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

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The Centers for Disease Control and Prevention'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 CDC's 5-year plan for accelerating technology transfer during 2013–2017. CDC has the following five goals for accelerating technology transfer and commercialization of federal research:

1. Increase the number of technology transfer partnership activities with nonfederal entities (commercial, research, and nonprofit organizations).
2. Improve CDC's technology transfer business processes.
3. Expand technology transfer knowledge among CDC community members.
4. Improve collaboration with other federal agencies that focus on human and animal diseases.
5. Measure impact of CDC's technology transfer program.

This report also includes detailed objectives, metrics, and timeline for accomplishing these goals.

The overarching aim of the plan is to encourage formation of technology transfer partnerships between CDC and federal and nonfederal entities, including private firms, research organizations, and nonprofit entities. Implementation of the plan also should improve the efficiency of CDC's technology transfer program, allowing professional staff to increase their focus on marketing and partnership activities. This approach should increase both the number and rate of formation of technology transfer partnerships.

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 memo states in part,

> "Innovation fuels economic growth, the creation of new industries, companies, jobs, products and services, and the global competitiveness of U.S. industries. One driver of successful innovation is technology transfer, in which the private sector adapts Federal research for use in the marketplace. One of the goals . . . is to foster innovation by increasing the rate of technology transfer and the economic and societal impact from Federal research and development (R&D) investments. This will be accomplished by committing each executive department and agency (agency) that conducts R&D to improve the results from its technology transfer and commercialization activities. The aim is to increase the successful outcomes of these activities significantly over the next 5 years."

The memorandum mandates each federal agency to

1. establish goals for technology transfer and develop appropriate measures to evaluate progress,
2. streamline the federal government's technology transfer and commercialization process, and
3. facilitate commercialization through local and regional partnerships.

CDC's Technology Transfer Program: How It Supports the Agency's Mission

CDC's mission is "Collaborating to create the expertise, information, and tools that people and communities need to protect their health — through health promotion, prevention of disease, injury and disability, and preparedness for new health threats." (See http://www.cdc.gov/about/organization/mission.htm for additional information.)

The agency accomplishes its mission through multiple strategies, including working with partners throughout the nation and globally to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training in public health practice.

CDC's mission also is advanced by dissemination of intramural and extramural research findings (through publications and presentations), grants, cooperative agreements, and contracts. Intramural laboratory research outcomes (e.g., proprietary and patented knowledge and unique biologic materials) are made available to commercial entities and public health partners around the world through various agreements. In certain instances, transfer of knowledge and material to commercial partners is critical for further development, testing, validation, production, or distribution of products and services that improve public health. Diagnostic products, unique biologic reagents, vaccine candidates, and occupational safety, health, and environmental tools are the major components of CDC's intellectual property portfolio.

CDC's technology transfer program provides leadership and expertise to facilitate external partnerships for achieving timely exchange of knowledge and technologies for development and advancement of products and methodologies that improve public health. Through the technology transfer process, the federal investment in CDC research yields public health and economic benefits. Material transfer agreements (MTAs), biologic material transfer agreements (BMLAs), cooperative research and development agreements (CRADAs), patent license agreements (PLAs), and proprietary technology license agreements (PTLAs) are examples of the agreement types used by CDC to facilitate technology transfer.

Technology transfer at CDC is conducted through:

1. the Technology Transfer Office (TTO) located in the Division of Laboratory Policy and Practice, Laboratory Science, Policy and Practice Program Office (LSPPPO). LSPPPO is one of four program offices in CDC's Office of Surveillance, Epidemiology, and Laboratory Services); and
2. five Technology Development Coordinators (TDCs), with one each located in the National Institute for Occupational Safety and Health (NIOSH), the Office of Infectious Diseases (OID), the Center for Global Health (CGH), the National Center for Environmental Health (NCEH), and the Office of the Associate Director for Communication (OADC).

TTO's and the TDCs' efforts, which include complementary and overlapping activities that require coordination and cooperation, comprise the CDC technology transfer program. These activities are summarized in Table 1.

