business.)

As the years pass since the receipt of a Phase II SBIR to commercialize a project, awardee businesses ultimately achieve sales or else reach an endpoint—the discontinuation of the unsuccessful product, the sale or licensing of the technology to another business, the sale or merger of the company, or the cessation of the company. Some awardee businesses achieve some sales and then move to an endpoint. For others, the product may go back for further development and subsequent commercialization, as the product is modified and fine-tuned. For still others, sale or licensing of the technology or the sale or merger of the company is a successful endpoint.

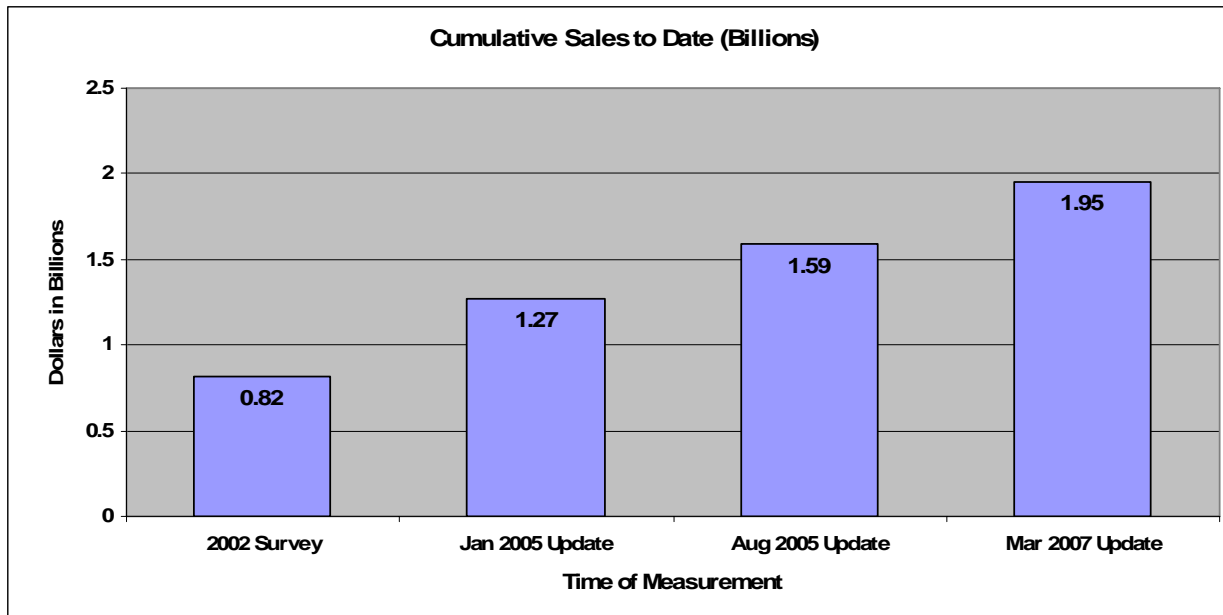
Thus, the companies whose projects achieve sales at some point may not have ongoing projects at a later point. In past reports on outcome measure updates, we looked at projects achieving sales as a percentage of ongoing projects. With the passage of time, we are learning that this may *not* be a valid way of gauging commercial success. Currently, for example, the number of

the use of the “\$50,000 or less” category by some respondents for reporting no sales affects only insignificant digits in the estimate of cumulative sales. Its range is from \$1.953 to \$1.956 billion.

projects achieving sales is estimated as 390 (the midpoint of the range 311 to 469). At the high end of this range, there may be more projects achieving sales than there are currently ongoing projects (461).

The next exhibit shows the increase in cumulative sales over time, from the 2002 survey to the most recent update in March 2007. With the passage of time, *total* cumulative sales to date have increased 238% from 2002 to 2007.

