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Overview and Analysis of Technology Transfer from Federal Agencies and Laboratories

Prepared for

National Institute of Standards and Technology
Technology Partnerships Office
100 Bureau Drive
Gaithersburg, MD 20899

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- Department of Health and Human Services, Center for Disease Control
- Department of Health and Human Services, National Institutes of Health
- U.S. Department of Agriculture

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Case Study	Topic	Author(s)
DOC, NIST	Cybersecurity Framework	Christopher Hayter (Arizona State University)
Department of Defense (DoD), Air Force	Attenuating Custom Communications Earpiece System (ACCES)	Kyle Clarke-Sutton (RTI)
DoD, Army	Japanese Encephalitis Virus (JEV) Vaccine	Michael Hogan (RTI)
DoD, Navy	Port Security Barrier System (PSB)	Zack Oliver (RTI)
Department of Interior (DOI), U.S. Bureau of Reclamation	Flexible Fluxprobe Diagnostic Tool	Christopher Hayter (Arizona State University)
DOT, Federal Highway Administration	Mobile Solution for Assessment and Reporting (MSAR)	Zack Oliver (RTI) and Gretchen Jordan (360 Innovation)
Department of Health and Human Services (HHS), Centers for Disease Control	Human Microvascular Endothelial Cell Lines (HMEC-1)	Christopher Hayter (Arizona State University)
HHS, National Institutes of Health	Human Papillomavirus (HPV) Vaccine	Troy Scott (RTI)and Zack Oliver (RTI)
USDA, Agricultural Research Service	Tifton-Bred Turfgrasses	Gretchen Jordan (360 Innovation)

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Executive Summary

The purpose of this report is to present a series of analyses of technology transfer activities across federal agencies and their research laboratories.

Public support of efforts to transfer technology from federal agencies to private and public organizations has long had bipartisan support from both Congress and the White House. To emphasize this point, and thus to provide context for this study (Chapter 2), we first provide an overview of federal technology policies as they relate to U.S. federal agencies and their research laboratories. The lesson learned from this overview is that such policies have been promulgated without political bias over at least the past four decades. In addition, this overview provides some institutional context for this study.

With this context in mind, we then provide a summary of the relevant academic and policy literatures related to technology transfer (Chapter 3). This review concludes with the observation that not only have there been a few systematic studies describing technology transfer activities across federal agencies, but also that those studies have not been encompassing or detailed in their descriptive analyses of economic impacts associated with federal technology transfer. We conclude that the reason for both of these limitations is associated with the lack of relevant public domain data related to the process of technology transfer at a level of aggregation (i.e., at the agency and/or laboratory level) that facilitates understanding both the genesis of the technology transfer process beginning with intramural research and development (R&D) investments and concluding with metrics that describe the paths through which technology leaves an agency or laboratory and enters into another organization, as well as the economic impact of transferred technology on the recipient organization.

This study advances our understanding of technology transfer across federal agencies and laboratories in several ways. First, we describe publicly available information and data on technology transfer mechanisms from federal agencies and laboratories (Chapter 4). The source of this information is the annual versions of the Federal Laboratory (Interagency) Technology Transfer Summary Reports, prepared by the Technology Partnerships Office at NIST and submitted to the Office of the President and to Congress. The technology transfer mechanisms that are described are the same mechanisms that have been emphasized in the extant academic and policy literature: patent applications, patent issues, licenses, cooperative R&D agreements (CRADAs), publications, and public software downloads of open-source governmental software. Although an understanding of these mechanisms does provide insight about technology transfer activities from within to outside organizations, and to some extent across agencies and their research laboratories, that understanding, in the absence of information about how the transferred technology is used by the adopting organizations, is insufficient to offer insight about trends and nuances associated with technology transfers.

As an initial step in that direction, an approach was developed to provide a logical framework to bound the study and the information we obtained from federal agencies and laboratories that agreed to participate in this study: (1) disaggregated information and related data on their technology transfer efforts and (2) background information on what they considered to be a particularly successful technology transfer effort for a case study (Chapter 5).

The disaggregated data were sufficient only for a preliminary look at elements of the economic consequences associated with the technology transfer from the participating federal agencies and laboratories; the background information on successful technology transfer efforts was sufficient to develop illustrative case studies (Chapter 6).

One characterization of the disaggregated data related to the geospatial distribution of organizations to which federal agency technology is transferred (Chapter 7). Using National Institute of Standards and Technology (NIST) data, there is suggestive evidence that CRADA activity occurs closer to the participating

agency than does licensing activity. Regardless, the geospatial analysis in Chapter 7 does illustrate that technology transfer activities are national in scope.

The disaggregated data allowed for a descriptive analysis of the sales growth associated with organizations to which agencies licensed technology (Chapter 8). We conclude that licensed technologies from a federal agency and laboratory have an overall positive association with the sales of private-sector company licensees. However, the available data do not allow us to control for company or other economic factors that are also associated with sales growth.

As stated in 15 USC 3710a(c)(4)(A), CRADA preference to small companies is required: "The laboratory director in deciding what cooperative research and development agreements to enter into shall—(A) give special consideration to small business firms, and consortia involving small business firms; …." Our analysis of available disaggregated data confirms that this is the case (Chapter 9). On average, the majority of CRADAs were with small companies measured in terms of number of employees.

The case studies we conducted to complement the main analysis were structured to conform to a logical framework designed to document successful technology transfer efforts through the identification of specific outcomes and impacts associated with a technology transferred from a federal laboratory, accounting for contingencies that served as success factors (Chapter 10). The case studies illustrate that bringing innovations derived from federally transferred technology to the private-sector marketplace takes time as well as the federal laboratories' long-term commitment to investments in R&D. Federal laboratory management may facilitate the success of technology transfer by providing resources, championing the to-be-transferred technologies, and instilling a culture in the federal laboratory that values such activity. Lastly, the federal laboratory's co-development of a transferred technology with individuals or companies with supplementary expertise increases the likelihood that the transferred technology will have market success.

1 Introduction

This report summarizes efforts by researchers at RTI, the University of North Carolina at Greensboro (UNCG), Arizona State University (ASU), and 360 Innovation

- to assemble data related to technology transfer activities across federal agencies and laboratories,
- to use those data to provide an overview and analyze the use of technology transfer mechanisms across federal agencies and laboratories, and
- to present suggestive estimates of the economic impacts associated with technology transfer activities from federal agencies and laboratories.

These objectives were realized through the use of agency technology transfer data provided by the Technology Partnerships Office at NIST and the collection and analysis of technology transfer data from participating federal agencies[1] and from information collected through nine case studies of successful technology transfers from federal agency laboratories.

As background, the Interagency Workgroup on Technology Transfer (IAWGTT) is charged with making recommendations to the Department of Commerce for improving technology transfer across federal agencies.[2] These recommendations are to include improved practices related to current technology transfer programs and standards for assessing the effectiveness of these programs, new or creative approaches to technology transfer that might serve as model programs for federal agencies, new criteria to assess the effectiveness and impact on

[1] Agencies for which technology transfer data at the laboratory level were collected and the types of data collected are listed in Table 6-1.

[2] The IAWGTT comprises technology transfer representatives from each involved agency, of which there are 11. Its purpose is to discuss best practices in technology transfer from federal agencies.

the nation's economy of planned or future technology transfer efforts, and methods for an assessment of CRADAs. The IAWGTT is coordinated by the director of the Technology Partnerships Office at NIST.[3]

On October 28, 2011, President Barack Obama sent a Presidential Memorandum, *Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses,* to the heads of executive departments and agencies.[4] Prefacing the memorandum was the following policy statement:

> 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 of my Administration's "Startup America" initiative, which supports high growth entrepreneurship, is to foster innovation by increasing the rate of technology transfer and the economic and societal impact from federal R&D investments. This will be accomplished by committing each executive department and 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, while simultaneously achieving excellence in our basic and mission focused research activities.

In the memorandum, President Obama directed heads of executive departments and agencies to take three actions:

- Establish performance goals, metrics, and evaluation methods, as well as implement and track progress relative to those goals.

[3] NIST also has a statutorily defined role as the host agency for the Federal Laboratory Consortium (Zielinski, 2014).

[4] See https://obamawhitehouse.archives.gov/the-press-office/2011/10/28/presidential-memorandum-accelerating-technology-transfer-and-commerciali.

- Streamline the federal government's technology transfer and commercialization process.
- Facilitate commercialization of federal laboratory technologies through local and regional partnerships.

In November 2012, the IAWGTT prepared a response to the President's October 2011 memorandum.[5] Comments from 11 agencies formed the basis of the IAWGTT's response report.[6] The responding agencies affirmed the need for the actions specified in the President's memorandum, and agencies acknowledged that "it is the impact of their technology transfer activities that is important, rather than tallies of output. However, no efficient way to consistently measure impact in the aggregate or to calibrate the impact of one technology transfer activity over another has been identified."[7]

Prior to President Obama's memorandum, agencies were already involved in performance planning as directed by the GPRAMA (Government Performance and Results Modernization Act of 2010, Public Law 111-352):

> Not later than the first Monday in February of each year, the head of each agency shall make available on a public website of the agency, and notify the President and the Congress of its availability, a performance plan covering each program activity set forth in the budget of such agency … and provide a description of how the performance goals are to be achieved …

Building on the concept of public accountability as quantified through meeting performance goals, President Donald Trump set forth the President's Management Agenda, which "sets out a long-term vision for effective and modern government

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[5] See https://www.nist.gov/tpo/agency-responses-presidential-memorandum

[6] These agencies were the Department of Agriculture (USDA), Department of Commerce (DOC), Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS) (separate reports for Centers for Disease Control and Prevention [CDC], Food and Drug Administration [FDA], and National Institutes of Health [NIH]), Department of Homeland Security (DHS), Department of Interior (DOI), Department of Transportation (DOT), Department of Veterans Affairs (VA), Environmental Protection Agency (EPA), and National Aeronautics and Space Administration (NASA).

[7] See https://www.nist.gov/tpo/agency-responses-presidential-memorandum, p. 2.

capabilities that work on behalf of the American people" (undated, p. 7).

To begin to fulfill this vision, the Agenda identifies Cross-Agency Priority (CAP) Goals. As related to this study, CAP Goal 14 is designed to improve the transfer of federally funded technologies from the lab to the market. Three goals listed in the Agenda are associated with this priority:

- Improve the transition of federally funded innovations from the laboratory to the marketplace by reducing the administrative and regulatory burdens for technology transfer and increasing private-sector investment in later-stage R&D.
- Develop and implement more effective partnering models and technology transfer mechanisms for federal agencies.
- Enhance the effectiveness of technology transfer by improving the methods for evaluating the return on investment (ROI) and economic and national security impacts of federally funded R&D and using that information to focus efforts on approaches proven to work (undated, p. 49).

Motivating the third bullet above is the following observation:

> The Federal Government invests approximately $150 billion annually in research and development (R&D) conducted at federal laboratories, universities, and other research organizations. For America to maintain its position as the leader in global innovation, bring products to market more quickly, grow the economy, and maintain a strong national security innovation base, it is essential to optimize technology transfer and support programs to increase the return on investment (ROI) from federally funded R&D (undated, p. 48).

The Trump Administration's support for enhancing technology transfer from federal laboratories was recently reiterated in the July 31, 2018, memorandum from the Office of Management and Budget, "FY 2020 Administration Research and Development Budget Priorities:"

> Federally funded R&D can lead to transformative products and services that solve problems from the boardroom to the classroom. Agencies should

> continue to focus on the basic and early-stage applied research that provides the fundamental building blocks of new technological advances and expand efforts that empower the private sector to accelerate the transfer of research discoveries from the laboratory to the marketplace.

The remainder of this report is outlined as follows.

In Chapter 2, we provide an overview of U.S. technology transfer policies as they relate to federal agencies and their laboratories. Historically, U.S. technology transfer policies have been broadly supported by both parties in Congress. An in-depth discussion of these enabling policies is in Appendix A. This chapter provides context for the importance of the measurement of technology transfer across federal agencies and laboratories.

In Chapter 3, we review the relevant academic and policy literature related to technology transfer across federal agencies and laboratories. This review also provides both academic and policy contexts for our findings in later chapters.

In Chapter 4, we describe public domain technology transfer information for the seven agencies and their laboratories that participated in this study.[8] This information, reported by the Technology Partnerships Office, can be used to characterize technology transfer activities from federal agencies. These data are used in later chapters to offer observations about economic impacts that might relate to "the effectiveness of technology transfer" (*Agenda*, undated, p. 49).

In Chapter 5, we present the logic model that bounded our data collection efforts and the emphasis of the case studies. This model represents the framework that we followed throughout this study. It highlights not only data collection but also the framework for case studies about successful technology transfers by federal laboratories.

In Chapter 6, we describe the disaggregated data that were collected from the seven participating agencies. We matched these data to various categories of data from secondary sources to use in latter chapters.

[8] The agencies that participated in this study are DOC, DoD, HHS, DOI, DOT, EPA, and USDA. See the Acknowledgments section above.

In Chapter 7, we describe the geospatial distribution of agency technology transfer partners as measured by the location of the partner organization.[9] Our findings in this chapter offer a characterization of the proximity of the spillover of R&D-related technology transfer activities.

In Chapter 8, we explore the relationship between both the timing of the execution of licenses and the subsequent trajectory of the sales of the licensees. Licensing is one of several technology transfer mechanisms used by federal agencies and their laboratories described in Chapter 4, and measuring the association between licensing activity and the sales of licensees offers suggestive evidence of the economic impact of licensing.

In Chapter 9, we examine CRADA activity, and in particular, we explore the propensity of agencies to engage in CRADAs with smaller-sized companies as directed in President Obama's memorandum. CRADAs are another technology transfer mechanism used by federal agencies and laboratories described in Chapter 4. In this chapter, we offer a characterization of federal CRADA efforts across partner companies, with an emphasis on the size of the partner companies.

In Chapter 10, we chronicle the case studies' findings in terms of the factors that contributed to their technical and market success. These case studies offer a qualitative understanding of technology transfer activities that is not evident through empirical measures of technology transfer activities that are already captured in the Technology Partnerships Office's annual reports to the President and the Congress; Federal Laboratory Technology Transfer.

Finally, in Chapter 11, we summarize our overall findings from this study.

[9] We use the word *partners* broadly to refer to the external partners for each CRADA as well as licensees.

2 Technology Transfer Policies toward U.S. Federal Agencies and Laboratories

In this chapter, we provide an overview of the federal government's technology transfer policies as they relate to federal agencies and laboratories. More detail about the historical evolution of these policies is captured in Appendix A.[10]

President Carter's Domestic Policy Review in 1979 emphasized the importance of the transfer of technical knowledge:[11]

> Often, the information that underlies a technological advance is not known to companies capable of commercially developing that advance. I am therefore taking several actions to ease and encourage the flow of technical knowledge and information. These actions include establishing the Center for the Utilization of Federal Technology at the National Technical Information Service to improve the transfer of knowledge from Federal laboratories ….

President Carter's charge was, in part, motivation for the passage of the Stevenson-Wydler Act of 1980, Public Law 96-480. This legislation is generally considered to

[10] This chapter and Appendix A draw directly from Link and Oliver (2017).

[11] See President Carter's Industrial Innovation Initiatives Message to the Congress on Administration Actions and Proposals (October 31, 1979): http://www.presidency.ucsb.edu/ws/index.php?pid=31628 This message to Congress was in response to the productivity slowdown throughout the U.S. economy as discussed in Appendix A.

be the first public policy to address the transfer of technology developed in federal laboratories to the private sector.

The stated purpose of the Act is to:

> improve the economic, environmental, and social well-being of the United States by … promoting technology development through the establishment of centers for industrial technology … [and to encourage] the exchange of scientific and technical personnel among academia, industry, and Federal laboratories.

The Act emphasizes that there is a need for a national policy supporting domestic technology transfer and supporting the use of the science and technology (S&T) resources of the federal government.

The Act also makes clear that it is the responsibility of each federal laboratory to establish an office as well as mechanisms to transfer its technology to those organizations that will benefit: "The Federal Government shall strive where appropriate to transfer Federally owned or originated technology to State and local governments and to the private sector."

The Bayh-Dole Act of 1980, Public Law 96,517, a complement policy initiative to the Stevenson-Wydler Act of 1980, permitted universities, small businesses, and nonprofit organizations to patent and license technologies directly developed from federally funded research or developed though cooperative agreements.

To enhance the technology transfer mission of federal agencies and laboratories, a bipartisan Congress, with support of President Ronald Reagan, amended the Stevenson-Wydler Act of 1980 in 1986 with the passage of the Federal Technology Transfer Act of 1986 (FTTA), Public Law 99-502. Whereas the Stevenson-Wydler Act made explicit the technology transfer responsibilities of federal agencies and laboratories, the FTTA facilitated technology transfer by permitting the laboratories to enter into CRADAs with public and private organizations. The FTTA also established the Federal Laboratory Consortium for Technology Transfer (FLC) and the National Bureau of Standards (NBS, which later became NIST) as the host agency.

The FLC would, among other things, "develop and … administer techniques, training courses, and materials concerning technology transfer to increase the awareness of Federal laboratory employees regarding the commercial potential of laboratory technology and innovations …."

Federal agencies and laboratories have traditionally transferred their technology in the form of patents, licenses to laboratory-developed technologies, and CRADAs, as well as through publications, standards, and other modes. Many of these technology transfer mechanisms and other metrics are reported at the agency level in the federal laboratory Technology Transfer Report to the President and the Congress, which is prepared by the Technology Partnerships Office at NIST on behalf of the agencies and using data gathered from the agencies. Metrics presented in these reports are discussed in Chapter 4. The limitations of these metrics, which are defined by federal legislation, to describe fully the technology transfer process from federal agencies and laboratories and the potential economic impact of transferred technology were a motivation for this study.

3 Academic and Policy Literatures on Technology Transfer from Federal Agencies and Laboratories

Summary

- The academic literature (in Section 3.2) on technology transfer is limited. Existing studies find that CRADAs and patenting activity increased in response to federal policy changes in the 1980s. Authors suggest that laboratory activity was more responsive to the Federal Technology Transfer Act of 1986 than to earlier legislation in the way that observed levels of technology transfer activity increased.
- The policy literature (in Section 3.3) on technology transfer has focused on governance models, mechanisms, best practices, barriers to cooperative research, and technology transfer's role in economic development. On the whole, this literature suggests more efficient and effective ways for using federal S&T assets.

The literature that is focused on technology transfer mechanisms can be divided into two broad areas for summary purposes: the academic literature and the policy literature.[12]

[12] We use the term *policy* to refer to papers authored by government agencies or the U.S. Congress, papers commissioned by government agencies, or papers with a primary focus on federal technology transfer that were written for a nontechnical audience. The literature review that follows draws directly from Link and Oliver (2017).

3.1 LITERATURE REVIEW METHODS

We conducted a literature review on identified peer-reviewed journal articles based on the research experience of the authors of this study. The initial compilation of articles was complemented with online desktop research using various publication search engines, web-search engines, and specific websites such as the FLC. Search terms included combinations of the following words and phrases: *federal laboratory*, *technology transfer*, *CRADAs*, *licenses*, *patents*, *impact*, *effect*, and *economic.*

We selected for review and inclusion in this report the articles that were focused specifically on technology transfer mechanisms and their associated metrics. We eliminated articles that were historical overviews or institutional case studies. Thirteen journal articles and working papers from the academic literature and 12 articles and reports from the policy literature are summarized briefly below and in greater detail in Appendices B and C, respectively.

3.2 ACADEMIC LITERATURE[13]

The early academic research on technology transfer from federal laboratories was by Ham and Mowery (1995, 1998) and then later by Mowery (2003). Because of data constraints, their approach to the study of a single technology transfer mechanism, CRADAs, was case based, and it involved a small sample of five collaborations between DOE and companies. Ham and Mowery (1995) pointed out some limitations of CRADAs as a technology transfer mechanism, while Ham and Mowery (1998) described some characteristics that are fundamental to CRADA success. Ham and Mowery (1995) also emphasized that laboratories do not possess a panacea of on-the-shelf technology that is ready to be transferred to private-sector partners. Instead, they described a more realistic framework for considering CRADAs that is defined by three

[13] The paucity of academic scholarship about technology transfer from federal laboratories relative to the scholarship on university technology transfer is, in our view, due to researcher problems in obtaining data from federal laboratories on relevant technology transfer metrics.

broad classes of cooperative activity: (1) transfer, (2) co-development, and (3) R&D services.[14]

In the late 1990s and early 2000s, a series of articles began to bring together disaggregated datasets related to federal agency technology transfer activities. These studies were limited to specific agencies that were willing to share information. For example, Jaffe et al. (1998) and Jaffe and Lerner (2001) undertook a significant data collection effort for their empirical study of NASA and DOE patenting. Their two papers concluded that the federal policy changes in the 1980s were followed by increased patenting activity at both NASA and DOE. Jaffe and Lerner (2001) found that as a result of this increase, federal laboratories reached parity with universities in terms of patents per R&D dollar without an overall decline in patent quality. Using NASA data, Jaffe et al. (1998) established that patent citations are a reasonable, but still noisy, measure of technology spillovers.[15] Furthermore, geographic proximity between a company and the laboratory increases knowledge spillovers as measured by citations.

The study by Adams et al. (2003) represents a novel approach to the study of technology transfer. They examined R&D activity in industrial laboratories in an effort to identify activity conducted in cooperation with federal laboratories and to identify the nature of those collaborations. They found that CRADAs lead to higher levels of company patenting than did other mechanisms because of the intensive collaboration between laboratories and companies. Mowery (2003) pointed out that the technology transfer data used by Adams et al. (2003) are limited to relatively large, publicly traded companies because of data constraints, so generalizations should be made with caution.[16]

Link et al. (2011) represents a longitudinal study of overall patenting activity at two federal laboratories: NIST and separately at Sandia National Laboratories (combined). They

[14] Relatedly, Guston (1998) described and documented the use of CRADAs at NIH.

