



Executive Summary
for the
**Biomedical Entrepreneurial
Science Working Group**

August 1, 2003
Bethesda, Maryland





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Executive Summary

Introduction

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) supports both the development of novel technologies and the subsequent translation of those technologies into applications for the benefit of public health. Congressional legislation mandates that the NIBIB “facilitate the transfer of technologies to medical applications.” In accordance with this mandate, the Biomedical Entrepreneurial Science Working Group was held on August 1, 2003 in Bethesda, Maryland, to attain specific recommendations regarding the role of the NIBIB in the translation of fundamental discoveries and innovative research into biomedical applications.

Session I: Current Government Practices

Throughout the many years of government-supported research, several barriers to technology transfer have arisen. Government funding agencies have, in turn, employed various strategies to overcome these obstacles, achieving the successful commercialization of emerging technologies. Current government practices include special funding mechanisms, academic-industrial partnership programs, and interagency collaborations.

The federal government utilizes several funding mechanisms to foster the development and commercialization of novel technologies. Many agencies employ the Small Business Innovative Research (SBIR) Program, which supports the research and development activities of small companies featuring a potential commercial product through feasibility, Phase I, and prototype development, Phase II, awards. To further enhance the success of the SBIR program, the National Institutes of Health (NIH) has recently implemented a competing continuation Phase II award that provides additional support, after the first Phase II award period, of up to \$1 million for pre-clinical research. Other mechanisms, including Phased Innovation Awards (R21/R33), center grants, and contracts, are especially effective in translating discoveries to application by stipulating the delivery of a product as a requirement of the award.

Government agencies also engage in various activities that foster partnerships between academia and industry. Establishing strong relationships between academia and industry can provide resource-leveraging opportunities, as well as invaluable business expertise to research projects. An example is a pilot program at the National Aeronautics and Space Administration (NASA), which aims to promote the early interaction of small businesses, established companies, and venture capital firms. Supporting early communication between small business investigators and experienced professionals from industry should

provide the necessary expertise to help generate market-worthy products. The National Cancer Institute (NCI) also promotes partnerships with industry. At annual investigator meetings, NIH grantees present their research, industry leaders introduce their businesses, and the parties engage in networking. A program geared for success at the NSF is Partnerships for Innovation (PFI). This recently inceptioned program provides resources for partnerships between academic institutions and industry. Collaborations with local and state government are also strongly encouraged. Partnering academic innovators, who typically lack commercialization know-how, with businesses should help promote technology transfer from academia and create more stable and lucrative businesses.

A recent study of the medical technology industry identified the Food and Drug Administration (FDA) regulatory requirements and the Center for Medicare and Medicaid Services (CMS) medical coverage and reimbursement requirements as two of the biggest hurdles affecting technology development. The Interagency Council on Medical Imaging in Oncology, organized by NCI, serves as a sounding board for investigators and manufacturers attempting to take emerging medical imaging technologies to market. This multi-agency council allows the CMS, FDA, and NIH to assist industrial developers and scientists in the commercialization process.

Session II: Barriers to Technology Transfer

Scientific knowledge and discoveries are increasing at a tremendous rate. However, efforts to translate these findings into medical applications and products are often obstructed. The most apparent barriers to technology transfer include academic culture, researchers, funding, technology transfer offices, and government hurdles.

Academic culture practiced by many university administrations and colleagues alike inhibits commercialization and hinders even experienced investigators with keen entrepreneurial vision. Many academic institutions have not fully embraced the intellectual significance and social value of facilitating the transfer of concepts and products to the user community. In an effort to change this culture, it is suggested that academic institutions seek innovative methods for engaging their research community in successfully transferring technology to the commercial sector.

The researcher is considered the driver in translating research discoveries. It is often the case that researchers know little about good business practices, lack the resources necessary to move their research into application, and are not fully aware of the implications of intellectual property. Establishing early partnerships with industry, venture capital firms, and patent attorneys is critical to effective product development.

Procuring financial support in a timely fashion is essential in sustaining technology development and becomes even more critical in transferring the technology to the market. Generally, researchers obtain funding in intervals, creating sizeable funding gaps. This problem is evident in the NIH SBIR program, where the time delay between the Phase I and the Phase II award can render a small business insolvent. Furthermore, the two phases of the SBIR award may allow an investigator to establish the feasibility of a

potential product but may not always provide the necessary resources to commercialize the product.

Despite the efforts of technology transfer offices, most universities are relatively unsuccessful at commercializing technology. This failure may be attributed to the fact that universities traditionally have not assumed the role of transferring technology into application. There is very little incentive offered to researchers who wish to take their technologies to market, and there are many issues related to intellectual property retention. Aside from the deep-rooted culture of academic research, it has been observed that technology transfer offices manage a sizeable workload with insufficient staff and with little insight from industry. Many offices have not been able to provide adequate or timely counseling to its researchers due, in part, to a lack of human resources.

Certain government practices may serve to impede technology transfer. While it has been noted that the SBIR program may not provide sufficient financial support for prospective entrepreneurs, the review of SBIR grant applications has also generated some concerns. A major issue with SBIR review practices has been the inadequate scrutiny of an application's potential for commercial success. A scientifically meritorious proposal that receives a grant award but lacks a strong and effective business plan is unlikely to be successful in commercializing a product. The FDA and CMS are also cited as major obstacles to technology transfer. As the CMS is a relatively new agency, it is intent on improving its practices to operate more efficiently with other government agencies, as well as investigators.