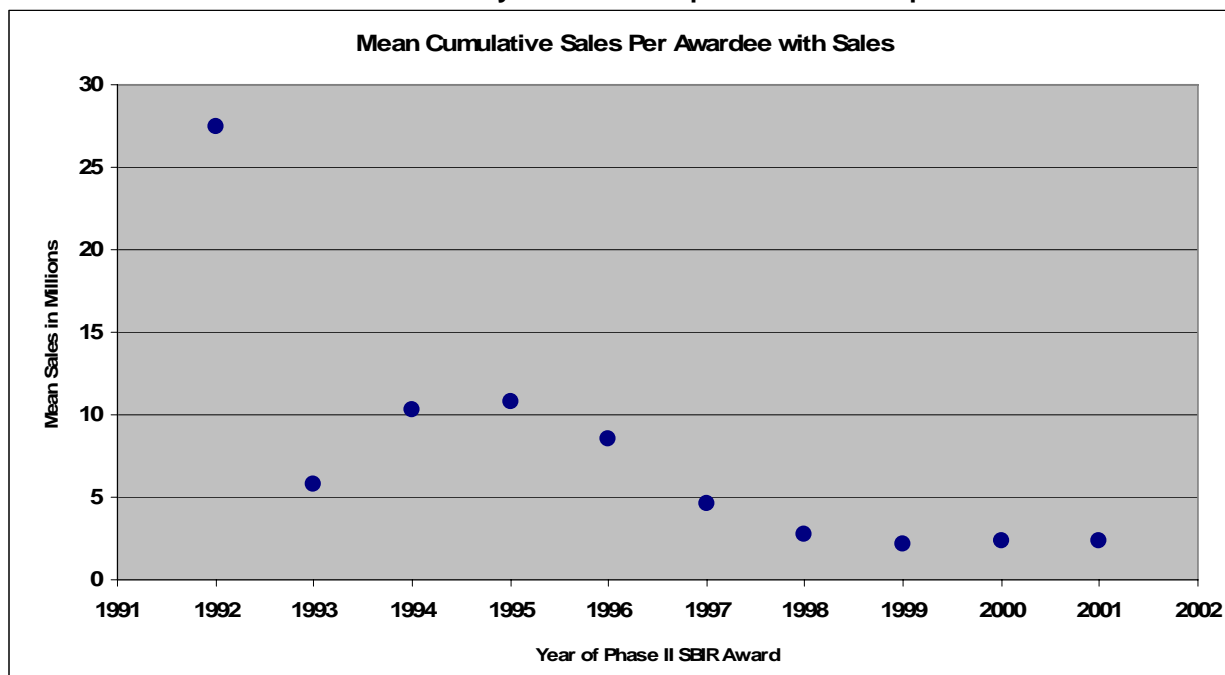
Exhibit 8: Cumulative Sales of Awardees' Products Increase over Time



The cumulative sales to date achieved by the commercialization of the awardees' products, processes, and services increases over time. At the time of the 2002 survey, total cumulative sales were approximately \$820 million. At the most recent update in March 2007, total cumulative sales were \$1.95 billion, more than two-and-one-third times as large as they were in 2002. (Cumulative sales to date are estimated using the midpoints of sales categories and the start point of the final unbounded category. 469 awardees)

The 768 awardee projects included in the 2002 survey received their Phase II SBIR awards in the ten-year period from 1992 through 2001, with nearly three-quarters of the awards received in the most recent five years of this period (1997 through 2001). Thus, at the time of the March 2007 update, for nearly 75% of the awardees, from nine to five years had elapsed since the receipt of their awards. This time period is generally sufficient for evaluating the success of the awardees in commercializing their projects. The next exhibit shows the *mean* cumulative sales to date for those awardees whose projects have achieved sales.