[15] Anecdotally, some patents are cited at the recommendation of lawyers and may have nothing to do with technology transfer. For some discussion of "defensive" citation, see Hall and Ziedonis (2001).

[16] For another detailed overview of the CRADA literature, refer to Mowery (2003).

examined the trend in patenting in these laboratories in response to the Stevenson-Wydler Act and the FTTA, and they inferred from the time series that the latter Act had the greater impact on patenting.

Stevens et al. (2011) developed an approach for exploring the social value of intramural research that had been transferred to private-sector partners. Specifically, they investigated the degree to which successful drug discovery and development projects were derived from public-sector research. Public-sector research institutions were defined as all universities, research hospitals, nonprofit research institutes, and federal laboratories in the United States. They did not identify the mechanism by which public-sector research was transferred to the private sector, but given that they attributed technology to public-sector research institutions based on patents, it is likely that the method of transfer was a license negotiated between the public sector and the company. They found that medical technologies derived from public-sector research (likely through licenses) are expected to have a significant therapeutic effect; more than half are used in treating cancer or infectious diseases.

Chatterjee and Rohrbaugh (2014) built on the work by Stevens et al. (2011) by analyzing NIH's Intramural Research Program's (IRP's) contribution compared with that of all other public-sector research institutions collectively referred to as extramural public-sector research institutions.[17] Overall, their study found that NIH's intramural contributions are disproportionately larger than their level of research funding. For example, the NIH IRP contributed 14.4% of new drugs brought to market based on 11.2% of research funds.

Within the last few years, several other important papers on technology transfer have been published. A working paper by

[17] Chatterjee and Rohrbaugh (2014) do not account for funding sources for extramural public-sector research institutions. They describe funding sources as follows: "The extramural institutions are primarily funded under a competitive peer review system with grants and contracts from federal agencies and foundations. They receive additional funding from state governments, foundations and corporate sponsors. In contrast, the NIH IRP is funded prospectively by the U.S. government to conduct research within the mission of each of the NIH institutes and centers. Unlike recipients of grants and contracts, peer review of each principal investigator's laboratory in the NIH-IRP is conducted retrospectively by outside expert review panels." (p. 54)

Chan (2014), for example, represents a novel approach to linking licensing to the amount of citations (albeit, a noisy indicator) that the licensed patents receive relative to nonlicensed patents. Studying more than 800 licensed patents at DOE since 2000, he infers that licensing increases the annual citation rate to a patent between 20% and 37%. Over 80% of subsequent patents that cite a licensed patent come from companies other than the licensee company, which means that the impact of licensing is quite broad and is not concentrated within the licensee company.

Recently, Popp (2016a) investigated the role of government research and government funding in private-sector publications and patenting as well as the flows between these two sectors. He estimated that an additional $1 million in government funding leads to one to two additional publications on alternative energy technologies but with lags of up to 10 years between initial funding and publication. He also found that wind publications are the most likely to be cited by a patent.

In a companion publication based on two decades of scientific articles on renewable energy,[18] Popp (2016b) found that renewable energy articles most highly cited by other scientific articles are also more likely to be cited by future patents. Therefore, journal-to-journal citations might be a good indicator of the impact of an article on technology development. He also found that government publications are more likely to be cited by patents than publications from universities and other institutions. In other words, research performed at government institutions (e.g., federal laboratories) has an important role in translating between basic and applied research.

Finally, Chen et al. (2018) used a dataset of CRADA activity at NIST over the years 1978 through 2014 to explore several research questions: Did the FTTA have an impact on CRADA activity at NIST? Is CRADA activity at NIST a cyclical phenomenon? At what frequency do private-sector companies engage in CRADA activity with NIST? They characterize this last research question as an exploratory test of the relationship between company size and the propensity to engage in a CRADA. The authors found suggestive evidence that the FTTA began to influence NIST's CRADA activity within 2 to 3 years

[18] Specifically, Popp (2016b) focused on biofuels, solar energy, and wind energy.

after its passage and that CRADA activity moves with the business cycle. The authors also found that most companies that were engaged in CRADA activity were engaged only once; only the larger companies continued to engage over time in CRADAs with NIST.

Summarizing the academic literature, CRADAs and patenting activity increased in response to federal policy changes in the 1980s, perhaps more in response to the FTTA than to earlier legislation. Also, there is some evidence that certain technology transfer mechanisms are complementary in terms of uptake; federal technology transfer can have an outsized role in certain contexts, company size matters in terms of patterns of partnering with federal agencies and laboratories, and research funding and legislation do affect the volume of technology transfer activity.

3.3 POLICY LITERATURE

A policy literature on federal technology transfer developed in parallel to the academic literature. Many of the same key agencies—DoD, DOE, and NASA—are discussed in it. While some of the same themes emerge at times, there are different emphases in each. While the peer-reviewed literature is very focused on mechanisms and associated metrics and on teasing out the effect of various factors, the non-peer-reviewed literature tends to focus on barriers to accomplishing specific goals of technology transfer such as partnerships with the private sector for commercialization and contributions to regional economic development. This literature is, in general, very DOE-centric, with relatively little attention paid to the rest of the federal laboratory system. The non-peer-reviewed literature also documents success stories and provides guidance to research managers both in the laboratory and in the technology transfer office (TTO).

The policy literature includes two major categories of publications:

1. Assessments of technology transfer activities, mechanisms, and policies based on qualitative and quantitative data on performance or effectiveness
2. Best practice documents for government researchers and technology transfer practitioners who are involved in developing and transferring technology

Assessments of technology transfer have been conducted by both internal and external evaluation teams. Most of the policy literature is qualitative, descriptive, or based on secondary sources. However, a major quasi-internal evaluation effort, commissioned by the U.S. Congress, was undertaken by NIH in the early 1990s. It is titled *Technology Transfer and the Public Interest* and focused on the usefulness of CRADAs as a collaborative mechanism.[19] It is important to point out that at the time of the NIH report, CRADAs had only then been recently established by the FTTA in 1986. The NIH Office of Inspector General (OIG) found the CRADA mechanism was useful for collaboration by helping to pool public and private resources, protecting the intellectual property (IP) rights of the government, and facilitating technology transfer to the private sector. The NIH OIG also identified several challenges for managing CRADAs such as a mismatch between some CRADA projects and what the mechanism was intended to accomplish (i.e., technology transfer out of federal laboratories); a lengthy and complex process for establishing CRADAs; limited oversight; and the pricing of products that emerge from CRADAs, which is out of the control of federal laboratories.

After a decade lull in the commission of policy reports from 2000 to 2010, there has been a flurry of assessment activity. A series of three reports was published between 2011 and 2013 by the Science and Technology Policy Institute within the Institute for Defense Analysis (IDA) (IDA, 2011; 2013a; 2013b). These reports explore barriers to technology transfer, identify innovative strategies and best practices, and discuss measurement issues. The first report, entitled *Technology Transfer and Commercialization Landscape of the Federal Laboratories*, commissioned by the Economic Development Administration within DOC and by NIST, examined the entire landscape of technology transfer mechanisms across the federal laboratory system. IDA focused their descriptive analysis on licenses, CRADAs, user facility agreements, work for others, and partnership intermediary agreements (IDA, 2011).

A second IDA report, entitled *Exemplar Practices for Department of Defense Technology Transfer*, published in 2013 (IDA, 2013a), was commissioned in response to an executive order, by the Office of Science and Technology Policy (OSTP) in

[19] NASA does not engage in CRADA activity.

conjunction with the Office of Management and Budget. This report outlined policies that could address barriers to technology transfer from federally sponsored aeronautics R&D programs to civil and national security applications. The barriers that could be addressed fall into four broad categories: coordination and awareness of the National Aeronautics Research and Development Policy plans, communication and liaison among stakeholders, maturity of new technology, and institutional practices and culture.

The final IDA report, entitled *Expediting the Transfer of Technology from Government Laboratories into the Aeronautics Industry*, also published in 2013, documents seven broad categories of best practices for DoD laboratories ranging from organizational structure to use of mechanisms for outreach and marketing (IDA, 2013b). These best practices might be useful outside of the immediate DoD laboratory domain as well.

In 2013, NIST commissioned a literature review on technology transfer research and evaluation to help inform its response to the 2011 Presidential Memorandum previously discussed. Bozeman (2013) made several recommendations about measurement issues including the need to identify expected ranges of impact; better scientific and technical human capital metrics, relating process reforms to activities; and the use of logic models and mapping techniques. A major finding of Bozeman's study is that relatively few studies assess the impact of federally developed technologies. Most of the literature on technology transfer impact involves academic institutions or federal extramural projects.

In 2013 and 2014, the Information Technology and Innovation Foundation (ITIF) and the Brookings Institution published reports that emphasized ways in which DOE's laboratories could be reinvigorated, perhaps through improved technology transfer activities. The ITIF (2013) suggested an overhaul of the entire management model of the laboratories, arguing that DOE's laboratories have adhered to a cold-war era model that has not kept up with "the pace of innovation and the complexity of national challenges" (p. 5). This slowness to change is perhaps a result of institutional factors and inefficiencies such as duplicative regulations, micromanagement, and biases against technology transfer to the private sector. The ITIF recommended that laboratories move to a model focused on

contractor accountability (rather than micromanagement), recognizing that funding and management are aligned with innovation goals and providing incentives and flexibility to push more technology to market.

The Brookings report makes the argument for enhancing the connections between federal laboratories and their regions to improve the laboratories as a regional economic development asset (Andes et al., 2014). The authors believe that DOE should reconsider its ability to engage locally given that regional clusters have grown in economic importance. To enhance connection to the region, Andes et al. argue that laboratories should open up to small companies (i.e., referred to as small- and medium-sized enterprises or SMEs) and increase the relevance of their work to emphasize regional effects. Finally, the report emphasizes the need for greater flexibility in oversight and funding, similar to the emphasis of the ITIF report.

Partially in response to reports by ITIF, Brookings, and others (e.g., National Academies studies), DOE's Argonne National Laboratory commissioned a report focused on enhancing partnership. Their report was released in 2016 by Innovation Associates. The report highlights a few exemplary cases where laboratories have attempted to address barriers to partnerships and commercialization. Major barriers include over-centralization and a lack of experimentation by laboratories about how they approach these issues, mixed messages about the importance of technology transfer including a lack of funding and incentives, aversion to risk, and a lack of commercialization experience/capacity for research staff. In many ways, these barriers require a culture change as much as a policy change. The report also discusses ways to enhance partnerships by leveraging existing programs and federal resources such as the Small Business Innovation Research (SBIR) program, the Small Business Technology Transfer (STTR) program, the National Network for Manufacturing Innovation (NNMI), and the Manufacturing Extension Program (MEP).

TechLink—a partnership intermediary of DoD—released a study in 2016 of DoD licensing activities from 2000 to 2014 that attempted to quantify the economic contributions of these licenses. Using surveys of licensees, the study found $20.4

billion in total sales of new products and services resulting from these licenses. Sixty-nine percent of this total derived from a single license of the respiratory syncytial virus antibody that was developed by the Uniformed Services University of the Health Sciences within DoD.

There is also a body of publicly available best practices documents for practitioners. As one example, a year 2000 document released by DOE was written to help scientists get their ideas to market using a more intentional approach toward the innovation process.

The FLC periodically publishes a desk reference, the most recent of which is *Technology Transfer Desk Reference: A Comprehensive Guide to Technology Transfer* (2013). The desk reference is written as a primer and comprehensive reference for TTO staff. It specifically addresses issues in CRADAs and IP. The *Desk Reference* enumerates the benefits of involvement in technology transfer, as selectively quoted from the *Desk Reference*:

- For the government, benefits can be derived from technology moving out of the laboratories, as well as technical expertise coming into the laboratories. Technology transfer activities can be used to assist with accomplishing mission-oriented R&D, for example, when academic or industrial researchers provide needed expertise on collaborative efforts, thus leveraging all parties' research dollars. In the other direction, the government as a whole benefits when technology moves out of the laboratories.
- Federally funded R&D is being put to new or expanded uses. This also results in a better ROI and expedites the rapid movement of technology to the field.
- The government and individual laboratories also benefit financially to the extent that technology transfer provides royalty payments to the government.
- For industry, involvement in technology transfer projects can provide an increased awareness of government needs, giving commercial companies the opportunity to better serve government customers. As is the case for the government partner, the business partner can

leverage R&D costs by building on the relevant R&D that has already been done in or through new collaborations with the federal laboratories, resulting in improved and more cost-effective technology development. Business partners may also benefit by using government facilities (e.g., for product testing) rather than building new facilities, and making use of the expertise of federal scientists and engineers.

- Researchers at universities and nonprofit organizations can benefit financially from various parts of the entire technology transfer spectrum, e.g., as participants in proposals and joint ventures for R&D grants. Individual researchers may benefit intellectually from the close contact with leading technologists in both government and industry.
- For the individual scientist or technologist in a federal laboratory, benefits include possible financial gain from awards and royalty payments, in addition to the personal satisfaction and professional recognition gained from holding a patent or participating in the launch of a new product. The collaboration with other scientists and technologists from industry and academia may improve the employee's ability to accomplish mission tasks and will provide the knowledge that one is a strong contributor to government-mandated technology transfer processes.
- While federal technology transfer benefits national economic growth and competitiveness, these national-level benefits are a compilation of those realized at local, regional, and state levels. State and local government economic development efforts are supported and enhanced by partnering with federal labs via technology transfer initiatives. (FLC, Desk Reference, 2013, pp. 6–7)

Another FLC reference is the *Mechanisms Matrix* (2008). It documents various technology transfer authorities, the agencies that use them, and websites accessible for additional information. Finally, the *FLC Playbook* (undated) describes 15 "plays" ranging from rewarding researchers to working through foundations. Each "play" outlines details, key questions to

consider, and specific agency examples. This is also intended to be a helpful reference resource for TTO staff.

Summarizing the policy literature, many of the policy reports have focused on barriers associated with technology transfer from federal agencies and their laboratories, and best practices in the aggregate and at the agency level. Much like the academic literature, the quantitative analysis summarized above has focused on CRADAs and patents perhaps because information on those mechanisms is more readily available.

4 Public Domain Information on Technology Transfer across Federal Agencies

Summary

- The Technology Partnerships Office at NIST documents a number of technology transfer mechanisms and metrics by agency and by fiscal year in its annual *Federal Laboratory (Interagency) Technology Transfer Summary Report* to the Office of the President and to Congress.
- The number of reported patent applications, patents issued, newly executed licenses, and newly executed CRADAs varies by agency.
- In general, the values of these technology transfer metrics have increased over time.

As previously discussed, the Technology Partnerships Office at NIST prepares and delivers to the Office of the President and to Congress each year a summary report on agencies' technology transfer activities. This annual summary report is entitled *Federal Laboratory (Interagency) Technology Transfer Summary Report*.[20]

The foreword to the FY 2015 summary report states:

> This report fulfills the requirement of Title 15 of the United States Code, Section 3710(g) (2), for an annual report summarizing the use of technology transfer authorities by federal agencies. It highlights

[20] These summary reports are publicly available at https://www.nist.gov/tpo/federal-laboratory-interagency-technology-transfer-summary-reports.

> the achievements of federal technology transfer and includes data on the use of specific transfer authorities. Future editions of this report will be used to continue to keep the President and the Congress informed of the on-going efforts of Federal laboratories to expand our technology transfer efforts in partnership with U.S. industry, academic institutions, non-profit foundations, and state, local and tribal governments. These efforts will continue to play a vital role in building the Nation's economic strength.

A tabular description of mechanisms and metrics that describe each agency's recent technology transfer activities, along with a select number of examples of successful technology transfer efforts, is included in each summary report. The tabular descriptions only provide information on the scale of technology transfer activity by agency and not on their economic impact.

In this chapter, we focus on patents, licenses, and CRADAs from 2003 through 2014, although other mechanisms are described in the summary reports such as invention disclosures and licensing income. Patents, licenses, and CRADAs are generally viewed as the primary technology transfer mechanisms from federal laboratories, and they are the mechanisms generally referred to in the literatures summarized in Chapter 3. Publications, while not included in this chapter, are another important mechanism of technology transfer (specifically, knowledge transfer).

These three technology transfer mechanisms for the seven agencies that participated in this study are illustrated for 2003 through 2014 in the following figures to provide general information on levels of activity.[21,22] The underlying data are in the technology transfer summary reports, as noted above. Figure 4-1 shows the number of patent applications by year, Figure 4-2 shows patents issued by year, Figure 4-3 shows the number of licenses by year, and Figure 4-4 shows the number of CRADAs by year across these agencies.

[21] The agencies represented in these figures are DOC, DoD, HHS, DOI, DOT, EPA, and USDA.

[22] Technology transfer metrics on these mechanisms are not available separately for CDC, NIH, and FDA within HHS. Similarly, metrics on these mechanisms are not available separately for the Air Force, Army, and Navy within DoD.

Figure 4-1. Graphical Description of Federal Patent Applications Filed, by Fiscal Year across Participating Agencies

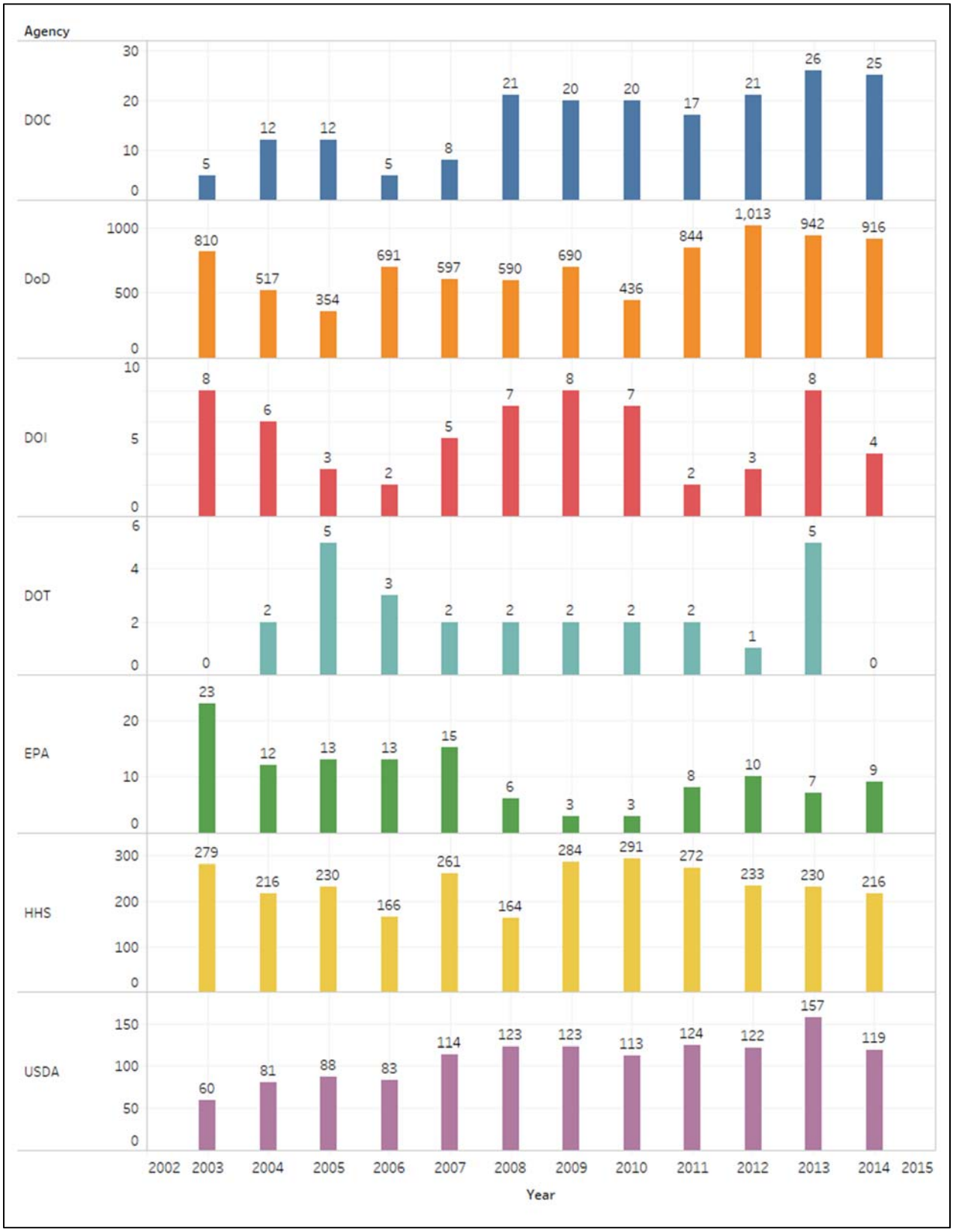


Figure 4-2. Graphical Description of Federal Patents Issued, by Fiscal Year across Participating Agencies