Session III: Entrepreneurial Education

Several academic institutions are actively creating an entrepreneurial environment for students and researchers. Implementing joint business and science programs and degrees, universities are cultivating a new breed of investigators. It is the hope that these investigators will gain the necessary business tact to become prosperous entrepreneurs. The more promising programs have established cooperatively taught courses and have promoted student interactions with industry.

With increasing emphasis on entrepreneurial education, current researchers may benefit from newly available information and resources, as well as from the burgeoning entrepreneurial spirit. Institutions are beginning to provide access to business consultants and venture capitalists and are initiating mentor programs between ex-CEOs and faculty. In addition, a cultural revolution is occurring throughout universities with successful technology transfer offices. Academic administrations are gradually being swayed to invest more effort in entrepreneurial endeavors. The result of such a top-down approach is the creation of an environment at the universities that allows for the recruitment and retention of truly entrepreneurial faculty. Commercial success is likely to be attained at universities where the faculty are proactively promoting and fostering start-up companies and where industry partnerships are prevalent.

Session IV: Role of the NIBIB

Throughout the working group, many suggestions were given regarding the role of the NIBIB in the translation of innovative research into biomedical applications. Addressing the identified barriers, participants recommended that the NIBIB focus on empowering students and researchers with entrepreneurial training opportunities and incentives, offer opportunities for researchers to establish viable industrial partnerships, and improve the grant review of technology-driven applications, all in an effort to drive research closer to market potential. In addition, it was recommended that the NIBIB consider providing information to interested parties about discoveries and innovations funded by the Institute that have market potential. Because of the broad range of technologies funded by the NIBIB, the Institute should consider developing several distinct strategies for technology transfer.

Participants specifically recommended that the NIBIB facilitate technology transfer by:

- **Empowering students and investigators with entrepreneurial training opportunities and incentives.**

Participants expressed the need for federal funding to develop entrepreneurial coursework at universities. On a smaller scale it was recommended that the NIBIB support academic programs for students and faculty that foster an entrepreneurial environment. Educating the future drivers of technology transfer may help establish a market-conscious culture in academia. Providing incentives, such as offering supplemental funding to investigators who wish to move research toward application, may also encourage commercialization. Participants recommended that the NIBIB employ funding mechanisms that require deliverables, such as contracts, cooperative agreements, and Phased Innovation Awards to generate greater success in moving novel technologies to application. Contracts and cooperative agreements would enable the NIBIB to actively assess commercial potential and include requirements for technology transfer.

- **Offering opportunities for researchers to establish viable industrial partnerships.**

Investigators who have established viable partnerships from the outset of their research with entities that aid in facilitating technology transfer have been very successful in translating technology to application. Before entering a partnership, investigators may need to determine which route to commercialization should be pursued. The NIBIB should consider creating an infrastructure to help investigators identify whether licensing to existing companies, creating a start-up company or using other avenues are the most appropriate routes to move technology from the laboratory to users.

Participants of the working group suggested that the NIBIB implement a grant mechanism encouraging investigators to collaborate with business associates, patent attorneys, and other appropriate parties in order for the investigators to gain a better perspective on the commercialization process. They also recommended that the NIBIB consider hosting regular, noncompetitive forums involving industry, academia, and federal agencies, specifically the FDA and CMS. Implementing programs and initiating forums that provide networking opportunities would enable investigators to establish necessary partnerships.

- **Improving the review of technology-driven grant applications.**

The nature of the grant review cycle at government agencies has been criticized for impeding the efficacious delivery of cutting-edge technologies to application. Thus, the NIBIB should consider testing an expedited review cycle, where there is minimal time delay between receipt of an application and award. The shorter cycle would be especially beneficial for grants proposing research with near-term application potential. The apparent funding gaps between successive grant awards, particularly in the SBIR program, might also be suppressed by a revamped review process, thus decreasing the rate of failure of small businesses. Participants indicated the perception that the current review rewards SBIR applications written to satisfy the culture of the research minded reviewers. Study Sections that review SBIR proposals should have a significant number of business-wise panelists who can comment on the likely business potential of the proposal. Reviews of SBIR proposals should have a scoring system that would explicitly value the commercial potential of the proposed work.

As the NIBIB develops strategies to address the issues surrounding technology transfer, it should continue utilizing and improving upon existing programs. Furthermore, the Institute should periodically assess the state of technology development and transfer of funded grants and should evaluate the success of its programs in this regard. Facilitating technology transfer remains a significant goal of the NIBIB, for technology cannot benefit public health until it is brought to application.



Biomedical Entrepreneurial Science Working Group
Hosted by the National Institute of
Biomedical Imaging and Bioengineering
Bethesda, Maryland
Friday, August 1, 2003

AGENDA

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|----------|---|
| 8:00 AM | Welcome
Christine Kelley and Robert Nerem |
| 8:10 AM | Introduction to NIBIB
Donna Dean |
| 8:30 AM | Session I: Current Government Practices
Moderator: Christine Kelley |
| 9:45 AM | Break |
| 10:00 AM | Session II: Barriers to Technology Transfer
Moderator: Robert Nerem |
| 11:30 AM | Lunch |
| 12:30 PM | Session III: Entrepreneurial Education
Moderator: Carlo De Luca |
| 1:30 PM | Session IV: Role of NIBIB
Moderator: Linda Griffith |
| 3:00 PM | Adjournment |

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