Table 1. CDC's Technology Transfer Program

Technology Development Coordinators	Technology Transfer Office
• Negotiate collaboration agreements (e.g., CRADAs, BMLAs, or MTAs) for basic and applied research as well as research and development projects to advance development and commercialization of technologies. These enable access for CDC programs and external parties to proprietary materials and information and other resources needed to enhance technology transfer.	• Evaluates CDC invention disclosures and obtains and protects patent rights as needed to promote development and commercialization of the intellectual property. • Secures high-value, commercially attractive patents for CDC intellectual property. • Negotiates patent and proprietary technology license agreements to transfer CDC patent rights, proprietary technologies, and materials to private-sector partners for development and commercialization.

BMLA = biologic material transfer agreement; CRADA = cooperative research and development agreement; MTA = material transfer agreement.

CDC's Small Business Innovation Research Program

CDC's Small Business Innovation Research (SBIR) program is another avenue through which CDC technology transfer efforts can be maximized for large scale impact. The SBIR program encourages domestic small businesses to engage in federal research/research and development (R/R&D) that has the potential for commercialization. CDC's SBIR program is administered by staff throughout the agency's national centers, program officers, and institute and is coordinated by the Office of the Associate Director for Science.

Small businesses face barriers in identifying opportunities to commercialize federal technology. For example, prevention research often involves long timelines, complex and expensive research models, and difficult regulatory and market adoption challenges. The technology transfer program coordinates with the SBIR program to bring CDC inventions to the attention of small businesses. Working together, the technology transfer program and the SBIR program will facilitate more partnerships which can potentially result in the commercialization of more CDC technologies, ultimately leading to improved health. Strengthening this partnership is a key focus of the 5-year plan.

Current Technology Transfer Program Goals

As of April 2012, the five principal goals of CDC's technology transfer program are as follows:

1. Facilitate exchange of proprietary materials and information needed to advance techniques and tools to improve health.
2. Establish collaborations to advance research and to advance development of new research resources and new products to benefit public health.
3. Secure rights to CDC inventions by acquiring intellectual property protection.

4. Promote development and commercialization of CDC's commercially viable intellectual capital by assigning licensing intellectual property rights and research materials to private sector partners.
5. Foster partnerships between CDC and external entities.

Fiscal Year 2011 Technology Transfer Program Accomplishments

Table 2 presents information on the agreements, patent applications, patent issuances, royalties, and other indicators of the accomplishments of CDC's technology transfer program during FY 2011.

Table 2. Key Accomplishments of CDC's Technology Transfer Program, FY 2011

Output	No.
Biologic material license agreements	8
Material transfer agreements	241
Cooperative research and development agreements	2
Exclusive patent license agreements	2
Co-exclusive patient license agreements	1
Nonexclusive patient license agreements	5
Commercial evaluation license agreements	3
Proprietary technology license agreements	4
Employee invention reports received	52
Patents filed	87
Patents issued	60
Patent pending material transfer agreements	20
Total royalties collected by CDC's Technology Transfer Office	$1,127,457
Total royalties collected by CDC's Office of Infectious Diseases Technology Development Coordinator	$ 339,024

CDC Plan for Accelerating Technology Transfer and Commercialization

The new CDC 2013–2017 plan has five goals has one or more objectives, and each of those will be pursued through specific tasks. Progress toward each objective will be based on measurable outputs (i.e., metrics) (Table 3).

The overarching aim of the plan is to increase the number of CDC's technology transfer partnerships with federal and nonfederal entities, including private firms, research organizations, and nonprofit entities. The plan also will improve the efficiency of the agency's technology transfer program through automation of common, high-volume activities, enabling professional staff to focus more on marketing and partnership development and engagement activities. This approach is expected to increase both the number and rate of formation of technology transfer partnerships.

The plan is intended to be an evolving document. During the first year, CDC will work toward achieving the initial metrics, develop methods to capture the data for each task, and initiate collection of baseline measures. CDC will conduct ongoing evaluation and will adjust the goals, tasks, metrics, and timeline, as needed.

Table 3. CDC Plan for Accelerating Technology Transfer and Commercialization

- **Performance Goal 1: Increase the number of technology transfer partnership activities with nonfederal entities (commercial, research, and nonprofit organizations).**

No.	Objective	Task	Metric	Timeline
1	Increase awareness about CDC technology transfer program among nonfederal partners	• Explore new outreach activities (e.g., trade meetings, social media, and targeted marketing) • Expand collaboration with GeorgiaBIO™ (a nonprofit, membership-based organization that promotes interests and growth of the life sciences industry), Georgia Research Alliance (an independent not-for-profit entity governed by leaders from industry and academia), CDC Foundation, and local chambers of commerce • Explore collaboration with local and regional biotechnology, pharmaceutical, and occupational safety-focused companies located in other parts of the United States where CDC offices are located	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	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

