Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses

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The Food and Drug Administration's Plan to Accelerate Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses

Executive Summary

This report is in response to the presidential memorandum of October 28, 2011, directing federal agencies to improve the results of their technology transfer and commercialization activities. It presents FDA's 5-year plan for accelerating technology transfer during 2013–2017. FDA has the following three goals for accelerating technology transfer and commercialization of federal research:

1. Increase the number of technology transfer partnership activities with nonfederal entities, including industry, academia, and nonprofit organizations
2. Improve FDA's technology transfer business processes.
3. Expand technology transfer knowledge among FDA community members and increase the Agency's awareness of the value of its technology transfer program.

This report also includes detailed objectives, tasks, measures, and timelines for accomplishing these goals.

The overarching aim of the plan is to increase the impact of technology transfer by encouraging the formation of technology transfer partnerships between FDA and federal and nonfederal entities, including industry, academia, and nonprofit organizations. Also, implementation of the plan should improve the efficiency of FDA's technology transfer program, allowing the program to increase its focus on marketing and partnership activities. This approach should increase both the number of technology transfer partnerships and the rate at which the partnerships are established. During the first year of the 5-year plan, FDA will work to identify initial metrics, develop methods to capture data, initiate collection of baseline measures, and ensure ongoing evaluation of program improvements, adjusting goals as needed.

Introduction

A presidential memorandum directing the acceleration of technology transfer and commercialization of federal research in support of high-growth entrepreneurship was issued by President Barack Obama on October 28, 2011 (available at: http://www.whitehouse.gov/the-press-office/2011/10/28/presidential-memorandum-accelerating-technology-transfer-and-commerciali).

The memorandum mandates each federal agency to:

1. establish goals and measure progress,
2. streamline the federal government's technology transfer and commercialization process, and
3. facilitate commercialization through local and regional partnerships.

FDA and Innovation: How FDA's Technology Transfer Program Supports the Agency's Mission

The U.S. Food and Drug Administration (FDA)'s mission is to protect and promote the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. Since 2009, it also has the responsibility for regulating the manufacture, marketing, and distribution of tobacco products. FDA's responsibilities toward public health and safety cover a broad range of regulated products, accounting for about 25 cents per dollar spent by American consumers each year. FDA carries out its mission through efforts from the Office of Commissioner, its seven component Centers—Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), as well as the Office of Regulatory Affairs (ORA).

FDA is committed to modernizing its science and regulatory paths to promote innovation, as evidenced by its recently published innovation blueprint.[1] FDA's innovation blueprint outlines strategies to help reposition the U.S. medical product industries to adapt to the changing scientific landscape and drive innovation forward to provide Americans with cutting edge treatments and therapies that are safe and effective. At the same time, the outlined strategy will support economic growth and development in a critical sector of the economy. As noted in President Obama's Strategy for American Innovation, the private sector is the engine of innovation. FDA recognizes that much of this innovation, especially in biomedical products, is generated by small business. To better support small business needs, FDA has established initiatives directed toward small business, including the Small Business Liaison program at FDA. With support from the White House Office of Science and Technology Policy, CDRH established the Entrepreneurs-in-Residence-Program to develop new operational procedures in

[1] "Driving Biomedical Innovation: Initiatives to Improve Products for Patients"—report released by FDA on October 7, 2011

areas that impact innovation. These programs will better support small business by enhancing FDA's knowledge and understanding of what it takes to start and run a small biomedical business. These programs will also ensure that individuals with small business experience can serve as an FDA resource to stakeholders.

FDA's Technology Transfer Program recognizes the importance of partnerships that drive science and innovation by combining scientific expertise, cutting edge ideas, and resources, including new technologies. FDA partnerships range from public-private partnerships for engagement in collaborative scientific computing to license agreements allowing companies to use FDA inventions for development into products that would then be available through the commercial sector. Some examples of the benefits of FDA's Technology Transfer Program at different FDA centers are:

