The NIH Plan for
Accelerating Technology Transfer and Commercialization of Federal Research in Support of High Growth Businesses

Introduction

The National Institutes of Health (NIH) is the nation's biomedical research agency. The NIH's extramural funding supports research at more than 3,000 institutions. A portion of this funding supports the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which play a critical role in supporting the agency's mission to improve human health. The programs are uniquely positioned to convert basic research ideas into commercially viable products and services available to the general public. The NIH intramural program includes about 6,000 scientists working at the NIH. Their output of inventions has grown over the years, resulting in the largest biomedical patent and licensing portfolio among public sector institutions worldwide. The NIH has achieved great success in licensing inventions made by the scientists who work at the NIH and the U.S. Food and Drug Administration (FDA), with 25 FDA approved products and hundreds of others having reached the market. NIH scientists have collaborated with other institutions, both for-profit and non-profit, to leverage the scientific discoveries that ultimately benefit public health worldwide.

The NIH Technology Transfer Program: What it is and how it supports the NIH Mission

The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The NIH accomplishes its mission through many channels, including direct support of extramural research (via grants, cooperative agreements, and contracts), support in kind through programs such as Bridging Interventional Development Gaps (BrIDGs), and through its intramural research program.

The schematic below depicts two distinct but closely related processes by which NIH shares the benefits of its research programs with the public. The top portion of the diagram illustrates the cycle that is critical to discovery and innovation: new ideas prompt research, research yields knowledge, knowledge is shared through scientific and health-related publications, giving rise to new ideas and further research. Many of these ideas advance fundamental understandings of biology leading either to new strategies for the treatment or prevention of disease or to public and private sector development of medical products or services. Some of these ideas constitute inventions that lead more directly to products of interest to the public consumer and "spin out" of the research cycle to enter a development phase where they are further refined, tested, and commercialized - moving into the marketplace as useful products and services to benefit public health.

From Ideas to Knowledge and Commercialization

The objective of the NIH Technology Transfer Program ("Program") is to facilitate the application of new knowledge to further research and to optimize commercialization by building partnerships to develop and commercialize inventions arising from NIH and FDA intramural research so that public investment in NIH research yields benefit for the people in the U.S. and abroad.

The Program consists of two essential components: 1) research collaborations and 2) acquisition of intellectual property rights (patents) in NIH and FDA inventions and transfer of these rights and related materials to private sector partners through license agreements to support and enable development and commercialization of the inventions.

Technology transfer at NIH is carried out by its component Institutes and Centers (ICs) through the offices of their respective Technology Development Coordinators (TDCs) and by the central NIH Office of Technology Transfer (OTT). The efforts of the TDCs and OTT, which include complementary activities that require coordination and cooperation, together comprise the Program. The OTT also manages the patenting and licensing of inventions made by FDA scientists. Thus, the OTT activities, but not the IC activities, discussed in this report apply to NIH as well as FDA intramural inventions. The NIH activities are summarized in the table below.

ICs	OTT
• Negotiate agreements that enable IC access to proprietary materials and information and other resources needed by the IC research programs	
• Evaluate invention disclosures to obtain and protect patent rights as needed to promote development and commercialization	• Evaluate invention disclosures • Secure high-value, commercially attractive patents for NIH inventions
• Negotiate collaboration agreements for basic research as well as research and development projects to advance development and commercialization • Monitor collaboration agreements, including Cooperative Research and Development Agreements (CRADAs), for diligence and change in research scope • Assure IC's receipt of payments due from collaborators under CRADAs • Lead in developing technology transfer policy	• Negotiate and execute license agreements to convey NIH patent rights and unpatented materials to the private sector for research, development and commercialization • Monitor license agreements for diligence and proper royalty payments • Manage the royalty payments from licensees that are paid to inventions and to NIH Institutes and Centers

The effectiveness of the Program depends on

- People
    - Innovative and highly productive scientists and research staff who participate in the Program
    - Skilled and experienced technology transfer professionals who work closely with NIH scientists, research staff, and others to execute the Program
- Discoveries
    - A well resourced and robust biomedical research endeavor that can yield inventions for which important public health needs and markets exist and that can be commercialized successfully
- Processes
    - Evaluating and protecting inventions and creating the appropriate patent management strategy
    - Determining the value proposition for emerging technologies as it relates to medical/scientific utility, ability to attract funding/collaborators, ability to market viability

