Metrics for NCI SBIR Program

The Small Business Innovation Research (SBIR) program has the potential to accelerate progress toward NCI's Challenge Goal to eliminate suffering and death due to cancer by 2015. To harness this potential, the SBIR program should be strategically integrated into planning and priority setting activities at NCI. The NCI Metrics Team was formed with this aim in mind. The team consists of experienced program managers, as well as personnel from the NCI Office of Evaluation and the NCI Office of the Director. The team was charged to select metrics to evaluate the NCI SBIR program, to use these metrics to evaluate the past performance of NCI Phase II SBIR grants, to determine whether current SBIR grants support NCI high priority research areas, and to develop a plan for how metrics information will be collected in the future by SBIR program managers on an ongoing basis.

The Congressional legislation creating the SBIR program, the Small Business Development Act of 1982 (P.L. 97-219), allows each participating federal agency to determine the program's topics, selection process, and administration. It is expected that each agency use the SBIR program in a way that best suits the agency's mission. Naturally, the freedom to choose how the SBIR program is implemented has led to a diversity of approaches both within and across agencies. All of these approaches, however, must ultimately meet four SBIR program objectives established by the 1982 legislation. These are:

1. To stimulate technological innovation
2. To use small business to meet federal research and development needs
3. To increase private-sector commercialization of innovations derived from federal research and development
4. To foster and encourage participation by minority and disadvantaged persons in technological innovation

The rest of this document is organized into sections that align with the Team tasks described above.

I. Selection of Metrics

The SBIR program offers an opportunity to accelerate progress toward the elimination of suffering and death due to cancer. This opportunity derives from the unique nature of SBIR grant awards with their emphasis on commercialization of innovative ideas.

The NIH SBIR program previously undertook a survey of NIH SBIR programs and this survey is currently the only resource that has detailed information describing the outcomes of NIH and NCI's SBIR program. The NCI Metrics Team used the data in the PODS database (the database containing the survey information) to assess how well NCI SBIR recipients are meeting the program's objectives by selecting a series of questions from the PODS database that were thought to the most informative. Responses to these questions were also used to compare the performance of the NCI SBIR program to those of other NIH ICs.

Selecting metrics for the NCI SBIR program is a challenge that stems from the underlying diversity of the supported research activities. SBIR supports the whole spectrum of activities from the bench to the bedside. In light of this diversity, it is not surprising that no single

measure can capture the breadth of SBIR outcomes and impacts. The team desired to select the metrics that most accurately reflected the overall contributions of the program while understanding that this assessment is constrained by the amount of reliable data on which it could be based. Consequently, the team selected two overlapping sets of metrics; one set based on innovation and the other based on commercialization. These metrics encompass three of the four congressionally mandated SBIR objectives.

The first set of metrics evaluates innovation or the creation and dissemination of science-based discoveries intended for the market. One metric measures the extent to which companies expect value from their SBIR research and is based on their decision to pursue intellectual property (IP) protection, including patents copyrights and trademarks. The next two innovation metrics, publications and conferences, capture the dissemination of valuable scientific information to the wider community. The NCI SBIR innovation metrics are based on:

1. Patents (pending and approved)
2. Copyrights
3. Trademarks
4. Publications (forthcoming or in print)
5. Conference presentations

The second set of metrics evaluates commercialization, the process of getting innovations into marketplace. It is a complex and multidimensional process that involves an array of business oriented functions including meeting regulatory standards, manufacturing, marketing, and product/service support. The NCI SBIR commercialization metrics are:

1. Number of products yielding sales (includes licenses)
2. Dollar volume of cumulative sales (includes licenses)
3. Number of license agreements
4. Number of FDA approvals for marketing
5. Company sold or merged
6. Acquisition of outside capital to continue product development.

II. Existing Data on Past SBIR Projects

In 2002 the Office of Extramural Research commissioned a national survey from Humanitas, Inc., to evaluate the SBIR program at NIH, including all institutes and centers. One purpose of the survey was to determine if the NIH SBIR program as a whole is meeting the 1982 legislative program objectives described above. The NIH designed and implemented this survey, and NIH SBIR program managers identified metrics for the survey, potential data sources, and methods for data collection. The survey focused only on the first three legislative objectives and did not evaluate if the program is fostering participation by minority and disadvantaged persons in technological innovation.

The survey, released in 2003 as the *National Survey to Evaluate the NIH SBIR Program*, is a census of all 1,052 recipients of NIH SBIR Phase II awards from 1992 through 2001. For those firms that received more than one Phase II award, only one of their Phase II projects was randomly selected for the survey. With this design, each individual survey represents a single

Phase II project and a single SBIR Phase II recipient firm. There was an 85 percent response rate to the survey instrument. Of the 768 respondents, 130 were Phase II SBIR grants funded by NCI.

