SBIR and STTR Programs for Assistive Technology Device Development: Evaluation of Impact Using an ICF-based Classification

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Abstract

The purpose of this paper was to evaluate the impact of Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grant programs of 5 federal agencies National Institutes of Health (NIH), National Science Foundation (NSF), U.S. Department of Education (USDE), U.S. Department of Agriculture (USDA), and Department of Transportation (DOT) on the development of assistive technology (AT) devices using an International Classification of Functioning, Disability and Health (ICF)-based framework

SBIR and STTR awards were reviewed for the period 1996 through 2005. An ICF-based classification system, inclusion-exclusion criteria and assignment heuristics was developed. Awards were classified in reference to ICF components: *Body Structures and Functions, Activity, Participation* (separated in this system from *Activity*) and *Contextual Factors*, and further classified within each component. More than 24,000 SBIR and STTR, Phase I and Phase II grants were reviewed. Findings include the distribution of SBIR and STTR grants for assistive technology device (ATD) development, by component and category (of the ICF-based classification system); awards and funding by agency and year; cross-agency and temporal funding patterns; and concordance of funding patterns to agency missions. The authors concluded that the NIH and the USDE are the key SBIR funders for ATD development. The ICF-based classification scheme successfully differentiated agency award portfolios at both the component and category levels. The NIH is the key STTR funder for ATD development however the STTR program is relatively underutilized by ATD manufacturers. The USDE had the smallest SBIR program, yet was second in importance as an SBIR funder only to the NIH. The USDE mission is focused on addressing the needs of people with disabilities. No other agency mission had an analogous focus.

Introduction

People with disabilities use assistive technology devices (ATD) to enhance their levels of independence and to participate in activities of daily living, education, employment, recreation, and community living. Historically, many AT products have lagged behind mainstream products in terms of functionality, performance, quality, availability and cost. The ATD market landscape is dominated by niche markets and served by small manufacturers. Even within a specific disability market, customer diversity further reduces business opportunity as a

driver for innovation. In general, additionally, innovation by most small manufacturers is constrained by limited financial, technical, or infrastructural capacities. To help overcome these challenges, some ATD manufacturers rely on Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grants that are administrated and funded by certain large federal agencies.

SBIR and STTR programs fund small ATD manufacturers to conduct applied research and development activities with the intended outcome being the commercialization of new and improved products. SBIR and STTR funding is especially important for ATD manufacturers who develop products for small markets unlikely to attract investment capital. Studies conducted by the General Accounting Office (GAO) have concluded that the SBIR and STTR programs provide tremendous impetus for high-risk research, product development, and economic growth (GAO/T-RCED-98-218, 1998; GAO/T-RCED-99-198, 1999; GAO-05-861T, 2005). However, use of these programs by ATD manufacturers and the impact of SBIR and STTR programs on ATD development and commercialization is unstudied and unknown.

The Rehabilitation Engineering Research Center on Technology Transfer (T2RERC) based at the University at Buffalo conducted a public policy project that examined federal agencies and programs that support research activities that impact AT development. This paper focuses on five federal SBIR programs and two federal STTR programs that are developing a broad spectrum of ATDs. To accommodate the great diversity of ATDs, associate ATD development with industry segments, and assess the impact of the SBIR and STTR programs on ATD development, an ATD classification system was developed based upon the International Classification of Functioning, Disability and Health (World Health Organization, 2001). Expected outcomes from this effort are multifold:

1. Study findings will facilitate further research and analysis. These findings will include on a yearly and aggregate basis: company-level award data (companies receiving awards, number of awards received, funding per award, types of ATDs funded); agency-level award data (number of awards, funding levels, ATD award portfolios); interagency comparisons of award data (award number, funding levels, ATD award portfolios); and inter-program (SBIR v. STTR) comparisons at the company and agency levels.
2. Study findings will guide ATD manufacturers to the most appropriate SBIR and STTR funding sources. In turn, these resources will facilitate the development of high-risk, high-need ATDs.
3. Study findings will allow federal agencies to compare and optimize the makeup and foci of their SBIR and STTR grant portfolios. In particular, the findings will reduce portfolio similarities, accentuate portfolio differences, and allow appraisal of SBIR and STTR programs with regard to mission fulfillment.
4. Study findings may guide policy leaders (in state and federal legislative bodies). In turn, policy leaders set government priorities, establish program mandates, and evaluate program performance.
5. Study findings will inform disability advocates wishing to evaluate government programs. In particular, advocates will be able to compare and contrast the impact of different programs on IWDs.
6. Finally, the ICF-based classification system should have many additional

applications in the domains of policy and disability research. Formal validation of the ICF-based classification system was planned for Spring, 2009.

This paper begins with a detailed background of SBIR and STTR programs with the intent of informing small business ATD manufacturers. Reports suggest that about 13% of ATD manufacturers initiate and seek funding from SBIR and STTR programs (U.S. Department. of Commerce, 2003). Subsequently, existing government reports appraising the impact of SBIR and STTR programs are systematically reviewed to provide a context for the current research effort. The methodology section introduces the ICF model and ICF-based classification system and describes the data collection protocols. The results section includes a classification and analysis of grant awards and funding for the five SBIR and two STTR programs over the period 1996 through 2005. The concluding sections include data interpretation and comparisons, implications and future work.

Background

In 2003, the U.S. Department of Commerce, Bureau of Industry and Security (BIS) published the *Technology Assessment of the Assistive Technology Industry*. The BIS developed a survey for domestic businesses involved in the design, testing, research, development, manufacture and distribution of ATDs. An opportunistic sample comprised of 359 AT product companies completed the survey and only 10 of these companies did not qualify as small businesses. Among many important findings, only 52 (14%) of these companies had applied for SBIR funding during the period 1997 to 1999. None of the companies noted applying for STTR awards (U.S. Department of Commerce). In January 2008, the Assistive Technology Industry Association was comprised of 130 members. For the period 1996 to 2005 only 16 (13%) of these ATIA members *had received* one or more SBIR awards from the NIH, NSF, USDE, DOT or the USDA (Bauer & Flagg, 2008). These results suggest that most ATD manufacturers were either unaware of, or uninterested (for unknown reasons), in competing for SBIR or STTR funding. For this reason, the background section of this article includes substantial detail and references for both programs.

The SBIR program was established under the Small Business Innovation Development Act of 1982 (P.L., 97-219); it was reauthorized until September 30, 2000, by the Small Business Technology Transfer Act (P.L. 102-564), and reauthorized again until September 30, 2008, by the Small Business Reauthorization Act of 2000 (P.L. 106-554). The current embodiment of this law will be referred to as the 'SBIR Act.' The SBIR Act (Public Law 97-219) requires that large federal agencies with extramural research budgets of at least $100 million set aside 2.5% of these funds for grants to small U.S. businesses. The expressed purpose of the SBIR Act is to stimulate technological innovation in the private sector, increase the role of small businesses in meeting federal research and development needs, and to increase private sector commercialization of innovations derived from federally supported research and development efforts. The act also encourages the participation, by women-owned and socially disadvantaged small business firms.

Table 1
Typical SBIR Phases.

• **Phase I** awards are up to 6 months duration at up to $100K. Phase I activities typically establish the technical feasibility of a *proof-of-concept prototype*. The small business must complete at least of two-thirds the Phase I award. Subcontractors can complete up to one-third of the award and their participation is often encouraged. Upon concluding Phase I, a final report is required, summarizing progress toward stated Phase I objectives.
• **Phase II** awards are up to 2 years long and up to $750,000 total. Only Phase I award winners can apply for Phase II funding and applications must be accompanied by the Phase I final report. Phase II activity typically supports development of a proof-of-product and demonstrates commercial potential. The small business must complete at least 50% of the Phase II award while subcontractors can complete up to 50% of the award.
• **Phase III** has indefinite duration and is unfunded. A successful Phase III outcome is a new or improved technology or commercial product. Phase III is the 'proof of the pudding' in terms of program performance and return-on-investment, however participating manufacturers are not required to report Phase III outcomes. This creates difficulties for agencies and other entities charged with program oversight.

Source: U.S. Small Business Administration. (n.d.). *Office of Technology SBIR/STTR.* Retrieved January 20, 2009, from http://www.sba.gov/aboutsba/sbaprograms/sbir/index.html

The second of these objectives "to use small business to meet federal research and development needs" [§2(b)(2)] has special significance. Each federal agency's mission is distinct, and the research and development sponsored by these agencies to address 'mission-driven needs' should be expected to vary accordingly. In practice, some SBIR programs will be more relevant to ATD manufacturers than others.

The basic requirements for participation in an SBIR program are: (a) U.S. business, (b) U.S. owned (≥51%) and operated, (c) principle investigator is employed by business, (d) business has less than 500 employees, and (d) business is a for-profit entity. In fact, almost all U.S. ATD manufacturers qualify as small businesses (U.S. Department of Commerce, 2003). There is variation across federal agencies, but SBIR programs typically have three phases and similar funding levels and grant periods. Typical SBIR phases are summarized in Table 1.

Many SBIR grants result in patentable intellectual property (inventions). Small businesses generally retain title to these patents. In turn, the invention is the basis for, or incorporated into, new and improved products, tools, and services that meet private sector needs. The small business must grant the federal government a non-transferable license to practice the invention. In turn, the federal government may ask other public or private entities (e.g., a private subcontractor) to practice the invention on its behalf. Non-transferrable licenses are one of the principle mechanisms through which SBIR programs address an agency's 'mission critical needs.'

At least 11 federal agencies currently have SBIR programs including the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services (NIH, n.d.), Homeland Security, Transportation, Environmental Protection Agency, and National Aeronautics and Space Administration (NASA), and NSF. Each agency sets the goals and objectives for its SBIR programs, administrates its program and

must report yearly performance data to the Department of Commerce, Small Business Administration (SBA). In turn the SBA produces annual reports with aggregate information on SBIR and STTR program activities. While informative, SBA annual reports offer few specifics on the technologies developed or products commercialized (GAO/T-RCED-99-198, 1999; GAO-07-38, 2006).

SBIR programs are broadly classified as being acquisition- or non-acquisition-based. Acquisition-based SBIR programs are employed to develop technologies for an agency's own use. In effect, the federal agency is the primary market for technologies developed through acquisition-based SBIR programs. Acquisition-based SBIR programs typically employ tightly constrained solicitations, giving small businesses little leeway regarding the scope and purpose of research efforts. Examples of federal agencies with acquisition-based SBIR programs include: the Department of Defense, sectors of the Department of Energy, and NASA.

Non-acquisition-based SBIR programs are employed to develop technologies for the *private sector*. Non-acquisition-based SBIR programs typically employ solicitations with broadly stated requirements, giving small businesses great leeway regarding the scope and purpose of research efforts. Examples of federal agencies with non-acquisition-based programs include: the Departments of Agriculture, Education, Transportation and sectors of the Department of Energy, as well as NIH; and NSF. While this study focuses on non-acquisition-based SBIR and STTR programs, it is reasonable to assume that some acquisition-based programs (e.g. NASA) play a significant role in ATD development.