- Deploying marketing strategies to direct appropriate technologies to those stakeholders that can best commercialize them
- Licensing of inventions
- Identifying collaboration partners
- Negotiating agreements governing the exchange of research resources, including drugs, biologics and research tools, and research and development collaborations
- Evaluating the regulatory and policy environment to determine the implications for NIH technology transfer

- Information Technology (IT)
  - Developing an organized and robust data management system where information can be utilized, harvested easily, made transparent, and internal and external stakeholders have access to appropriate information

A key feature of the Program is to promote efficient transfer of technologies to the private sector for commercialization. Efficient transfer involves high quality disclosures, avoidance of unnecessary patent costs, high volume of licenses, timely licensing of valuable inventions, successful commercialization of inventions, and as a result, more products on the market to benefit public health, create jobs, and generate royalty income.

Background

The biomedical industry has undergone significant changes that require concomitant adjustments by NIH in its technology transfer efforts. Some of these include mergers between large pharmaceutical companies leading to fewer potential "customers" for technologies, cutbacks in industry internal research programs, fewer venture capital funds focusing on early-stage research, and a more risk-averse approach to investing in assets. The product development model, borne out in NIH's own data, has moved more to smaller companies taking the early stage risk, and at a later point sublicensing to or being acquired by large biotechnology and pharmaceutical companies. Many biomedical companies have returned to an open innovation approach where they actively seek ideas from the outside and collaborate with others to develop new products or repurpose others that have been developed and approved for one indication and may be useful for the treatment of other diseases. This approach lowers the barrier for collaborations between internal and external investigators, creates a free exchange of ideas between scientists from traditionally closed entities and contributes to the advancement of science.

The NIH is cognizant of the necessity to meet these changing needs through new and innovative approaches to technology transfer and the award of SBIR/STTR grants and contracts. Accordingly, the Program has begun to implement initiatives intended to enhance NIH's technology transfer and commercialization activities.

These include:

1. Facilitating the exchange of proprietary materials and information needed to advance biomedical research: NIH has developed an electronic Transfer Agreement Dashboard (TAD) to streamline the transfer of NIH-developed research materials to the biomedical research community via Material Transfer Agreements (MTAs). NIH has also launched the electronic Research Materials website (eRMA), an analogous system for licensing unpatented research materials to for-profit entities. The two web-based systems are expected to reduce dramatically the transaction time for transferring NIH-developed materials.

2. Streamlining licensing procedures and reducing the time required to license technologies:

    a. NIH is reviewing all its model license agreements in order to simplify and expedite the licensing process.

    b. To simplify and expedite royalty payments, NIH has implemented Pay.gov, a web-based application allowing licensees to make payments by debit from a checking or savings account. NIH continues to market this option to companies in order to broaden its use. This process speeds licensing, particularly when an initial payment is required prior to shipping biological materials under a license.

    c. NIH created a Start-Up license to expedite the process for start-up companies to license technologies for drugs, vaccines, and therapeutics. The new license reduces both the costs and paperwork requirements for start-up companies. NIH has developed a similar license for non-profit institutions, such as non-government organizations (NGOs) and product development partnerships (PDPs) that play an increasing role in developing new products to diagnose, treat, or prevent disease in low income regions of the world.

    d. In 2010, the NIH National Cancer Institute (NCI) first utilized the SBIR/Technology Transfer (SBIR/TT) mechanism to facilitate the development of an NIH invention under an SBIR contract award. Other ICs are now exploring its use for their technologies.

3. Reviewing practices for establishing CRADAs with the goal of reducing the time required to establish CRADAs: NIH is designing a new process and procedure for CRADAs that should greatly reduce the negotiation time as well the internal approval time.

4. Facilitating commercialization through local and regional partnerships – NIH has a number of partnerships in place with local and regional partners:

    a. Partnership Intermediary Agreement between OTT and Tech Commercialization, a Texas based entity established to provide regional small businesses and educational institutions with technical assistance aimed at helping them identify

and develop appropriate federal technologies for licensing and commercialization.

b. Partnership Intermediary Agreement between NCI and Maryland Technology Development Corporation (TEDCO).

c. Partnership Intermediary Agreement between OTT and BioHealth Innovation (BHI), an innovation intermediary in Montgomery County, Maryland, and the Greater Baltimore, Maryland region, that translates market-relevant research into commercial success. Under the agreement, BHI recently employed and placed an Entrepreneur-in-Residence within OTT to evaluate and identify licensing opportunities for intramural biomedical inventions.

d. Memorandum of Understanding between NIH OTT and Maryland TEDCO.