Exhibit 9: Mean Cumulative Sales Vary with Time Elapsed Since Receipt of Award

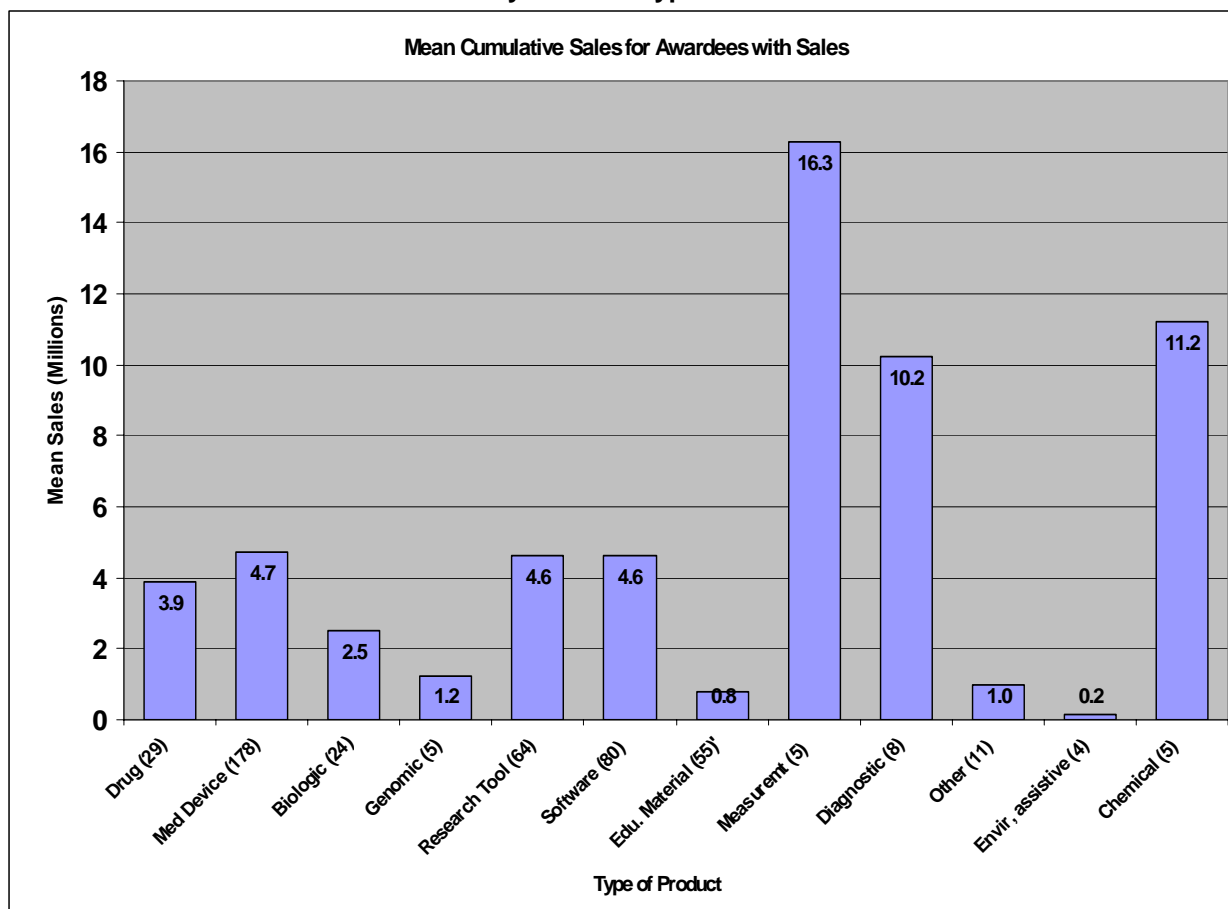


The mean cumulative sales to date, per awardee achieving sales, are greater for those awardees who received their Phase II SBIR awards earlier in the survey study period of 1992 through 2001. In general, mean sales per awardee decline as the time elapsed since the receipt of the Phase II award decreases. (The number of Phase II SBIR awards granted by NIH each year of the study period increased from a low of 39 in 1992 through a high of 257 in 2001. Awardees with sales range from 1 with a 1992 award to 91 with 2001 awards. 469 awardees)

With a much larger initial data set, perhaps collected annually, it would be possible to monitor cohorts of awardees by the year of the receipt of their awards. This is part of the longer range goals for PODS. Ideally, the final progress reports, which are required from all Phase II SBIR awardees at the culmination of their projects, would be collected online and used to establish baseline data for the awardees of any given year. Subsequent outcome measure updates could monitor successful commercialization of the funded projects among a cohort of awardees with a common “start” point.

In addition to the time elapsed since the receipt of the Phase II SBIR awards, the type of product (product, process, or service) planned for commercialization affects the cumulative sales. Some products require a longer development time, some require heavier financial investment, some must meet FDA approval and testing requirements, and some just sell for appreciably more than others. The following exhibit shows the variation among different products in the achievement of sales. (The apparent differences should be understood as suggestive and not definitive ones because of the small sample sizes for some of the product types.)