No.	Objective	Task	Metric	Timeline
2	Expand and diversify the number of opportunities for small businesses to seek SBIR funding	• Increase the number of CDC topics included in the annual SBIR grant and contract omnibus announcement • Initiate targeted CDC SBIR funding announcements throughout the year with varying due dates	Number of SBIR topics published in annual omnibus solicitations Number of targeted CDC SBIR funding announcements published	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress
3	Increase outreach efforts to small businesses to facilitate information sharing on funding opportunities and technical assistance	• Develop SBIR outreach and training materials targeted to small businesses and associated organizations • Develop SBIR collaborations with state-level economic and business development centers	Number of SBIR webinars developed and conducted Number of CDC-SBIR Internet hits and material downloads Number of teleconferences attended and presentations made	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress
4	Increase access to partners by developing comprehensive Internet-based listings	Update marketing materials — List of patents and proprietary materials available for licensing — List collaboration opportunities — Coordinate technology transfer and national center, program office, and institute Internet sites and links — List unique biologic materials and cell lines licensed in the past and still available for licensing	Number of hits to the Internet content Number of license applications established through such awareness	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

SBIR = Small Business Innovation Research.

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

No.	Objective	Task	Metric	Timeline
1	Modify CDC technology transfer policies to be more effective and user-friendly while maintaining statutory requirements	• Form an internal working group to examine CDC 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. CDC will perform an annual review to develop more specific activities to measure agency progress
2	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. CDC will perform an annual review to develop more specific activities to measure agency progress
3	Streamline CDC technology transfer partnership processes and procedures to maximize transfer effectiveness	• Form a working group to identify areas needing improvement and design strategies for improvement and implementation • Improve and simplify model agreements (MTAs, CRADAs, PTLAs, PLAs, and other collaboration agreements) to reduce resources and time spent on negotiation • Identify internal bottlenecks and devise approaches to eliminate or reduce them	After the baseline is determined in 2013, percentage reduction in the average time between submission of CRADA proposal and execution After the baseline is determined in 2013, percentage reduction in the average time in the execution of other license agreements	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure progress

No.	Objective	Task	Metric	Timeline
4	Improve synergy, collaboration, and coordination between technology transfer professionals throughout CDC program activities and the Technology Transfer Office	• Create a single website for the technology transfer program • Unify intellectual property databases within CDC to improve data sharing to maximize efficiency	Creation of content for technology transfer program website. Unify the intellectual property databases	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress
5	Explore use of automated workflow systems for routine transfer agreements and royalty distribution	• Form a working group to identify and implement new systems for managing material transfer and simple agreements	Number of automated systems reviewed Number of automated systems adapted Implement an automated royalty payment system	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

CRADA = cooperative research and development agreement; MTA = material transfer agreement; PLA = patent license agreement; PTLA = proprietary technology license agreement.

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

No.	Objective	Task	Metric	Timeline
1	Increase awareness and participation in technology transfer efforts within CDC by — Improving technology transfer training for CDC scientists and staff — Forming an internal working group to identify impediments to technology transfer efforts — Market Technology Transfer Office services to CDC scientists and staff	• Develop a training plan for CDC • Develop and implement a training module with tracking and reporting capability • Develop plans to reduce or manage the identified impediments • Identify external experts to present seminars • Develop a plan to better market Technology Transfer Office services to CDC scientists and staff	Percentage of scientists having completed CDC technology transfer training Number of employee invention reports from newly trained staff	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

No.	Objective	Task	Metric	Timeline
2	Provide opportunities for CDC scientists to learn more about technology transfer and the business side of science and marketing	Expand skill sets of CDC 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 CDC 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. CDC will perform an annual review to develop more specific activities to measure agency progress
3	Improve awareness of the technology transfer program and its benefits to CDC's national centers, program offices, and institute and to CDC's leadership	• Increase awareness of the technology transfer program throughout CDC and among agency leadership • Develop annual reports to highlight services provided by the Technology Transfer Office and its benefit to CDC	Number of presentations to CDC leadership Annual report delivered to CDC's national centers, program officers, and institute	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

No.	Objective	Task	Metric	Timeline
4	Increase and improve awareness across CDC 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 CDC SBIR intranet site	Number of presentations to CDC staff Number of attendees at SBIR presentations Number of hits to CDC SBIR intranet site	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

SBIR = Small Business Innovation Research.