5. Promoting NIH inventions and technologies for development and commercialization: NIH has developed electronic and social media tools to promote its inventions available for licensing and collaboration. These include websites, RSS fees, iPhone and iPad apps, e-mail subscriptions, Twitter, and Facebook. NIH also participates in CTSAIP.com, a website that aggregates technologies from across the NIH-supported Clinical and Translational Science Award consortium of medical research institutions.

The NIH Plan for Accelerating Technology Transfer and Commercialization (the "Plan")

The overarching aim of the Plan is to increase the number and pace of effective technology transfer and commercialization activities in partnership with non-federal entities, including private firms, research organizations, and nonprofit entities. The Plan covers two distinct programmatic areas: the first part involves research and development activities that occur at the NIH; the second part involves extramural SBIR/STTR grants and contracts. The Plan presents activities to accelerate technology transfer and commercialization, but also focuses on non-partnership activities such as improving procedural efficiencies and automation of common high volume activities, which in turn will free up time for NIH technology transfer professionals to dedicate to partnership activities. This approach is expected to increase both the number and pace of formation of technology transfer partnerships without sacrificing quality and conformance with policy. The Plan also describes intermediate to long term investments in human capital development and information technology (IT) to better leverage limited technology transfer resources going forward as to well as improve methods for understanding the impact of the Program.

The Plan is intended to be a living document. In the first year, NIH will finalize the initial measures, develop methods to capture the data for each measure, and initiate collection of baseline measures. Most of the measures are available from existing metrics collected or from reports generated by the NIH internal database for tracking all patenting and licensing activities

and the number of CRADAs. In the first year, OTT and the ICs will put in place some new means of tracking activities that are not already captured by the existing procedures. NIH will continue to evaluate the gathered measures in light of the objectives and will adjust the objectives, tasks, and measures if necessary and appropriate to pursue the stated performance goals. In addition, throughout the duration of the Plan, NIH will seek ways to better understand the long-term and far-reaching impact of the Program.

The NIH will utilize a variety of specialized programs and resources to accelerate technology transfer. For example, the recently formed NIH National Center for Advancing Translational Sciences (NCATS) utilizes partnerships with the public and private sectors to develop innovative ways to reduce, remove, or bypass bottlenecks in the translational pipeline of drug development. The NIH Clinical Center is a national resource that makes it possible to rapidly translate scientific observations and laboratory discoveries into new approaches for diagnosing, treating, and preventing disease. The Vaccine Research Center pursues cutting edge vaccine research and development with scientists in academic, clinical, and industrial laboratories through a program of national and international collaborations. Other activities related to accelerating technology transfer from the NIH will come from the Frederick National Laboratory for Cancer Research (FNL), a Government Owned, Contractor Operated (GOCO) laboratory. The Advanced Technology Research Facility recently constructed in Frederick will house many of the advanced technology laboratories of the FNL. The building provides significant space for partners who are advancing NIH technologies to work side by side with the FNL laboratories, thereby accelerating the transfer of federal lab technologies to the public sector.

Current Technology Transfer Metrics

NIH has developed an interactive metrics tool that displays a wide range of technology transfer metrics. The tool allows the user to view the last fiscal year in a pie chart or to see a multi-year view that can be manipulated. The metrics displayed include the number of inventions and licenses, patents, licenses by type of agreement, U.S. or non-U.S. licensees, licensee by business type, exclusive versus nonexclusive licenses, first time licenses by business type, new and active CRADAs, and CRADA-related inventions. Additionally, annual and cumulative royalties, royalty income by type, and royalty distribution are displayed.

NIH will utilize the following goals and metrics to evaluate its efforts under the Plan.