The STTR program, roughly one-tenth the size of the SBIR program, was established under the Small Business Technology Transfer Development Act of 1992 (Title II, Public Law 102-564) and subsequently reauthorized in 1997 and 2002. The STTR legislation requires large federal agencies to set aside 0.3% of their extramural budget for their STTR programs. The STTR and SBIR programs have similar missions with mostly minor differences. The STTR program also has three phases. Nominally, Phase I is funded at $75,000 for up to 9 months, and Phase II at $500,000 for up to 2 years, while Phase III is unfunded. The STTR principle investigator may be affiliated with a U.S. university (or other non-profit entity) or U.S. manufacturer. In Phase I, the university can complete up to two-thirds of work while a small business can complete up to one-third of the work. In Phase II, the small business can complete up to one half of the work. Accounting for program size, it is unknown whether ATD manufacturers prefer SBIR and STTR programs. If there is a preference, the reasons for this preference have not been explored.

In addition to annual reports, the SBA records yearly SBIR and STTR awards across all agencies in the Tech-Net database. Collected data for Phase I and Phase II awards include the proposal title and abstract, company name and address, principle investigator and contact information, grant number, phase, amount and awarding agency, and the start and end dates for the award. The Tech-Net database was intended to be the central cross-agency repository for SBIR records dating from the inception of the SBIR legislation. The Tech-Net database is in principle an excellent concept and public resource. However, GAO studies have criticized the quality and completeness of Tech-Net records (GAO-07-38, 2006).

Starting in the late 1990s some federal agencies (e.g., DOT, USDA) created their own databases to house SBIR and STTR program data. Other agencies (e.g., NIH,

NSF, and USDE) maintained parallel, independent databases starting from the inception of their respective SBIR and STTR programs.

Problem Statement

All federal agencies compile aggregate performance statistics for their SBIR and STTR programs on a yearly basis. These statistics typically include: (a) the number of Phase I applicants, (b) the number of Phase I awardees, (c) the number of Phase II applicants, (d) the number of Phase II awardees, (e) total Phase I funding, and (f) total Phase II funding. These statistics form the basis for most GAO and annual SBA reports but provide neither details on industry segments, manufacturers, and technologies, nor on products that are being developed. The SBA Tech-Net database and agency SBIR and STTR databases do include details on the manufacturers being funded and research abstracts. However, analysis of these databases is hindered by the lack of a universal classification system for industry segments and product types. Two federal agencies, the National Research Council (NRC) and NIH, recently evaluated and reported on the merits of key SBIR programs. These reports were reviewed in detail in order to gain insight on ATD development.

Starting in 2003 the NRC began publishing studies on large SBIR programs and, in 2007, the NRC published a summative study of the five largest SBIR programs (DOD, NIH, DOE, NASA, and NSF) comprising more than 96% of all SBIR expenditures (Wessner, 2007a-d, 2008a-b). No similar large studies have been published for the STTR programs, nor have studies been published for smaller SBIR programs such as those run by the USDE, DOT, or USDA.

Section 108 of The Small Business Reauthorization Act of 2000 requires that the NRC conduct comprehensive studies of federal agencies with SBIR budgets exceeding $50 million. Five agencies, in rank order of their SBIR program outlays, met these criteria in 2000: DOD, NIH, NASA, DOE, and NSF. The overall goal for these NRC studies was to determine how the SBIR program has stimulated technological innovation and used small businesses to meet federal research and development needs. The NRC study is summarized in Table 2.

Overall, the NRC study results suggest that SBIR programs are a critical and effective resource for small businesses developing and commercializing high-risk products. Two study findings are immediately relevant to ATD manufacturers. In 2003, 2005, and 2006 NIH and NSF funded the majority of Phase I SBIR applicants, and a large portion of NIH and NSF Phase I awards went to first-time applicants. The NIH (n.d.) and NSF (n.d.) mission statements have no apparent bias for or against the development of technologies benefiting individuals with disabilities. Assuming an absence of bias, NIH and NSF should be preferred funding sources for ATD development. It is also unclear whether the absence of a barrier-to-entry for first-time applicants applies similarly for ATD manufacturers.

For those ATD manufacturers considering SBIR funding for product development, the NRC study shows a recent downward trend in the number of Phase I awards and a parallel upward trend in both the size and number of Phase II awards. Stated another way, Phase I awards have become more competitive and a Phase I award-winner is more likely to win a larger Phase II award. As a consequence, more SBIR funding is being focused on fewer manufacturers. At completion of a Phase I grant, manufacturers have typically completed a *proof-of-concept prototype*. At completion of a Phase II grant, manufacturers have typically made significant progress toward a *proof-of-*

Table 2
NRC Study of the Five Largest SBIR Programs

Report	National Research Council (2007)
Federal Agencies Reviewed	• Agencies listed in the rank order of their SBIR programs: Department of Defense, National Institutes of Health, Department of Energy, National Aeronautics and Space Administration, and the National Science Foundation
Goals & Objectives	To examine the role of SBIR programs in technological innovation and their benefits to small businesses to meet federal research and development needs by: • Clarifying the quality of research conducted • Economic benefits achieved • Non-economic benefits achieved • Trends in SBIR funding allocation from 1983 to 2000 • Agency procurement of technologies developed with Phase II funding • Recommendations
Method	Survey • Respondents: 1,916 small businesses • Sampling: Stratified random sampling, targeting 20% of small businesses receiving Phase II awards from each of the five SBIR programs. Study achieved a 42% response rate (1,916 of 4,523 firms contacted). • Inclusion Criteria: Any firms receiving one or more Phase II awards for the period 1992 to 2001
Key Findings	• In 2003, 2004, and 2005, NIH funded 23%, 19%, and 18% of Phase I applicants. For the same years, NSF funded 21%, 17% and 14% of Phase I applicants. A downward trend in the percentage of funded Phase I applicants and an upward trend in the percentage of funded Phase II applicants (along with increased award size) was noted for these years. • For the period 2000 to 2005, about 62% of NIH Phase I awards went to first time applicants. • For the period 1996 to 2003, about 53% of NSF Phase I awards went to first time applicants. • 43% of respondents received additional non-SBIR investment averaging about $1.54 million. • 78% of respondents reported that obtaining Phase I and Phase II SBIR funding was the key to obtaining further non-SBIR investment. • 54% of small businesses receiving a Phase II award reported receiving at least one additional related Phase I SBIR award, and 40% received at least one related Phase II award. • 47% of Phase II awards led to commercial products, 19% expected to culminate in commercial products, while 5% of the projects were still ongoing. • Respondents reported that product development would definitely (38%) or probably (33%) not have been initiated without SBIR funding. Only 13% of respondents would have initiated product development without SBIR funding. • 5% received royalties for technologies developed with SBIR funding.
Conclusions	• The pool of small businesses funded by SBIR programs is dynamic with a low 'barrier-to-entry' for first-time applicants. • SBIR programs are a critical and effective resource for small businesses to develop and commercialize high-risk products. • SBIR programs have excellent commercialization and licensing outcomes.
Limitations	• Study did not identify or classify technologies developed or licensed, products commercialized, or participating firms. • Firms receiving multiple Phase II awards were more likely to complete the NRC survey. • Firms receiving multiple Phase II awards were underrepresented in the sample.

Source: Wessner, C. W. (Ed.). (2007d). *An assessment of the Small Business Innovation Research Program.* Washington, DC: National Research Council.

product. In effect, large SBIR programs have shifted their investments from exploratory Phase I activities to more commercial Phase II activities. The NRC study found that manufacturers successful in receiving Phase II awards are likely to attract follow-on funding from non-SBIR sources such as angel investors and venture capitalists. Follow-on

funding is critical to resource-constrained small businesses since development costs typically escalate greatly as an innovation progresses from proof-of-concept to proof-of-product. It is unclear how the shift of agency investment from Phase I to Phase II impacts ATD manufacturers, or whether ATD manufacturers winning Phase II awards similarly attract follow on funding. For example, agencies might award fewer Phase I grants and proportionately more or larger Phase II grants. However, would it be necessary for these agencies to narrow their funding priorities and would (currently funded) AT fall under these priorities?

The NRC study found that across the five agencies, at least 47% and at most 71% of Phase II awards led or will lead to commercial products. It is unclear if this outstanding record for commercialization is also found for ATD manufacturers. The reasons for any such deviation should it be found is also unknown. Moreover, several respondents reported that product development *would definitely* (38%) or *probably not* (33%) have been initiated without SBIR funding. As a fundamental barrier to analysis, the NRC study does not identify or classify participating companies, industry segments, technologies developed, or products commercialized. As a consequence, it is impossible to ascertain the impact of SBIR funding on ATD development.

In 2003, the NIH published a comprehensive self-study of their SBIR program. The methodology and findings from this study are presented in Table 3 in a similar format as that of the NRC. In congruence with the NRC findings, the conclusion of the NIH study was that the SBIR program provides a crucial impetus for small business manufacturers in technology development.

In corroboration with the NRC study findings, NIH SBIR awardees showed a strong ability to receive additional SBIR and non-SBIR funding for further development of their core technology. NIH awardees reported generating 'revenue' of $821 million through product sales and technology licensing. These revenues include: follow-on funding from angel investors and venture capitalists, additional SBIR grants that extend work completed under the initial SBIR grants, license royalties from patented technologies developed under the SBIR grants, and revenues from the sale of commercial products. NIH Phase II awardees reported additional benefits related to obtaining SBIR funding included the creation of new knowledge, scientific publications, knowledge dissemination, and networking opportunities.

In contrast to the NRC study, the NIH study did employ an ad hoc classification system (see Figure 3) to support the analysis of its SBIR program's impact on industry and market segments. The classification scheme does provide insights regarding large-scale NIH investments in technology and product development. The classification scheme does not however, provide insights regarding ATD development in ATD industry segments. This is not unexpected since development of ATDs is unlikely to account for more than a low percentage of the total NIH SBIR funding.