1. A major success in FDA technology licensing is the transfer and development of a vaccine conjugation technology developed by CBER. The invention, combined with the collaborative efforts of CBER scientists and the PATH's Meningitis Vaccine Project, resulted in a vaccine product, MenAfriVac™, that will be used to immunize approximately 300 million people living in the meningitis belt of Africa. Preliminary results from using MenAfriVac in the large scale immunization of more than 60 million Africans are overwhelmingly positive, revealing only four confirmed cases in 2011 (compared to over 2700 cases with 13% mortality rate in 2009).
2. To support regulatory innovation, CDRH recently established the Innovation Pathway 2.0 pilot program. Innovation Pathway 2.0 is intended to deepen collaboration between CDRH and innovators early in the medical device development process, prior to pre-market submission, with the goal of making the regulatory and product development process more efficient and timely.
3. FDA's NCTR recently established a regional partnership to facilitate technology transfer and commercialization. This partnership with the State of Arkansas Virtual Regulatory Science Center fosters engagement with regional business leaders, who can provide insight and entrepreneurial expertise to NCTR researchers. This knowledge will help FDA better understand the interests and needs of companies who might consider licensing FDA technologies for development. NCTR will be able to share its research expertise with the external partner, consistent with its mission.
4. ORA scientists perform research that has very practical regulatory applications in compliance and enforcement. At ORA's Forensic Chemistry Center, scientists invented an innovative handheld device for counterfeit drug detection. This device is poised for technology transfer and commercialization through licensing to an external partner in the near future. This device is a powerful tool that can contribute to minimizing the risks to the public from counterfeit drugs getting into the supply chain.

While these are very recent examples of innovation through partnerships and transfer of federal technology from some of FDA's Centers, all the FDA components collaborate with outside entities to enhance their programs and strive to make the Agency's public health innovations available to the public through technology transfer and commercialization by the private sector.

Federal technology transfer authorities provide mechanisms, such as those used for the vaccine conjugation technology, through which collaborative research and development activities can be achieved. This strengthens FDA's ability to promote use of new knowledge and to create partnerships that lead to further innovations or make FDA technologies available through the commercial sector. FDA defines technology transfer as the practice of conveying scientific findings, know how, inventions, or research materials from one organization to another for further development and commercialization. In the course of their mission-related work, FDA researchers gain new scientific insights and also make inventions that have the potential to become viable commercial products. Through transfer of FDA technologies under license agreements, new products in the areas of vaccines, food-pathogen detection systems, and counterfeit drug detection, to name a few, can be developed and become available through the commercial sector. New knowledge can be shared through publication or used in collaboration with outside partners to drive the innovation cycle.

FDA Technology Transfer Program Structure

FDAT2 activities are implemented by FDA's component Centers and ORA and are led by the Technology Transfer and Intellectual Property Team within the Strategic Partnership and Intellectual Property Division (SPIP) in the FDA's Office of the Chief Scientist.

Technology transfer at FDA is conducted through:

1. the Technology Transfer and Intellectual Property Team within the Strategic Partnership and Intellectual Property Division (SPIP), located in the FDA's Office of the Chief Scientist
2. Technology Transfer Representatives (TTRs) located in different organizational positions, depending on the FDA Center or Office of Regulatory Affairs preference and organizational structure. Each of the seven component Centers and the Office of Regulatory Affairs has at least one assigned TTR, although for the majority of TTRs, technology transfer is not a primary function.
3. the NIH Office of Technology Transfer

SPIP has the lead on developing and updating FDAT2 policies and procedures, working in coordination with the component Centers and ORA. FDAT2 negotiates agreements, intakes and evaluates invention reports, manages FDA's invention portfolio, and assists FDA inventors in developing collaborations to further early-stage FDA inventions. The patenting and licensing of FDA inventions, along with administration of royalty payments, are amongst the services provided to FDA by the National Institutes of Health's Office of Technology Transfer (NIH OTT) under an interagency agreement. The coordinated, overlapping activities of various Offices and Centers within FDA and NIH provide FDA with a complete and integrated technology transfer program. These activities are shown in the table below.

Table 1. FDA's Technology Transfer Program and Roles

Technology Transfer Representatives- FDA Centers and Office of Regulatory Affairs	Technology Transfer and Intellectual Property Team- FDA Office of the Chief Scientist	NIH Office of Technology Transfer
• Negotiate agreements (e.g., CRADAs, RCAs, or MTAs) that enable FDA Center or Office access to proprietary materials and information and other resources needed by the FDA research programs. These agreements are used to establish partnerships that advance development and commercialization • Monitor collaboration agreements, CRADAs, for diligence and change in research scope • Assure Center's/Office's receipt of payments due from collaborators under CRADAs		
	• Evaluate invention disclosures to obtain and protect patent rights as needed to promote development and commercialization • Manage the royalty payments from licensees that are paid to inventors and Centers	• Evaluate invention disclosures • Secure high-value, commercially attractive patents for FDA inventions • Negotiate and execute license agreements to convey FDA 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 FDA.