Performance Goal 4: Improve collaboration with other federal agencies that focus on human and animal diseases.

No.	Objective	Task	Metric	Timeline
1	Expand interaction with other federal agencies that have human and animal health interests	• Collaborate with the National Institutes of Health and the U.S. Department of Agriculture to identify technologies of common interest • Bundle common technologies and jointly market through Internet sites and advanced search tools • Implement joint marketing of bundled technologies by using the National Institutes of Health, CDC, and the U.S. Department of Agriculture Internet sites and other marketing venues	Number of bundled technologies identified Number of bundled agreements signed Increase in revenue generated from bundled agreements	Baseline tasks to be identified by 2013. CDC will perform an annual review to develop more specific activities to measure agency progress

- **Performance Goal 5: Measure impact of CDC's technology transfer program.**

No.	Objective	Task	Metric	Timeline
1	Understand the impact of CDC technology transfer program	Survey and evaluate health and economic indicators	Total revenue generated by CDC licensees Number of jobs supported by licensee agreements Total royalties accrued to CDC	CDC will identify internal and external partners to assist in developing an evaluation plan for a long-term trending and impact study

Cross agency opportunities to be considered by CDC

- One common theme emerging from the responses is that most of the agencies face the same challenges (level of training, lack of awareness, lack or less use of electronic tools for technology transfer, complicated processes and delays in execution). It is promising to note that most of the agencies are thinking about solutions which can expand and augment technology transfer as an engine for job creation. CDC is likely to benefit from the progress made by NIH and FDA. In addition, CDC is very much interested in exploring other cross agency opportunities and ready to adopt innovative practices followed in other agencies.

- As already mentioned in the draft plan, CDC will work with NIH and USDA to jointly market and commercialize technologies of common interest.

- DOE, USDA and VA have identified process improvements. CDC technology transfer professionals will reach out to the colleagues in DOE, USDA and VA, understand the specifics, and adopt, if applicable.

- Almost all of the agencies are exploring options to enhance the utility of CRADA and SBIR programs. CDC will specifically benefit from the efforts at the NIH and will adopt the improvements as they become available through the PHS Technology Transfer Policy Board. Another possibility is to adopt the steps taken by EPA on CRADAs.

- CDC will examine if the pre-commercialization license terms being discussed by the USDA is helpful to CDC.

- CDC will also examine the utility of the Start-Up license, license for non-profit institutions, such as non-government organizations (NGOs) and product development partnerships (PDPs) developed by NIH.

- CDC will explore the utility of the new licensing programs developed by NIST/DoC for assisting startups and small businesses.

- CDC has placed lot of emphasis in the development and adoption of Electronic Laboratory Records (ELR) and Electronic Health Records (EHR). Collaborations with in and outside of CDC are ongoing to develop appropriate software in this regard. If CDC is successful in developing such tools, CDC may benefit from the model software development CRADA and the terms being considered by FDA. At the right juncture, CDC will reach out to FDA and use those as a baseline for CDC negotiations.

- The Material Transfer Research Agreement (MTRA) indicated in the USDA plan is attractive to CDC. CDC will consider the new instrument to broaden collaboration and product development.

- CDC will also evaluate use of new tools, such as the NIH electronic Transfer Agreement Dashboard (TAD), to streamline material transfer processes. NIH had given a demo of TAD to CDC technology transfer community. Further discussion may have to be established. The electronic Research Materials Catalog (eRMa) will also be helpful.

- CDC has implemented Pay.gov, a web-based application allowing licensees to make payments by debit from a checking or savings account. However, more marketing is needed for licensees to be aware of this avenue and use this for future royalty payments. CDC technology transfer professionals will reach out to NIH, understand the lessons learned and apply them in CDC's context, to expand royalty receipt through Pay.gov.

- As mentioned in the DHS draft plan, it is possible for CDC to explore inventions previously not reported through Employee Invention Reports (EIRs) in an incremental fashion and with due consideration to the available resources and potential impact.

- CDC is interested in the development of strategies and tools to help leverage and facilitate collaboration with other agencies in order to increase co-funding of SBIR grants and contracts. NIH uses the IMPAC II/eRA system internally and within HHS to facilitate co-funding, but it remains difficult to identify other interested agencies outside of HHS.