In a review of SBIR program research, including GAO reports, SBA annual reports, NRC studies, and the NIH study, a few observations can be made. First, none of these reports or studies focused on ATDs, ATD manufacturers or industry segments. Second, where classification schemes have been employed, they are irrelevant to ATD development. The current study is focused on ATD development supported by SBIR and STTR funding. A detailed and comprehensive classification scheme for ATDs and ATD industry segments is needed to carry out

Table 3
NRC Study of the NIH SBIR Program

Report	National Institute of Health (2003)[1]
Federal Agencies Reviewed	• National Institutes of Health
Goals & Objectives	• G1: Evaluate the extent to which NIH SBIR awardees stimulate technological innovation, meet federal R&D needs and commercialize innovations supported through SBIR awards • G2: Comply with statutes and regulations requiring assessments of federal programs to demonstrate their contribution to the nation's economic well-being • G3: Test the feasibility of using an evaluation framework as the analytic basis for a dynamic project monitoring system
Method	• Survey (alternative formats) • Inclusion/Exclusion: 1052 firms receiving a NIH Phase II SBIR award from 1992 to 2001 • Sampling: 768 firms (95% of firms receiving one or more Phase II awards) • Used classification system described in the *Industry* and *Market* segments
Key Findings	• 73% of awardees commercialized 670 new or improved products, processes, usages, and/or services • Respondents produced 2,203 technical articles, 666 patents, 2,850 conference presentations, 453 copyrights, 252 awards, and 322 trademarks • 52% (399) of respondents received additional Phase I or Phase II awards related to the continued development and exploitation of their core technology. • 37% (291) of respondents also obtained non-SBIR funding related to the continued development and exploitation of their core technology. • NIH invested $551million in the firms receiving Phase II awards • Respondent firms generated $821M in revenues from sales and licensing. Many other technologies were in a pre-commercial stage • 64% of respondents would not have pursued product development without SBIR funding • Respondents also thought that SBIR awards impacted pursuit of high-risk ideas (87%), personnel hiring (87%), raising additional capital (44%), and fostering partnerships (70%)
Conclusions	• First comprehensive review of NIH SBIR program • Basis established for systematic collection and analysis of NIH SBIR program outcomes • NIH has made significant contributions to the three goals and objectives (G1, G2 and G3)
Limitations	• Analysis does not reflect costs and revenue generation of non-extent firms and non-respondents • No reason to believe that the industry and market framework used for classification and analysis would generalize to other agencies (e.g. DOD, DOE, NASA) or programs (e.g. STTR)

Source: National Institutes of Health. (2003). *National survey to evaluate the NIH SBIR*

analysis across the SBIR and STTR programs under consideration.

The Technology Related Assistance for Individuals with Disabilities Act (Tech Act) of 1988 (P.L. 100-407) as amended in 1994, defined an ATD as "any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities" [§3(1)]. This definition places some constraints on the meaning of an ATD but does not establish a classification system.

The International Classification of Functioning, Disability and Health (ICF) was endorsed by the Fifty-Fourth World Health Assembly for international use in 2001 and "provides a unified and standard language and framework for the description of health and

health-related states" (World Health Organization [WHO], 2001, p.3). The ICF model is comprehensive, systematic, and detailed. It provides an excellent framework upon which to build a comprehensive classification scheme for ATDs.

Five non-acquisition-based SBIR programs and two acquisition-based STTR programs are considered in the current study. Among the five federal agencies supporting these programs, we will find that the NIH, USDE, and NSF SBIR programs are the dominant funding sources for ATD development. NIH and NSF have been evaluated in large agency self-studies and NRC studies. However, as a small federal agency, the Small Business Reauthorization Act of 2000 does not require the USDE to receive a comprehensive evaluation by the National Research Council and no other comprehensive studies of the USDE SBIR program have been done. A review of the USDE SBIR program web pages reveals that in 2003 and 2004, USDE funded 9% and 11% of Phase I SBIR applicants, or at roughly half the funding rate of NIH and NSF SBIR applicants. In addition, from 2000 through 2004, the USDE funded no more than 56 Phase I SBIR grants (2002), and 17 Phase II SBIR grants (2003). Total SBIR funding never exceeded $3.1 million (2004; U.S. Department of Education, n.d.). A simple comparison of scale between the USDE SBIR program and the NSF and NIH SBIR programs might suggest that these programs should provide far more support for ATD development. However, the NIDRR exercises significant influence on USDE SBIR solicitations.

The NIDRR mission is:

> to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and also to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. (National Institute on Disability and Rehabilitation Research, n.d.)

In contrast, the NIH and NSF missions do not place a special emphasis on meeting the needs of people with disabilities through the development of ATDs and products (NIH mission statement, NSF mission statement). Of the five agencies studied, only the NIH and the NSF have STTR programs. The Small Business Technology Transfer Reauthorization Act of 2001 does not mandate that large STTR programs should be reviewed in a manner analogous to Section 108 of the SBIR Act. As a consequence, performance data on STTR programs is limited to small studies undertaken by the Congressional General Accountability Office and the Department of Commerce Small Business Administration. As noted for SBIR programs, GAO and SBA reports do not support detailed analysis.

Research Objectives

This study has three research objectives:

1. Identify the Phase I and Phase II SBIR (for five agencies) and STTR (for two agencies) awards and funding for ATD development for the period 1996 through 2005. Classify the awards and funding using an ICF-based taxonomy.
2. Evaluate Phase I and Phase II SBIR and STTR awards and funding on a yearly and aggregate basis by: (a) types of ATDs funded (component and category); (b) agencies (number of awards, funding levels and award portfolios); (c) inter-agency comparisons (award numbers, funding levels and award portfolios); and (d)

inter-program comparisons (SBIR and STTR programs) and trends.

3. Interpret data and draw conclusions regarding SBIR and STTR award and funding trends for companies, agencies, across-agencies, across programs and across-technology domains (industry segments). Analysis will especially include longitudinal trends and a comparison of award portfolios.

Method

Methods address four principle issues. These issues are: (a) gathering of SBIR and STTR award data, (b) construction of an ICF-based classification system, (c) inclusion and exclusion criteria for ATDs, and (d) and assignment heuristics to place ATDs into the ICF-based classification system.

Gathering SBIR and STTR Award Data.

SBIR and STTR awards from NIH, NSF, USDE, USDA, and DOT were reviewed for the period 1996 through 2005. Agency databases were the primary sources for award data (Table 4). For each award the following information was entered into a Microsoft Access® database: award title, year, type (SBIR, STTR), Phase (I, II), amount, and abstract; principle investigator, organization name and address; and funding agency.

There is some variation in how SBIR and STTR award data is documented by the agencies studied. NIH maintains two complementary databases. The NIH CRISP database contains all the needed data except award funding which must be found in the NIH SBIR/STTR Award database or SBA Tech-Net. NIH tracks yearly Phase II sub-awards with unique award numbers and sub-awards. As a consequence, NIH award, and

Table 4
SBIR and STTR Databases

Database	URL
1. DOT, Volpe Library SBIR Awards (1999-present)	http://www.volpe.dot.gov/sbir/previous.html
2. NIH, *CRISP* (Computer Retrieval of Information on Scientific Projects, 1983-present)	http://crisp.cit.nih.gov/
3. NIH, SBIR/STTR Award Data (1996-present)	http://grants.nih.gov/grants/funding/award_data.htm
4. NSF, Award Search (1983-present)	http://www.nsf.gov/eng/sbir/
5. Small Business Administration, Tech-*Net* (1983-present)	http://technet.sba.gov/
6. USDA, SBIR Awards (2002-present)	http://www.csrees.usda.gov/funding/sbir/sbir_abstracts.html
7. USDE, Historical SBIR Database (1983-2000)	http://www.ed.gov/programs/sbir/database.html
8. USDE, Recent SBIR Awards (2001-present)	http://www.ed.gov/programs/sbir/awards.html

Table 5
ICF Model

Part	Components	Domain Examples	Levels (Codes)
I: Functioning & Disability	Body Functions	Global Mental Functions	b110*-b199*
		…	…
		Functions of the Skin	b810*-b899*
	Body Structures	Structures of the Nervous System	s110*-s199*
		…	…
		Skin & Related Structures	s810*-s899*
	Activities & Participation	Learning & Applying Knowledge	d110*-d199*
		…	…
		Community, Social and Civic Life	d910*-d999*
II: Contextual Factors	Environmental Factors	Products & Technology (Assistive Technologies)	e110*-e199*
		…	…
		Services, Systems, Policies	e510*-e599*
	Personal Factors	N/A	N/A

(* indicates further coding levels)

funding data must be carefully aggregated.

The USDE Historical Awards Database records are complete for the period 1996 through 2000. For 2001 to 2005, the USDE Recent SBIR Awards database records include only the award title, principle investigator and organization. Information lacking in the USDE Recent SBIR Awards database was obtained from SBA Tech-Net.

The NSF maintained complete award records since the inception of its SBIR and STTR programs through 2007. In 2008, NSF shifted award record-keeping entirely over to SBA Tech-Net. USDA and DOT established SBIR award databases in 2002 and 1999 respectively. Both databases are easy to use and contain complete records (for our purposes). Prior to establishing these databases, SBA Tech-Net served as the primary data source for USDA and DOT awards.

Three search heuristics were followed to ensure that collected award data was substantially complete and accurate: if an (a) investigator received a Phase II ATDs award, then databases are searched until the corresponding Phase I award was identified; (b) investigator received a Phase I or Phase II award, then databases are searched for other awards using this investigator's name as the keyword; and (c) organization received a Phase I or Phase II award, then databases are searched for other awards using the organization's name as the keyword.

The first heuristic ensures that no Phase I award is missed given that a Phase II award has been recorded. The second and third heuristics assume that investigators and companies that obtain SBIR or STTR funding to develop ATDs will be inclined to seek further SBIR or STTR funding. The second and third heuristics also provide a means to find Phase II awards subsequent to recording a Phase I award. Finally, all award data, component and category assignments were reviewed by at least two study personnel.

ICF-Based ATD Classification System.

The ICF is a model that classifies individuals across various levels of health, health-related outcomes, and functioning by use of a

standard set of terminologies and classification scheme. Applying the model to evaluate SBIR and STTR programs aligns with one of the fundamental uses of this multipurpose tool, which is to "to permit comparison of data across health care disciplines, services and time" (WHO, 2001, p. 5). As a social policy tool, application of the ICF model provides a basis to evaluate the design and implementation of these programs at the federal level. The overall ICF is sufficiently structured, detailed and logical to provide a framework upon which to construct a comprehensive and intuitively appealing ATD classification.

The ICF is an extensible, hierarchical classification scheme composed of parts, components, domains, and levels (see Table 5). Part I: Functioning and Disability is comprised of two components: Body Functions and Structures (BFS), and Activities and Participation (AP). Part II: Contextual Factors is also comprised of two components: Environmental Factors, and Personal Factors. The ICF classification further expands upon the first three components. BFS AP and Environmental Factors (EF). Each component is divided into domains, and domains are further divided into levels with corresponding classification codes.

The ICF framework assigns all ATDs under Part II: Context, Environment (component), Products and Technologies (domain) and 14 levels, corresponding to different types of ATDs. Table 6 illustrates the assignment of ATDs under the ICF framework.

Disability and Health (Short Version). Geneva: World Health Organization, p. 3.