CRADA = cooperative research and development agreement; RCA = research collaboration agreement; MTA = material transfer agreement.

FDA Technology Transfer Program Goals

The FDA Technology Transfer Program (FDAT2) strives to maintain an active and robust Agency resource with the following goals:

1. Facilitate exchange of proprietary materials and information needed to advance techniques and tools to improve health.
2. Efficiently establish collaborations that enhance FDA's research programs and promote technology transfer
3. When possible, foster partnerships between FDA and medical product industry, academia, nonprofit organizations and government collaborators.
4. Identify FDA inventions as intellectual property
5. Acquire intellectual property rights to the inventions
6. Convey these rights to private sector partners through license agreements that enable development and commercialization of the inventions to promote innovation while meeting FDA's mission to protect and promote the public health.

These core activities of FDAT2 enhance the yield from the public investment in the FDA's regulatory mission and related research and innovation programs.

To meet these goals, FDAT2 carries out a wide range of activities to support the following objectives:

1. encourage the reporting of inventions by FDA researchers;
2. facilitate the building of collaborative relationships between FDA staff and the broader scientific community, including industry, academia, nonprofit organizations, and government collaborators, to develop research partnerships and commercialize FDA inventions; and
3. support these activities by continually updating relevant policies and procedures.

FDA Plan for Accelerating Technology Transfer and Commercialization

The new FDA 2013–2017 plan has four goals, each of which has one or more objectives. Each objective will be pursued through specific tasks. Progress toward each objective will be based on measurable outputs (i.e., metrics). (See Table 3 for performance goals, objectives, and measures.)

The Plan establishes these goals to increase the number and pace of effective technology transfer and commercialization activities in partnership with nonfederal entities, including private firms, research organizations, and nonprofit entities. The initiatives and activities outlined in the Plan contribute to accomplishing the goals. The Plan includes initial milestones and measures for evaluation purposes. The Plan covers the 5 year period from 2013 through 2017.

While the Plan presents initiatives and activities to accelerate technology transfer and commercialization under partnerships with nonfederal entities, it will also present objectives to improve the Agency's internal processes needed to establish and carry out the partnerships.

The plan's overarching aim is to increase the impact of FDA's technology transfer program by encouraging the establishment of technology transfer partnerships with government collaborators and nonfederal entities, including industry, academia, and nonprofit organizations. Implementation of the plan will streamline business processes to improve the efficiency of FDA's technology transfer activities, thus increasing the number and rate of establishing partnerships. Implementation of the plan will also allow the program to increase its focus on technology marketing toward commercialization partnerships, thus increasing the technology transfer opportunities.

The Plan is intended to be a living document. In the first year FDA will finalize the initial measures, develop methods to capture the data for each measure, and initiate collection of baseline measures. FDA will continue to evaluate the gathered measures in light of the objectives and will adjust the objectives, tasks, and measures as necessary and appropriate to pursue the stated performance goals.

New FDA Technology Transfer Initiatives

Initiative 1: New SBIR Technology Transfer Program

The innovative technologies made by FDA scientists stem from research across a broad range of disciplines, as broad as the range of regulatory responsibilities covered by the Agency. However, developing the FDA technologies to the point of commercial viability most often requires the efforts and innovations of the private sector. Contributions from the private sector fill technology gaps and bring the resulting product into the marketplace. It is often the small business entities, themselves born from innovations that are ideal candidates for commercializing FDA technologies.

FDA T2 will work with other FDA offices to establish an SBIR-TT program to support the awareness of and transfer and development of FDA technologies, while concurrently providing support to small business initiatives. The proposed SBIR-TT program will exist within FDA's currently established SBIR program and will not require new funding. The intent of FDA SBIR-TT will be to have SBIR-TT awardees move commercially-viable FDA technologies to the marketplace. Recipients of an SBIR-TT award would be granted a royalty-free, non-exclusive internal research-use license to develop an FDA technology into a commercial product providing benefit to the public. The use of SBIR in combination with the transfer of federal technology is consistent with the intent of the Small Business Innovation Development Act of 1982 and the Small Business Technology Transfer Act of 1992. In establishing the SBIR-TT program, FDA has the opportunity to benefit from the experience of agencies like the National Institute of Standards and Technologies (NIST), which piloted an SBIR-TT program in 2008,[2] and NIH, which piloted a program in 2011.