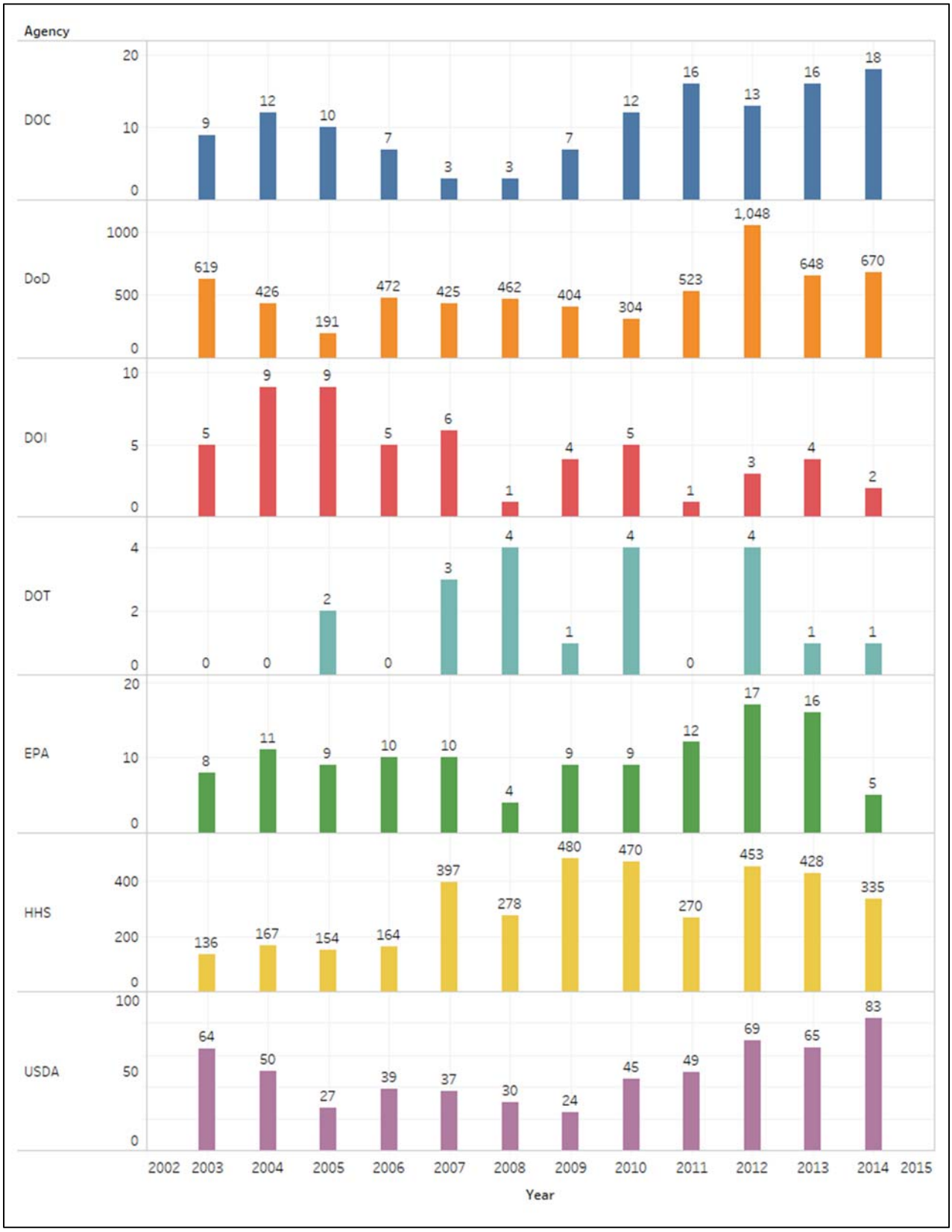
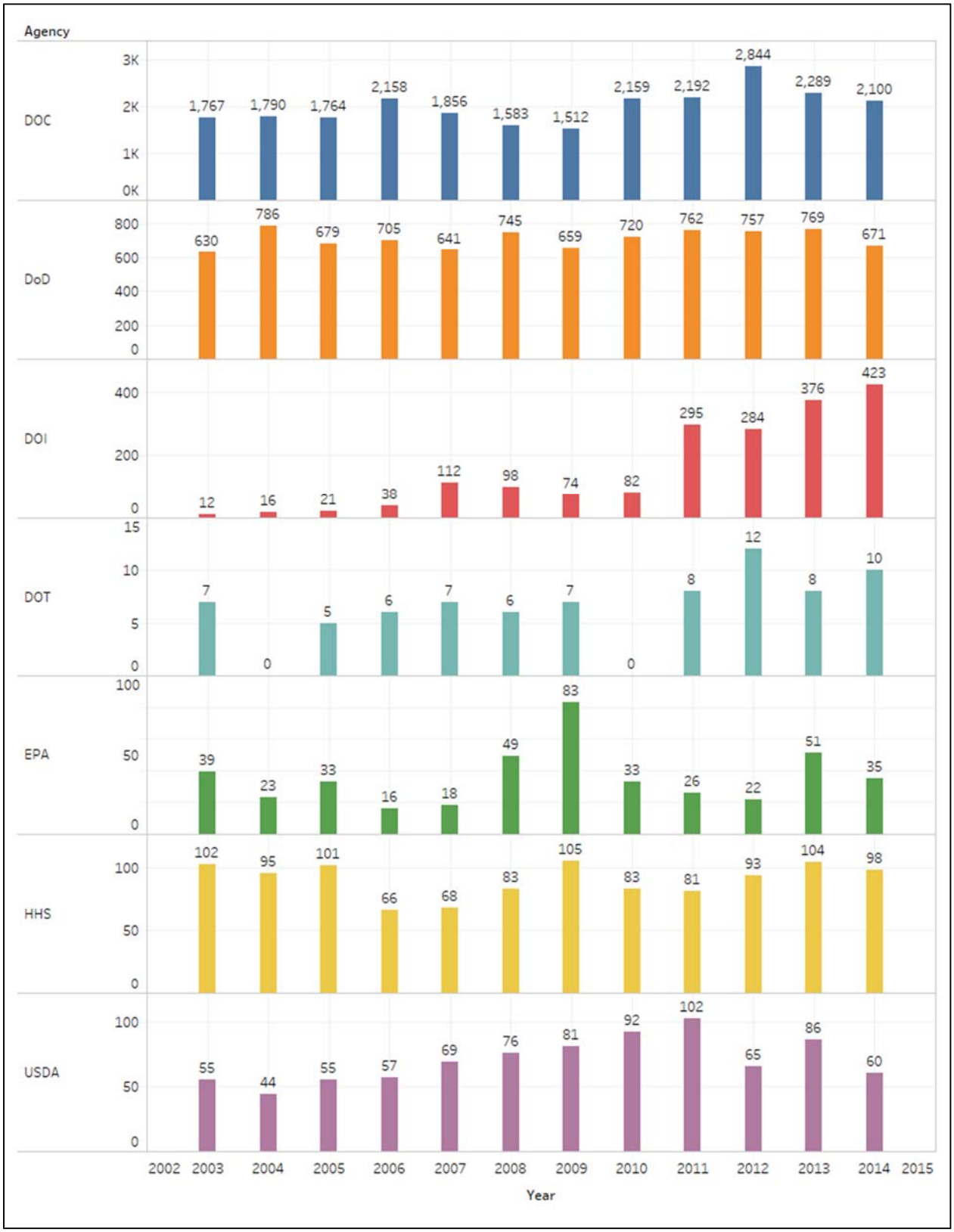


Figure 4-3. Graphical Description of Newly Executed Federal Licenses, by Fiscal Year across Participating Agencies

Figure 4-4. Description of Newly Executed Federal CRADAs, by Fiscal Year across Participating Agencies



Figures 4-1 and 4-2 show that DoD is the most active of the seven agencies in the filing of patent applications and patents issued. HHS is the most active agency in the issuance of new licenses (Figure 4-3). DOC is the most active agency in forming CRADAs (Figure 4-4).

Using annual data on new patents issued along with data on each agency's contemporaneous annual inflation-adjusted federal R&D allocations,[23] we approximated the correlation between the percentage change in new patent applications and the percentage change in R&D. This elasticity measure, a 10% increase in an agency's federal R&D allocations, is associated with a 9.98% increase in patents issued.[24] This elasticity is not an economic impact measure. It is a descriptive measure that reflects the approximate relationship between internal R&D and a dimension of internal agency activity.

The data reported in the summary reports and illustrated in the figures above are by themselves insufficient to use statistically to infer insight on the economic impacts associated with technology transfer from federal agencies. The chapters that follow offer an initial step forward in that direction in two ways. First, using disaggregated data provided by the agencies that participated in this study, we drew relationships that suggest elements of economic benefits from transferred technologies. Second, using case study information, we provide specific examples of economic impacts associated with some of the more successful agency transfer efforts selected in collaboration with participating agencies.

[23] Federal R&D data, adjusted for inflation, across the seven agencies and over time are available from https://www.aaas.org/page/historical-trends-federal-rd#Agency.

[24] This estimate comes from the estimation of a log-log ordinary least squares regression model on the panel of data on new patent applications for the seven agencies involved in this study over the years of available data. Held constant in the regression model is a binary control for instances when patents issued are 0 for a given year in a given agency.

5 Approach to this Multiple-Agency Study

This chapter describes our approach to this multiple-agency study of their reported technology transfer activities. We conducted economic analyses of technology transfer at two levels, both based on having access to data provided by the seven agencies in support of this study: (1) broad empirical analyses and (2) agency-level mission-specific case studies.

Economic analyses, couched in terms of both case studies and empirical inquiries that follow, were conducted by examining agency data and pooled administrative agency data (licenses and CRADAs) to approximate (discussed in each relevant chapter) the economic and social value of technology transfer activities. Per feedback received from agencies in the first year of this study, all administrative data provided to us from the seven participating agencies are confidential and were to be used by the study authors only for this effort. The use of these data is discussed in detail in the relevant chapters that follow.

In addition to conducting broad empirical analyses using pooled data, we conducted one case study of successful technology transfer for each participating agency.

5.1 GUIDING LOGICAL FRAMEWORK

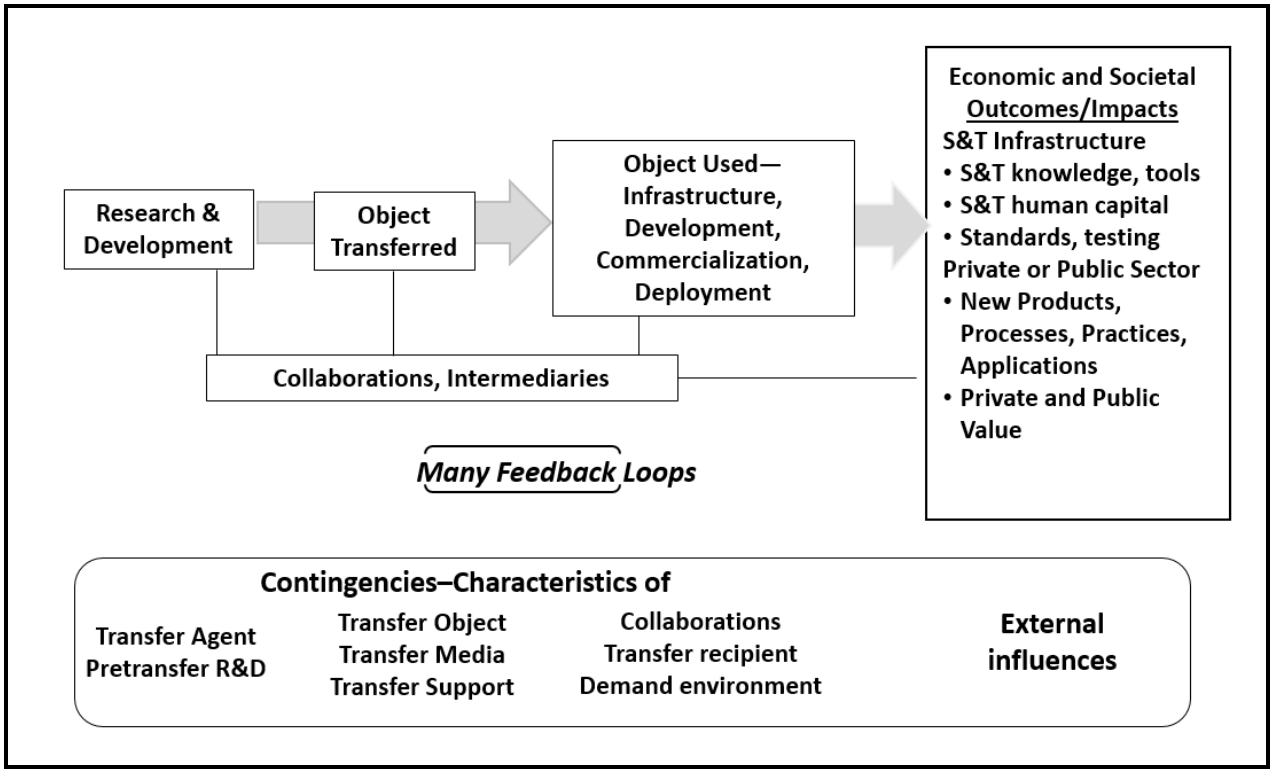
Once the purpose of this study was defined and the literature reviews completed, it was necessary to specify the process of technology transfer and its effects. Following good practices in evaluation, we developed a logical framework to guide the collection of quantitative information about technology transfer activity in the laboratories of various agencies and to focus the

development of case studies on successful technology transfer efforts. A logical framework includes a logic model or "theory of change" and the research questions that follow from that model. Data needed to answer these questions were then determined. Data collection and analysis are discussed in Chapter 6 for the quantitative study and Chapter 10 for the case studies.

5.1.1 The Logic Model

The logic model in Figure 5-1 is a simple linear representation of what is generally understood to be a nonlinear process with many feedback loops, contingent on different characteristics of the technology, market, actors, and context. However simplistic, it is a useful pedagogical device for this study to ensure consistency in our approach to each agency and in our reporting of each agency's technology transfer efforts.

Figure 5-1. A Logic Model for Transfer of Technology from Federal Laboratories



The term *outcomes* in a logic framework is actually a sequence of short-, intermediate-, and long-term outcomes that result from reaction to and use of the outputs, meaning the direct results of a program's activities. *Impact* is defined several ways. Some use *impact* as only that part of observed outcomes that can be credited to the program. More frequently people use *impact* interchangeably with outcomes, particularly with longer-term outcomes. The logic model in Figure 5-1 has the following five basic elements plus contingencies and external influences:

- the R&D expenditures, planning, implementation, and results of that R&D from discovery to proof of application and technical disclosure in a federal laboratory
- the transfer of an R&D-based object (technical knowledge and/or a prototype technology), and the process and mechanisms of transfer
- the receipt and use of that object by the recipient who adds resources to use the transferred object from the general technical infrastructure or to further specific technology development and commercialization of what resulted from the technology transfer
- the collaborations and intermediaries involved in the transfer
- and the technical, social, and economic outcomes for both private and public benefits associated with the transferred object

To summarize, R&D in federal laboratories leads to an object that is transferable. After the transfer, resources (physical capital and human capital) are added by the recipients in an effort to put the object to use as a product, process, service, or practice that has economic benefit. Collaborators or intermediary supporting organizations are often involved in one or more steps along the way.

The model also calls out "contingencies," or characteristics, of each instance of technology transfer that will affect the timing, parties involved, and size and type of outcome/impact of the transfer. Characteristics have been defined for each element of the logic model; that is, characteristics will vary depending on the laboratory and the specific R&D, the object transferred and transfer mechanism, the transfer recipient and demand

environment, and the agency mission and a broad notion of the pathways to economic and or social value.

The characteristics for the eight aspects or contingencies influencing technology transfer success are shown in the logic model. Five contingencies are from Bozeman (2013). The three we have added are preceded by an asterisk in the bulleted list below. The contingencies that must be considered are as follows:

- **Transfer agent**: Transfer agents are the innovating institutions. The national laboratories (the subject of this report) vary widely and are characterized by such factors as technological niche, mission, sector, scientific and technical human capital, resources, geographic location, organizational design, management style, and political constraints. The nature of the R&D leading up to the transfer varies.
- **Transfer object**: Characteristics of the technology transferred vary in terms of type. It may be software or hardware, for example. Other characteristics to examine include what they in terms of value to potential users, such as comparative advantage, compatibility, complexity, and observability.
- ***Technology transfer support**: This category includes characteristics of agency and laboratory leadership, allocation of resources for technology transfer, and the capabilities and actions of technology transfer staff.
- **Transfer media**: The way in which the technology is handed off to private or public entities varies. Federal laboratories typically employ cooperative research agreements, licensing, open-source software, material transfers, publications, and occasionally business start-ups.
- **Technology recipient**: Characteristics of the entities that acquire the innovation depend on the type of innovation acquired and vary in terms of resources and areas of expertise, geographic location, size, and power to make and implement decisions.
- ***Transfer collaborations and intermediaries**: The extent to which other entities are involved in the development, transfer, and commercialization varies, as do the characteristics of those entities. It also depends on the type of innovation being transferred.
- **Demand environment**: This category is the nature of the target market's demand for the specific innovation,

such as level of existing demand for a comparable technology. It could also include characteristics of the existing supply chain and required supporting technology and infrastructure. The demand market may be obscure, as is the case for innovations for the common good.

- *__External influences__: In addition to the other categories of contingencies, many other factors outside of a program's efforts or control can either drive or restrain success. For example, there may be unexpected technical breakthroughs, a competing technology may enter the market first, regulations may support adoption, or cultural norms or an economic recession might slow adoption.

5.1.2 Research Questions

We developed two sets of research questions, one for the broad empirical analysis and one for the case studies. There is some overlap between questions, but they are mostly distinct in order to be complementary. The empirical analyses cover a much wider range of technologies and are thus more broadly representative of technology transfer activities than individual case studies. The case studies demonstrate consideration of contingencies of successful technology transfer to a much greater degree than do the empirical analyses.

Broad Empirical Analysis Research Questions

The broad empirical analyses explore the extent to which technology transfer has resulted in regional-, industry-, and company-level associations. Specifically, our driving research questions for the empirical analysis are:

1. Is the geographic location and volume of technology transfer activity of an agency's research facility related to industry growth in the region?
2. What is the scope of geographical influence of each agency's research facilities?
3. Is participation in observable technology transfer activities related to company growth?
4. What technology transfer trends have occurred over time?

Case Study Research Questions

The seven main research questions follow the logic model from left to right, with the seventh question wrapping back to assess the federal laboratory's contribution to observed outcomes. All

of the research questions apply to the qualitative case studies, which look in-depth at individual instances of technology transfer. The seven questions are:

1. What is the "technology" and how does it perform when compared with the next best alternative?
2. What federal lab/agency is involved in the research and technology development of this technology and what has that involvement been over time?
3. Who else was involved in the R&D, aside from federal entities, before and during the technology transfer and what is known about their interactions with their federal counterparts?
4. What were the circumstances surrounding the federal transfer of the technology to the private (or public) sector?
5. What has happened to the technology since its federal transfer to another party? What benefits, if any, occurred as a result of the technology transferred being adopted and/or commercialized?
7. What did the federal technology development and transfer effort contribute to observed outcomes (after the technology was in private-sector hands) and how did contextual factors contribute to these observed outcomes?

5.2 OUR APPROACH TO ENGAGING FEDERAL AGENCIES

Table 5-1 shows our efforts to solicit support from all appropriate federal agencies to share their disaggregated technology transfer data with our research team in an effort to prepare as complete a picture as possible of technology transfer from U.S. federal agencies and their laboratories to other parties.

The activities in Table 5-1 describe the process through which our team attempted to collect limited laboratory-specific technology transfer data, and that information is described in the remaining chapters of this report.

Table 5-1. Engagement with the Government, Evaluation, and Academic Community

Activity	Description	Date(s)
Project kickoff	Discussed NIST's vision for the study, expectations, and timeline.	February 17, 2016
Initial outreach to agencies' points of contact	Email outreach.	Early 2016
Briefing for the IAWGTT	Initial presentation of the study's scope to the entire Interagency Workgroup on Technology Transfer in Washington, DC.	May 11, 2016
Workshop entitled "Opportunities and Best Practices for Technology Transfer from Federal Laboratories"	Invitation-only workshop in Phoenix, AZ, with Agency TTOs. Solicited feedback on study scope and data collection activities that would be required of participating agencies. The goal of this meeting was to build buy-in for a common set of research questions of interest to agencies.	November 3, 2016
Technology Transfer Society presentation	Presented study goals and solicited feedback from the academic community at the Technology Transfer Society Annual Conference in Phoenix, AZ.	November 4, 2016
Other IAWGTT activities	Multiple presentations by Courtney Silverthorn, Deputy Director, Technology Partnerships Office at NIST, presented multiple times to the IAWGTT; emails; etc. Altered study scope according to feedback from the agency TTOs.	
Transfer of requested microdata on CRADAs, licenses, and other mechanisms	NIST and EPA provided data in 2016, while most of the other participating agencies provided data starting in December 2017.	Primarily between December 2017 and April 2018
Selection of case studies and interviews	Selected case studies for participating agencies and began primary data collection through interviews.	October 2018 to May 2018
One-on-one communications with agencies	Conference calls, webinars, emails, etc., to garner buy-in, gather data, answer/ask questions, and coordinate.	Early 2016 to July 2018
Presentation at the FLC	Briefed the technology transfer community about progress on the study and preliminary findings.	April 25, 2018
Presentation at American Evaluation Association 2018 Conference	Presentation of the scope of the study to the Research, Development, and Technology Topical Interest Group consisting mainly of professional evaluators.	October 28, 2018
Feedback from agencies on case studies and results		April 2018 to 2019

It is worth noting that one of the initial concepts for this study was that in the process of collecting administrative data to be used in our own analyses, we would set up a data infrastructure similar in spirit to the Census Bureau's Research Data Centers, where researchers could access the administrative data in a secure environment with preapproved research plans and protocols. Researchers would only be allowed to publish summary results and parameters as to protect the confidentiality of the administrative data.

After much discussion with agencies, our team, in consultation with NIST, abandoned the data infrastructure concept. Data constraints and privacy concerns proved to be too large of an issue to address within the scope, budget, and timeline afforded this project. CRADA and license partners' identities, for example, are considered to be confidential and sensitive information by multiple agencies.

Therefore, throughout the process of engagement, learning about constraints, and securing buy-in, we moved away from the data infrastructure concept and refocused its efforts toward using the data provided by the participating federal agencies solely for a set of common research questions of interest.

We were able to obtain some level of participation in the study, whether through contributions of administrative data or case study topics from the 10 agencies.

6 Summary of Primary and Secondary Data

Summary

- A motivation for linking technology transfer data with company-level data sources using company names and addresses is that data linkage facilitates descriptive and empirical analyses of technology transfer partners in lieu of conducting direct surveys.
- We linked technology transfer metrics with company names and address information to the National Employment Time-Series (NETS) database, a proprietary database with longitudinal company-level information.

This chapter describes key features of both the primary and secondary data collected for this study as well as the methodology developed to link these data.