ATDs are classified within the ICF as *Products & Technology* under the contextual component. However, ATDs can easily be related to all ICF Part I chapters and domains to

Table 6
Classification of ATDs in ICF as Products and Technology

Part	Component	Domain	Levels	Codes
Contextual Factors	Environmental Factors	Products and Technology	Products or substances for personal consumption	e110
			Products and technology for personal use in daily living	e115
			Products and technology for personal indoor and outdoor mobility and transportation	e120
			Products and technology for communication	e125
			Products and technology for education	e130
			Products and technology for employment	e135
			Products and technology for culture, recreation and sport	e140
			Products and technology for the practice of religion and spirituality	e145
			Design, construction and building products and technology of buildings for public use	e150
			Design, construction and building products and technology of buildings for private use	e155
			Products and technology for land development	e160
			Assets	e165
			Products and technology, other specified	e198
			Products and technology, unspecified	e199

Source: World Health Organization. (2001). *ICF: International Classification of Functioning,*

encompass and distinguish diverse ATDs and ATD industries. Simply stated, the idea of the proposed classification is not to map or 'mold' the ICF classification to fit the ATD industry, but to classify the segments of the ATD industry to the ICF components and domains. It must also be noted that although ATD impact the entire span of the ICF framework, the purpose of the classification is to categorize ATD industry segments by their functionality and specific relevance to the ICF components and domains.

ATD categories were assigned to the ICF components of BFS, AP, and EF based on the conceptual definition of these components. ATD categories were exclusively assigned to the Activity component and Participation component considering a fundamental distinction in their conceptual definition-'activity' being "the execution of a task or action by an individual, while participation being the fulfillment of roles by "involvement in a life situation" (WHO, 2001, p. 10). The fourteen ICF levels under Part II: Contextual Factors, EF component were retained as an ATD category, *Contextual ATD*. A rarely used ATD category 'other' was added under each of the four 'components' Body Functions and Body Structures, Activities, Participation, and Environmental Factors.

The following are the definitions of the ATD categories based on their conceptual relevance to the ICF components. The classification was formulated using descriptors that defined the ATD categories as listed in Table 7.

ATD for body function and structure. This is any technology that is implanted in an individual's body (intrinsic), with a permanent configuration (*fixed*), used to fulfill many or all life roles (*pervasive*), across many or all contexts (*pervasive*). For example, cochlear implants, hip replacements, and cardiac pacemakers are implanted in the individual, closely configured to the individual, to support many or all roles, and in many or all contexts.

ATD for activity. This is any technology that is external to but accompanies the individual (*extrinsic*), with single or multiple configurations (*customizable*), used to perform particular activities, to accomplish many or all life roles (*pervasive*), and in many or all contexts (*pervasive*). Examples include hearing aids, Braille note-takers, and power wheelchairs, and which are external to but accompany the individual, and are customized for individual use to support many roles in many contexts.

ATD for participation. This includes any technology encountered in particular environments (*environmental*), that is configurable for individuals with similar functional abilities (*group*) to accomplish specific life roles (situational), and in specific contexts (*situational*). Examples include screen reader software, personal lifts, and assistive listening systems encountered in particular environments, which meet the needs of individuals with similar abilities for specific

Table 7
AT Classification Rules

ICF Component	Descriptors			
	Integration	Customization	Context(s)	Role(s)
Body Structure & Function	*Intrinsic*	*Fixed*	*Pervasive*	*Pervasive*
Activities	*Extrinsic*	*Customizable*	*Pervasive*	*Pervasive*
Participation	*Environmental*	*Group*	*Situational*	*Situational*
Contextual	*Societal*	*Cross-Group*	*Facilitator*	*Facilitator*

Table 8
ICF-Based Classification Scheme: Body Functions & Structure

ICF Domains	ATD Categories
Mental functions; Structures of the nervous system	Cognition
Sensory functions; The eye, ear and related structures	Sensory (Hearing and Vision)
Voice and Speech functions; Structures involved in voice and speech	Communication
Functions of the cardiovascular, hematological, immunological and respiratory systems; Structures of the cardiovascular, hematological, immunological and respiratory systems	Cardiovascular and Respiratory Health
Functions of the digestive, metabolic and endocrine functions; Structures related to the digestive, metabolic and endocrine functions	Digestive System
Genitourinary and reproductive functions; Structures related to genitourinary and reproductive functions	Genitourinary System
Neuro-musculoskeletal and movement related functions; Structures related to movement	Neuromuscular System
Products and technology, other unspecified	Other

roles in specific contexts.

Contextual ATD. This is any technology, service or tool (*societal*), for individuals with similar or dissimilar abilities (*cross-group*), that increases the use, function, or availability of ATD across roles and/or contexts (*facilitator*). An example would include an online database used to locate ATD for individuals with diverse functional abilities, and used in various roles and contexts.

The ICF-based classification scheme used in the current study is summarized in Tables 8-

Table 9
ICF-Based Classification Scheme: Activities

ICF Domains	ATD Categories
Learning and applying knowledge	Cognition
General tasks and demands: Self care; Community, social and civic life	Independent Living; Health
Communication; Interpersonal interactions and relationships	Communication; Sensory (Hearing and Vision)
Mobility	Mobility and Seating; Prosthetics and Orthotics
Major life areas	Education; Employment
Products and technology, other unspecified	Other

11. There are 13 ATD categories under BFS; 14 ATD categories under Activities; 14 ATD categories under Participation; and 14 ATD categories under EF. The ICF-based classification is comprehensive in that all ICF codes are mapped onto ATD categories. This mapping can be found on the T²RERC Public Policy webpage (Public Policy, RERC on Technology Transfer, n.d.).

Inclusion-Exclusion Criteria

When classifying SBIR and STTR awards, inclusion-exclusion criteria are first applied to distinguish ATD from non-ATD. According to the 2004 Tech Act, assistive technology is "any item, piece of equipment or product system acquired commercially off the shelf, modified, or customized used to increase, maintain, or improve functional capabilities of people with disabilities" [§3(4)]. According to the (1990) Americans with Disabilities Act the term disability means, with respect to an individual (a) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (b) a record of such an impairment; or (c) being regarded as having such impairment [§12102 (1)]. Our understanding of the concepts of major life activities and disability continues to evolve under a series of Supreme Court rulings (National Council on Disability, 2003). Inclusion and exclusion criteria are summarized below.

Inclusion criteria. This is any item, piece of equipment or product system used to increase, maintain, or improve functional capabilities. The item, piece of equipment or product system should be used by an individual with a physical or mental impairment that substantially limits one or more of the major life activities on a permanent or intermittent basis.

Exclusion criteria. This is any item, piece of equipment or product system used primarily to treat, diagnose or rehabilitate an injury, illness, or exposure or to protect or maintain the health or well-being of people without disabilities. Examples of excluded technology include diagnostic or screening tools, and exercise equipment and splints worn to promote healing as opposed to facilitate function.

Classification Assignment Heuristics

Once an award is included, each technology is then assigned to a component and a

Table 10
ICF-Based Classification Scheme: Participation

ICF Domains	ATD Categories
Learning and applying knowledge	Cognition
General tasks and demands: Self care; Community, social and civic life	Independent Living; Health
Communication; Interpersonal interactions and relationships	Communication; Sensory (Hearing and Vision)
Mobility	Mobility and Seating; Prosthetics and Orthotics
Major life areas	Education; Employment
Products and technology, other unspecified	Other

corresponding domain. A set of heuristics for assignment of ATD to classification categories was adopted to ensure that each technology is assigned uniquely to one classification category.

1. In selecting a category, the order of precedence for technology assignment is disability > context > role. For example, a technology for children with *blindness* for use in an *educational setting* would be assigned to the *Activity Component* and *Sensory (blind)* category as opposed to the *Context Componen*t and *Education* category.
2. In selecting a category, when a technology serves two or more disabilities, assignment is based upon context. For example, a technology for individuals with *blindness* or *cognitive impairment* for use in a *vocational setting* would be assigned to the *Participation Component* and *Employment* category.
3. In selecting a category, when a technology has relevance to two or more categories under a component and the assignment cannot be made using rules 1 or 2, the technology is assigned to 'Other.' For example, an electrode technology used to produce neural stimulation in the brain for *cognitive* and *motor impairments* would not be assigned to the *Body Function and Structure Component* and *Cognitive* category or the *Neuromuscular* category, but instead would assigned to the *Other* category.

Table 11
ICF-Based Classification Scheme: Environmental Factors

ICF Domains	ATD Categories
Products or substances for personal consumption	Consumption
Products and technology for personal use in daily living	Independent Living
Products and technology for personal indoor and outdoor mobility and transportation	Mobility
Products and technology for communication	Communication
Products and technology for education	Education
Products and technology for employment	Employment
Products and technology for culture, recreation and sport	Recreation
Products and technology for the practice of religion and spirituality	Religion
Design, construction and building products and technology of buildings for public use	Public Building Access
Design, construction and building products and technology of buildings for private use	Private Building Access
Products and technology for land development	Lands
Assets	Financial
Products and technology, other unspecified	Other

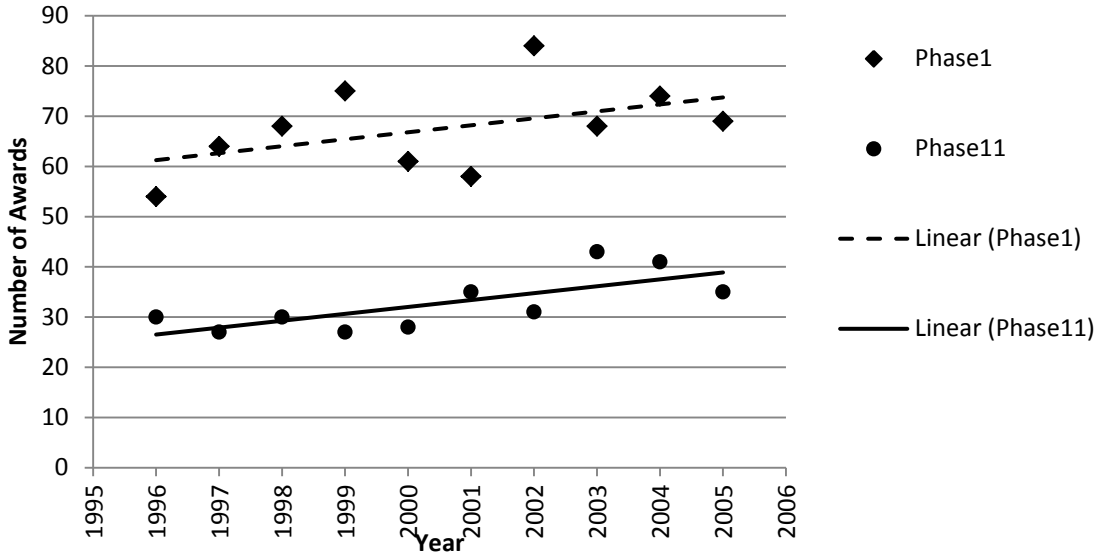

Figure 1. SBIR Phase I and Phase II awards for ATD development (1996-2005).

Results

For the 10-year period 1996 through 2005, more than 22,354 SBIR grant abstracts (16,764 Phase I; 5,590 Phase II) and more 1,717 STTR grant abstracts (1,453 Phase I; 264 Phase II) were reviewed. The SBIR and STTR grant records were found in eight federal databases (see Table 12). Awards meeting the inclusion criteria for ATD were classified using the ICF-based taxonomy.