Exhibit 10: Mean Cumulative Sales Vary with the Type of Product Commercialized

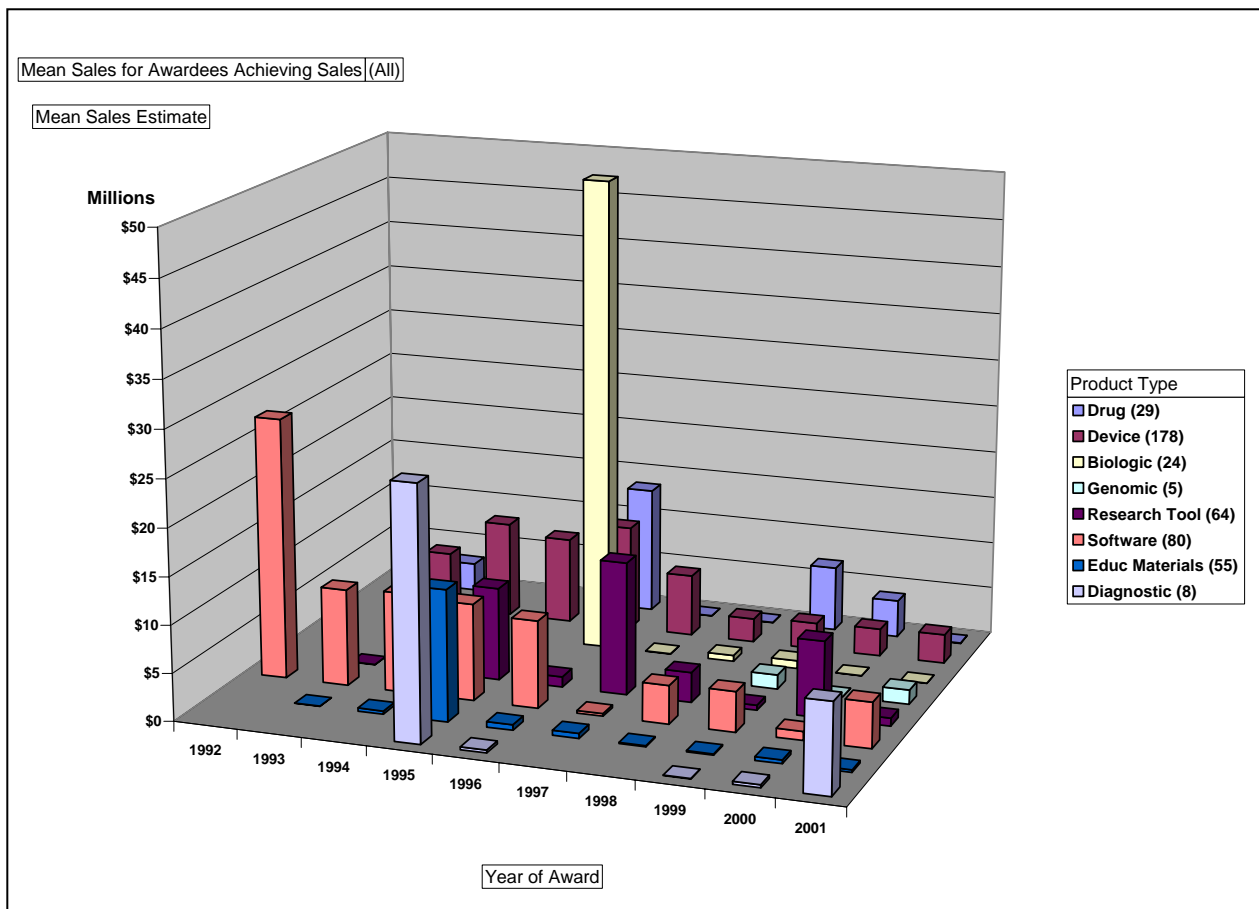


The mean cumulative sales to date, per awardee achieving sales, vary by the type of product planned for commercialization. Since some of the bars above represent relatively few awardees (the number in parentheses is the number of awardees achieving sales of each type of product), looking primarily at those products representing larger numbers of awardees, we see that drugs, medical devices, research tools, and software achieve higher mean cumulative sales per awardee than biologics and educational materials. Elapsed time since the receipt of the Phase II SBIR award also influences cumulative sales. (468 awardees)

Time elapsed since receipt of the Phase II award and the types of products commercialized likely interact. For example, most drugs and many medical devices require FDA approval and, perhaps, clinical testing. Thus, they may typically require a longer lead time before commercialization and concomitant sales than other products. We attempted to get an overview of this likely interaction in a three-dimensional bar chart in the next exhibit.

For clarity, the product categories with small numbers of awardees—measurement or assessment tools; environmental, ergonomic, or assistive tools; chemicals or chemical processes; and other products—are not shown in the bar chart. For consistency, in both this exhibit and the prior one, the product categories that awardees selected in the 2002 survey are used. By and large, the updated product categories (which are those selected either in the 2002 survey or a subsequent update and displayed in the March 2007 update for possible modification) are the same as those selected in 2002. When mean cumulative sales are broken out into 80 cells (ten award years by eight product categories), most of the cell counts are very small, so apparent variations should be viewed as indicative of individual “success stories” and not patterns of success.