1. Improve the returns from Federal R&D Investments
While maintaining current high quality, increase the number of:
Invention disclosures
Licenses on existing patents
CRADAs
Industry partnerships
New products
Successful transfers to start-up companies

2. Streamline the Technology Transfer and Commercialization Process
Reduce the time required to license technology
Reduce the time required to establish CRADAs
Reduce the time from SBIR/STTR grant application to award

3. Facilitate Commercialization through Local and Regional Partnerships
Increase engagement with external partners

Performance Goal 1: Increase the number of effective technology transfer and commercialization activities in partnership with non-federal entities, including private firms, research organizations, and non-profit entities

	Milestone	*Evaluation Methods*	*Timeline*
1	Increase awareness of and participation in the Program by non-federal partners by Initiating new outreach activities, e.g., trade meetings, social media, targeted marketing	Establish baseline and measure trend over time.	Establish baseline 2013 and measure progress annually.
2	Evaluate use of SBIR/TT program to advance the development and commercialization of early stage, high risk inventions, and expand use as appropriate	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.	Establish baseline in 2013 and annually establish goals for the subsequent year.
3	Develop improved strategies for invention evaluation and appropriate scope of IP protection	Establish baseline in 2013 and annually establish goals for the subsequent year.	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.
4	Leverage available internal NIH resources to help de-risk early stage NIHinventions	Establish baseline in 2013 and annually establish goals for the subsequent year.	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.
5	Develop more effective outreach materials and methods	Establish baseline in 2013 and annually establish goals for the subsequent year.	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.

Performance Goal 2: Increase the pace of effective technology transfer and commercialization activities in partnership with non-federal entities, including private firms, research organizations, and non-profit entities

	Milestone	*Evaluation Methods*	*Timeline*
1	Maximize flexibility and effectiveness of NIH technology transfer policies by: • Examining current NIH policies to maximize flexibility and effectiveness under existing authorities • Implementing changes identified above	Depending on the outcomes of the tasks, other measures will need to be established to assess impact on this objective.	Establish baseline 2013 and measure progress annually.
2	Streamline NIH technology transfer partnership processes and procedures by: • Identifying bottlenecks and devise approaches to eliminate or reduce them • Implementing approaches identified above • Improving and simplifying model agreements (licenses, CRADA, collaboration agreements) to reduce resources and time spent on negotiation	Depending on the outcomes of the tasks, other measures will need to be established to assess impact on this objective. Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals. Seek feedback from licensees and those conducting the licensing for changes and improvement to the terms and process.	Establish baseline 2013 and measure progress annually. For Start up Licenses, evaluate 4Q12 and implement changes 1Q13. Assess annually. For Nonprofit Licenses, evaluate 1Q13 and implement changes 2Q13. Assess annually. For all model licenses, complete review by 4Q12 and implement changes 1Q and 2Q13.
3	Implement automated workflow systems for routine activities where applicable and practical, e.g., Transfer Agreement Dashboard (TAD) and eRMa	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.	Establish baseline 2013 and measure progress annually.

Performance Goal 3: Develop the Technology Transfer Knowledge of the NIH Community

	Milestone	*Evaluation Methods*	*Timeline*
1	Improve synergy, collaboration, and coordination among NIH technology transfer professionals	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.	Establish baseline 2013 and measure progress annually
2	Expand skill sets of NIH technology transfer professionals	Measure each year relative to preceding year(s) and consider program modifications to enhance achievement of goals.	Establish baseline 2013 and measure progress annually
3	Explore possible "Entrepreneurship Sabbaticals" (leave of absence to develop inventions in incubator or other facility) for NIH scientists.	Depending on the outcomes of the tasks other measures will need to be established to assess impact on this objective.	Establish baseline 2014 and measure progress annually

The NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

The second part of the plan involves the extramural SBIR and STTR programs at NIH, which play a critical role in supporting the agency's mission to improve human health. The programs are uniquely positioned to convert basic research ideas into commercially viable products and services available to the general public.

The NIH SBIR and STTR programs are characterized by several unique features; 1) The pace and nature of biomedical research present small businesses with extremely long timelines, expensive multi-tiered phases of R&D, and often arduous regulatory and market adoption challenges; 2) the funding model is primarily investigator-initiated in order to fully take advantage of the innovative and unpredictable way that the best and brightest ideas and solutions to problems can come; 3) flexibility in allowing multiple submission dates throughout each fiscal year and awarding grant budgets aligned with the project requirements and market realities has made the programs entrepreneur friendly; and 4) the NIH encourages open communication between agency staff and small businesses and makes its policies and processes transparent to public.

Challenges Overcome:

The NIH SBIR programs have been extensively evaluated. The agency has, over the years, responded to many recommendations both from the National Academies' reports as well as input from its main stakeholders – the small business community.