Humanitas analyzed the national survey data, which are referred to as the 2002 PODS data. They found very few statistically significant differences between individual ICs or groups of ICs. With respect to the trans-NIH SBIR program, they conclude, "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." (page ix of *National Survey to Evaluate the NIH SBIR Program*)

To shed light on the relative performance of NCI's SBIR program, the NCI Metrics Team requested Humanitas to partition the 2002 PODS data into NCI, NHLBI (a comparably sized institute), and other NIH ICs. As part of this request Humanitas prepared descriptive charts and tables to compare these groups using a number of metrics in PODS.

The remainder of this section is organized by the individual SBIR program objectives established by the 1982 legislation. When interpreting these data it is important to keep in mind three caveats. First, the responses to the survey were voluntary, and it is difficult to assess whether there is any response bias. Second, not all survey respondents answered every question. Third, the sample sizes for individual institutes are relatively small; 130 NCI funded grants and 107 NHLBI funded grants were included in the survey. These samples become dramatically smaller when they are split into technology areas and product groupings (i.e. drug development). In these circumstances, the data should be interpreted with caution.

Objective #1: To stimulate technological innovation

The evaluation framework established for the national survey defined standards and indices to benchmark program expectations for this objective. The standard states that some SBIR awardees produce products, processes, usages, and services. For this standard, two indexes are defined. The first index states that 40% or more of the NIH SBIR Phase II awardees produce new or improved products, processes, usages, and/or services in support of the NIH mission to "uncover new knowledge that will lead to better health for everyone." The second index states that 10% or more of NIH SBIR awardees receive additional Phase I or Phase II awards that relate to their core technology. Table 1 below is taken from the national survey's final report and summarizes both the indices and measures used.

Table 1: Summary of Awardee Performance for SBIR Objective #1

	Findings	
Stimulate Technological Innovation	**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**

Source: *National Survey to Evaluate the NIH SBIR Program*, 2003, page 3-2

As requested by the NCI Metrics Team, Humanitas, using the PODS data, compiled comparative data on NCI, NHLBI, and all other ICs using measures the team determined were related to innovation. Table 2 below shows the breakout of these innovation metrics (including "awards" and "other" categories) in the leftmost column. Each institute or group has two columns. The first column, called "Respondents," gives the number of survey respondents and the percent of survey respondents for each metric. Because multiple responses are included, the percentages are based on the number of respondents indicating that metric and do not add to 100%. The second column, called "Items," gives the total count for each metric as well as the average number per respondent.

Table 2: Comparative Innovation Metrics Using 2002 PODS Data

	NCI		**NHLBI**		**Other ICs**	
	Respondents	**Items**	**Respondents**	**Items**	**Respondents**	**Items**
Patents	44 34%	70 2	51 48%	151 3	192 36%	445 2
Copyrights	28 22%	66 2	15 14%	27 2	106 20%	360 3
Trademarks	30 23%	57 2	31 29%	48 2	138 26%	217 2
Publications	92 71%	361 4	67 63%	260 4	353 66%	1,566 4
Conference presentations	102 78%	398 4	79 74%	410 5	402 76%	2,042 5
Pending patents, papers	5 4%	5 1	0	0	9 2%	14 2
Awards	22 17%	29 1	17 16%	36 2	80 15%	187 2
Other	3 2%	12 4	2 2%	7 4	18 2%	50 3
Totals and	**130**	**998**	**107**	**939**	**531**	**4,881**

means	**100%**	**8**	**100%**	**9**	**100%**	**9**

Generally, these data show that NCI, NHLBI, and the group of other ICs are very similar across the various innovation metrics. The only statistically significant difference occurs between NCI and NHLBI on the percentage of respondents reporting USPTO approved patents (statistically significant at 5% level) – 48% compared with 34%. However, it is important to include patents still in the regulatory process to get a more accurate picture that is not skewed by approval delays (or count approved patents by date of application).

For NCI, Table 2 indicates that 34% of funded Phase II projects lead to patents and roughly 22%-23% lead to other forms of intellectual property. However, in terms of dissemination, the percentages are much larger, 71%-78% of Phase II projects lead to publications and conference presentations. IP outcomes are *less* frequent than knowledge dissemination outcomes.

Objective #2: To use small business to meet federal research and development needs

The national survey defined the following standard for this objective: Most NIH SBIR awardees make contributions to knowledge, increase the dissemination of information, and are satisfied with the usefulness of the Program. For this standard, three indices were defined with the expectation of seeing at least 50% for each. Table 3 below, which is taken from the national survey's final report, defines the three indices (item numbers 2.1, 2.2, and 2.3) and shows the survey results.