In the Microsoft® Access© database, yearly NIH Phase I sub-contracts (for the same Phase I award) were aggregated into single Phase I awards. Yearly NIH Phase II sub-contracts (for the same Phase II award) were similarly treated. Rare NSF Phase Ia, IIa, or IIb awards were aggregated with the corresponding NSF Phase I or Phase II award. A Phase I award from one agency

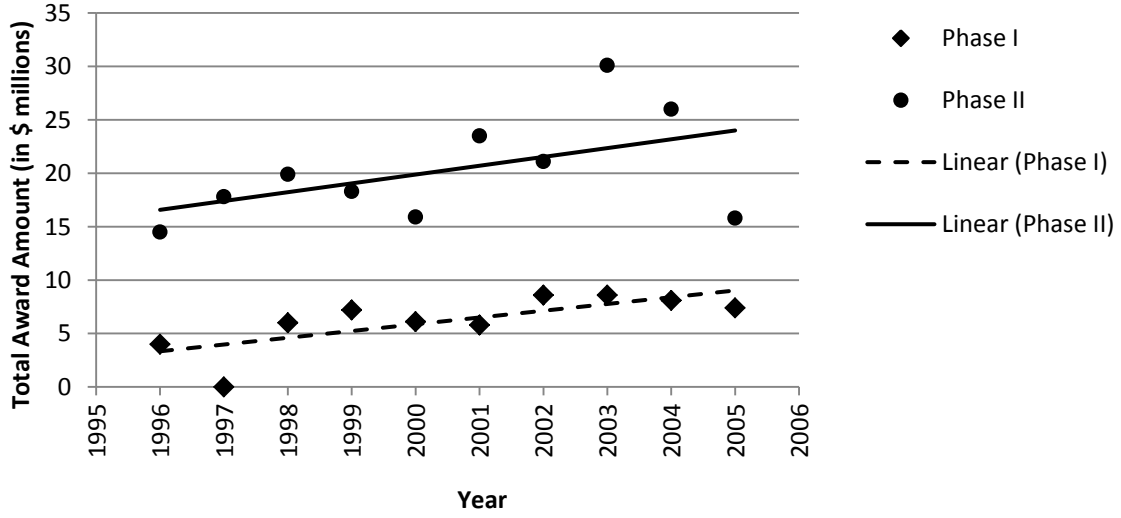

Figure 2. SBIR Phase I and Phase II funding for ATD development (1996-2005).

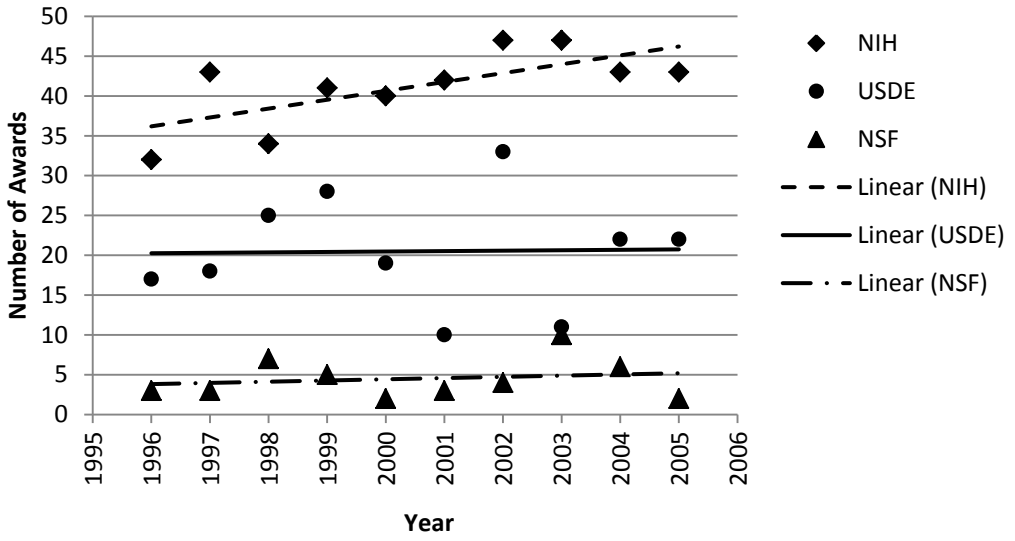

Figure 3. Number of Phase I SBIR awards by agency for ATD development (1996-2005).

followed by a Phase II award from another agency was counted against each agency's numbers and amounts.

All data including award year, number of awards, type of award (SBIR, STTR), Phase (I, II) and grant size pertain specifically to SBIR and STTR grants to small businesses for the purpose of ATD development and commercialization.

SBIR Award Data

From 1996 through 2005, five federal agencies (NIH, USDE, NSF, USDA, and DOT) awarded 675 SBIR Phase I and 329 SBIR Phase II grants to small businesses supporting the development of ATDs. The total value of SBIR Phase I grants and SBIR Phase II grants was $68.3 million and $202.2 million respectively. For these agencies, SBIR Phase I and Phase II grants for ATD development constituted 4.0% of all SBIR Phase I grants (675 of 16,764) and 5.9% all SBIR Phase II grants (329 of 5,590) respectively. The number of Phase I and Phase II awards generally grew from 1996 through 2005 (see Figure 2).

Funding of SBIR Phase I and Phase II grants for ATD development included $68.3 million for all Phase I SBIR grants and $202.2 million

Table 12
Awards and Funding for ATD Development by Agency and by Year (1996-2005)

SBIR Awards	Federal Agency				
	NIH	USDE	NSF	USDA	DOT
N Phase I Grants	414	206	46	8	4
Phase I Funding	$46.0 M	$12.04 M	$4.0 M	0.42 M	$0.4M
M Phase I Award	$114.08 K	$64. K	$109.6K	$70K	$100K
N Phase II Grants	220	83	20	6	0
Phase II Funding	$162 M	$ 26.2 M	$11.6M	$2.2M	$0.0M
M Phase II Award	$754.6 K	$320.1 K	$580.0K	$366.7K	$0.0K

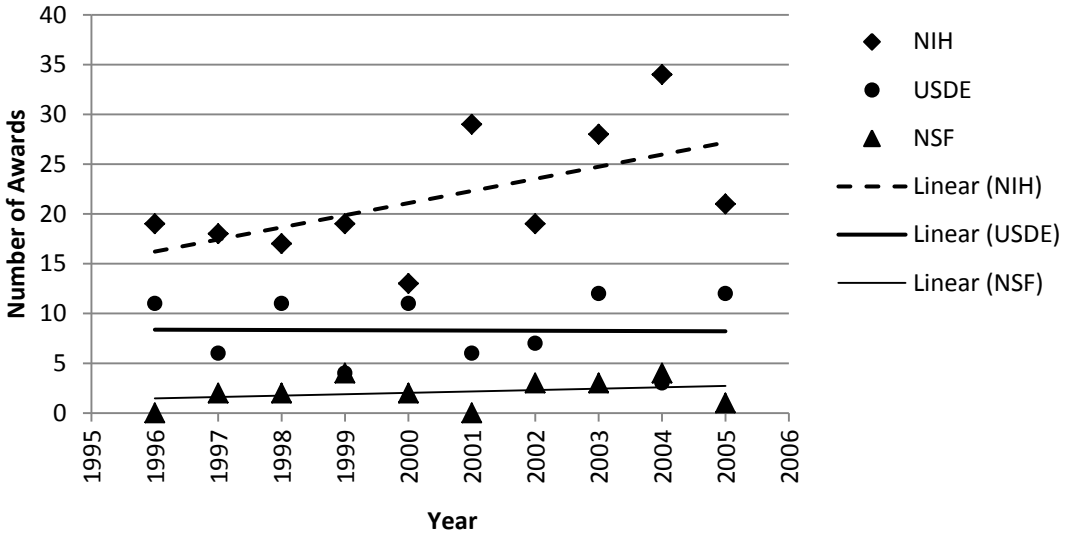

Figure 4. Number of Phase II SBIR awards by agency for ATD development (1996-2005).

for all SBIR Phase II grant. A small downturn in SBIR Phase I funding after 2002 and a sharp downturn in SBIR Phase II funding after 2003 may be taking place (Figure 3).

From 1996 through 2005, three federal agencies (NIH, USDE, and NSF) dominated in both the number of awards and total funding while USDA and DOT played minor roles (see Table 12). Across the five agencies studied, Phase I SBIR awards ($63.2 million) accounted for about 24% of all SBIR funding ($265.2 million). Phase II SBIR awards ($202 million) account for about 76% of all SBIR funding.

NIH, USDE, and NSF differ greatly in the average funding per grant. From 1996 to 2005, the ratio for NIH to USDE SBIR Phase I awards is 1.78 ($114.1 thousand/$64.9 thousand), while the ratio for NIH to USDE SBIR Phase II awards is 2.4 ($754.6 thousand/$320.1 thousand). The ratio for total NIH to NSF SBIR Phase I awards is

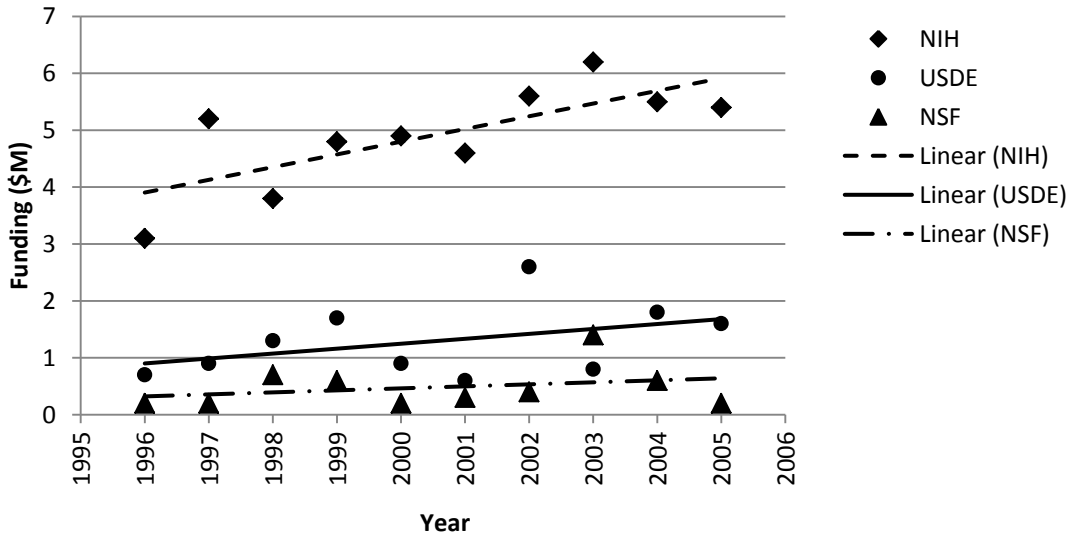

Figure 5. Phase I SBIR funding by agency and year for ATD development (1996-2005).