6.1 PRIMARY DATA

We requested the following administrative data from each agency:

- **Patent data** including the patent number, laboratory name(s), and inventor name(s) and affiliation(s)
- **License data** including the license title, license type (e.g., exclusive, nonexclusive, and partially exclusive), laboratory name(s), start date, end date, licensee company/organization name(s), licensee address(es), cumulative license revenue to date, and associated patent(s)
- **Completed cooperative agreement data** (e.g., CRADAs and others) including the agreement title, agreement type, laboratory name(s), agency researcher(s), start date, end date, external

company/organization name(s), company/organization address(es), external researcher name(s)

Completeness of the information provided by the agencies to us varied widely based on the availability of historical information and other agency resources and perceived data constraints due to confidentiality concerns. Some fields were not provided, and for those fields that were provided there was often missing information.

Table 6-1 summarizes the technology transfer mechanism information provided to us by the agencies and the associated years. USDA did not provide information directly but referred us to the *Federal Register* in which USDA disclosed the intent to exclusively license a technology. Technology transfer data are also time sensitive and are known to vary depending on the time of year of data collection.[25]

Table 6-1. Description of Technology Transfer Data Collected from Participating Agencies, by Agency and by Years of Availability

Agency	Patent Data	Licensing Data	CRADA Data
DOC: NIST	1968–2014	1981–2015	1978–2015
DoD: Air Force	1997–2017	1993–2017	1998–2017
DoD: Army	1945–2017	1995–2017	1995–2017
DoD: Navy	—	—	1988–2017
DOI: U.S. Bureau of Reclamation	1984–2012	2000–2010	2009–2017
DOT	—	—	2014–2016[a]
EPA	1986–2015	1999–2016	1984–2016
HHS: CDC	—	1989–2004	1988–2017
HHS: NIH	1948–2017	1977–2017	1987–2017
USDA	—	1994–2017	—

[a] DOT provided only a small sample of CRADA data, and we could not determine its representativeness.

[25] See footnote 6, page 10 of FY2015 Federal Technology Transfer report for additional details.

6.2 SECONDARY DATA

Our secondary data source for this study is the NETS Database, provided by Walls & Associates and Dun & Bradstreet. The NETS Database provides time-series data on companies including

- sales performance,
- industry, and
- location.

The NETS Database includes more than 58 million companies from 1990 through 2014 and includes over 390 data fields. This database was used to identify licensees and CRADA partners using a consistent linkage methodology across participating agencies.

6.3 RECORD LINKAGE

A major motivation for linking technology transfer data with other data sources is that the linkage facilitates descriptive and empirical analyses of technology transfer partners without having to conduct direct surveys. This approach allows for reliance on reported information from companies that is within the NETS Database.

We linked federal technology transfer data with the NETS Database to provide a longitudinal history on companies that are engaged in licensing and/or cooperative research with government agencies.

We accomplished this through a series of steps including:

- Standardizing company names and address fields in the technology transfer data and the NETS Database,
- Operationalizing a matching algorithm to link the technology transfer data to the NETS Database,
- Reviewing manually all of the linked records above a certain score threshold to assess the quality of the match, and
- De-duplicating data when multiple matches were returned.

Outside of working with agencies to shape the project and determining which agencies wanted to participate in the study, data cleaning and record linkage were the most resource-intensive aspect of this study.

The record linkage program we used for this project is a general-purpose "fuzzy" linkage package in Stata statistical software called *reclink2*,[26] which we tailored to this project. "Fuzzy" linkage refers to the fact that the fields that are used for linkage are not spelled precisely the same across datasets. We opted for a linkage algorithm that placed greater weight on address information than on company name. Our rationale for this approach was that an address is a more unique identifier of a company than is the company's name itself (which was more likely to be similar to other company names). However, both company name and address are needed together. If one was missing, we were unable to link to the NETS Database. We confirmed that weighting the address more heavily yielded better matching results, based on some comparisons we conducted with subsamples of data that were matched with different algorithms weights and manually reviewed for accuracy.

For the records that had sufficient information to be matched with the NETS Database (that is company name and address information), we were able to match 68% of the name and address records to companies in the NETS Database.

In an effort to ensure preciseness of the matches, we used a two-stage approach to linking the data. First, the matching algorithm generated a similarity score between records in the administrative data and the NETS Database, and we imposed a criterion to eliminate the most likely nonmatches. Specifically, we used manual review of matches and assigned a manual review category based on the quality of the match. The 68% match rate represents records that were assessed by a human reader as being in one of the categories "definitely a match" or "very likely a match."

Table 6-2 shows our match rate by participating federal agency by technology transfer mechanism. This table shows how well the linkage algorithm worked across agencies.

[26] See Wasi and Flaeen (2015) for more information.

Table 6-2. Record Linkage Match Rate: Percentage of Administrative Technology Transfer Records Matched to NETS Database, by Participating Federal Agency

	License Data			CRADA Data		
Agency	**No. of Records**	**No. High Quality Matches**	**%**	**No. of Records**	**No. High Quality Matches**	**%**
DOC: NIST	122	80	66%	3,601	1,359	38%
DoD: Air Force	—	—	—			
DoD: Army	—	—	—	1,557	1,293	83%
DoD: Navy	—	—	—	3,050	2,671	88%
DOI: U.S. Bureau of Reclamation	—	—	—	19	5	26%
DOT	—	—	—	—	——	
EPA	37	25	68%	485	288	59%
HHS: CDC						
HHS: NIH	921	703	76%	2,073	1,649	80%
USDA						
Total	**1,080**	**808**	**Mean= 75%**	**10,785**	**7,265**	**Mean= 67%**

7 Geospatial Analysis of Technology Transfer Partners

Summary

- There are 181 physical laboratory locations within the 10 agencies participating in this study.
- Since 1978, there has been at least one CRADA partner located in each state. California, Massachusetts, and Maryland are home to the largest number of CRADA partners.
- While key data linking specific CRADAs to specific laboratory locations are unavailable in many cases, analysis of available NIST data suggests that cooperative research is more important regionally than are licenses, which tend to be more geographically dispersed. NIST CRADA partners are roughly 3 times more likely to be located within a 500-mile radius of NIST's Gaithersburg, Maryland, location than are NIST licensees.

In this chapter, we explore the geospatial distribution of federal technology transfer partners including licensees and CRADAs. The data used in this chapter included any administrative record with address information for the partner organization that could be geocoded to a latitude and longitude regardless of whether that record could be linked with the NETS Database. Geocodes were derived from available geographic information in the administrative records.

In most cases, the administrative data provided by the participating federal agencies did not link activities to individual federal laboratories, but rather activities were linked to the agency as a whole. Therefore, the geospatial analysis that follows should be viewed as descriptive.

7.1 FEDERAL LABORATORY LOCATIONS

Depending on the specific definition of a federal laboratory that is used, the number of laboratories can vary drastically. Because it is out of the scope of this study to develop a precise and broadly agreed upon definition of a federal laboratory, we use the FLC's membership list to illustrate the geographic reach of a laboratory's technology transfer and to provide context for the maps of partners that follow in Sections 7.2 and 7.3.

Figure 7-1 shows the FLC's membership list mapped, limited to the set of agencies participating in this study. There are 181 physical laboratory locations across the 10 agencies participating in this study.

Figure 7-1. Federal Laboratories Associated with the Federal Agencies Participating in this Study

7.2 LICENSES

Table 7-1 shows the number of administrative records (defined below) provided by each participating federal agency and the number of the records that were able to be geocoded based on data quality. Five agencies provided sufficient address information to geocode their administrative records. Overall, 68% of all license records were able to be geocoded to a latitude and longitude pair. If DoD Air Force and DoD Army are excluded because they did not provide sufficient information to be geocoded, then the percentage geocoded is 81% (not shown in Table 7-1).

Figure 7-2 displays the locations of licensees by agency.[27] There is often overlap between where laboratories are located and where licenses are located. However, licensees span a broader range of locations. The geographic relationship between licensing and federal laboratory location is explored in Section 7.3.

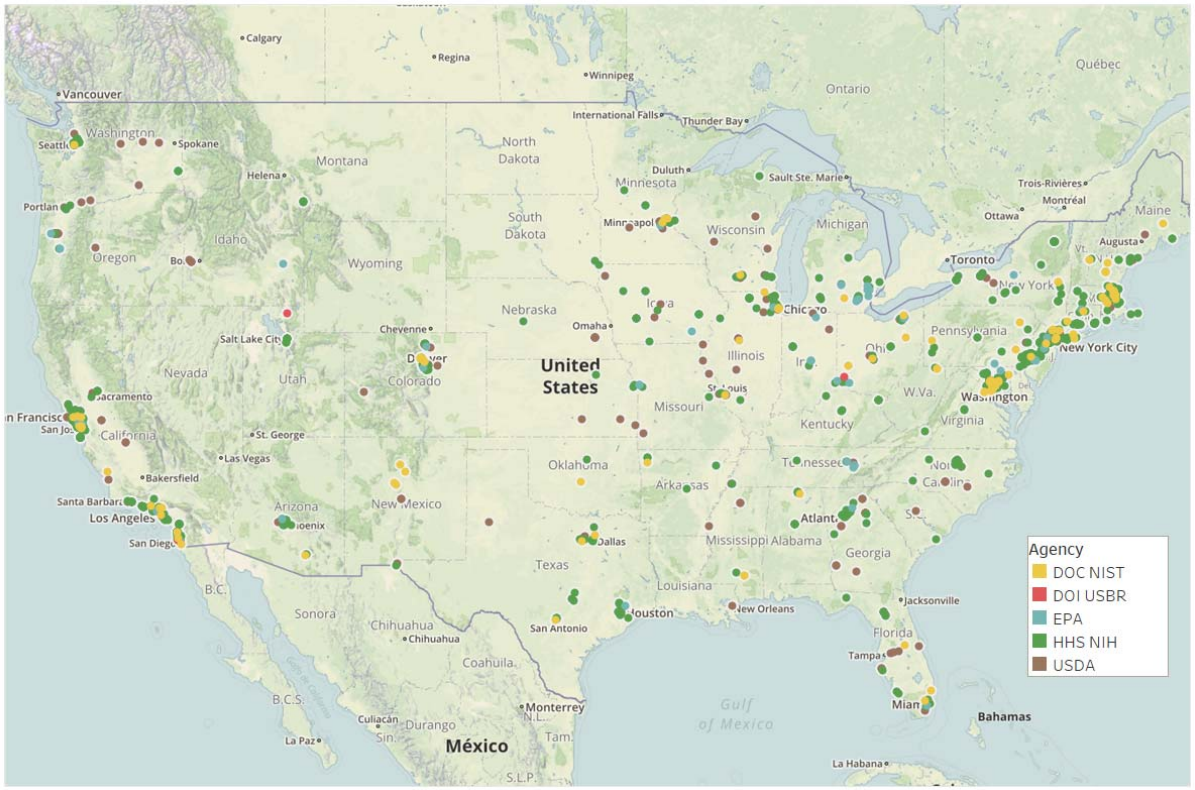
Table 7-1. Percentage of Administrative License Records Successfully Geocoded, by Agency[a]

	DoD Air Force	DoD Army	EPA	NIH	NIST	USBR	USDA	Total
No. of records	156	183	53	1,280	185	5	229	2,091
No. geocoded	—	—	49	1,074	125	4	175	1,427
Percentage geocoded	—	—	92%	84%	68%	80%	76%	68%

[a] As noted in Table 5-2, DoD Navy did not provide licensing data for this study.

[27] Individual agency maps are available from RTI upon request.

Figure 7-2. Locations of Licensees in the Continental United States (1978—2017), by Five Participating Federal Agencies



7.3 CRADAS

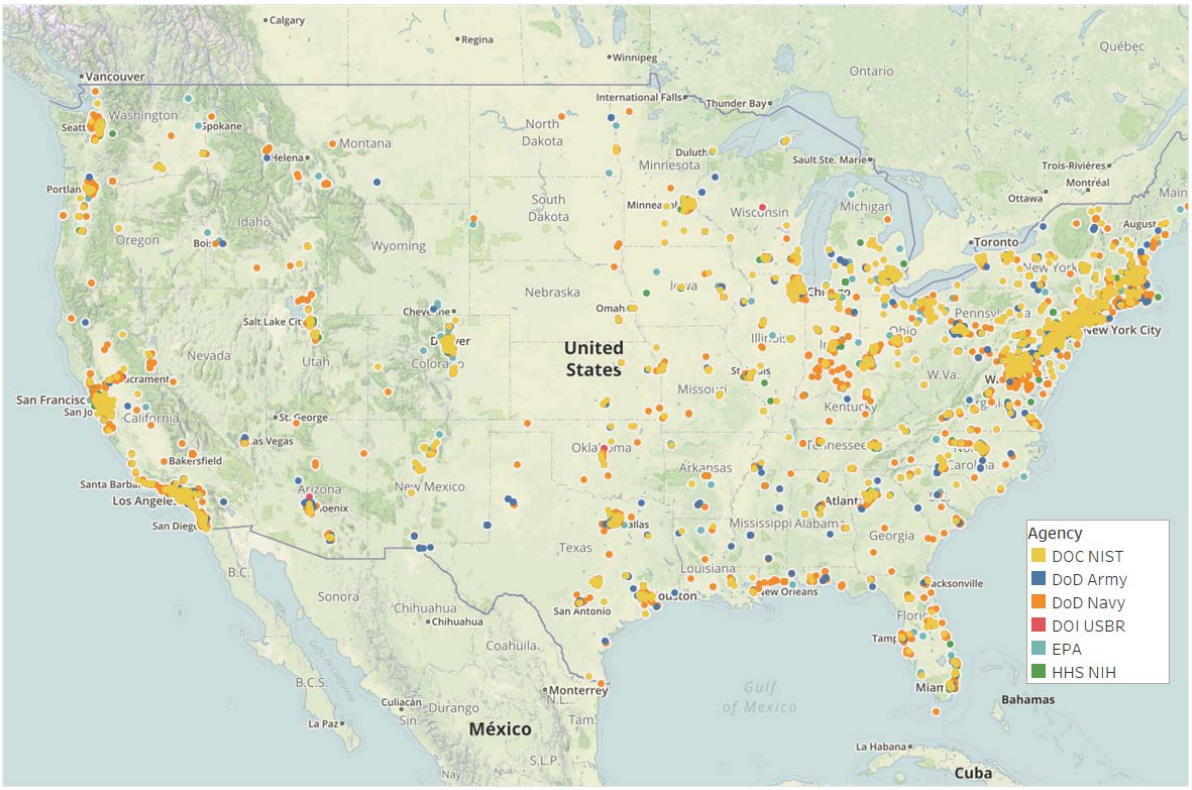
Table 7-2 shows the number of administrative records provided by each agency and the number of records that were able to be geocoded based on data availability. Six agencies provided sufficient address information to geocode their administrative records. Overall, 70% of all CRADA records were geocoded to a latitude and longitude pair. If DoD Air Force and DOT are excluded because they did not provide sufficient information to be geocoded, then the percentage geocoded is 75% (not shown in Table 7-2).

Table 7-2. Percentage of Administrative CRADA Records Successfully Geocoded by Agency

	DoD Air Force	DoD Army	DoD Navy	DOT	EPA	NIH	NIST	USBR	Grand Total
No. of records	1,038	2,821	3,904	37	823	2,747	3,779	26	15,175
No. geocoded	—	754	3,691	—	492	2,302	3,303	25	10,567
Percentage	—	27%	95%	—	84%	84%	87%	96%	70%

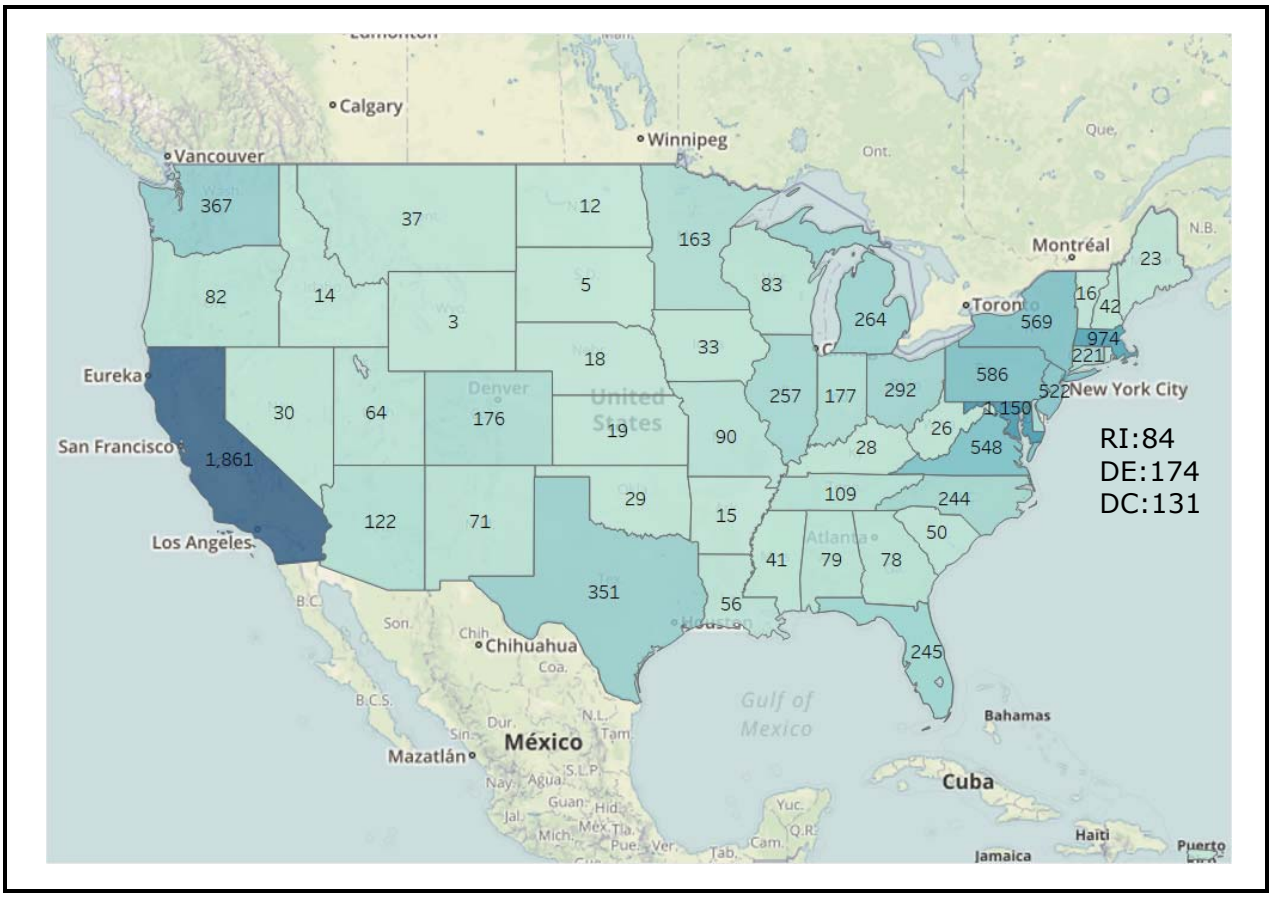
Figure 7-3 displays the locations of CRADA partners in the continental United States by agency. Obvious concentrations appear in urban areas, especially along the northeastern seaboard, and around the San Francisco Bay area and southern California coast. However, there are strong clusters elsewhere. One downside to the number of CRADA partners as a measure of activity is that it does not capture the degree of intensity (i.e., the scale of resources invested) of any individual cooperative R&D project. However, we do not have data on the amount of funding or research hours allocated to different projects that could be used as a proxy for intensity.

Figure 7-3. Locations of CRADA Partners in the Continental United States (1978—2017), by Six Participating Federal Agencies



Based on available data, we identified at least one CRADA partner in every state including Alaska and Hawaii (see Figure 7-4). California, Massachusetts, and Maryland are home to the largest number of CRADA partners because of a variety of contributing factors, including but not limited to, large populations and company clusters in California, high-tech company clusters and human capital strengths in the greater Boston area of Massachusetts, and proximity to federal agencies in Maryland.

Figure 7-4. Number of CRADAs by State in the Continental United States (1978—2017)



[a] Location based on location of CRADA partner, not the location of the federal laboratory. For CRADAs with multiple partners, the location of the primary partner listed on the CRADA was used. Each CRADA is only counted once.

7.4 COMPARISON OF THE GEOSPATIAL DISTRIBUTION OF LICENSES AND CRADAS

Although key data linking specific CRADAs to specific laboratory locations are incomplete in many cases, analysis of NIST data suggests that cooperative research is more prevalent regionally than are licenses, which tend to be more geographically dispersed. Specifically, NIST CRADA partners are roughly 3 times more likely to be located within a 500-mile radius of the NIST Gaithersburg, Maryland, location than are NIST licensees.

8 Toward an Understanding of the Relationship between Company Sales and Licensed Public-Sector Technology

Summary

- This chapter is exploratory and uses available data for a small number of laboratories. We analyze relationships between firm growth and firms having licensed technologies. We do not have definitive information about the relationship between the licensed technologies and commercialized products and services. Therefore, we can only provide suggestive information about the growth of firms engaging with laboratories and not about the commercial success of technology originating in the laboratories.
- The manufacturing sector and the professional, scientific, and technical services sector (using North American Industry Classification System [NAICS] category designations) are the two dominant industries engaged in licensing technologies from participating agencies and partnering with them on CRADAs.
- Based on EPA, NIH, and NIST data, evidence suggests that having a license from a federal lab has a positive effect on the sales of private-sector licensees, but the percentage changes cannot be attributed entirely to the licenses.
- The detected sales effect does not vary systematically across companies of varying sizes.
- Further research is needed to more definitively answer the question of the economic impact of licenses on private-sector sales.
- Most of the CRADAs with a federal agency involved small companies.

In this chapter, we first explore the licensee's sales before and after it licensed a technology from a federal agency, and then we explore the size characteristics of a federal agency's CRADAs partners.[28] These were separate analyses, but both represent new suggestive information about aspects of federal agency technology transfers.

Organizations license technologies with the purpose of incorporating them into products, services, and processes that could directly or indirectly serve to increase sales.[29] The licenses that we explore in this chapter include federal patent licenses and biologic material licenses.