Table 3: Summary of Awardee Performance for SBIR Objective #2

	Findings	
Use of Small Business Concerns to Meet Federal R&D Needs	**Indices**	**Measures**
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**

Source: *National Survey to Evaluate the NIH SBIR Program*, 2003, page 3-13

The performance of NCI funded awardees were very similar to those awardees funded by NHLBI, and the group of other ICs. The NCI Metrics Team recommends not to track these indices in the future, as contributions to knowledge (index 2.1) and dissemination (index 2.2) are already captured by our set of innovation metrics.

The use of small businesses to meet NCI research and development needs is a central motivation for the current effort to strategically integrate the SBIR program into the planning and priority setting activities at NCI. The SBIR program should align with NCI strategic priority areas, and the Metrics Team recommends an additional metric to measure what fraction of SBIR funded grants align with NCI priority areas. Section III of this document recommends actions for strategic integration.

<u>Objective #3</u>: To increase private-sector commercialization of innovations derived from federal research and development

The national survey defined the following standard for this objective: Some NIH SBIR awardees increase the commercialization of health-related products and services resulting from federal support for research and development. For this standard, two indices were defined with the expectation of seeing at least 40% for each. Table 4 below, which is taken from the national survey's final report, defines the two indices (item numbers 4.1 and 4.2) and shows the survey results.

Table 4: Summary of Awardee Performance: SBIR Objective #3

	Findings	
Increase the Commercialization of Innovations	**Indices**	**Measures**
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		**11**
4.2.2 Median number of full-time employees		**10**

Source: *National Survey to Evaluate the NIH SBIR Program*, 2003, page 3-31

After tailoring to the NCI Challenge Goal, the Metrics Team believes the set of "commercialization" metrics described in Section I is appropriate for measuring performance related to this program objective. The NCI metrics include many of the components of index 4.1 but not any from index 4.2.

As requested, Humanitas compiled comparative data on NCI, NHLBI, and all other ICs from the 2002 PODS data. Data were available for all of the NCI commercialization metrics. Table 5 presents information on number of products achieving sales (the percentage of all funded projects is reported in parentheses), cumulative sales volume, and mean sales volume per project/firm.

Table 5: Number and Volume of Sales (including licenses) in 2002

	NCI	NHLBI	Other ICs
Percent of All Awardees	35 (27%)	24 (22%)	143 (27%)
Total Sales	$113.9	$71.9	$635.5
Mean Sales	$3.3	$3.0	$4.4

Dollar figures are in millions. Please note that the sales figures are approximations estimated using the midpoints of the categories in the NIH national survey, with the start point used instead of the midpoint for the final (unbounded) category.

There are no statistically significant differences in these metrics across NCI, NHLBI, and other ICs. However, the percentages reported understate the sales "success rate" for projects. The reason is that some SBIR projects were undertaken *without any expectation* of achieving sales. There were 105 NCI projects in which the company expected sales. Of these, 37 achieved sales, which is 35% of the firms expecting this outcome. (Note Table 5 lists 35 instead of 37 projects achieving sales. Two were dropped from Table 5 because they did not report sales volume information.) Further, when interpreting these figures, it is important to keep in mind that cumulative sales are a function of the length of time since receipt of the SBIR award, the awardees' main fields of business, and the type of product, process, or service planned for commercialization. None of these influences are factored into the estimates.

The NCI Metrics Team also had Humanitas determine the extent of commercialization by type of product or service. There were no statistically significant differences across the ICs, and overall, a smaller fraction of SBIR awardees who proposed developing either a diagnostic or drug achieved sales than did SBIR awardees who proposed developing other types of products or services. This can be at least partially accounted for by their more lengthy and rigorous approval processes.

Regarding the number of FDA approvals for marketing, 37% of the NCI projects were for SBIR results that require FDA approval. Looking at the comparative data for projects that require

FDA approval, there are not any statistically significant differences between NCI, NHLBI, and other ICs. Table 6 shows the percent of these products that have been submitted to the FDA. There is a significant "time lag" problem for these data, as it typically takes ten to thirteen years of R&D before a new drug application for a novel biopharmaceutical compound can be submitted. R&D gestation periods are shorter for new devices.

Table 6: Fraction of FDA relevant Phase II Projects Submitted to the FDA by 2002			
	NCI	**NHLBI**	**Other ICs**
Submitted to FDA	31%	25%	28%

Table 7 presents the 2002 PODS data for the other commercialization metrics. Because multiple responses are included, the percentages are based on the number of respondents and do not add to 100%.