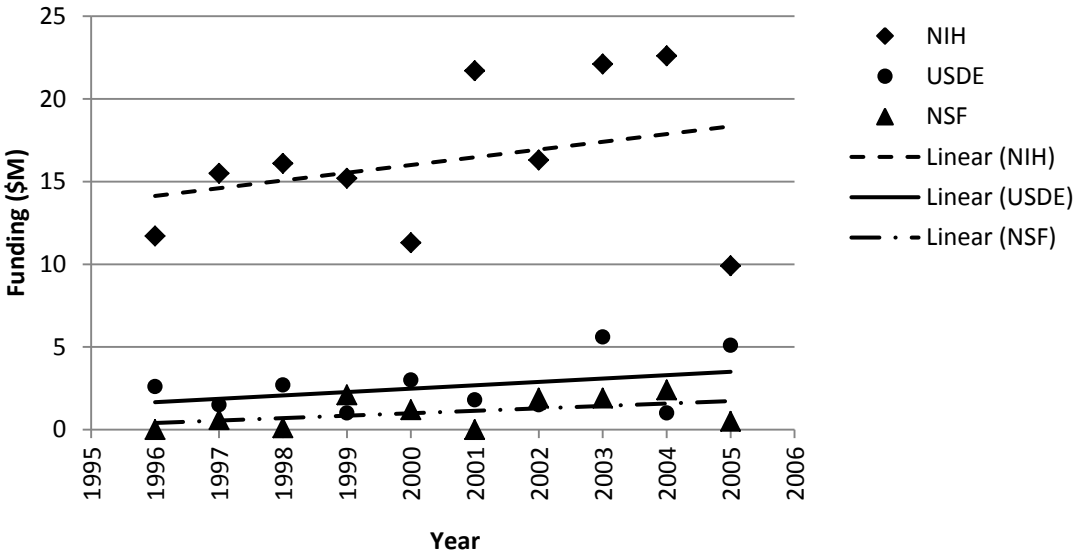

Figure 6. Phase II SBIR funding by agency and year for ATD development (1996-2005).

1.04 ($114.08 thousand/$109.6 thousand), while the ratio for NIH to NSF SBIR Phase II awards is 1.3 ($754.6 thousand/$580.0 thousand).

Phase I SBIR grants are typically used to demonstrate a 'proof of concept' for an innovative product or technology prototype. Across the five agencies studied, from 2003 to 2005 small ATD businesses received 68, 74, and 69 Phase I SBIR grants totaling $8.6 million, $8.1 million, and $7.4 million respectively (see Figure 4).

Phase II grants are typically used to establish commercial viability and to initiate development of a 'proof of product.' Across the five agencies studied, from 2003 to 2005 small businesses received a total of 43, 41, and 35 Phase II SBIR awards worth $30.05 million, $26.0 million, and $15.8 million respectively. The large drop in 2005 Phase II SBIR funding reflects a drop in the number of NIH awards from 34 (2004) to 21 (2005) and NSF awards from 4 (2004) to 1 (2005). An increase in the number of USDE awards from 3 (2004) to 12 (2005) could not compensate for these losses (see Figure 5).

Phase I SBIR award trends are shown in Figure 6. As expected, NIH clearly dominates SBIR Phase I funding after 1995.

Phase II SBIR award trends are shown in Figure 7. A precipitous drop in NIH Phase II SBIR funding occurs from 2004 (about $23.5 million) to 2005 (about $9.9 million).

Table 12
Ratio of Phase II / Phase I Awards

SBIR Awards	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
N Phase I	606	369	184	43	6	4
N Phase II	272	177	69	20	6	0
Phase II / Phase1 Ratio	0.45	0.48	0.38	0.45	1	0.00

Table 13
Number of Phase I and Phase II SBIR Awards by ICF Component and Agency

ICF Component	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
	Phase I/II	I/II	I/II	I/II	I/II	I/II
BFS	100/44	92/40	3/2	5/2	0/0	0/0
Activity	152/73	113/63	29/9	9/0	1/1	0/0
Participation	350/183	180/102	138/60	27/18	4/3	1/0
Context	75/31	28/16	36/12	5/1	3/2	3/0
Totals	678/331	414/221	206/83	46/21	8/6	4/0

We have seen that USDE Phase II SBIR grants are significantly smaller than NIH and NSF Phase II SBIR grants. Another important consideration for small businesses is the likelihood of winning a Phase II award subsequent to winning a Phase I award. NIH has the highest ratio of Phase II winners to Phase I winners (Table 12). On average, an NIH SBIR Phase I award winner was 1.3 and 1.2 times more likely to win a subsequent Phase II award than a USDE or NSF SBIR Phase I award winner.

Almost all SBIR Phase II grants are awarded one year after the corresponding SBIR Phase I grant. In Table 12, SBIR Phase I grants are totaled from 1996 through 2004 and SBIR Phase II grants are totaled from 1997 through 2005. For these timeframes, the ratio of Phase II to Phase I award winners for NIH is 52.7% (218/414), for NSF is 45.6% (20/46) and for USDE is 40.8% (84/206).

The distribution of Phase I and Phase II SBIR awards was further broken down by agency and component (see Table 13). The component level ratios of Phase II to Phase I award winners were BFS 44% (44/100), *Activity* 48.0% (73/152), *Participation* 52.6% (184/350), and *Context* 41.3% (31/75). Across agencies, Phase I SBIR awards funded the development of ATD for BFS 14.7% (100/678), *Activities* 22.4% (152/678), *Participation* 51.6% (350/678) and *Context* 11.1% (75/678). By agency, Phase I SBIR awards were distributed NIH 61.1% (414/678), USDE 30.4% (206/678), NSF 6.8% (46/678), USDA 1.2% (8/678), and DOT 0.6% [4/678]. Similarly, Phase II SBIR awards were distributed NIH 66.8% (223/334), USDE 25.1% (83/331), NSF 6.3% (21/331), USDA 1.8% (6/331), and DOT 0.0% (0/331).

The percentage of Phase I SBIR awards by ICF component and agency is given in Table 14. The NIH funding pattern is *Participation* (44%) > *Activity* (27%) > BFS (22%) > Context (7%). The NSF has a similar pattern of *Participation* (59%) > *Activity* (20%) > BFS

Table 14
Percent of Phase I Awards by ICF Component and Agency

ICF Component	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
BFS	0.15	0.22	0.01	0.11	0.00	0.00
Activity	0.22	0.27	0.14	0.20	0.13	0.00
Participation	0.52	0.44	0.67	0.59	0.5	0.25
Context	0.11	0.07	0.17	0.11	0.38	0.75

Table 15
SBIR Phase I & Phase II Awards by Agency and by BFS Domain.

Body Function & Structure	Federal Agencies					
	Total	NIH	NSF I / II	USDE	DOT	USDA
	Phase I / II	I / II		I / II	I / II	I / II
Cognition	7/2	5/1	1/0	1/1	0	0
Communication	2/1	2/1	0	0	0	0
Cardiovascular & Respiratory	27/16	26/15	0	1/1	0	0
Digestive	2/1	2/1	0	0	0	0
Genitourinary	9/3	9/3	0	0	0	0
Neuro-Musculoskeletal	18/4	17/4	1/0	0	0	0
Sensory (Blind)	2/0	2/0	0	0	0	0
Sensory (Deaf)	7/3	7/3	0	0	0	0
Sensory (Impaired Hearing)	2/1	2/1	0	0	0	0
Sensory (Impaired Vision)	2/2	2/2	0	0	0	0
Other	22/11	18/9	3/2	1/0	0	0
Total	100/44	92/40	5/2	3/2	0/0	0/0

(11%) = *Context* (11%). The USDE has a significantly different funding pattern of *Participation* (67%) > *Context* (17%) > *Activity* (14%) > *Body Function and Structure* (1%). Presumably component level funding patterns are signatures of each agency's mission.

Similar agency funding patterns (e.g., NIH, NSF) may still be differentiated at the category level. In Tables 15 through 18 SBIR awards are classified under one of four ICF components and further sub-classified into categories. There were a total of 100 Phase I awards and 44 Phase II awards for the development of ATD for *Body Function and Structure* (Table 15). NIH funded 92% (92/100) of Phase I awards and 91% (40/44) of Phase II awards with USDE and NSF making minor contributions.

Categories accounting for 67% (67/100) of all Phase I SBIR awards were cardiovascular-respiratory 27% (27/100), "other" 22% (22/100) and neuro-musculoskeletal 18% (18/100). 20 of twenty-two "other" Phase I SBIR awards funded the development of electrode technology with applications across multiple categories (e.g. sensory [*], cognitive, CVR, DE, GU, and NMS).

There were a total of 152 Phase I SBIR awards and 76 Phase II SBIR awards for the development of ATD for *Activity* (see Table 16). NIH is the dominant funding source with 74% (113/152) of Phase I SBIR awards and 84% (64/76) of Phase II SBIR awards. Of lesser importance, USDE and NSF provided 19% (29/152) and 6% (9/152) of Phase I awards and 13% (10/76) and 1% (1/76) of Phase II awards.

Categories accounting for 65% (98/152) of all Phase I SBIR awards were mobility 27% (41/152), prosthesis 24% (37/152) and communication 13% (20/152). The USDE is a significant Phase I and Phase II funding source for mobility products 26.8% (11/41) and 24% (5/21) respectively. Finally, 0% (0/10) of NSF Phase I SBIR awardees were successful in winning a Phase II SBIR award.

There were a total of 350 Phase I SBIR awards and 180 Phase II SBIR awards for the development of ATD for *Participation* (see

Table 17). Categories accounting for 73% (254/347) of all Phase I SBIR awards were deaf 17% (60/350), cognitive 26% (91/350), blind 14%(49/350), health 14%(49/350), and access 12.1% (43/347). NIH and USDE dominate funding with 51% (180/350) and 39.7% (139/350) of Phase I SBIR awards and 56% (101/180) and 32.7% (59/180) of Phase II SBIR awards respectively. Of lesser importance, NSF provided 7.7% (27/350) of Phase I SBIR awards and 9.4% (17/180) of Phase II SBIR awards.

NIH and USDE funding patterns have apparent differences at the category level. NIH and USDE categories with at least 10 Phase I SBIR awards are listed in descending rank order with uncommon components bolded.