We emphasize that the analysis in this chapter is exploratory because many factors can affect a company's sales over time other than the introduction of a licensed technology. We do not have sufficient information on other possible factors to infer from our descriptive findings that the difference between sales after the license began compared with before the license began is due entirely to the presence and effect of the licensed technology, if at all. However, our exploratory analysis does suggest that, taking inflation into account, on average, the company's sales increased significantly after it acquired the licensed technology.[30]

8.1 CHARACTERISTICS OF LICENSEES

The primary data on federal licenses to private-sector companies in support of the analysis in this chapter were provided by three of the seven agencies that participated in this study, namely EPA, NIH, and NIST.[31] Licensing data for EPA cover the period 2000 through 2015; for NIH, the licensing data cover the period 1975 through 2017; and the NIST data cover

[28] We use the terms *organization* or *establishment* because of differences in the organizational structure of the units of observation in the NETS Database, as discussed below.

[29] The Government Accountability Office (2018) recently released a report with recommendations to improve the licensing of patented federal laboratory innovations.

[30] Future studies might investigate possible covariates associated with increases and decreases in company sales after a technology was licensed from a federal laboratory.

[31] Table 5-2 shows that more agencies provided licensing data than EPA, NIH, and NIST. However, those agencies did not provide either the company name that licensed the technology and/or the company's location; thus, those data could not be matched to the NETS data (discussed below and in Appendix D) to obtain relevant sales information.

the period 1981 through 2015. We know from each agency's licensing data the date that each license started, meaning the date that a technology was transferred to a private-sector company through a licensing arrangement. We do not know when or if the company that licensed the technology incorporated it into a product or process that gained traction in the market.

We first matched the agency-reported licensee information to corresponding information in the NETS Database, which is the source of our sales data. The NETS Database provides information on company sales over the period 1990 through 2014 for all companies that were operating for all or a part of that period of time. For the following descriptive statistics, we focus on the characteristics of licensees at the time of licensing.

The following tables and figures in this section document the characteristics of licensees that were matched to the NETS Database. Characteristics described include:

- sales (nominal),
- employment,
- type of company,
- sector (2-digit NAICS), and
- industry (3- and 4-digit NAICS).

At the time of licensing, EPA licensees tend to be smaller than NIH and NIST licensees as measured by average sales and average levels of employment. At the median, however, EPA licensees tend to be similar in size to NIH and NIST licensees (see Table 8-1). Companies varied widely in terms of sales at the time the license was granted, from $3,000 in sales to more than $2 billion in sales. Employment at the time the license was granted ranged for the licensees from a single employee to more than 12,000 employees.

The companies in the NETS Database that were matched to the data provided by the participating agencies included a variety of types, from headquarters to branch locations to stand-alone operations (single company). Table 8-2 includes a breakout of the types of companies by agency. In some cases (21% of companies), we had to aggregate the separate enterprises within a company in the NETS Database to arrive at information for the overall company. Detailed definitions are included in Appendix D.

Table 8-1. Descriptive Statistics of Licensee Companies, at Time of License (1990–2014)

	EPA	NIH	NIST
Sales ($)			
Average	28,529,719	46,369,342	47,637,546
Median	4,234,550	4,491,700	4,080,000
Minimum	20,000	3,000	28,300
Maximum	169,700,000	2,067,686,272	540,995,008
Employment			
Average	160	269	392
Median	47	43	35
Minimum	1	1	1
Maximum	1,000	12,284	6,029

Table 8-2. Percentage of Licenses by Type of Licensee Company (1990–2014)

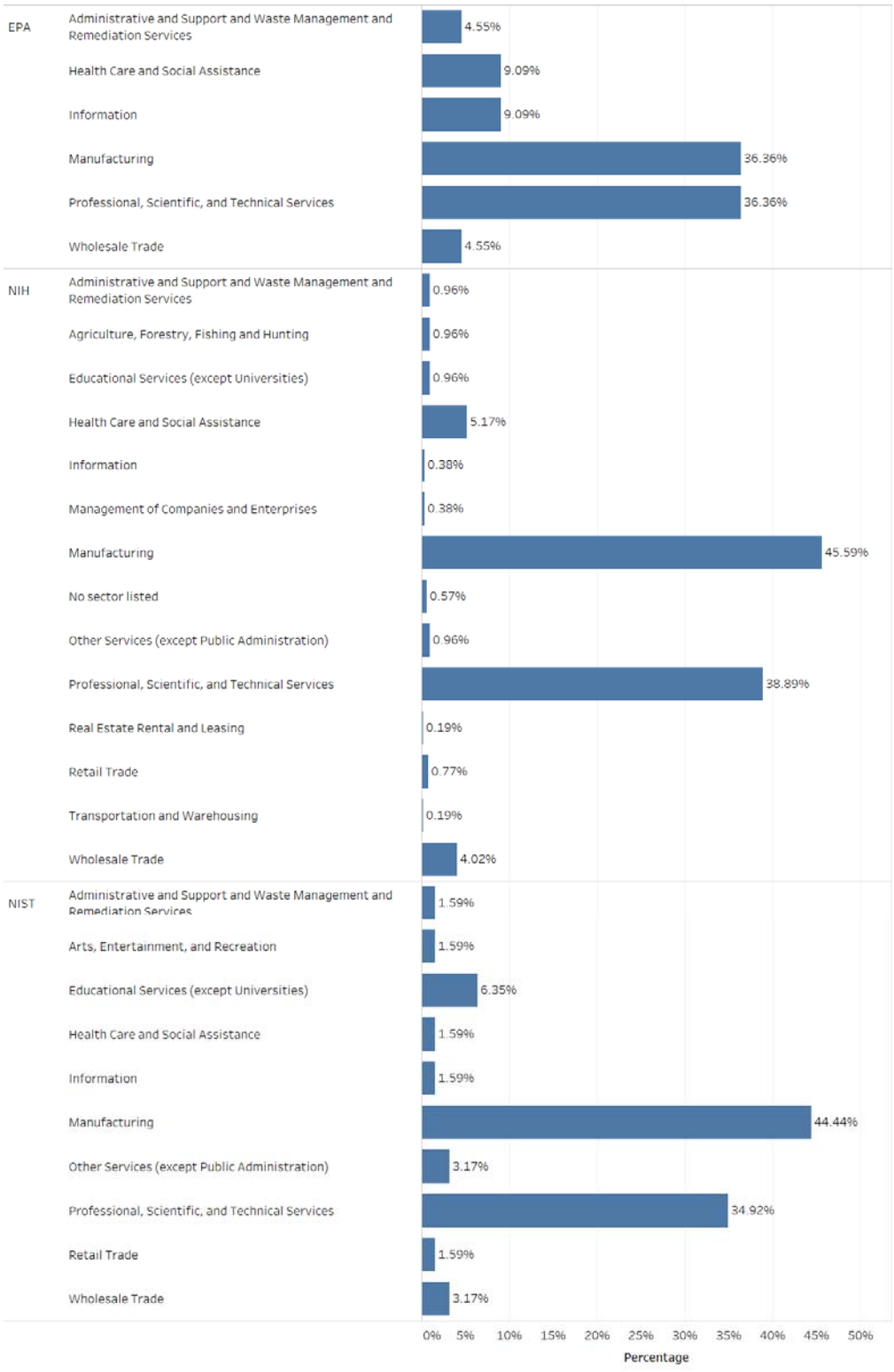
	EPA	NIH	NIST
Headquarters	18%	31%	25%
Branch	5%	6%	11%
Stand-alone	14%	42%	27%
Aggregated[a]	64%	20%	37%

[a] Aggregated records are entities that are combinations of companies of various types (headquarters, branches, and stand-alone) that are present in the NETS Database at the same physical location but have different time series for sales and employment. Additional detail is provided in Appendix D.

Figure 8-1 shows the composition of licensees by agency in terms of the industry sectors at the time of licensing based on NAICS codes. The manufacturing sector and the professional scientific, and technical services sector are the two dominant sectors engaged in licensing technologies from EPA, NIH, and NIST. Deleted from Figure 8-1 are organizations in the public administration sector (NAICS 92) and universities. We excluded these organizations because they do not represent examples of technology transfer from government to the private sector.

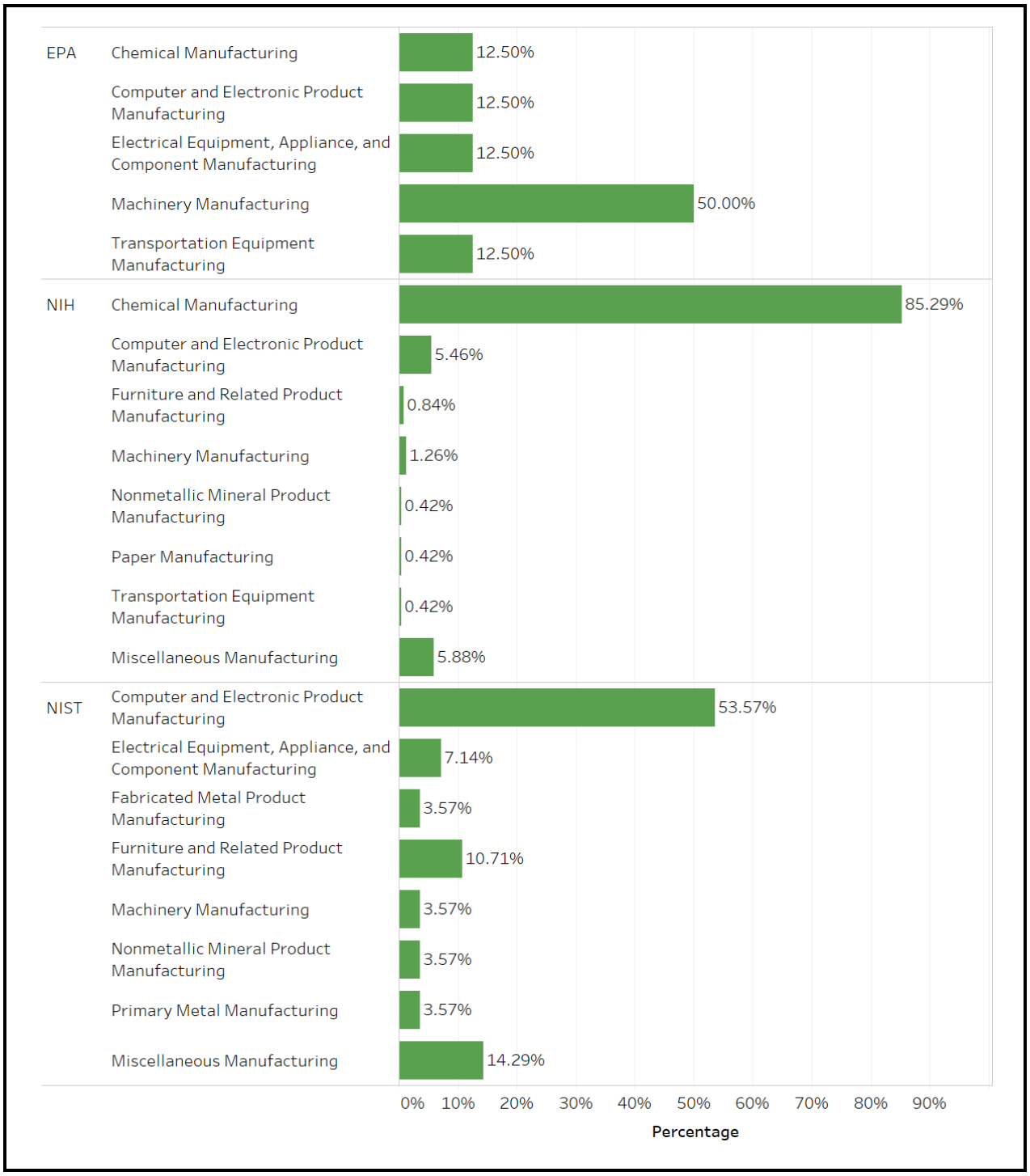
In the manufacturing sector, chemical manufacturers (such as biopharmaceutical companies) comprise the majority of NIH licensees. Computer and electronic product manufacturers comprise the majority of NIST licensees. Finally, machinery manufacturers comprise the majority of EPA licensees (see Figure 8-2).

Figure 8-1. Percentage of Licensee Organizations by Sector, at Time of License (1990–2014)



Source: Analysis of 2-Digit NAICS codes from the NETS Database

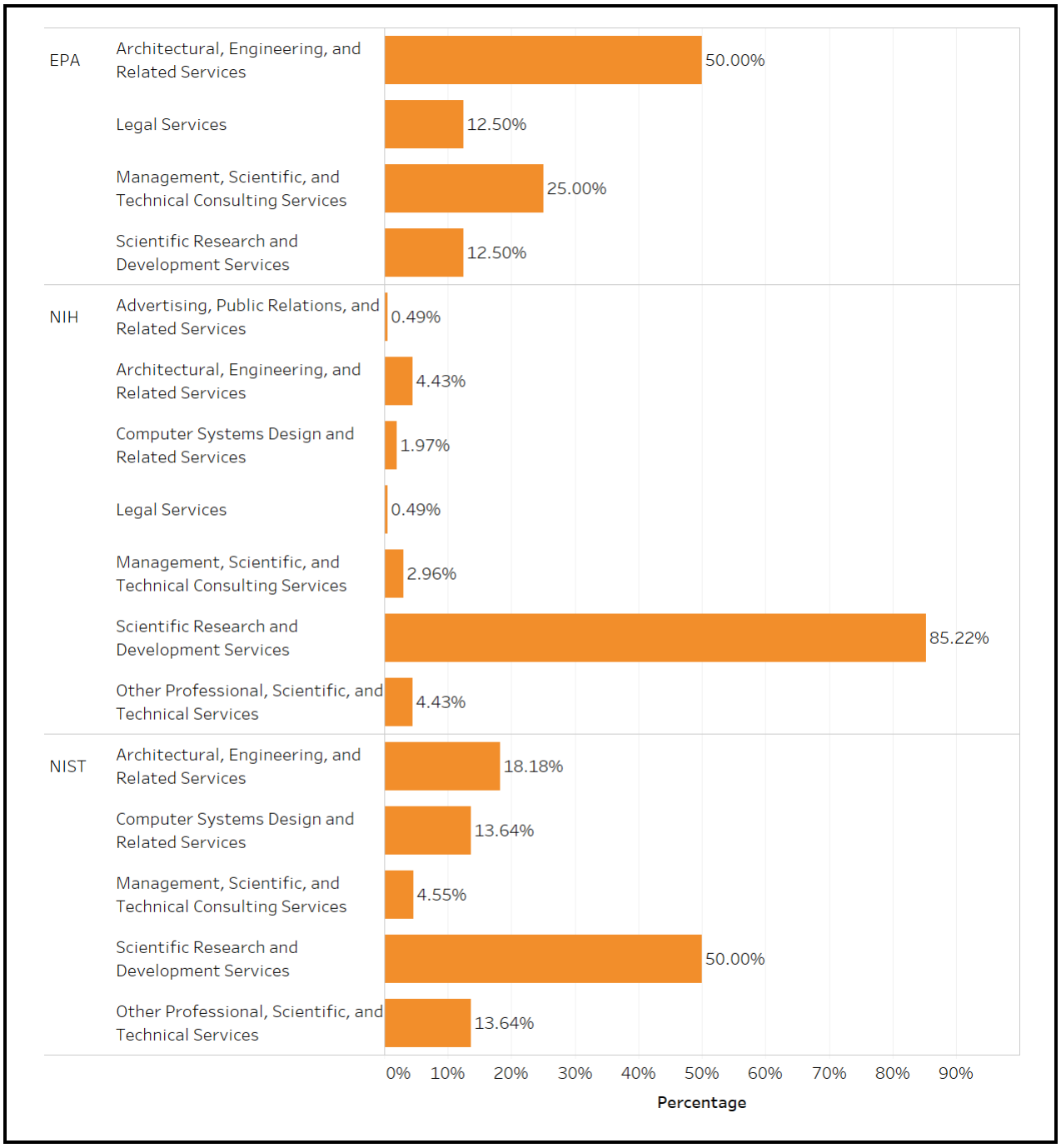
Figure 8-2. Manufacturing: Percentage of Licensee Companies at Time of License (1990–2014)



Source: Analysis of 3-digit NAICS codes from the NETS Database.

In the professional scientific, and technical services sector, scientific R&D service companies comprise the majority of NIST and NIH licensees, while architectural and engineering service companies comprise the majority of EPA licensees (see Figure 8-3).

Figure 8-3. Professional Technical and Scientific Services 4-Digit NAICS: Percentage of Licensee Companies at Time of License (1990–2014)



Source: Analysis of 4-digit NAICS codes from the NETS Database.

8.2 THE RELATIONSHIP BETWEEN COMPANY SALES AND LICENSED PUBLIC-SECTOR TECHNOLOGY

Protocols were adopted to arrive at a final sample of companies to which an agency had licensed a technology and for which sufficient years of sales data are available. Table 8-3 describes the protocols that we adopted for the data reduction process.

We followed the protocols described in Table 8-3 for the analysis of each agency's licensing data. First, we adjusted all sales figures to constant dollars ($1,000) referenced to 2010 using the gross national product implicit price deflator.[32] Second, we calculated for each company the mean value of inflation-adjusted sales before the license started and the mean value of inflation-adjusted sales after the license started (the year the license started is treated as a year after the license started). Third, we calculated for each company the percentage change in mean inflation-adjusted sales as:

[(mean inflation-adjusted sales after the license started less mean inflation-adjusted sales before the license started) / mean inflation-adjusted sales before the license started].

Table 8-3. Data Reduction Protocols and Affected Companies, by Agency (1990–2014)

	EPA	NIH	NIST
Number of license records provided by the agency that could be matched to a company using the NETS Database (excludes companies in the public administration sector and universities)	25	703	80
Less number of matched companies for which any sales data were not available both before and after the license started	−2	−221	−19
Less number of matched companies for which less than 3 consecutive years of data were available on sales before the license started as well as after the license started (we include the year of the license as a year after the license started)	−4	−92	−10
Less number of matched companies with missing sales data	0	0	−1
Outliers or questionable data[a]	0	−1	0
Companies in the final sample	19	389	50

[a] One stand-alone company that licensed a technology from NIH had a sales increase after the license started by 1,118,700.6%. We deemed this company to be an outlier and we deleted it; we suspect that its sales data were not reported correctly in the NETS Database.

[32] For the source of information on implicit price deflators, see https://fred.stlouisfed.org/.

Table 8-4 reports, by agency, the mean of the percentage change in inflation-adjusted sales for all companies, for those companies that had an increase in mean inflation-adjusted sales, and for those companies that had a decrease in inflation-adjusted sales.

For EPA, of the 14 companies for which the mean inflation-adjusted sales increased after the license started, the mean percentage increase was 172.9%. For the 5 companies for which the mean inflation-adjusted sales decreased after the license started, the mean percentage decrease was 18.8%.

For NIH, of the 297 companies for which the mean inflation-adjusted sales increased after the license started, the mean percentage increase was 513.1%. For the 92 companies for which the mean inflation-adjusted sales decreased after the license started, the mean percentage decrease was 33.5%.

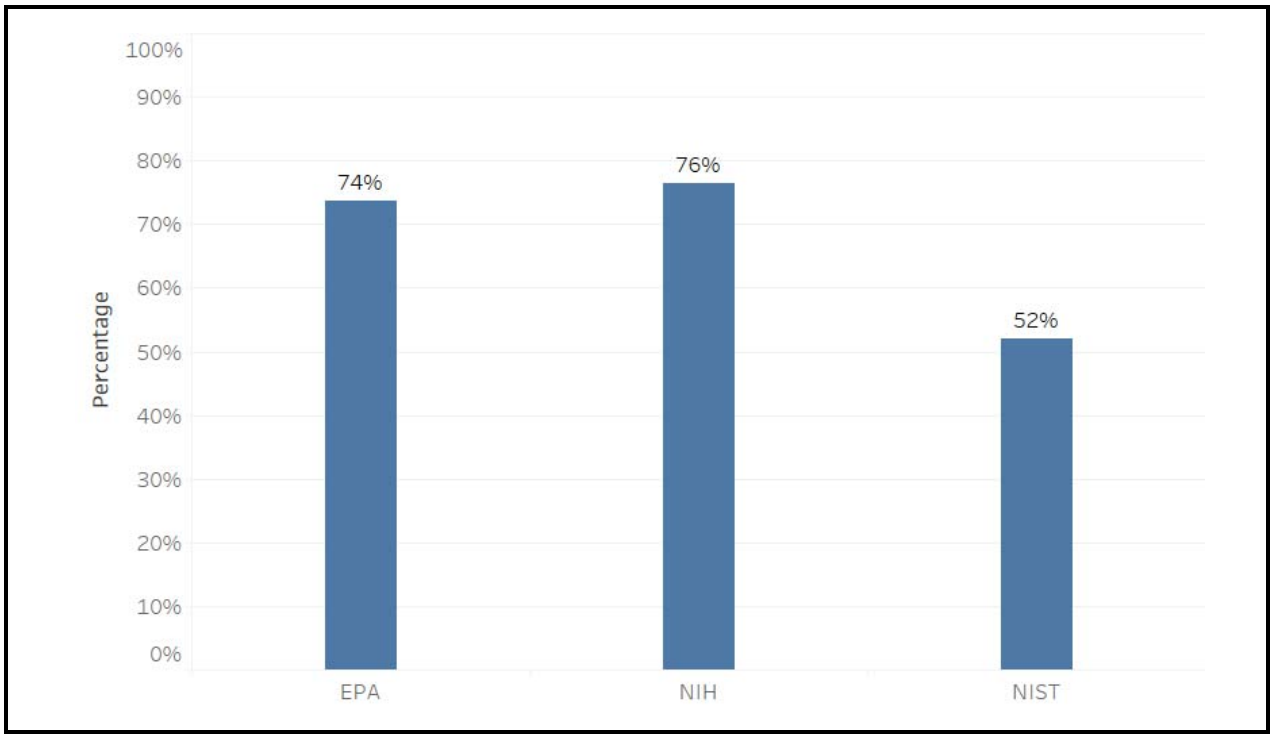
For NIST, of the 26 companies for which the mean inflation-adjusted sales increased after the license started, the mean percentage increase was 161.3%. For the 24 companies for which the mean inflation-adjusted sales decreased after the license started, the mean percentage decrease was 29.2%.