Exhibit 11: Mean Cumulative Sales Vary with Product Type and the Year the Award was Granted



The mean cumulative sales to date, per awardee achieving sales, vary by the elapsed time since the receipt of the award and the type of product commercialized. Looking primarily at the time period from 1995 through 2001, when about 75% of the Phase II awards were granted (and the cell counts are higher), we see that the commercialized products of earlier awards often achieve higher mean cumulative sales per awardee than those of more recent awards. Though some product types achieve higher mean sales than other types, there are clearly individual variations. The very high bars are typically individual “success stories.” (443 awardees. The numbers after each product type indicate the number of awardees commercializing that type of product.)

In summary, the 390 projects estimated to have achieved sales (the range is from 311 to 469) account for an estimated **\$1.95 billion** in total cumulative sales to date. This figure does not include sales information for those seven awardees who reported achieving sales but did not provide the amount. *The total cumulative sales figure was calculated from categorical data, and thus is an estimate of the actual number.* In 2002, the similar estimate for total cumulative sales to date was \$821 million. The current estimate in March 2007 is more than two-and-one-third times as large.

The number of years elapsed since the receipt of the Phase II award and the type of project planned for commercialization affect cumulative sales. Awardees with more years elapsed since the receipt of their awards and drug, medical device, research tool, and software projects tend to achieve higher mean cumulative sales. However, there are clearly individual variations in achieving commercial success—high sales.

5. Additional Non-SBIR Funding

The March 2007 update asked about the receipt of any additional non-SBIR funding or capital since the awardee received the Phase II SBIR award. Increasing numbers of awardees report receiving additional funding. Exhibit 12 shows this increase over time.

Exhibit 12: SBIR-Funded Awardees Receiving Additional Non-SBIR Funding or Capital over Time

768 initial projects (100%)	2002 Survey	2004 Update	January 2005 Update	August 2005 Update	August 2005 Update
Projects receiving additional non-SBIR funding or capital	281 37%	319 42%	348 45%	364 47%	375 49%

This table shows the number of awardees receiving additional non-SBIR funding or capital and the percentage that they are of the original 768 respondents to the 2002 survey. Awardee respondents report a total of 375 SBIR-funded awardees (nearly half of the original 768 awardees) that have received additional non-SBIR funding or capital. This is an increase of 33% since 2002.

Nearly half of the original 768 respondents to the 2002 have received additional non-SBIR funding or capital for their projects. This suggests that funding sources other than SBIR found merit in these awardees—in the projects they planned to commercialize and in their ongoing achievements.

6. Conclusions

The basic conclusions from the earlier updates continue to be valid:

- *Successive updates reach different subsets of awardees, thus reaching a relatively large number of unique awardees.*

Combined, the four 2004, 2005, and 2007 updates reached 568 unique respondents or 74% of the original 768 survey respondents.

- *Email updates are cost and time efficient and produce fairly good response rates without any telephone follow up.*

The March 2007 update reached 275 awardees, which is 56% of the 487 awardees believed to be eligible (projects ongoing or company not sold or out of business).

- *Regular updates document the continued achievements of the SBIR awardees over time.*

From 2002 to March 2007, the number of awardees with FDA approval increased from 59 to 89; the number of awardees achieving sales increase from 224 to approximately 390 (range of 311-469); and the number of awardees receiving non-SBIR funding increased from 281 to 375. The estimated cumulative sales to date increased from \$821 million in 2002 to \$1.95 billion in 2005.

- *Some wording on the update form can be fine tuned to maximize response and increase data accuracy.*

The FDA item needs the “review ongoing” category removed. The two categories about the type of FDA approval for which the awardee applied encompasses the single initial category.

- *Ongoing updating of the contact information in PODS for awardees and their spokespersons is critical in maintaining contact with the awardees and learning latest outcome measures for ongoing projects.*

Collecting update information at routine intervals is critical for maintaining up-to-date contact information for awardees. Some potential awardee respondents are “lost” each update, presumably because their awardee businesses have ceased to exist. However, it is likely that a prior update has collected outcome measures before the businesses ended. Without periodic updates, it would be more difficult for NIH to quickly communicate with spokespersons for these projects and such interim information would be lost.