1. Fast-Track Awards: Per regulations, all small businesses must progress through the program first by competing, receiving, and completing Phase I funding and then competing and receiving Phase II funding. This basic program structure, albeit necessary

to ensure proper vetting of promising ideas, has provided additional challenges for some small businesses that had the momentum and quality of work to complete the two phases quickly. The NIH Fast-Track program was created to address the limitation of a Phase II funding gap, the time after Phase I where company applies and may wait seven to nine months before Phase II would be awarded. The Fast-Track entails one application for both Phase I and II, effectively eliminating the funding gap between Phase I and Phase II and allowing the research to move forward without delay or interruption.

2. Targeted Announcements: Approximately 70 percent of awards are made to applications submitted through the annual agency-wide grants Omnibus Solicitation. In order to afford small businesses additional flexibility to apply when ready and at the same time allow the agency to be more strategic in addressing certain research priorities, targeted announcements are released throughout the year with varying due dates, project durations, and budget levels. On average, the agency releases between 60-70 targeted announcements each year.

Opportunities:

1. The NIH continually explores its required two-tiered peer review process to make these programs as entrepreneur-friendly as possible and practicable. Shortening the timeline for making awards to small businesses from the time they apply continues to be one such area of focus. NIH SBIR and STTR applications are currently on an accelerated receipt timeline. With the passage of the bill to Re-Authorize the SBIR and STTR programs (P.L. 112-81), the agency will be working to identify steps in the overall process from receipt of application to award that could further reduce the time from receipt to award. The legislation calls for the NIH to make final award decisions within 12 months. The NIH, by and large, already accomplishes this, but will continue to explore ways in which the timeline can further be reduced in the next year.
2. The agency has always practiced, and will continue to practice transparency in publicly posting the timelines for the grant award cycle, the names of reviewers and schedules for all review panels, and the overall success rates for our programs. NIH SBIR and STTR program staff always have been and will continue to be available to help answer any questions small business applicants and awardees may have.
3. NIH employs specific SBIR/STTR review panels for all applications in response to these programs. Each panel is comprised of expert scientists and engineers with the appropriate expertise to review the applications, including those from the private sector (typically SBIR and STTR award winners from small companies). This is an area the NIH

will continue to be vigilant about so that small business applications continue to receive a fair merit peer-review.

4. Because the biomedical enterprise is inherently a capital-intensive undertaking, early-stage life science companies that receive NIH SBIR/STTR funding are particularly vulnerable and often at risk of perishing during economic struggles and in general. NIH instituted funding gap programs to help small businesses reach further across the proverbial "valley of death." Notably, the Phase IIB competing renewal SBIR and STTR awards established in 2004, address a critical funding gap by providing small businesses follow-on funding to their original Phase II project for work that requires costly pre-clinical and clinical studies, animal toxicology studies for submission to the FDA, device prototype scale-up, and other important R&D activities. Additionally, the NIH leverages its investment by helping small businesses become market ready through a suite of Technical Assistance Programs: The Niche Assessment Program (NAP) offered to Phase I SBIR awardees provides an in-depth market opportunity analysis information and the Commercialization Assistance Program (CAP) is a customized mentoring and training program to help Phase II SBIR awardees develop actionable business strategies through addressing challenges in intellectual property, reimbursement, market penetration, financing, or other areas unique to each selected company. The recent Re-Authorization increases the amount of funding NIH can spend on technical assistance programs and expands the technical assistance to include STTR awardees. NIH will implement changes to these programs in the next year.
5. Outreach to small businesses is one the main goals of the SBIR and STTR programs. The agency organizes and attends numerous conferences and events to bring important information and resources to to researchers, inventors, and entrepreneursacross the nation. The SBIR/STTR office collaborates with state-level economic and business development centers to jointly present to local businesses either by traveling to these locations in person or by utilizing 21st Century technologies such as webinars.
6. An important aspect of the Re-Authorization is an increased emphasis on tracking scientific, commercial and economic outcomes of the SBIR and STTR programs. NIH will be working closely with SBA and its sibling SBIR agencies to implement common metrics across agencies for this purpose in the coming year to further enhance its tracking of outcomes for its programs.

The NIH will continue to enhance, evaluate, and improve the SBIR and STTR programs. The recent reauthorization of the programs will also require NIH to make concerted and coordinated efforts in the areas listed above.