The percentage changes in company sales, by participating federal agency of the licensed technology, are in Figure 8-4.

Table 8-4. Descriptive Information on the Percentage Change in Companies' Sales, by Agency (1990–2014)

	EPA	NIH	NIST
Number of companies that had an increase in inflation-adjusted sales after the license started compared with before	14	297	26
Number of companies that had a decrease in inflation-adjusted sales after the license started compared with before	5	92	24
Mean of the percentage change in inflation-adjusted sales for all companies	122.5%	384.0%	69.9%
Sales Increase			
Mean of the percentage increase in inflation-adjusted sales for those companies that had a mean sales increase after the license started compared with before the license started	172.9%	513.1%	161.3%
Sales Decrease			
Mean of the percentage decrease in inflation-adjusted sales for those companies that had a mean sales decrease after the license started compared with before the license started	18.8%	33.5%	29.2%

Figure 8-4. Percentage of Licensees with an Increase in Company Sales After the License Started (1990–2014)



To further describe the percentage changes in inflation-adjusted sales, Table 8-5 shows the distribution of percentage changes in sales by quartile and by agency. The first quartile for NIH is a positive percentage change, whereas the first quartiles for EPA and NIST are negative percentage changes. For NIH, the maximum value for a company's percentage change is 18,333.8%.[33]

Table 8-5. Comparison of Percentage Changes in Company Sales, by Percentage Change Quartiles and Agency (1990–2014)

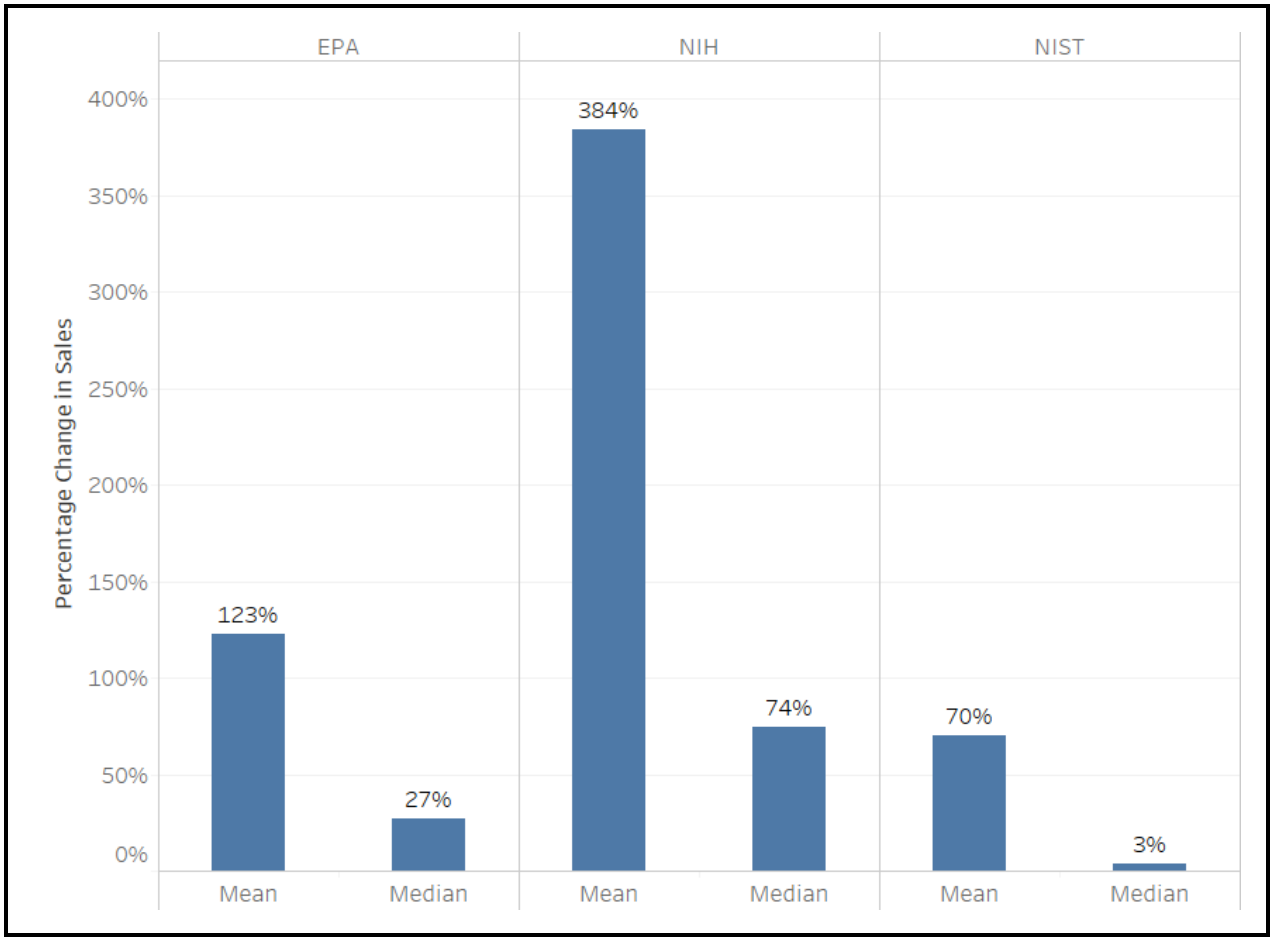
Quartile	EPA (n=19)	NIH (n=389)	NIST (n=50)
1Q	−2.00%	2.20%	−22.30%
2Q (median)	26.70%	74.40%	3.30%
3Q	184.90%	233.40%	113.40%
4Q (maximum)	976.90%	18,333.80%	493.90%

[33] The next highest value of a company's percentage change in sales is 16,448.3%; thus, we do not consider the former value an outlier.

The percentage changes in Table 8-4 and in Figure 8-4 merely suggest that the licensed technology is positively associated with inflation-adjusted company sales (our research only shows a correlation). Thus, generalization from these descriptive relationships should be made with caution. Figure 8-5 shows the overall mean and median percentage change in company sales by agency of the licensed technology.

As emphasized above, the percentage increases and decreases in company sales cannot be attributed to the presence of a licensed federal technology. Other factors that we cannot control for are lags between when the license started and the licensed technology becoming an integral part of a company's products, sales, or processes; whether the licensed technology became a product or process integral to the company's sales; managerial differences across companies in all aspects of the

Figure 8-5. Mean and Median Percentage Change in Company Sales (1990–2014)



company's operations; and changes in market and economic conditions, although converting sales into inflation-adjusted sales accounts in part for changes in economic conditions over time.

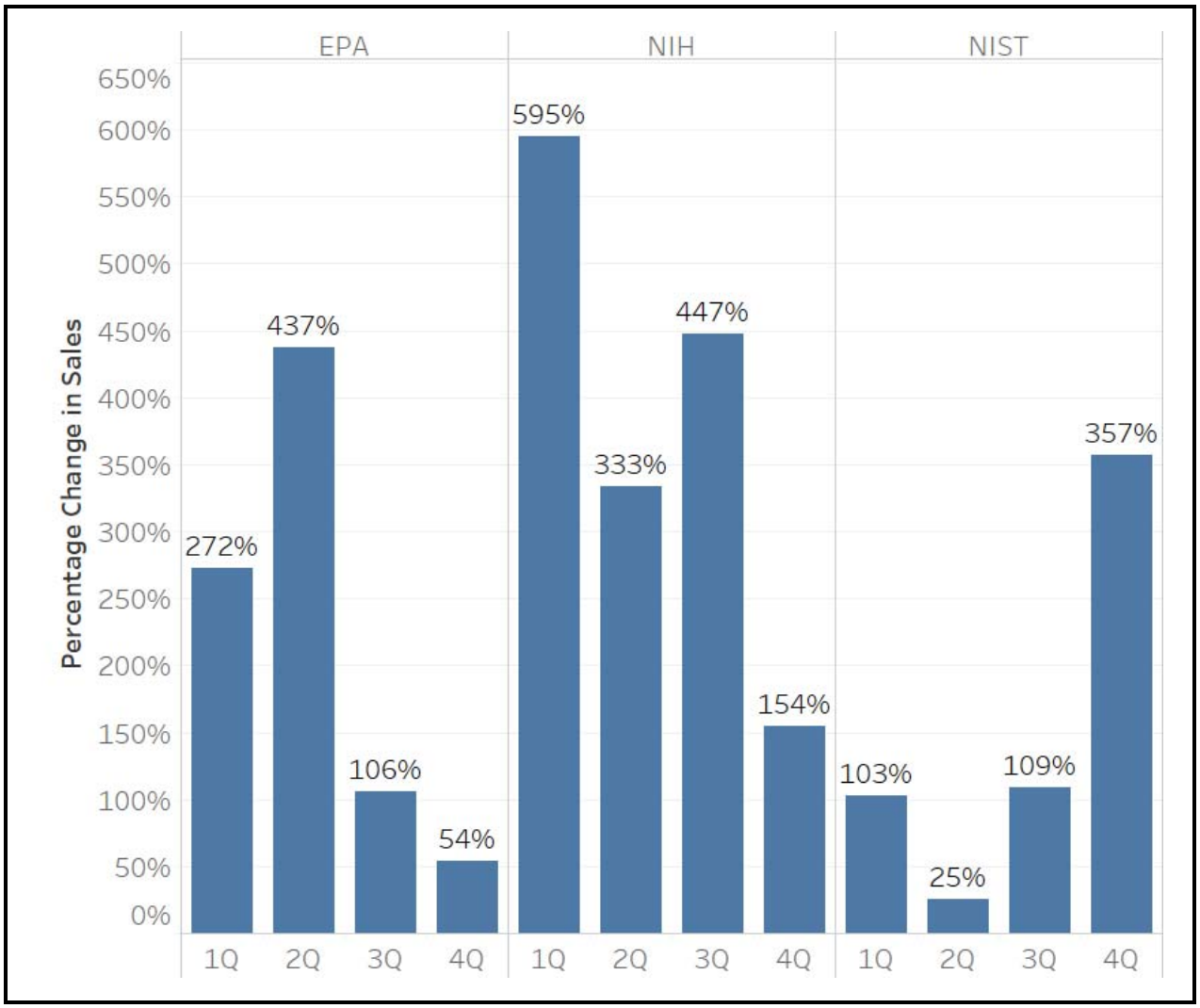
We also considered the relationship between company size and the percentage change in sales after licensing. Using the number of company employees at the time the license started as an indicator of company size, we computed percentage changes in inflation-adjusted company sales by employment size quartiles (see Table 8-6 and Figure 8-6). For EPA, the percentage change in mean inflation-adjusted company sales increases with company size for the smaller 50% of the companies, and then it decreases for larger companies. There is no similar pattern among the NIH companies. Among the NIST companies, the percentage change in mean inflation-adjusted company sales continually increases for the larger 75% of the companies.

In summary, one should not generalize from the qualitative information in this chapter, or if one does, any generalizations should be offered cautiously. Nevertheless, the qualitative information in this chapter may possibly be a starting point for more detailed studies of the sales impact of licensed federal technology to private-sector companies. Surveys of the relevant companies for primary source information would confirm what we suspect to be a relationship between licensing and increased sales of the licensed company.

Table 8-6. Comparison of Percentage Changes in Company Sales, by Employment Quartiles and Agency (1990–2014)

Quartile	EPA (n=19)	NIH (n=389)	NIST (n=50)
1Q	272.4%	594.7%	103.2%
2Q (median)	437.3%	333.1%	25.3%
3Q	105.8%	447.4%	108.8%
4Q (maximum)	54.3%	154.4%	356.5%

Figure 8-6. Comparison of Percentage Changes in Company Sales, by Employment Quartiles and Agency (1990–2014)



9 Toward an Understanding of Cooperative R&D Agreements with Federal Laboratories and Company Size

Summary

- Descriptive data show that federal agencies have a higher propensity to conduct cooperative R&D with smaller-sized companies than with larger-sized companies.

In this chapter, we investigate the propensity of private-sector companies to engage in CRADA activity with a federal laboratory. Information was provided by the participating agencies on their CRADA activity by year. For each CRADA, we also know the year in which the CRADA began and the employment size of the private-sector company at the time they participated.

Our hypothesis is that smaller-sized companies are more active in CRADA activity than larger-size companies. Motivating this hypothesis is Title 15 of the U.S. Code. Therein it states in § 3710a. Cooperative research and development agreements, that: "Each Federal agency may permit the director of any of its Government-operated Federal laboratories … (1) to enter into cooperative research and development agreements on behalf of

such agency … with industrial organizations …" And, in 15 USC 3710a(c)(4)(A), it states that "The laboratory director in deciding what cooperative research and development agreements to enter into shall—(A) give special consideration to small business firms, and consortia involving small business firms; …" Our analysis suggests the legally mandated propensity of the participating federal agencies to engage in CRADAs with small firms.

The six agencies that provided information on their CRADA activities are : DoD, U.S. Army and U.S. Navy; DOI, Bureau of Reclamation; EPA; NIST; and NIH.

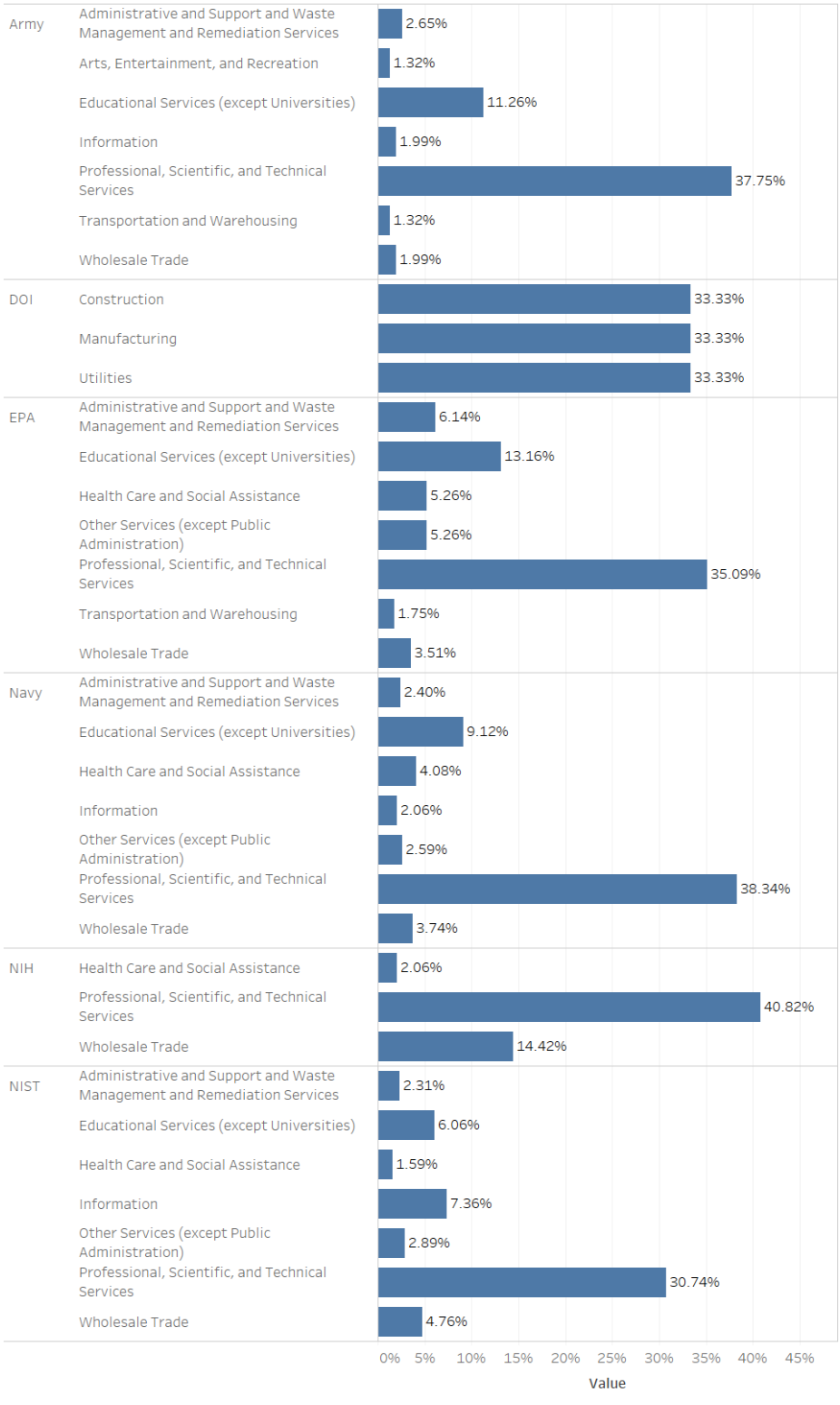
Table 9-1 shows the data reduction process. The tabular analysis that follows relates to the bottom two rows of the table. For example, of the 512 companies that could be matched to NETS data, 128 of them met the protocols and had at the time the CRADA was initiated 500 or fewer employees (which defines a small firm herein).

Figure 9-1 shows the distribution of CRADAs across 2-digit NAICS sectors.

Table 9-1. Data Reduction Protocols and Affected Companies, by Participating Federal Agency

	DoD Army	DoD Navy	DOI Bureau of Reclamation	EPA	NIH	NIST
Number of agency provided CRADAs that were matched to NETS data	512	2,579	4	181	1,542	1,217
Less CRADAs with missing information on NAICS codes and employment levels	152	2,105	3	120	1,068	704
Less CRADAs that involved a public agency or university or medical school	136	1,883	3	99	1,058	653
Less CRADAs with more than 500 employees	128	1,689	2	87	915	568

Figure 9-1. Percentage of Companies Involved in a CRADA by Sector, at Time of CRADA[a] (1990–2014)



[a] For readability, this figure excludes any sector with less than 1% of companies.

Table 9-2 shows the distribution of employment quartiles for each agency according to the protocols above, except for the small firm criterion. Table 9-3 shows the distribution of employment quartiles after implementing the small firm criterion.

Table 9-2. Employment Quartiles (CRADAs with any number of company employees)

Quantile	DoD Army (n=136)	DoD Navy n=1,883)	DOI Bureau of Reclamation (n=3)	EPA (n=99)	NIH (n=1,058)	NIST (n-653)
1Q	9	9	1	8	12	11
2Q (median)	31	35	20	20	60	45
3Q	103	150	1,009	175	200	250
4Q (maximum)	3,170	21,300	1,009	29,186	5,000	19,000

Table 9-3. Employment Quartiles (CRADAs with 500 or fewer employees)

Quantile	DoD Army (n=128)	DoD Navy n=1,689)	DOI Bureau of Reclamation (n=2)	EPA (n=87)	NIH (n=915)	NIST (n-6568)
1Q	8	7	1	6	9	9
2Q (median)	28	25	11	15	42	30
3Q	99	100	20	60	160	113
4Q (maximum)	460	500	20	425	500	500

10 Case Studies of Successful Technology Transfer from Federal Laboratories

Summary

- Government R&D that leads to federal laboratory technology transfer serves the public through new innovations and their economic, environmental, and health benefits.
- Bringing innovations derived from federal transferred technology by the company into the market takes time as well as a long-term commitment to investments in R&D. It also takes a commitment from individuals, both federal and private, with expertise in the transferred technology.
- Federal laboratory management can facilitate the successfulness of technology transfer by providing resources and a culture that values such activity.
- Potential federal innovations can come from nonresearch staff as well as research staff if the organization is structured to allow it. Generally, allowing nonresearch staff to be involved in the innovation process requires some decentralization of decision-making authority.
- Clear market need accelerates the transfer and later adoption of the innovation.
- Co-development by federal labs of a transferred technology with individuals of companies with supplementary expertise appears to increase the likelihood that the federal transferred technology will have market success.

Mission-specific case studies, one for each participating agency, are included as an integral part of this study. They document outcomes and impacts of federal technology development and transfer from the federal laboratories. They also document federal TTO support, transfer mechanisms (including knowledge

transfers) used, and the contexts in which the transfer occurred.

Based on available information, we document observed outcomes in each case study and trace how the federal agency and laboratory support, as well as other factors, contributed to these outcomes. Each participating federal agency worked with the project team to select a case study topic for greatest relevance and value to the agency. Participating agencies had the opportunity to review their draft case studies before publication. Nine reviewed case studies are presented in this report.

Anticipating that a broad range of federal technologies could be transferred from federal agencies and federal laboratories, we followed a case study protocol to ensure consistent definition of terminology and a consistent logic and line of inquiry, despite heterogeneity in the underlying technologies, agencies, and mechanisms.[34] Many scenarios are possible in efforts to develop and commercialize technologies for societal impact in alignment with federal agencies' missions, particularly those that involve a handoff from government-funded R&D to the private sector. Each case study investigates and reports important milestones and contextual factors along the development-commercialization-adoption path of the federal transferred technology; each also reports the contribution of agency activities to observed progress and success. Agency activities may be specific programs, approaches, R&D effort, and technology transfer activities.

Because the case studies were conducted by different members of the team, consistent use of terminology is important to ensure comparisons across the various studies. Common terminology is as follows.

Technology may be hardware or software; a service such as calibration or certification; a technical standard, measurement tool, or dataset; a process, practice, or business model; or knowledge or know-how. In addition to a stand-alone item, the technology may be a component that is embedded in a new or existing product, process, practice, or policy.

[34] Case studies conducted with the same evaluation protocol allow for easier comparison and synthesis across studies.

Commercialization is defined here as "at least one technology sold (or utilized) in the market." There are different ways of categorizing stages in the development of a new technology, including the stages of the stage-gate process (Cooper, 2008): preliminary and detailed investigation, development, validation, and commercial launch or the sequence of clinical trials for a new biomedical innovation.