Additional conclusions about the follow-up process in general may be drawn after this last update. The four updates conducted during the five years that have elapsed since the 2002 survey have leveraged the efforts expended in tracking and locating the original survey respondents and eliciting their cooperation. The updates have maintained contact with many of the original respondents, updated their contact information, project status and data, and collected new outcome measures. This information supplemented that from the 2002 survey and was useful in documenting continued progress in project commercialization. However, after five years, we are approaching a point where subsequent updates may collect information from smaller samples, making it less generalizable to the populations of interest.

The reasons for the current update approach becoming less useful in the future include the following.

1. *Baseline information is becoming dated*

The baseline information, collected for all respondents during the survey in 2002, is becoming dated. Some respondents have never updated any of their outcome measures; others have updated only once or twice, and that may have been in the earliest updates.

2. *More original awardees are becoming ineligible*

The fate of SBIR-supported projects (and most small-business startups in general) is that some succeed and some do not. Over time, some projects are discontinued, some awardee companies are sold or go out of business, and some projects or companies remain on hold—hanging in for additional funding.

3. *Summary statistics are becoming less accurate*

The original 2002 survey respondents encompassed awardees who received their Phase II SBIR awards over the 10-year period 1992-2001 (though about 75% of the

awards were received in the second half of that period). From the survey and update data, we have learned that successful commercialization is associated with factors such as time since award and type of project planned for commercialization. As the size of the group of awardees with ongoing projects declines, the subgroups of projects with the same products and year of award grow even smaller. Thus, the subgroup statistics lose some of their validity and usefulness.

4. *Project update data do not describe a consistent sample of awardees*

Voluntary updates do not generate the consistent data sets that are required to derive summary statistics about trends over time. When summary statistics are needed to assess particular project outcomes, for example, the awardee businesses receiving additional non-SBIR funding, we typically use data from the 2002 survey. This is because it is difficult to meaningfully combine data obtained at different times from overlapping but different subgroups of respondents who have received their Phase II awards at different times.

The declining usefulness of the current update approach suggests these additional conclusions.

- *Another cohort of awardees would be advantageous*

The awardees from the 2002 survey have been tracked and successive updates have provided more current outcome measures. However, at this point or in the near future, most of the SBIR-supported projects have or will have reached endpoints—either positive or negative endpoints. Many have received FDA approval, are in use by their target populations, achieved sales, and/or received additional non-SBIR funding. Others are discontinued or their awardee company has been sold or gone out of business. For these reasons and those itemized above, further updates may yield relatively little new information or information of limited usefulness. Following up a new cohort of awardees will provide better data. In effect, it would be akin to restarting the cycle—measuring the success of awardees in commercializing their SBIR-supported projects since the receipt of their awards for a new group of awardees.

- *Awardees submitting online final progress reports within the same year may constitute a good cohort for follow up*

Such a group typically has received their Phase II SBIR awards at the same time, and the final progress report may be viewed as a set of baseline measures. Following up this group leverages the data that will become available online as the movement from paper final reports to online submissions becomes complete.

- *Tracking a cohort who received their SBIR awards in the same year will yield more generalizable statistics*

When the group of awardees received their awards in the same year, comparisons are more meaningful. This is because there is a fairly strong association between time since award and successful outcome measures. Large cumulative sales to date, for example,

indicate a certain amount of success. This is not the case for awardees with varying award dates, when large cumulative sales for a 10-year old project may not be more meaningful than relatively small cumulative sales for a 1-year old project.

- *The survey planned for fall 2007 will capture outcome measure data in the interim before the online final reports do*

NIH/SBIR is currently seeking OMB approval for a survey, very similar to that conducted in 2002, that will be implemented in the fall of 2007. Its goal is to capture outcome measure data for those awardees receiving Phase II awards from 2002 through 2006, the time since the 2002 survey study period. Hopefully, thereafter the online final reports will be fully implemented and serve to capture baseline measures for SBIR awardees, in addition to concluding Phase II for their supported projects.