Tasks, measures, and timeline for this initiative are found in Table 3, performance goal 1, objective 2 (page 11).

Initiative 2: New model CRADA for software development projects, based on establishing strong software policies

FDA, as a primary component of the Public Health Service (PHS), uses the PHS model CRADA to engage in collaborations with partners. Often the work under FDA CRADAs is focused on development of new software tools, which would then be considered new intellectual property under the agreement. Software can be both a patentable invention and copyrightable material. It is vitally important that FDA develops strong policies for handling software intellectual property, when the software is developed in CRADA partnerships.

FDAT2 will establish strong intellectual property policies for software developed under CRADA collaborations. The policies will maintain appropriate Agency rights and access to the software with recognition of the CRADA partner's interests in commercialization of software inventions. The current PHS model CRADA was primarily addresses biomedical research collaborative

[2] Clara Asmail, "Use of Small Business Innovation (SBIR) Program in Support of Technology Transfer," les Nouvelles, vol. XLV, No. 3, pp 135-139, Sept 2010.

activities, as opposed to software development. In addition there is uncertainty around the area of handling of rights in copyrightable work by US government employees. FDAT2 will establish a model software development CRADA with terms that are relevant and fair to the parties, and that will align with the CRADA software intellectual property policies that will be developed. Establishment of this software intellectual property policy and a software model CRADA will help increase the pace of effective technology transfer and commercialization activities carried out with nonfederal organizations, thereby furthering the goals of the President's Strategy for American Innovation.

Tasks, measures, and timeline for this initiative are found in Table 3, performance goal 2, objective 8 (page 15).

Preparing for Next Generation Technology Transfer Activities

In order to garner the best possible use of innovation-derived research, entities should pool intellectual and material resources to drive new technologies into the commercial sector. Some of the research relationships remain relatively simple, as is the case with the transfer of unique research material. Other relationships are complex, as is case with CRADA work that might also involve federal contractors along with the CRADA partner. It is important that the FDAT2 continues to identify areas that can be improved to streamline technology transfer-related processes and to enhance coordination between FDA's component Centers, ORA, and Agency level functions to reach the next generation of technology transfer activities. Table 2 below contains selected initiatives for which FDAT2 will implement improvements intended to strengthen and enhance ongoing and future technology transfer and commercialization activities.

Table 2. Preparing for Next Generation Technology Transfer Activities.
For related tasks, measures, and timelines refer to corresponding goal and objective in Table 3 (starting on page 10).

Initiative	Performance Goal and Objectives (as listed in Table 3)
Increase visibility of FDA inventions and opportunities	Goal 1 objective 3
Identify FDA technologies for collaborations leading to commercialization	Goal 1 objectives 2 and 3
Assist FDA inventors in identifying partners, especially small businesses	Goal 1 objectives 2 and 3
Increase visibility of technology transfer opportunities by engaging in different outreach venues, including workshops and trade meetings.	Goal 1 objective 1
Facilitate collaboration between FDA and potential partners	Goal 2 objective 6
Facilitate exchange of appropriate proprietary research materials and information	Goal 2 objective 4
Enhance FDA Technology Transfer Program transparency for internal and external clients	Goal 2 objective 2

Initiative	Performance Goal and Objectives (as listed in Table 3)
Continue to identify areas for business process improvement	Goal 2 objective 4
Increasing technology transfer training opportunities for FDA researchers and staff	Goal 3 objectives 1 and 2
Increase Agency awareness of how technology transfer creates partnerships and adds value	Goal 3 objective 3

Table 3. FDA Plan for Accelerating Technology Transfer and Commercialization

Performance Goal 1: *Increase the number of technology transfer partnership activities with nonfederal entities, including industry, academia, and nonprofit organizations.*

No.	Objective	Task	Metric	Timeline
1	Increase awareness about FDA technology transfer program among nonfederal partners	• Explore and engage in new outreach activities (e.g., trade meetings and workshops) • Explore collaboration with local and regional biomedical companies, universities, non-profit research organizations located in other parts of the United States where FDA offices and laboratories are located, (e.g., FDA's National Center for Toxicological Research in Arkansas) • Explore partnerships with innovation intermediaries and economic development organizations	Number of negotiations initiated with existing partners Number of executed agreements with existing partners Number of negotiations initiated with new partners Number of executed agreements with new partners	Tasks to establish baseline metrics to be identified by 2013. FDA will measure progress annually.