Success may be represented in the form of improved capabilities, improved knowledge, and new hypotheses on which future innovation can build, where innovation is defined as introduction to the market of something new or improved that adds value (Organisation for Economic Co-operation and Development and Eurostat, 2005).

Innovation is interpreted to mean market or nonmarket adoption of a technology.

10.1 FRAMEWORK FOR THE CASE STUDIES

Fundamental to our evaluation planning and implementation is a logic model. The logic model guiding this study was discussed in Chapter 5 and is reproduced here as Figure 10-1.

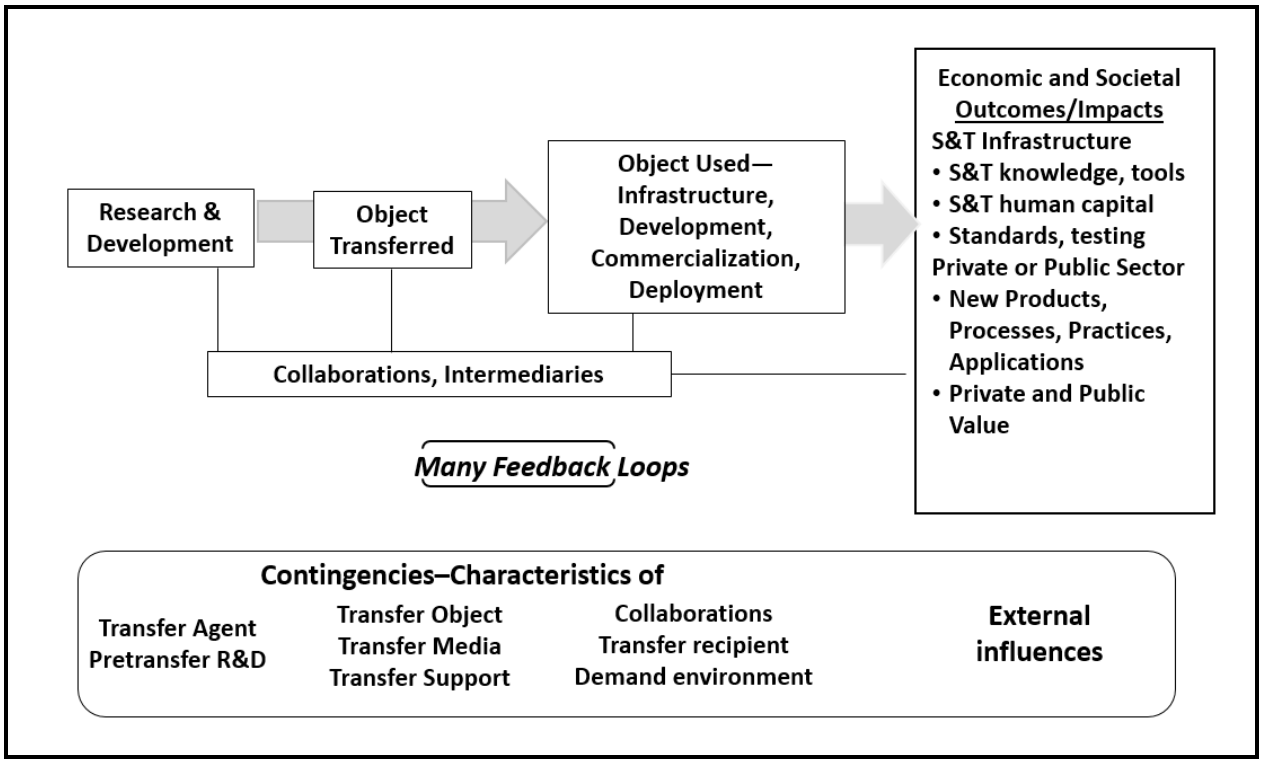
10.1.1 Characteristics of Factors that Influence the Success of Technology Transfer Efforts

As stated in Chapter 5, the model also calls out "contingencies," or characteristics, of each instance of federal technology transfer that affect the timing, parties involved, and size and type of outcome/impact of the transfer. Characteristics have been defined for each element of the logic model, and characteristics will vary depending on the laboratory and the specific R&D, the object transferred and transfer mechanism, the transfer recipient and demand environment, and the agency mission and a broad notion of the pathways to economic and or social value.

The characteristics for the eight aspects or contingencies influencing federal technology transfer success are shown in the logic model. Five are from Bozeman (2013), and the three we have added are preceded by an asterisk:

- transfer agent
- transfer object
- *technology transfer support

Figure 10-1. Federal Technology Transfer and Commercialization Logic Model with Contingencies



- transfer media
- technology recipient
- *transfer collaborations and intermediaries
- demand environment
- *external influences

Detailed descriptions of each contingency are included in Chapter 5.

10.2 CASE STUDY APPROACH

The objective of the case studies was to provide documentation of successful federal technology transfer activities through the identification of specific outcomes and impacts associated with a technology transferred from a federal laboratory. The case study information template used in each case study included the following seven broad questions:

1. What is the "technology" and what does it do compared with the next best alternative?

2. What is the history of federal lab/agency involvement in the research and technology development of this technology? What was the mechanism for the technology transfer?
3. Who else was involved in the R&D before and during transfer and what is known about their interactions?
4. What were the circumstances surrounding the federal transfer of the technology to the private (or public) sector?
5. What has happened since the transfer of the technology?
6. What benefits occurred as a result of its commercialization/adoption?
7. What did the federal technology development and transfer effort contribute to observed outcomes and how did contextual factors contribute to these observed outcomes?

Appendix E is a stand-alone document describing the protocol we followed for these case studies. It includes our full interview guide with detailed subquestions within each of the seven broad questions. Information related to these questions was initially collected from a review of documents,[35] the extant literature, and relevant websites, but the primarily source of information came from interviews with knowledgeable individuals familiar with key aspects of the case.[36]

Our findings were based primarily on content analysis of all the listed data sources. Analysis of benefits involved summarizing existing information on use or sales. When possible, other economic, social, environmental, and national security benefits were considered.

Our team spoke (generally through telephone interviews) with over 40 individuals across the nine case studies. As Table 10-1demonstrates, those interviewed included major

[35] Documents included 1) published papers and histories written by the technology developers, 2) writings by relevant technology and market experts found through web searches, 3) websites about and for the technology and related subjects, and 4) published licensing and royalty information and studies of economic impact where those had been done by others.

[36] Such individuals included the government inventor(s), those involved in the technology transfer, and the recipient of the transferred object and/or co-developers in industry. Most case studies included at least five interviews.

Table 10-1. Interviewees by Type of Stakeholder

	Type of Stakeholder				
Case Study	Government Technology Development and Transfer	Universities and Intermediaries	Industry	Other	Total
DOC, NIST	2	—	1	—	3
DOI, USBR	1	—	—	—	1
DoD, Air Force	2	—	3	1	6
DoD, Army	3	—	1	—	4
DoD, Navy	4	1	2	—	7
DOT, FHWA	2	—	—	4	6
HHS, CDC	2	—	—	—	2
HHS, NIH	3	3	—	—	6
USDA, Agricultural Research Service (ARS)	3	3	2	—	8
Total	22	7	9	5	43

Note: Counts include some unstructured interviews that provided critical information, as well as a few structured email exchanges when we were unable to arrange a time for a telephone interview.

stakeholder groups. The interviewers had more participation from licensees and other industry partners for some of the case studies.

10.3 CASE STUDY BENEFITS AND BENEFICIARIES

As expected, reported benefits and beneficiaries of the technologies studied reflect the agencies' missions as well as the sectors specific to their individual missions. To summarize:

- In all nine cases, the transfer of the federal technology contributed to achieving the agency mission.
- In all nine cases, the public benefited either directly or indirectly from the transferred technology.
- In eight of the nine cases, industry was involved and benefited from that involvement (CDC was not one).
- In six of the nine cases, government personnel and/or processes were the direct recipient of the federal technology transferred (NIST, DOI, Air Force, Army, Navy, DOT). In other words, the government was developing solutions for its own needs and the transfer of the technology to the private sector helped bring

additional resources and capacity to scale up the technology for use and/or opened up the opportunity for the private sector to commercialize the technology for use outside of the government.

- In two of the nine cases, the broader research community (i.e., government, industry, and universities) benefited directly from the transfer of the technology (CDC, USDA).

The federal technology transferred and its benefits and beneficiaries for each case are summarized in Box 10-1. The counterfactual as seen by interviewees when they were asked "what would likely have happened without the government R&D and transfer" is also briefly stated. Where data were reported by interviewees that quantified benefits or where such data were estimated by the case study author, these are also reported in the table. Complete case studies are in Appendices E through M.

10.3.1 DOC NIST Framework for Improving Critical Infrastructure Cybersecurity

In 2013, NIST, directed by a presidential executive order and led by the Information Technology Laboratory ITL, convened hundreds of public- and private-sector actors, including companies, associations, and government agencies, to create the Framework comprising standards, guidelines, and practices that help organizations reduce cyber risk while avoiding regulatory requirements. The Cybersecurity Framework, Version 1.0, was released in the open literature in February 2014, a guidance document in May 2015, and Framework Version 1.1 in April 2018.

The Framework evaluates the level of effort taken by an organization to reduce risk related to a cyberattack; a cybersecurity community actively shares lessons learned about specific threats and responses. Standards generate a public good the private sector could not create. Users of standards reduce their risks and associated risks for the public/their customers of cyberattack and accompanying costs. Such cyberattacks threaten national security or interrupt electric power or communication. Without the Framework, each government agency and other types of organizations would be left to establish their own cybersecurity protocols and strategies without a common reference.

Initially meant to improve cybersecurity in government, the Framework and its growing adoption continue to improve overall cybersecurity. According to NIST, 30% of organizations in the United States had implemented the Framework by 2015 with a projected 50% by 2020. These organizations represent 16 critical infrastructure sectors and 20 state governments. Further, a recent report finds that 28% of U.S. companies now require their vendors to follow the accepted Cybersecurity Framework, a supply chain response.

Cyberattacks disproportionately affect larger companies, and estimates of the average cost of an adverse cyber event range from $2.7 million to $21 million per event. The Framework has not only provided federal agencies with an important benchmark and the user community, but it has also given weight to federal agency resource requests in terms of cybersecurity budget and staffing

10.3.2 DOI Bureau of Reclamation Flexible Fluxprobe Diagnostic Tool

Jim DeHaan and the research group at the Bureau of Reclamation (the Bureau) saw the need for a diagnostic tool for large hydroelectric generators located on hydroelectric dams, developed it, and filed an invention disclosure report with the Bureau's TTO in 2000. The patent was awarded in 2002. During that period, the R&D group manufactured several flexible fluxprobes for use in the field. The Bureau then approached Iris Power, who agreed to work with the Bureau to transfer and further develop the technology, signing a nonexclusive licensing agreement with the Bureau for the flexible fluxprobe, as well as a entering into a CRADA. Iris Power made several functional improvements to the flexible fluxprobe, which it continues to offer to customers, companies, cooperatives, and governments that possess large-scale hydroelectric generation facilities.

The fluxprobe is a diagnostic tool for large hydroelectric generators located in hydroelectric dams. The tool attaches inside the rotor mounts of the generator and detects magnetic fields associated with the wear and tear of insulation. This diagnostic tool lowers a challenge of maintenance for these dams, both publicly and privately operated, reduces downtime, which translates into lower maintenance costs and more generation capacity. The Bureau of Reclamation operates many dams for the benefit of the public. It is unlikely that the private

sector would have developed the device on their own, or if they had, they would have taken a significantly longer period of time to do so.

The flexible fluxprobe and generator rotor monitor reduce the time required for offline component evaluation, improve diagnosis accuracy and maintenance schedules, and reduce the risk of catastrophic component failure. These benefits, in turn, translate into collective reduction of generator downtime, with operational savings and more reliable power generation. The agency also received modest licensing revenues of nearly $40,000 as of 2015, from Iris Power that were used to continue its technology transfer activities and provide incentives to inventors to further develop new, useful dual-use technologies.

By inventing the flexible fluxprobe to improve the operation and lifespan of government-owned hydroelectric power facilities, the Bureau of Reclamation created a new technology that also lowered the development costs for industry. Iris Power agreed to license the flexible fluxprobe because the technology aligned well with its corporate mission for helping its clients manage and maintain large-scale power equipment. Although the flexible fluxprobe is a low-volume product (about 366 units were sold by 2015), it enhances the products and services Iris Power offers. Iris Power has made functional improvements to the technology and developed complementary services, such as installation of the flexible fluxprobe, and it offers the device as part of larger product and service bundles to power generation companies around the world.

10.3.3 DoD Air Force Attenuating Custom Communications Earpiece System (ACCES)

ACCES was developed by the Air Force Research Laboratory's (AFRL) 711th Human Performance Wing (711 HPW) and Westone, a hearing protection technology company, through a CRADA. ACCES improved on an existing Westone earmold technology. Westone introduced it the enhanced technology commercially in 2007.

ACCES includes a silicone custom-molded earpiece that joins with a speaker cable to deliver audio to the user at very high altitudes and detaches easily if the pilot needs to eject. Air Force pilots of fighter aircraft using this system have reduced their risk of hearing loss due to extreme noise, increased their ability to communicate with others during flight, and experience

less risk of injury if they eject from the aircraft while wearing this earpiece. The requirements of the Air Force for supply of the ACCES technology are likely too small of a market to have triggered private-sector investment in R&D.

Initially, the Air Force pilots' use of ACCES earpieces was limited to use in fighter jets, but over time the ACCES technology was certified by the Air Force for use across a variety of airframes. Additionally, pilots' use of the ACCES technology began to spread to other aircraft crew members' and ground crew personnel's use. Air Force personnel of approximately 10,000, were likely users of the ACCES product from 2007 to 2017. For this time frame, we estimate this population of potential users in the Air Force to be over 88,000 individuals, suggesting an estimated market penetration of 11% within the Air Force. ACCES not only protects hearing and reduces hearing loss and its associated costs, but also improves pilot retention and user effectiveness in times where safety, awareness, and effective communication are paramount. Although the Air Force remains the dominant purchaser of ACCES, Westone also markets the product to other branches of the military, friendly foreign militaries, law enforcement, and the commercial space industry. From 2007 to the end of 2017, Westone sold 13,755 ACCES units.

10.3.4 DoD Army Japanese Encephalitis Vaccine—Walter Reed Army Institute for Research

The JEV vaccine was developed in the DoD laboratory at Walter Reid Army Institute of Research (WRAIR) under a CRADA. In 1998, CJ Corp and WRAIR filed a patent application for a U.S. patent. That same year, CJ Corp left the partnership with WRAIR and sublicensed the rights to the vaccine to VaccGen. WRAIR and VaccGen moved the vaccine through Phase I and Phase II clinical trials, and the product received a patent in 2001. CDC selected the WRAIR/VaccGen/Intercell AG partnership to bring the new vaccine (IXIARO□) to market, guaranteeing availability to DoD for purchase of the vaccine immediately upon Food and Drug Administration (FDA) approval, which they did in 2009.

This FDA-approved vaccine protects U.S. military personnel and contractors stationed in specific parts of Asia for extended periods of time. The vaccine protects them from contracting JEV, a mosquito-borne illness in the same family as West Nile

and Zika. The U.S. military personnel, contractors, and families who accompany them are protected against sickness and a brain disease that can cause death, by a vaccine less toxic and more effective than alternatives, none of which are FDA approved. Producers and sellers of the vaccine receive revenue. Without the military's demand for the vaccine, it would not have been developed. There is no U.S. domestic market for this vaccine, because the virus is not endemic.

The IXIARO vaccine provides significant health and commercial benefits but is small in the broader context of JEV vaccines across the globe. As of 2014, 12 different JEV vaccines were on the global market, with most produced by China, Japan, Korea, and India. Of these vaccines, IXIARO is the only JEV vaccine approved in the United States and in many of its military allies including European countries and Canada. WRAIR's careful development of a safe, efficacious vaccine resulted in a safer product than its predecessor's and competitors' vaccines with fewer concerns about toxicity. Thus, use of IXIARO is considered safe not only for U.S. service personnel, but for their families as well; its use lowers the risk of military families in East Asia contracting the disease. Its exclusive approval for use in the United States allows IXIARO to dominate the JEV vaccine market there but also makes the vaccine more expensive to produce and less likely to be competitive outside of the primary U.S. market. Producers of the vaccine have been successful. DoD has been using the vaccine since 2011 and signed a 1-year contract with Valneva in 2017, worth nearly $40 million, to supply IXIARO to DoD.

10.3.5 DoD Navy Facilities Engineering Port Security Barriers (PSB)

Researchers at the Naval Facilities Engineering Service Center (NAVFAC NFESC), building on earlier work by Navy researchers, developed a step-change improvement in PSBs. They negotiated a patent license agreement with Harbor Offshore in 2004, giving Harbor Offshore the exclusive rights to market the patented PSB technology for commercial uses. The Navy retained IP rights over the technology for their own use. A second company, Truston, was able to negotiate a coexclusive license with the Navy in 2009. By 2016, variations of the new PSB technology had replaced the previous, now inferior, security system in all 24 Navy homeports.

The PSB system acts as a both a visible and physical deterrent to access port waters and greatly reduces the likelihood of unauthorized access to waterfront assets by small surface watercraft. In addition to the physical deterrent, the PSB system also acts to dissipate kinetic energy produced by a collision. The barriers protect waterfront assets and people present in the area for the Navy and nonmilitary users and thus lower the risk of attack and the accompanying economic costs and lives lost. The industry that produces and sells PSB receives revenue. Without the government R&D and technology transfer, the private sector would have eventually developed other solutions, but their systems would not likely have been as extensively tested as PSB.

The bulk of U.S. Navy PSB purchases occurred between 2004 and 2012, as the Dunlop system installations were replaced with the PSB system and as PSB systems were installed at Naval facilities with no prior marine barrier system. There are clear national security benefits evident because the fence "makes us a harder target." PSB has also been used to protect other high-value assets such as cruise ships, nuclear power plants, dams, and offshore oil rigs. Where PSBs are deployed, risks posed to human safety and loss of human life in both military and nonmilitary settings are reduced.

Harbor Offshore and Truston have developed portfolios of products related to the PSB technology, which has resulted in cumulative sales of about $185 million. The use of this technology reduces the economic risks and costs associated with an attack on a large hydroelectric facility or waterside nuclear energy plant. Such an attack on a hydroelectric facility would cause disruption in the availability of electricity and probable rise in prices due to the power shortage. Use of this technology also has the potential to reduce environmental risks. Where these are employed for offshore drilling and/or nuclear energy applications, it may reduce unintended leakage of oil and chemicals into waterbodies, were an attack to occur.

10.3.6 DOT FHWA Mobile Solution for Assessment and Reporting (MSAR)

A staff member at the DOT Federal Highway Administration saw a need, designed a solution with the target users, and contracted with a private-sector IT company Run Solutions to develop the software application to provide disaster

assessments more efficiently. Prior to DOT approval, the software was piloted in the field and licensed for free beginning in 2016 for use in the Federal Emergency Relief program with state partners and the Emergency Relief for Federal Owned Roads program.

This software application helps officials capture disaster damages to transportation infrastructure in the field by using ubiquitous smartphone and tablet technology and providing near real-time accessibility to assessments and intelligent routing for approvals. Federal and state governments can assess damages more quickly and efficiently and at lower cost to better inform decisions on funds to repair damages. Repairs completed more quickly translates to less social and economic disruption. Without the MSAR, many states likely would have developed processes using similar technology eventually or kept using their own processes. Cumulative development costs of better solutions would have been higher and there would be no overarching standard and little sight for FHWA into the real-time status of damages in a multistate region.

Pilot testing of the MSAR demonstrated a potential total labor savings of 17.5 hours (reduction from 63 hours to 44.5 hours) per damage assessment report. This frees up staff time for other activities. For Hurricane Harvey alone, TX DOT and local agencies documented over 900 sites in under 5 weeks. FWHA and TxDOT reported 17,500 labor hours of savings for this event alone.

Ancillary benefits provided by MSAR include improved reporting functions enabled by having standardized, digitized information stored in a single place. This eases the burden for federal, state, and local governments of reporting to congressional inquiries about the cost of recent natural disasters like Hurricane Harvey.

10.3.7 HHS CDC HMEC-1 Cell Line

The Human Microvascular Endothelial Cell Line (HMEC-1) was invented by Paco Candal in 1990 at CDC in Atlanta, Georgia. The NIH filed patents on behalf of CDC but, in the process, the agency learned that prior publication about the HMEC-1 cell line invalidated its ability to patent the invention. Nonetheless, CDC distributed the HMEC-1 cell line widely to hundreds of groups, especially nonprofit research organizations, through material

transfer agreements (MTAs), and these organizations further developed the HMEC line.

The HMEC-1 cell line provides a faster and lower cost process for producing endothelial cells that researchers use to understand how diseases spread in the body. The availability of this cell line to researchers improves their capabilities and productivity to study diseases or test new drugs. The discovery was driven by an individual researcher, Paco Candal. Given the obvious need for an alternative process, some improvement would eventually have occurred.

The HMEC-1 cell line multiplies rapidly, allowing for rapid production of the specified cells. Its creation aided CDC to better serve and uphold its health mission of protecting the U.S. public from the spread of communicable diseases and other public health threats. Further, CDC's dissemination of the HMEC-1 cell line to other government laboratories, universities, and companies—typically through MTAs and licensing agreements—further led to improved research productivity and health outcomes.

10.3.8 HHS NIH Human Papillomavirus (HPV) Vaccine

The National Cancer Institute's (NCI's) research collaborations with academic and industry colleagues and the German Cancer Research Center are credited with contributing to a rapidly evolving HPV knowledge base at a critical time for the HPV vaccine's development. Although Merck and Medimmune both licensed NCI's technology in 1997 (their nonexclusive licenses were converted to coexclusive licenses in the agreements following the patent-interference proceedings), this vaccine was brought to market by GSK using the NCI method of production.