- NIH: **health** (42), cognitive (51), deaf (23), blind (15), **mobility** (11), **hearing** (11), **vision** (10), other (0)
- USDE: cognitive (37), deaf (33), blind (25), other (0), **employment** (13), **education** (13)

NIH is the primary funding source for the development of products for Participation in health management, mobility, hearing, and vision. USDE is the primary funding source for the development of products for *Participation* in education and employment. Jointly, NIH and USDE are primary funding sources for the development of *Participation* based products for cognitive impairment, deafness, access, and blindness

There were a total of 75 Phase I SBIR awards and 31 Phase II SBIR awards for the development of ATDs for *Context* (see Table 18). USDE and NIH dominate funding with 48% (36/75) and 37.33% (28/75) of Phase I SBIR awards and 39% (12/31) and 48% (15/31) of Phase II SBIR awards respectively. Categories accounting for 81% (63/77) of all Phase I SBIR awards were communication 18.67% (14/75), other 18.67% (14/75), mobility 14.66% (11/75), education 14.67%

Table 16
SBIR Phase I (II) Awards by Agency and by Activity Categories

Activity	Federal Agencies					
	Total Phase I/ II	NIH I/ II	NSF I/ II	USDE I/ II	DOT I/ II	USDA I/ II
Cognition	9/4	5/3	0	4/1	0	0
Communication	20/8	17/6	0	3/2	0	0
Education	0	0	0	0	0	0
Employment	0	0	0	0	0	0
Health	2/2	2/ 2	0	0	0	0
Independent Living	0	0	0	0	0	0
Mobility and Seating	41/21	29/16	2/0	11/5	0	0
Prosthetics and Orthotics	37/15	28/14	5/0	4/1	0	0
Sensory (Blind)	12/3	7/3	2/0	3/0	0	0
Sensory (Deaf)	3/2	1/1	0	1/0	0	1/1
Sensory (Impaired Hearing)	12/7	11/7	1/0	0	0	0
Sensory (Impaired Vision)	16/11	13/11	0	3/ 0	0	0
Other	0/0	0/0	0	0	0	0
Total	152/73	113/63	10/0	29/9	0/0	1/1

(11/75), and employment 14.67% (11/75).

NIH and USDE funding patterns have apparent differences at the category level. NIH and USDE categories with at least 10 Phase I SBIR awards are listed in descending rank order with uncommon components bolded.

- USDE: **employment** (10), **education** (9), other (7)
- NIH: **communication** (10), **mobility** (7), other (5)

The USDE is the primary funding source for the development of Context-based products for employment and education. NIH is the primary funding source for the development of Context-based products for communication and mobility. Jointly, NIH and USDE are primary funding sources for the development of Context-based products for 'other.' Other includes awards that cannot readily be matched to a single Context/Environment description.

STTR Award Data

Of the five agencies studied, only NIH and NSF have STTR programs. Relative to their SBIR programs NIH and NSF provide few STTR awards for the development of ATDs. For both agencies, 1996 through 2005 there were a total of 29 Phase I STTR grants (see Table 19) with funding of $3.1 million and 10 Phase II STTR grants with funding of $5.7 million were identified (see Table 20).

For all components, the number of Phase I and Phase II STTR awards is very small relative to Phase I and Phase II SBIR awards. Almost half (13/29) of all Phase I STTR grants and half (5/10) of all Phase II STTR grants were for the development of ATDs for *Participation*.

The NIH and NSF STTR programs constitute 0.3% of their respective extramural research budgets. The NIH, NSF, USDE, DOT and

Table 17
SBIR Phase I (II) Awards by Agency and by Participation Categories

Participation	Federal Agencies					
	Total Phase I/II	NIH I/II	NSF I/II	USDE I/II	DOT I/II	USDA I/II
Cognition	91/41	51/22	3/2	37/17	0	0
Communication	11/5	5/3	3/0	3/0	0	0
Education	25/19	7/8	3/2	15/9	0	0
Employment	14/5	1/1	0	13/4	0	0
Health	49/34	42/30	2/1	4/2	0	1/1
Independent Living	6/4	3/3	0	1/0	0	2/1
Sensory (Blind)	49/27	15/9	9/5	25/13	0	0
Sensory (Deaf)	60/23	23/8	4/3	33/12	0	0
Sensory (Impaired Hearing)	17/10	11/6	2/2	4/2	0	0
Sensory (Impaired Vision)	13/7	10/7	1/0	2/0	0	0
Mobility and Seating	13/3	11/3	0	1/0	1/0	0
Prosthetics and Orthotics	1/1	1/1	0	0	0	0
Other	1/1	0/5	0/0	0/1	0	1/0
Total	350/180	180/101	27/17	138/59	1/0	4/3

Table 18
SBIR Phase I (II) Awards by Agency and by Context Categories

Context	Federal Agencies					
	Total	NIH	NSF	USDE	DOT	USDA
Private Building Access	1/1	1/1	0	0	0	0
Public Building Access	2/1	1/1	1/0	0	0	0
Communication	15/8	10/6	1/0	4/2	0	0
Consumption	0	0	0	0	0	0
Independent Living	2/0	1/0	0	1/0	0	0
Education	11/4	2/1	0	9/3	0	0
Employment	11/4	0	1/1	10/3	0	0
Financial	0	0	0	0	0	0
Lands	8/5	1/2	0	3/1	1/0	3/2
Mobility	11/3	7/2	0	2/1	2/0	0
Recreation	1/0	1/0	0	0	0	0
Religion	0	0	0	0	0	0
Other	14/5	5/3	2/0	7/2	0	0
Total	75/31	28/15	5/1	36/12	3/0	3/2

USDA SBIR programs constitute 2.5% of their respective extramural research budgets. For all years of this study, STTR Phase I and Phase II grants are normally smaller than corresponding SBIR Phase I and Phase II grants (see Table 21). Naively we would expect eight or fewer SBIR Phase I (Phase II) grants for ATD development for each STTR Phase I (Phase II) grant. Instead there are 23.2 (675/29) Phase I SBIR grants for each Phase I STTR grant and 22.7 (227/10) Phase II SBIR grants for each Phase II STTR grant.

Discussion

SBIR and STTR programs should be ideal funding sources for product development by small ATD manufacturers. A 2003 Department of Commerce study found that only 52 (13%) of 349 small ATD manufacturers participating in the study had submitted one or more SBIR proposals during the period 1997-1999. The DOC study employed opportunistic sampling and many types of ATD manufacturer (with respect to the ICF-based classification system) were underrepresented. Roughly one in eight Phase I SBIR proposals are funded, so the DOC findings suggest that very few small ATD manufacturers may compete for and win SBIR and STTR grants.

Table 19
STTR Phase I Awards by Component

STTR	Year										
Phase I	96	97	98	99	00	01	02	03	04	05	Totals
BFS	0	0	1	0	2	1	1	0	1	0	6
Activity	1	0	1	0	0	1	0	2	2	1	8
Participation	1	2	0	0	0	2	1	1	2	4	13
Context	0	0	0	0	1	0	0	0	1	0	2
Total	2	2	2	0	3	4	2	3	6	5	29

Table 20
STTR Phase II Awards by Component

STTR Phase II	Year										
	96	97	98	99	00	01	02	03	04	05	Totals
BFS	1	0	0	0	0	0	2	0	0	0	3
Activity	0	1	0	0	0	0	1	0	0	0	2
Participation	0	0	0	1	0	1	0	2	1	0	5
Context	0	0	0	0	0	0	0	0	0	0	0
Total	1	1	0	1	0	1	3	2	1	0	10

For the five agencies and timeframes considered, this current study establishes that the NIH and the USDE are the predominant sources of SBIR funding for ATD development. The NIH is the leading STTR funding source for ATD development. Across the five agencies studies, funding for ATD development constituted about 4.0% of all Phase I SBIR funding and 5.9% of all Phase II SBIR funding. At the component level, the NIH is the leading funder of ATD development for *BFS*, *Activity*, and *Participation*. The USDE is the leading funder for ATD development for *Context* and a secondary, but important, funding source for ATD development for *Activity* and *Participation*. The NSF (not the USDE) is (a minor), but secondary, funding source for ATD development for *BFS* and is the tertiary funding source for ATD development corresponding to the other three components. The DOT and the USDA provide little funding for ATD development. However, at the category level, these agencies may still have an important funding role. For example, the USDA was the only SBIR funder for ATD development for the Context component and public lands category.

The current study could not have been done without defining inclusion and exclusion criteria for ATDs, a detailed and comprehensive classification system for assistive technology, and assignment heuristics. The Assistive Technology Act and the Americans with Disabilities Act were used to define the inclusion and exclusion criteria. The International Classification System of Functioning, Disability and Health provided the framework for the ATD classification system. Assignment heuristics are based upon an ATD's integration, customization, role, and context of use. Using these assignment heuristics each SBIR and STTR award could

Table 21
Comparison of STTR and SBIR Awards by Phase

Program/Phase	Year										
	96	97	98	99	00	01	02	03	04	05	Totals
SBIR/Phase I	54	64	68	75	61	58	84	68	74	69	675
STTR/Phase I	2	2	2	0	3	4	2	3	6	5	29
Phase I Ratio	.037	.031	.029	0	.049	.069	.024	.044	.081	.072	.043
SBIR Phase II	29	27	30	27	28	35	31	43	40	35	325
STTR Phase II	0	1	0	1	0	1	3	2	2	0	10
Phase II Ratio	0	.037	0	.037	0	.029	.097	.047	.050	0	.031

be placed (in principle) into a unique component and category. The ICF-based classification system while not perfect (e.g., the "other" category though rarely used was required for each component) is a major outcome of the current study.

SBIR and STTR programs are subject to federal oversight by the U.S. DOC SBA and the U.S. Congress's General Accountability Office (GAO). SBIR programs have also been the subject of large studies by the National Academies of Science as required by the Small Business Innovation Research Act. However, the SBA and GAO reports, and NAS studies provide no information pertaining to ATD small businesses use of the SBIR and STTR programs or ATD development with SBIR or STTR support. The current paper reports the only large, systematic study of SBIR and STTR support for ATD development.

The Small Business Innovation Research Act (P.L. 97-219) requires (since 1997) that large federal agencies set aside 2.5% (2.0% in 1996) of their extramural research budgets for grants to small businesses. The Small Business Technology Transfer Act (P.L. 102-564) requires that large federal agencies set aside 0.3% of their extramural research budgets for grants to range of collaborations that include universities, research hospitals, and other entities in partnership with small business. For the period and agencies studied, total SBIR funding was $270.2 million and total STTR funding was $8.8 million.

Over the period and agencies studied, ATD manufacturers received 675 Phase I awards and 329 Phase II SBIR awards and 29 Phase I and 10 Phase II STTR awards. Across the five agencies studied for 2003 to 2005, the three most recent years of this study, ATD small businesses averaged 70 SBIR Phase I awards per year and 40 SBIR Phase II awards per year. Data collected in the NRC study suggest that about half of small businesses receiving a Phase II awards ultimately commercialize a product. Assuming that these results can be extended to Phase II SBIR grants that support ATD development and commercialization then these five programs supported the commercialization of about 20 products per year (Wessner, 2007d).

Five non-acquisition-based SBIR programs (NIH, USDE, NSF, DOT, and USDA) and two non-acquisition STTR programs (NIH, NSF) were evaluated. The NIH and NSF have the second- and fifth-largest SBIR programs. We conjecture that non-acquisition-based SBIR and STTR programs are more likely to fund ATD development (products that satisfy a market need) than acquisition-based SBIR and STTR programs (products that satisfy agency needs that are unlikely to involve ATDs). This conjecture should be validated (or refuted) in future studies.