- *New ideas will be needed for handling multiple SBIR awards per awardee and analyzing their impact on single or multiple projects*

The 2002 survey randomly selected a single SBIR award and its project as the focus of the survey. Thus, the 2004, 2005, and 2007 updates followed up on just a single award per awardee. This is an idealized situation, created to minimize respondent burden in the 2002 survey and to produce a useful and simple to understand set of statistics. Using a cohort of awardees means that, for a subset of awardees, there will likely be multiple awards per awardee. Some projects may be supported by contributions from more than one award, and other multiple or derivative projects may be result from a single award. Rational ways to handle these situations, analyze the resultant data, and draw useful and easily understood conclusions will be needed.

Secure Online Update of Phase II SBIR Project Outcomes

1.3.07

Award Number:
Date of Award:
Project Title:

Awardee Business:

- 1.** Are you a valid spokesperson for this awardee business—that is, are you employed by or associated with this company? (Valid employment or association includes PIs, other investigators, business officials, company officers, owners, and board members, regardless of full-time or part-time, paid or unpaid, or consultant status.)

Yes → GO TO Q4

No → CONTINUE

Other (please specify): _____
→ GO TO Q4

- 2.** Do you know who at this company is currently responsible for or knowledgeable about this project?

Yes → CONTINUE

No → GO TO EXIT

- 3.** If you can, please supply his or her name, telephone number, and email address:

Name: _____

Telephone: _____

Email: _____

→ GO TO EXIT

- 4.** We have the following information about the awardee company. Please update any information that is missing or no longer correct.

Business Name:
Business Address:

Business Telephone Number:
Business Website:

Awardee Spokesperson:
Spokesperson's Telephone Number:
Spokesperson's Email Address:

Information above is correct

Spokesperson's Role: **Select One** ↓

Initial principal investigator

Subsequent principal or other investigator (full-time, part-time, or consultant)

Business official on the SBIR application

Other business official (company officer, board member, owner, or other official)

Other (specify): _____

5. With regard to the project supported by this award, our records show the information listed below. Please update any information that is missing or no longer accurate.

Type of product, process, or service planned for commercialization or commercialized:	Select One ↓
	Drug
	Medical device
	Biologic
	Genomic
	Research tool
	Software or hardware
	Educational materials
	Diagnostic material or device
	Measurement or assessment tool
	Environmental, ergonomic, or assistive tool
	Chemical (non-drug) or chemical process
	Non-drug therapeutic
	Other (specify): _____

Trade or Commercial Name (if any): _____
<input type="checkbox"/> None yet; not applicable

We are interested in the *precise* trade or commercial name of the product, process, or service resulting from this supported research. A trade or commercial name, which may or may not be registered as a trademark, uniquely identifies the commercial product. The trade name is also commonly called the *brand name*.

Generic Name or Description: _____
<input type="checkbox"/> None yet; not applicable

The generic name is a *general* name for the product, process, or service. It is typically descriptive of an entire group or class of products.

6. What is the current status of this project?
- Under development (project being improved, refocused, evaluated, or in clinical trials)
 - Commercialization stage
 - In use by target population (project completed, commercially available, or in use)
 - Discontinued (project ended without commercialization or without significant sales) → GO TO Q10
 - On hold (project currently inactive or awaiting funding)
 - Other (please specify): _____
7. Was or is FDA approval (IND, NDA, IDE, PMA, 510(k), HUD, HDE) required for the product, process, or service?
- Yes
 - No → GO TO Q9.

8. Currently, in what stage of the FDA approval process is this product, process, or service?

- Not yet submitted for review
- Applied for *clinical trial* approval (IND, IDE, HUD)
- Applied for *marketing* approval (NDA, PMA, 510(k), HDE)
- Review ongoing
- Obtained approval to use in clinical trials (IND, IDE, HUD, granted an exemption from IND or deemed nonsignificant risk)
- Obtained approval for marketing (NDA, PMA, 510(k), HDE)
- Given orphan drug status
- Not approved
- Other (please specify): _____

9. What is the dollar range of cumulative sales to date—that is, total cumulative sales through December, 2006, related to the product, process, or service developed under this project? (Please do not give incremental sales, but indicate total cumulative sales from the first sales through the most recent sales.)

- No sales yet
- Less than \$50,000
- \$50,000 - \$99,999
- \$100,000 - \$499,999
- \$500,000 - \$999,999
- \$1,000,000 - \$4,999,999
- \$5,000,000 - \$24,999,999
- \$25,000,000 - \$49,999,999
- \$50,000,000 or more

10. Since the receipt of the Phase II SBIR award, has your company received any additional non-SBIR funding or capital for this project?

- Yes
- No

EXIT:

Thank you for your help. Please click on the "SUBMIT" button below to complete this update.