No.	Objective	Task	Metric	Timeline
2	Establish SBIR-TT program at FDA to advance the development and commercialization of early-stage technologies	• Coordinate with the FDA Office of Acquisitions and Grants Services (OAGS) to determine actions needed to establish SBIR-TT program • Identify FDA technologies for this program, based on technology type and stage of development. • Gather input from FDA inventors to formulate scope of work for technology development under SBIR-TT. • Develop scope of work for review. • Review by SBIR Selection Committee. • Write solicitation (OAGS and FDAT2). • Compare effectiveness of SBIR-TT program against licensing interest from marketing the same technologies through standard routes, such as Federal Register announcements and posting on the web.	Number of SBIR-TT topics published in annual omnibus solicitations Number of SBIR-TT funding announcements published Number of applicants responding to SBIR-TT opportunity Number of SBIR-TT awards made Percent of technologies that enter Phase II Percent of Phase II technologies that move toward commercialization	This is a new program for FDA. More granular tasks in establishing the SBIR-TT program will be identified by second quarter FY13, with goal of publishing first SBIR-TT funding opportunity by September 2013. Once established, FDA will perform an annual review of the SBIR-TT to measure agency progress.

No.	Objective	Task	Metric	Timeline

3	Increase access to partners by developing more effective outreach materials	• Update marketing materials
		  ○ List technologies available for licensing on the FDA.gov website in formats readily useful to potential licensees.
		  ○ List CRADA and other collaboration opportunities on the FDA.gov website in formats readily useful to potential collaborators.
		  ○ List unique biologic materials and cell lines available for licensing on FDA.gov website.
		  ○ Coordinate Agency-level technology transfer and FDA component websites, so that the FDA technology transfer program as a whole is more accessible to potential partners
		• Identify FDA technologies that can be made commercially viable through collaborative work and potential for commercialization and assist FDA inventors in identifying partners, especially small business concerns.
			Number of hits to the Internet content
			
			Number of license applications established through such awareness
				Tasks to establish baseline metrics to be identified by 2013. FDA will measure progress annually and review to develop additional metrics that measure agency progress.

SBIR = Small Business Innovation Research.

Performance Goal 2: *Improve FDA's technology transfer business processes.*

No.	Objective	Task	Metric	Timeline
1	Modify FDA technology transfer policies to be clearer, more effective, and user-friendly while maintaining statutory requirements	• Form an internal working group to examine FDA policies and identify areas needing improvement • Implement the identified improvements	Annual review of all policies Number of policies revised Number of policy changes implemented	Baseline tasks to be identified by 2013. FDA will perform an annual review to measure agency progress.
2	Enhance FDA technology transfer program transparency	• Publish standard operating procedures (SOPs) for FDA's T2 processes on a common website so they are easily available throughout the Agency. • Establish formal reporting processes between the FDA components and Agency-level technology transfer office to maintain current and comprehensive views of program activities.	Annual review of all existing SOPs Number of new SOPs created, base on gaps identified from annual review or in response to need during the year Number of modified SOPs based on need	Establish baseline in 2013. FDA will perform an annual review to measure agency progress.
3	Develop comprehensive strategies for invention evaluation and protection	• Form an internal working group to identify processes to increase the effectiveness of patent prosecution and cost-reduction considerations	Number of process changes identified Number of processes revised Number of process changes implemented	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress

No.	Objective	Task	Metric	Timeline
4	Streamline FDA technology transfer partnership processes and procedures to maximize transfer effectiveness and facilitate collaboration with external partners. Includes facilitating appropriate exchange of proprietary research materials and information needed to carry out regulatory science and biomedical research.	• Form a working group to identify areas needing improvement and design strategies for improvement and implementation • Improve and simplify model agreements (MTAs, CRADAs, RCAs, and other collaboration agreements) to reduce resources and time spent on negotiation • Identify internal bottlenecks and devise approaches to eliminate or reduce them	Percentage reduction in the average time between submission of CRADA research proposal to FDAT2 (through the Center representative) and completion of authorizing signatures on the CRADA. Percentage reduction in the average time in the execution of other agreements.	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress
5	Improve synergy, collaboration, and coordination between technology transfer professionals throughout FDA Office of the Chief Scientist, FDA Centers, and the Office of Regulatory Affairs.	• Consolidate technology transfer information into a single FDA website for the technology transfer program. • Identify and evaluate technology transfer database systems to maintain knowledge base of program activities, improve data sharing within the FDA components, as well as to provide a means to centrally track agreements through its lifecycle.	Number of new technology transfer content areas for the FDAT2 website. Number of updates to existing technology transfer content areas at the FDAT2 website.	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress

CRADA = cooperative research and development agreement; MTA = material transfer agreement; RCA = Research Collaboration Agreement

No.	Objective	Task	Metric	Timeline
6	Explore use of automated workflow systems for routine transfer agreements	• Form a working group to identify, evaluate, and implement tools, such as the NIH electronic Transfer Agreement Dashboard, for managing material transfer and simple agreements	Number of automated systems reviewed Number of automated systems adapted	Baseline tasks to be identified by 2013. FDA will perform an annual review to measure agency progress.
7	Improve synergy, collaboration, and coordination between FDA technology transfer program and the NIH Office of Technology Transfer	• Collaborate with the NIH Office of Technology Transfer to identify practices to streamline licensing and more effectively market FDA technologies, including use of the new NIH Start-Up license program	Number of new licensing practices identified Number of new licensing practices implemented	Baseline tasks to be identified in 2013. FDA will perform an annual review to measure agency progress and develop more specific activities that improve measurements.
8	Develop strong software policies and new model CRADA for software development projects	• Collect baseline data related to software collaborations, including frequency of collaborations, type of software developed, source code handling and access to background and developed software, and time spent negotiating CRADAs. • Finalize policy for software developed under CRADA • Apply software policy to draft new model software CRADA • Implement model software CRADA	Identify metrics by end of FY13 Metrics may include: Time for negotiations of CRADAs for software development Consistent and appropriate access to CRADA-developed software	Tasks to establish baseline metrics to be identified by 2013. FDA will measure progress annually. Finalize policy by end of FY14. Final model software CRADA for agency approval in first quarter FY15. Implementation of model software CRADA in second quarter FY 15.

Performance Goal 3: *Expand technology transfer knowledge among FDA community members.*

No.	Objective	Task	Metric	Timeline
1	Increase awareness and participation in technology transfer efforts within FDA by — Increasing the number of technology transfer training opportunities offered to FDA scientists and staff. — Improving technology transfer training for FDA scientists and staff — Market FDA Technology Transfer Program services to FDA scientists and staff	• Develop a training plan for FDA, including recurring, scheduled training directed at FDA scientists and staff on inventions, technology development, and technology transfer program goals. • Develop and implement a training module with tracking and reporting capability. • Identify external experts to present seminars. • Develop a plan to better market FDA Technology Transfer Program services to FDA scientists and staff, including marketing and training events such as internal workshops.	Establishment of recurring training course on basics of technology transfer. Number of training seminars offered to FDA labs Percentage of scientists having completed FDA technology transfer training Number of employee invention reports from newly trained staff Number of employee invention reports from existing inventors after training is offered	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress

No.	Objective	Task	Metric	Timeline
2	Provide opportunities for FDA scientists to learn more about technology transfer and the business side of science and marketing	Expand skill sets of FDA technology transfer staff, scientists, and engineers by making available training opportunities to understand — Business practices of the biotechnology and pharmaceutical sectors — Product development processes, including clinical and regulatory aspects — Communication and negotiation strategies — Market research to understand if or how inventions meet commercialization potential — Examine the Internet content of biotechnology and pharmaceutical companies, and identify collaboration interests of the companies and inform FDA scientists	Number of seminars and training opportunities Number of staff participating in technology transfer trainings Number of company interests shared with scientists	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress
3	Improve awareness of the technology transfer program and its benefits to FDA's national centers, program offices, and institute and to FDA's leadership	• Increase awareness of the technology transfer program throughout FDA and among agency leadership by offering overview presentations • Develop annual reports to highlight services provided by FDA Technology Transfer Program and the benefits and opportunities available to FDA as a result of these services	Number of presentations to FDA leadership Annual report delivered to FDA's national centers, program officers, and institute	Baseline tasks to be identified by 2013. FDA will perform an annual review to develop more specific activities and metrics to measure agency progress

No.	Objective	Task	Metric	Timeline
4	Increase and improve awareness across FDA of the SBIR program and its benefits to the agency	• Develop SBIR presentations to help disseminate information about the SBIR program within the agency • Develop FDA SBIR-TT intranet site	Number of presentations to FDA staff Number of attendees at SBIR presentations Number of hits to FDA SBIR-TT intranet site	Baseline tasks to be identified by 2013. FDA will perform an annual review to measure agency progress

SBIR = Small Business Innovation Research