Among the five agencies studied, the USDE has the smallest SBIR program, much smaller than the NIH or NSF SBIR programs and smaller than, but roughly comparable to, the USDA and DOT SBIR programs. For example, in 2005 these agencies had outlays for ATD development through their SBIR programs of $15.3 million (NIH), $0.7 million (NSF), $6.7 million (USDE), $1.2 million (USDA), and $0 million (DOT). Nonetheless, the USDE is second only to the NIH in terms of the total number and funding for Phase I and Phase II SBIR awards. This can reasonably be explained as an alignment between the USDE/NIDRR mission statement (with its focus on meeting the needs of individuals with disabilities) and the USDE/NIDRR mission statement. The mission statements for the four other agencies lack such a focus.

During the study period, Phase I SBIR awards (about 60%) amounting to $46 million came from the NIH. Phase I SBIR awards (about 30%) amounting to $12 million came from

the USDE. The majority of Phase II grants (about 68%) amounting to $162 million came from the NIH. A significant portion of Phase II grants (about 23%) amounting to $26 million came from the USDE. Accounting for over 90% of Phase I and Phase II SBIR grants and funding, the NIH and the USDE are critical SBIR sources of funding for ATD development. Any diminishment of SBIR funding by either agency is likely to have a large and negative impact on ATD development.

Approximately 51% (estimating the number of out-year Phase II SBIR awards) of Phase I awardees were successful in winning a Phase II grant. For ATD manufacturers successful in winning both a Phase I and Phase II SBIR grants, 53% of the Phase II grants occurred one year subsequent to the Phase I award, while 47% of the Phase II grants occurred two or more years after the Phase I grant.

At the component level for SBIR Phase I awards, the NIH is the primary funder for ATD development. Across the four components, NIH provided 61.06% (414/678 awards) of all Phase I SBIR awards. The NIH is an especially important funder for *Body Function & Structure* at 92% (92/100 awards) and *Activity* at 74.3% (113/152 awards). The NIH at 51.4% (180/350 awards) and the USDE at 39.4% (138/350 awards) are (roughly) co-leading funders for *Participation*. The USDE at 48.0% (36/75 awards) and the NIH at 37.3% (28/75 awards) are (roughly) co-leading funders for *Context*. The USDE is not important as a SBIR Phase I funder for *Body Function and Structure* at 3% (3/100 awards). The NSF is the second-most important Phase I SBIR funder for *Body Function & Structure* at 5% (5/100 awards) and the third-most important funder for *Activity* at 5.9% (9/152 awards) and *Participation* at 7.7% (27/350 awards). On face, the ICF-based classification system and assignment heuristics differentiated agency portfolios at the component level.

At the category level, 66.3% (61/92) of NIH Phase I SBIR awards for *Body Function and Structure* were cardiovascular and respiratory (26), other (18), or neuro-musculoskeletal (17). The eight remaining *BF&S* categories included the remaining NIH Phase I SBIR awards totaling 34% (31/92). The NIH and the USDE Phase I SBIR funding patterns for *Participation* at the category level show both similarities and differences. For similarities, the NIH and the USDE have at least 10 awards for the categories cognitive, deaf, other, and blind. For differences, the NIH and the USDE have at least 10 awards for the categories health, vision, mobility, and hearing. On face, the ICF classification system and assignment heuristics differentiated the NIH and the USDE portfolios at the category level.

ATD development through the NIH and the NSF, SBIR, and STTR programs was compared. On face, the STTR programs had too few awards (29 Phase I, 10 Phase II) to warrant examination at the category level. At the component level, there are 23.27 (675/29) Phase I SBIR grants for each Phase I STTR grant and 32.5 (325/10) Phase II SBIR grants for each Phase II STTR grant. These ratios are much lower than one might (naively) expect based upon the relative size (8.1:1) of the SBIR and STTR programs. Additional research is needed to determine why the STTR program is a relatively underutilized funding source for ATD development. Possible explanations range from barriers that deter ATD small businesses from pursuing STTR funding, to barriers that deter STTR programs from awarding grants to ATD small business applicants.

The current study has a number of limitations. The inclusion/exclusion criteria, classification system, and assignment heuristics should

uniquely classify all ATD-related awards and this was not always the case. For example, implantable electrodes were necessarily placed into the *Body Function and Structure* component and "other" category because these electrodes had applications in two or more categories. Across the four components, 37 ATD Phase I and 17 ATD Phase II SBIR awards were placed into an "other" category constituting 5.5% of all Phase I and 5.1% Phase II awards classified.

There are many applications for the ICF-based classification system. More work must be done to ensure that the classification system is valid and reliable. Applications include documenting ATD transferred from the federal laboratory system to the private sector via cooperative research and development agreements, license agreements and material transfer agreements (as required by the Stevenson-Wydler Act of 1980). A second application is the classification of ATDs transferred from U.S. universities to the private sector via license agreements and related mechanisms.

The current study lays the groundwork for future research. Issues to resolve by this research include: Why do so few ATD small businesses use the SBIR and STTR programs? For those ATD small businesses using SBIR and STTR programs, what is the rate of success obtaining follow-on funding, obtaining additional SBIR and STTR grants, and commercializing products? How do these rates compare to overall SBIR and STTR program rates? Why is the STTR program particularly underused by ATD manufacturers? What barriers hinder the use of the SBIR and STTR programs by ATD manufacturers? What can be done by the federal government, federal agencies, ATD manufacturers, and other entities (such as ATIA) to reduce barriers and encourage participation by ATD manufacturers? How do funding trends evolve and what implication does this have for ATD product development?

Conclusion

This study evaluated SBIR and STTR funding portfolios pertaining to ATD development and commercialization. To facilitate analysis, an ICF-based classification system was developed and employed throughout this study. Analysis included SBIR and STTR awards by agency, type, phase, year, funding level, agency mission, cross-agency comparisons, and longitudinal trends. Five non-acquisition-based SBIR programs (NIH, NSF, USDE, USDA, and DOT) and two non-acquisition-based STTR programs (NIH and NSF) were evaluated for the period 1996-2005. No similar or related study of ATD development with SBIR and STTR funding has been conducted.

Ultimately, federal public policy makers have the authority to set funding priorities for federal agencies, and to determine whether allocations for ATD development (4.0% of Phase I SBIR and 5.9% of Phase II SBIR grant dollars) and portfolio mix (at the component and category levels) are consistent with national priorities and interests.

This study and earlier studies by the National Research Council suggest that public policy makers lack critical data and constructs necessary to evaluate current SBIR and STTR programs, and to provide oversight and guidance to the agencies managing these programs. It is reasonable to expect that federal oversight is especially problematic for large, complex SBIR and STTR programs (especially DOD, NIH, DOE, NASA, and NSF). Lacking strong oversight, federal agencies are free to establish priorities and develop award portfolios independent of (not necessarily at odds with) national priorities and interests.

For federal policy makers to provide effective oversight, at least four issues must be addressed. First, a single, universal classification system must be developed. This classification system should have sufficient breadth, detail, clarity, reliability, intuitive appeal, ease of learning, and ease of use to reasonably distinguish or aggregate, (somehow) dissimilar or similar product types. The ICF-based classification system developed in this study along with its inclusion and exclusion criteria and assignment rules could serve as a model for this broader classification system. The authors recognize the challenge of such an undertaking but believe that this step is critical.

Second, all federal agencies must be required to use this classification system when stating their missions and priorities, describing award portfolios and when reporting grants and grant outcomes. By doing so, federal policy makers and federal agencies (interactively) can compare, contrast and adjust agency priorities and portfolios to better address national priorities and interests. Adjustment of agency priorities and portfolios might reduce funding redundancies and inadequacies and improve the overall effectiveness of the SBIR and STTR programs across agencies. By reviewing agency funding allocations, priorities, and portfolios, small businesses will know which SBIR and STTR programs are the most suitable funding sources.

Third, all small businesses receiving an SBIR or STTR grant (Phase I or Phase II) must be required to report Phase III (commercialization) outcomes. The NRC SBIR program studies provide a useful breakdown for 'types' of revenue generation. Establishing return on investment is critical for properly 'sizing' the SBIR and STTR programs. Commercialization outcomes mapped against the classification system would further guide federal public policy decisions and agency level program management.

Fourth, all SBIR and STTR performance data must be available from one entity through a single online web interface and database. The logical candidate for this entity is the U.S. DOC, Small Business Administration. The logical tool for the online web interface and database is an enhanced version of TechNet. All agencies must collect the same information and provide this information in a timely manner to the SBA (or equivalent). Currently, SBIR and STTR program outcomes are placed in distributed, partially redundant databases; include disparate, incomplete and dated information; and are accessed through search engines with inconsistent functionality. Lack of access to complete and consistent SBIR and STTR program outcomes creates a huge barrier to federal oversight, agency management, and academic research.

The current Small Business Innovation Research Act (P.L. 106-554) expired March 20, 2009 and Congress is now funding SBIR programs under a continuing resolution while house and senate business committees try to compromise their differences. Important issues to be resolved include: (a) the percentage of extramural funding allocated to SBIR programs, (b) small business ownership (by venture capitalists, by other U.S. companies); (c) recommended Phase I and Phase II grant size; and (d) funding allocation between Phase I and Phase II (SBIR Insider Newsletter, 2009).

With many details omitted, increasing total funding available through SBIR programs will (in principle) benefit ATD small businesses. Most ATD small businesses are not (and are not likely to be) owned by venture capitalists or to be subsidiaries of other U.S. companies. As a consequence, broadening the definition of 'small business owner' in either manner is

likely to increase competition for SBIR funding to the disadvantage of ATD small businesses.

Current Phase I grants are too small to substantially underwrite technology development and product commercialization activities. However, Phase II grants can have a major impact on the outcome of development and commercialization activities. It is reasonable to conjecture that larger Phase II grants would allow small businesses to take on greater risk and increase the rate of successful commercialization. However, ATD small businesses with promising Phase I outcomes are more likely to be rewarded with a Phase II award. The optimal balance between the size and allocation of Phase I and Phase II awards is not readily apparent at this time.

The current study provides a basis for future research. Such research might include: commercialization rates and revenue generation by ATD small businesses developing ATDs with SBIR and STTR funding; use (to include barriers and facilitators) of SBIR and STTR programs by small ATD businesses; the economic impact of SBIR and STTR funding (on the small ATD business, for the broader society); and the extension of all studies to acquisition-based SBIR and STTR programs. Finally, the impact of (particularly the changes to) the reauthorized SBIR Act on ATD development should be subject to study.

Study results will be broadly available to public policy makers, SBIR and STTR program managers, academics, small businesses and consumer advocates through the online peer-reviewed journal, Assistive Technology Outcomes and Benefits and abstracted and linked from the National Rehabilitation Information Center (n.d.). Finally, results will be shared with the Interagency Committee on Disability Research (ICDR), a leadership forum for federal agencies (Interagency Committee on Disability Research, n.d.).

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