SUBMIT

Appendix B-1: Outcome Update Email Message 1

From: Jo Anne Goodnight, NIH SBIR/STTR Coordinator
Sent: Date, Time
To: Dr. _____
Subject: Follow-Up: The Outcomes of Your SBIR-Supported Project
Importance: High

NIH continues to take pride in the continued successes of its SBIR awardees in developing and commercializing their funded projects. As part of an extensive follow-up with a small and select group of Phase II SBIR awardees, we would like to learn more about the outcomes associated with your project. This information, which will just take a few moments to provide, will expand upon what NIH learned in the 2002 *National Survey to Evaluate the NIH SBIR Program* and in subsequent updates of selected outcome measures.

The 2002 survey and following updates asked about the product, process, or service resulting from this SBIR Phase II award:

Company:
Principal Investigator:
Award Number:
Project Period:
Project Title:

Please click on the following link (or copy and paste it into your Internet browser window). It will take you to a secure online form (“padlock” in lower right corner), in which you can provide a few highlights about your *project outcomes*. Thank you in advance for taking a few moments to do this. We greatly appreciate your assistance.

<https://www.Humanitas.com/OMUpdate/respondentID>

If you have any questions or need additional information, please feel free to call or email me:

Jo Anne Goodnight 301-435-2688 jg128w@nih.gov

Many thanks for your help!

Appendix B-2: Outcome Update Reminder Email Message 2

From: Jo Anne Goodnight, NIH SBIR/STTR Coordinator
Sent: Date, Time
To: Dr. _____
Subject: Follow-Up: The Outcomes of Your SBIR-Supported Project
Importance: High

Last week, I sent you an email message asking for your help in updating NIH about the outcomes associated with your SBIR-supported project. This information will supplement what NIH learned in the 2002 *National Survey to Evaluate the NIH SBIR Program* and in subsequent updates of selected outcome measures.

We are especially appreciative of your help. You are part of a select group of Phase II SBIR awardees with whom we are conducting extensive follow-ups about their project outcomes, so that NIH can learn more about the impact that the SBIR Program has on product development and commercialization. Please take a few moments and give us updated information about your product.

The recent survey asked about the product, process, or service resulting from this SBIR Phase II award:

Company:
Principal Investigator:
Award Number:
Project Period:
Project Title:

Please click on the following link (or copy and paste it into your Internet browser window). It will take you to a secure online form (“padlock” in lower right corner), in which you can provide a few highlights about your *project outcomes*. Thank you in advance for taking a few moments to do this. We greatly appreciate your assistance.

<https://www.Humanitas.com/OMUpdate/respondentID>

If you have any questions or need additional information, please feel free to call or email me:

Jo Anne Goodnight 301-435-2688 jg128w@nih.gov

Thanks again!

Appendix B-3: Outcome Update Email Message 3

From: Jo Anne Goodnight, NIH SBIR/STTR Coordinator
Sent: March 5, 2007
To: Dr.
Subject: Last Call: Follow-up on the Outcomes of Your SBIR-Supported Project
Importance: High

I recently sent you an email message asking for your help in updating NIH about the outcomes associated with your SBIR-supported project. This information will supplement what NIH learned in the 2002 *National Survey to Evaluate the NIH SBIR Program* and in subsequent updates of selected outcome measures. The follow-up field period ends in three days on Wednesday, March 7.

We are especially appreciative of your help. You are part of a select group of Phase II SBIR awardees with whom we are conducting extensive follow-ups about their project outcomes, so that NIH can learn more about the impact that the SBIR Program has on product development and commercialization. Please take a few moments and give us updated information about your product.

The recent survey asked about the product, process, or service resulting from this SBIR Phase II award:

Company:
Principal Investigator:
Award Number:
Project Period:
Project Title:

Please click on the following link (or copy and paste it into your Internet browser window). It will take you to a secure online form (“padlock” in lower right corner) where you will be asked for your Username and Password. Once you have entered your Username and Password, you will be taken to a secure form in which you can provide a few highlights about your *project outcomes*. Thank you in advance for taking a few moments to do this. We greatly appreciate your assistance.

<https://www.Humanitas3.com/OMUpdate/>

Your Username is:
Your Password is:

If you have any questions or need additional information, please feel free to call or email me:

Jo Anne Goodnight
301-435-2688
jg128w@nih.gov

Thanks again!