Table 7: Company Events Related to SBIR Phase II Project				
Type of Event	**Survey Respondents**	**NCI**	**NHLBI**	**Other ICs**
Debt financing	# Respondents	16	9	82
	% Respondents	12%	8%	15%
Private placement	# Respondents	28	18	95
	% Respondents	22%	17%	18%
Public offering	# Respondents	6	1	14
	% Respondents	5%	1%	3%
Spin-off companies	# Respondents	15	11	37
	% Respondents	12%	10%	7%
Joint venture	# Respondents	24	18	89
	% Respondents	18%	17%	17%
Sold company	# Respondents	7	4	17
	% Respondents	5%	4%	3%

Merged company	# Respondents	1	5	15
	% Respondents	1%	5%	3%
Licensed agreement	# Respondents	32	22	108
	% Respondents	25%	21%	20%
Total responses	# Respondents	130	107	531
	% Respondents	100%	100%	100%

Once again, there are no statistically significant differences between NCI, NHLBI, and the group of other ICs. Looking within NCI, licensing agreements are a relatively frequent outcome with one in four project/firms pursuing this avenue of commercialization. Changes in company ownership status, either through sale or merger, are relatively infrequent.

Objective #4: To foster and encourage participation by minority and disadvantaged persons in technological innovation

The national survey defined the following standard for this objective: Most NIH SBIR awardees increase the participation of women, minority, and disadvantaged persons in technological innovation in health-related fields. For this standard, the program expectation for the index establishes that 10% or more of NIH SBIR awardees include women, minority, and disadvantaged employees engaged in technological innovation in health-related fields. (This is the Trans-NIH goal as stated in National Evaluation study.) The national survey's final report did not include any metrics for this program objective.

This SBIR legislative objective suggests the proposal selection process should favor minority and other disadvantaged groups, holding constant the other characteristics of the application including its scientific quality and commercialization potential. The NCI Metrics Team believes SBIR program statistics could be used to track application and award trends for these groups. The NIH IMPAC system contains this information.

III. Future Metrics Recommendations

Background

Michael Weingarten, NCI's Small Business Program Manager, has spearheaded a process to identify NCI Research priorities. He is using interviews with research area program managers and NCI Division Directors to identify high priority research areas that map to the NCI strategic plan for the 2015 Challenge goal. Once these high priorities are identified a portion of the SBIR grant funding will be dedicated to a focused marketing effort, designed to recruit leading small businesses in relevant technology areas. The SBIR program will also maintain a portion of its awards for the Omnibus solicitation.

Pre-Marketing Effort Metrics

Evaluation of Existing SBIR Grant Portfolio

Once these priority areas have been identified, a portfolio analysis will be requested from the Office of Science Planning and Analysis to determine the extent to which current Phase I and Phase II projects map to the priority areas previously identified. This mapping is a critical first step to permit subsequent steps in the process of evaluating and optimizing strategic fit.

For each emphasis area, it is important to know the number of active grants, the total investment, demographic information on principal investigators (for disadvantaged groups), and company demographic information. These data will facilitate the optimization process in two ways. First, they provide baseline information that can be used for evaluation going forward. Baseline information will consist of descriptive statistics for comparison of historical performance by projects and firms in the emphasis areas. Second, the data analysis will reveal over and under-represented areas among the program emphasis areas.

Those high priority areas already receiving substantial funding will not be targeted as strongly in the focused marketing effort as those areas not currently receiving adequate levels of support.

Post-Marketing Implementation Metrics

Part 1: Data Sources

A. NIH Wide Efforts

Meeting Congressionally mandated SBIR goals: Ms. Shino, the NIH SBIR/STTR Coordinator, has reported that eRA has a plan to work with Humanitas to integrate PODS into IMPACII as a final progress report tool for SBIR and STTR. This is on hold until more funds are available at eRA. The Metrics Team encourages NCI leadership to support this effort. The NCI SBIR/STTR Coordinator and support staff can use the metrics derived by this team to monitor ongoing SBIR performance.

B. Create an NCI SBIR Commercialization Database

With the appropriate supporting resources, the NCI Small Business Manager should create a "commercialization database" of SBIR project awards with particular detail on those projects in Phase II. This database will be a new management tool and will be a critical resource for monitoring and maintaining the strategic integration of NCI's SBIR program. It will provide NCI's Small Business Manager with the ability to track and assess the overall NCI SBIR portfolio both within and across program areas, including target areas.

The database should be constructed at the project level. Over time, it will evolve into a longitudinal database on current and past SBIR projects. While most of the information required to construct the database already exists at the NIH in either electronic or paper form, this information has not been brought together into a unified source. The NIH IMPAC database can provide some information on principal investigators, companies, and funding amounts. The NIH CRISP database can provide information on the nature of the projects as revealed by their

abstracts. However, critical information is missing from these sources. In particular, these sources are missing the commercialization information. Firms submitting Phase II proposal are required to provide commercialization plans that cover seven areas including expected commercial outcomes and societal benefits; company information; market, customer, and competition information; intellectual property protections; finance plan; production and marketing plan; and revenue stream generation. This is vital information that is not currently recorded in existing databases. The commercialization data in the NCI proposals must be extracted and inputted into the NCI Small Business Manager's commercialization database.

C. Collect Follow-up Information on NCI SBIR Awardees

It is recommended that the commercialization database be supplemented with additional data collected from NCI Phase II awardees. There is currently a trans-NIH project aimed at collecting *some* of the necessary information. It is called the Phase II Final Progress Report. However, this data collection effort does not allow sufficient time to elapse before observing performance metrics. The necessary time between research and market outcome will depend on research/market focus of the SBIR project. For instance, there are significant differences between the lengths of time required for new drugs versus new research tools. Thus, the Metrics Team recommends that NCI develop a mechanism to collect this information from awardees at least 24 months after the end of Phase II funding. While this time period does not perfectly match the varieties of SBIR market foci, it will vastly improve the accuracy of information on outcomes from SBIR supported research and commercialization. Collecting these data could be accomplished by a mechanism similar to current pilot instrument, called the Phase II Final Progress Report. If this approach is to undertaken, it may necessary to obtain OMB clearance for this type of survey, which can take some time.

Any or all of these methods of data collection would greatly increase the accuracy of any future analysis of how closely the SBIR program is meeting both innovative and commercialization metrics. Each of these methods would require some resources allocated to the project in terms of staff time or financial support, but the team feels that accurate data collection is vital to the metrics endeavor.

Part 2: Program Monitoring

A. Monitor and Update Strategic Priorities

On a biannual basis, the Small Business Manager should reevaluate the NCI program emphasis areas, target areas, and technology needs.

B. Track NCI SBIR Trends and Metrics

The NCI SBIR commercialization database is the core resource for tracking and assessing trends and outcomes going forward. Using whatever database information is available as described in the prior section, the Small Business Manager should analyze trends and metrics for individual program areas and for the NCI SBIR portfolio as a whole. Baseline information on performance by program area will be produced during the evaluation process discussed above. For the NCI SBIR program as a whole, NCI can adopt the standards used in the NIH national survey for interpreting observed metrics. These were described in Section II.

C. Determine the Effectiveness of the Focused Marketing Effort

The effectiveness of the focused marketing effort will be determined by identifying a "treated" group and a "control" group. We define the treated group to be those firms that receive an SBIR award through the targeted marketing effort in the priority areas. The control group will be those firms applying and winning SBIR awards through the regular Omnibus mechanism. The innovation and commercialization metrics described above will be used to compare the performance and effectiveness of applications funded under the targeted program with those funded under the Omnibus solicitation. These metrics will also be used to determine whether the proposed marketing and targeted solicitation efforts result in an overall increase in innovation and commercialization by NCI SBIR grantees. This will be done by comparing data from PODS with that obtained after this plan has been implemented. The fraction of SBIR funding committed to the NCI high priority areas before and after the marketing effort will also be determined to evaluate the effectiveness of the program.

IV. Conclusion

The NCI SBIR program has the potential to accelerate progress toward our Challenge Goal to eliminate suffering and death due to cancer by 2015. The NCI Metrics Team used the best available information to select program metrics, profile the current program, and recommend actions that will strategically integrate NCI's SBIR program. It is very important to keep in mind that the strategic integration of NCI's SBIR program is a long-term effort. It makes no sense to expect "immediate" results. After integrating the program, there will be a minimum three to five year gestation lag before accurate outcome metrics can be expected. Of course, in the area of new drug therapies (small or large molecule), a five year gestation lag is too short. For SBIR projects aimed at new drug therapies, appropriate three to five year metrics will be intellectual property protection as evidenced by patenting, particularly composition of matter patents.

Strategic integration of the SBIR program is (and was) the Congressional intention for how the program should function at participating federal agencies. The recommendations provided in Section III above will satisfy the program objectives mandated by Congress as well as accelerate progress toward our Challenge Goal. The successful integration of NCI's SBIR program, however, depends critically on having enough human and financial resources committed to this end. All of the recommendations provided above are contingent on this commitment.