HPV causes an estimated 610,000 cancers each year worldwide: 80% of these in less developed countries; in North America, 26,000 of the 1.6 million new cancer cases each year are attributable to HPV. Cervical cancer is the most common type of cancer attributable to HPV and the fourth leading cause of female cancer mortality. The vaccine was approved by FDA and was added to the United States' routine vaccination schedule for girls 11 or 12 years old and is recommended for girls and women aged 9 to 26. Today at least one of the two major HPV vaccines is licensed in more than 100 countries. In addition to the health benefits generated by this vaccine

including lives saved, it also results in reduced medical costs and provides income to producers/suppliers of the vaccine.

10.3.9 USDA Turfgrass Varieties

Scientists at the U.S. Department of Agriculture's (USDA's) ARS in Tifton, Georgia, developed the first seedless warm weather Bermuda grasses with characteristics that made them best sellers for their various uses. This study covers five turfgrasses patented and released by ARS and the University of Georgia through licenses between 1998 and 2014. The ARS and University of Georgia licensed their most recently developed turfgrasses to a company owned by Georgia sod producers, which then sublicenses to other producers.

This case study examined five varieties of certified, quality turfgrasses for recreation and home lawns, each with specific characteristics (e.g., can mow very short for golf greens, uses 38% less water) that are certified before sale. The producers in Georgia and elsewhere profit; many people are employed; and installation of this turf results in aesthetic, health, and environmental benefits. Related research is funded by licensing income. Without the innovative method of creating mutants from which to find grasses with improved characteristics desirable for their environmental and economic benefits, these five new varieties likely would not have been found or developed.

Total royalties collected on just the five turfgrasses between 1998 and 2017 was $9,700,000. Royalties for the five turfgrasses were almost triple the cost of all research on all grasses at Tifton. These royalties fund continued research. A 2012 study specific to Georgia concluded that turfgrass and related industries directly contribute $4.0 billion in output and indirectly another $3.8 billion for a total of $7.8 billion to Georgia's over $700 billion economy; is the source of 87,000 full- and part-time jobs, the majority of which are related to landscape maintenance, while 6,324 jobs are in agriculture; and contributes $4.6 billion in earnings and value added each year.

As the primary vegetative covers for home lawns, schools, parks, roadsides, sports fields, golf courses, and commercial and public buildings and spaces, turfgrasses also have environmental and health benefits. The National Turfgrass

Federation 2006 report provided some specifics. A 2,500 square foot lawn absorbs carbon dioxide and releases enough oxygen for a family of four; a healthy lawn absorbs rainfall and reduces runoff up to 80 times more efficiently than imperious surfaces such as driveways; to reduce injuries, over 90% of National Football League players prefer natural turf to artificial turf. The same safety benefits apply to all levels of athletic activity, including school playgrounds, and turfgrasses that use water and nitrogen more efficiently and are pest-resistant reduce the use of irrigation, fertilizer, and pesticide, particularly as these become costlier or less available.

10.4 TECHNOLOGY TRANSFER SUCCESS FACTORS

The nine case studies provide insight into success factors and challenges associated with the transfer of technology from federal laboratories. The discussion below is organized by the above discussed success factors. The factors highlighted are thought to be the primary or secondary factors as based on information from interviewees, conclusions from analysis of interviews, and other secondary research such as reviews of program documents. The generalizability of results is limited because of the way cases were selected (nonrandom) and the small sample. However, our findings are consistent with previous literature.

The **transfer agent** and R&D include characteristics of the innovating institutions and characteristics of both the researchers involved and the R&D that precedes the transfer. In most cases, the federal laboratory researchers had many years of expertise related to the technology transferred. The USDA researchers were part of a century of research developing improved turfgrasses. Army researchers had developed vaccines similar to the JEV vaccine. In about half the cases, federal researchers had direct experience related to the relevant "market" or access to the end-user perspective. For example, NIST had trusted relationships with industry for developing standards and guidelines. The FHWA has its own staff in the states and working relationships with related state and federal organizations that would ultimately be customers for the technology. For another four cases, it appeared that the government being the primary end user sped development and adoption of the technology. The presence of a person who consistently championed developing the technology over a

period of time was important in more than half these cases. Below are some details related to the transfer agent.

- Six of the nine had specific government research expertise and S&T resources (Navy, USDA, NIST, Army, NIH, and CDC).
- Five of the nine had a champion who advocated for the technology (DOT, Army, Air Force, DOI, and NIH).
- Four of the nine had market-related expertise, such as infrastructure or regulatory expertise (NIST, Army, DOT, and USDA).
- Three of the nine credited success to the key researchers being based within the government agency as critical (Navy, NIH, and USDA), although in most cases at least some of the key researchers for each case study were federal employees.[37]

The **transfer object** relates to the characteristics of the technology transferred in terms of type (such as software or hardware) and in terms of characteristics that influence perception of its value by potential users. In four of the nine cases, the characteristics of the technology itself were very important for its easy transfer and adoption by users. The earpieces developed for Air Force fighter pilots were designed to solve specific problems of working at high altitudes and detaching in case of ejection from the plane. Extensive input from people who would be using the cellphone or tablet technology to assess damage to highway infrastructure meant its design met their needs. NIH involvement in developing the HPV vaccine and the Tifton turfgrasses was similarly designed with an understanding of the target market's needs and interests.

The **transfer media** and transfer support vary and relate to how the technology is handed off to private or public entities. Somewhat typical for federal laboratories are cooperative research agreements, licensing, open-source software, material transfers, publications, and occasionally business start-ups that license federal technology. In the nine case studies presented for this project, seven federal laboratories transferred their underlying patents of the transferred technologies to industry by licensing. The NIST cybersecurity framework was put directly into the public domain, somewhat unique for NIST's

[37] DOT MSAR may be the only exception.

work in standards, which are usually established by standards development organizations (SDOs). CDC transferred its HMEC-1 cell line using MTAs after it was determined it could not be patented because of earlier HMEC-1 publications. Two other agencies used publications as one means of transfer, and CRADAs were part of the transfer process in three of the cases. Probably because of the number of years passing since the transfers occurred and the limited number of interviews conducted, specific assistance in the transfer process from TTOs was not reported and could not be included as a primary factor for success in any of the nine cases. In the USDA case, the agency turned the licensing process over to the University of Georgia, and multiple interviewees for that case study cited the university's expertise as a success factor.

The **transfer recipient** characteristics include the level of available resources and areas of expertise, capacity, geographic location, and company size. Of the nine case studies presented, five licensing laboratories cited the preexisting expertise of their industry partners as a success factor. For the DOT case study, DOT relied on the experience of the end users, who knew the old system and were involved early in designing and testing the new system. The pharmaceutical industry with its large expertise in vaccines invested early in NIH development of the HPV vaccine. The company that helped develop the flexible fluxprobe diagnostic tool already had both technical and manufacturing expertise in that area. The company working with the Air Force modified an existing item in their product line. The growers who licensed the new turf varieties from USDA/University of Georgia were experienced in growing and marketing certified turfgrasses.

The **transfer collaborations and intermediaries** of the transferred technologies**,** the extent to which other entities are involved in the transfer and commercialization and the characteristics of those entities, affect successful transfer. In all nine of the case studies presented, these sorts of partnerships were major contributors to successful technology transfer. In seven of the nine case studies, federal laboratory researchers (NIST, DOI, Army, Navy, Air Force, NIH, and DOT) codeveloped their technologies with industry partners and licensees. In the other two cases studies (CDC and USDA), federal laboratories codeveloped the technologies with university researchers. In three case studies (NIST, DOT, and NIH), federal researchers

codeveloped the subject technologies with other governments or end users. The federal laboratories involved in the development of both the HPV and JEV vaccines also relied on external partners to help fund development.

The **demand environment** is the nature of the target market's demand for the innovation, characteristics of the existing supply chain and required supporting technology and infrastructure, and relevant government policy. The first success factor from the demand environment in all nine of the case studies indicated there was a clear public need for the transferred technology for various reasons. In a few case studies, there were no alternative technologies; in others, the public's next best alternative fell short of the need because of shortage, poor performance, or regulatory requirements. In six of the case studies, the federal laboratory's R&D priorities were driven by the agency. A second factor easing successful transfer in all nine case studies was that the transferred technology was absorbed into a "market" that already existed so that the licensed company did not have to spend time and resources building supply chains or physical infrastructure.

The **external influences** are factors outside of the federal laboratory's control that can either drive or restrain success. For example, a company outside of the technology transfer relationship may achieve an unexpected technical breakthrough, or a competing technology may enter the market first. Federal regulations may support adoption or cultural norms, or an economic recession might slow adoption. Given the limited nature of the data we collected for these historical case studies, we were unable to complete a careful examination of external influences. It does appear, however, that the federal laboratories' technology transfer success was achieved in part by their acting on external driving events, such as the Navy's reaction to attacks on Navy ports, the Army's need for an FDA-approved JEV vaccine, overwhelming evidence of the public's need for a vaccine against HPV, and the public's increasing need for a more drought-resistant turf.

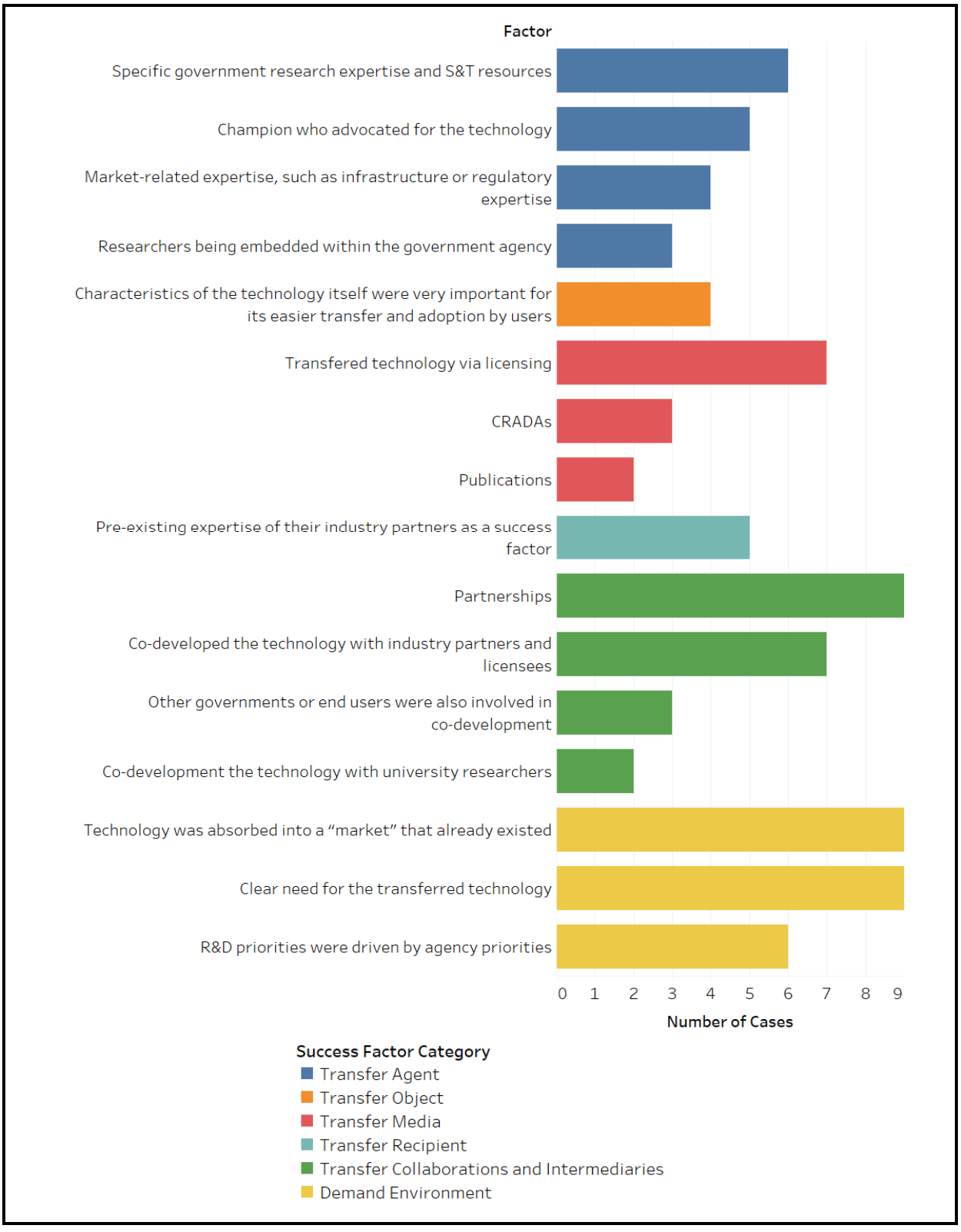
Figure 10-2 provides a summary of the common success factors across these different categories of the logic model.

In addition to the individual success factors, in many cases it was the combination of multiple factors working together that

drove technology development, transfer, and adoption. Here are some examples.

- For the DOC NIST case, NIST's history of working with industry and their reputation as a "trusted" facilitator were key factors in the adoption of the Framework. NIST also hired former industry experts to lead the initiative. Further, the industry's adoption of the Framework was voluntary; industry eventually participated because they viewed the Framework as preferable to a federal regulation that might mandate some type of costly or inflexible response to cyberattacks.
- For the DOI Bureau of Reclamation, the Bureau had a prior working relationship—prior CRADA and a licensing agreement—with a private-sector company that knew the technical area and had manufacturing capabilities and access to markets in the United States and abroad. The Bureau of Reclamation also had a staff of capable technicians aware of the dam operators' realities and problems who serve as intermediaries between the field and laboratory staff and facilities.
- For the DoD Air Force case study, the Air Force's R&D priorities were driven by the pilots' specific needs that the Air Force was willing to pay for. A champion within the Air Force pursued filling that need. A company, already present in the market with similar noise-dampening earpieces for musicians, heard of the Air Force's need and was able to modify its existing equipment. For the DoD Army case, WRAIR has a

Figure 10-2. Common Success Factors



Note: A case could have multiple success factors within a category. External influences varied greatly and were not necessarily common.

lengthy history of vaccine research, dating back to World War I, including extensive experience developing vaccines for the virus type of Japanese encephalitis. Private industry partners helped fund the necessary clinical trials. The Army had no alternative vaccines—none were on the market that were FDA approved, a requirement for any vaccine used for U.S. military personnel. For the USDA ARS case study, two award-winning researchers had worked in this area, one following in the footsteps of the other. The second developed a novel technique to make mutants of the sterile/seedless grasses and generated a test field of 27,000 plants they researched. The University of Georgia has a very experienced licensing organization, coupled with a state-run seed corporation that oversees growing the initial grasses sold, experienced nearby turf producers, and a state crop inspection requirement and testing group that certifies quality, all factors that provided a market advantage to producers.

Although these case studies are presented because the federal laboratory's technology transfer to a company or other entity was successful, each transfer of the technology faced challenges along the way. Because the interviews and written accounts of success of the raconteurs tended to emphasize what went right rather than what went wrong in the technology transfer case studies, our discussion here on challenges is likely to be incomplete and limited.

10.5 SUMMARY OF LESSONS LEARNED FROM THE CASE STUDIES

To summarize:

1. Government R&D that leads to federal laboratory technology transfer to the private sector may serve the public through new innovations and economic, environmental, and health benefits (see sections in case study Appendices F through N).
2. Bringing innovations derived from federally transferred technology to the private-sector marketplace takes time as well as the federal laboratories' long-term commitment to investments in R&D. It also takes a commitment from individuals with expertise in the transferred technology.
3. Federal laboratory management may facilitate the successfulness of technology transfer by providing resources, championing the to-be-transferred

technologies, and instilling a culture in the federal laboratory that values such activity.

4. Potential innovations may come from nonresearch staff and research staff, if the organization is structured to allow it. Generally, for the federal laboratory management to allow nonresearch staff to be involved in the innovation process requires some decentralization of decision-making authority.
5. Where an end user is involved in the technology development or transfer process, their perception of a clear market need helps to accelerate the transfer and later adoption of the federally developed innovation.
6. The federal laboratory's co-development of a transferred technology with individuals or companies with supplementary expertise increases the likelihood that the transferred technology will have market success.

Based on our initial and general findings from the case studies (given that the case studies were selected based on the market or other success of the transferred technology), we share two observations for federal agencies and laboratories to potentially improve and help evaluate their technology development and transfer activities:

1. Incorporate a periodic review of policies and practices related to technology transfer and innovation based on lessons learned from those reviews, as well as any advances in the practice of technology transfer garnered from academic and policy studies. Although there may be separation between TTOs and lab directors, the federal laboratory management should work with both groups to integrate periodic reviews of policies and practices across functions.
2. Incorporate successful and unsuccessful activities into internal playbooks to capture lessons learned for present and future staff involved in laboratory research and staff involved in technology transfer.

11 Conclusions

This study has drawn together, using existing data on technology transfer mechanisms, case studies, and third-party data sources,[38] information to describe technology transfer activities in federal agencies. This study identifies patterns of technology transfer we found and patterns of technology transfer that remain to be studied.

The patterns of federal technology transfer that we identified include the following:

- There are 181 physical federal laboratory locations associated with the 10 agencies participating in this study.
- Since 1978, there has been at least one CRADA partner located in each state. California, Massachusetts, and Maryland are home to the largest number of CRADA partners.
- Although key data linking specific CRADAs to specific federal laboratory locations were unavailable in many cases, our analysis of available NIST data suggests that cooperative research agreements are more prevalent regionally than are licenses, which tend to be more geographically dispersed. NIST CRADA partners are roughly 3 times more likely to be located within a 500-mile radius of NIST's Gaithersburg, Maryland, location than are NIST licensees.
- NIH and NIST tend to have a more skewed size distribution of licensees than EPA, but at the median

[38] The information used came from the Technology Partnerships Office's annual reports to the President and the Congress, data collected from the NETS Database, data from the FLC on federal laboratory locations, and additional data extracted from several public databases such as the Federal Register, and the open-source geocoding web platform provided by Texas A&M University GeoInnovation Center.

licensees across agencies are similar in median company size, as measured by sales and employment.

- The manufacturing sector and the professional scientific, and technical services sector are the two dominant sectors of the economy in which companies classified as such are engaged in licensing technologies from federal agencies and partnering with federal agencies on CRADAs.
- Based on EPA, NIH, and NIST licensing data, the evidence suggests that licensed technologies from a federal agency may have a positive effect on the sales of the private-sector company licensees, but the percentage changes cannot be readily attributed to the licenses, although the correlation exists.
- The sales effect of a licensed technology from a federal agency, if there is one, does not seem to vary systematically across companies of varying sizes.
- Descriptive data show that federal agencies have a higher propensity to engage in cooperative R&D with smaller-sized companies than larger-sized companies as mandated.
- Case studies describe the nonlinear nature of interactions between the private sector and laboratories and the factors key to successful transfer.

Many of these observations have not been frequently documented. Given the potential insight provided by this study, several patterns of technology transfer remain to be studied, including the following:

- In-depth research is needed to answer the question of the economic impact of federal licenses, if any, on private-sector sales.
- The role of federal agency R&D investments throughout the technology transfer process should be examined in greater detail. If the technology transfer process currently entails scientific discovery, inventions, invention disclosures, patent applications, patents issued, and licensing, then the follow-on elements of the process to be examined should include an understanding of role R&D spending plays in this process. Where in this discovery-to-licensing process is the greatest potential economic impact for the marginal federal R&D dollar invested?
- If scientific discovery-to-patents issued process describes a supply of technical knowledge or even a new

technology made available to the private and public sectors, then observed licensing activity may describe or be an indicator of a market clearing given the demand for technical knowledge and new technology from the private and public sectors. This raises the question: How do private- and public-sector potential licensees become aware of potentially relevant technical knowledge or a new technology available from federal agencies? In addition, how does this market for technical knowledge or new technology work in practice?

- A CRADA may potentially be seen as evidence of complementary supply and demand for technical expertise from both federal lab and private entity CRADA partners to be shared between them. How do private- and public-sector potential CRADA partners learn about a federal laboratory's relevant technical expertise? In addition, through what channels (e.g., R&D channels) do federal laboratories develop technical knowledge that is relevant to private- and public-sector CRADA partners?
- From existing federal agency technology transfer metrics, as reported by the Technology Partnerships Office, we have attempted to describe the extent to which private- and public-sector organizations license technical knowledge and new technology from federal laboratories and the extent to which private- and public-sector organizations partner with federal laboratories through CRADAs. In Chapter 8, we explored, to the extent to which the data allowed, the possible correlation between company sales and licensing activities. Information on the dynamics of how companies may benefit over time from having licensed technical knowledge or a new technology from an agency's laboratory or from having engaged in a CRADA is still unknown. Where these activities have been observed, what are, qualitatively and quantitatively, the realized benefits, if any, to a company from licensing federal technical knowledge or a new federal technology from an agency's laboratory or from participating in a CRADA? How do those realized benefits, if any, compare to the benefits that would have been realized (through the counterfactual methods) had the company pursued other methods to obtain the same level of technical expertise?

It is important to note that in studying patterns of technology transfer where CRADAs and licenses are employed, it provides a narrow view of technology transfer. Other mechanisms of technology transfer that can be further studied for impact

include publications, the students visiting a federal laboratory for postdoctoral training and their subsequent positions, student interactions with federal laboratory staff, adoption of documentary standards by the private sector, and laboratory personnel's interactions with SDOs to name a few. It is important to note that any impacts of technology transfer occur outside of the laboratory and in the marketplace or the public domain. The most accurate economic impact studies are those that, like the case studies presented, examine and follow one federal technology from the lab to the marketplace.

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Appendix A: Historical Overview of Technology Transfer Policies Toward U.S. Federal Laboratories from 1979 to the Present

As part of President Carter's Domestic Policy Review in 1979, he emphasized the importance of the transfer of technical knowledge (1979, unnumbered pages):[39]

> Often, the information that underlies a technological advance is not known to companies capable of commercially developing that advance. I am therefore taking several actions to ease and encourage the flow of technical knowledge and information. These actions include establishing the Center for the Utilization of Federal Technology at the National Technical Information Service to improve the transfer of knowledge from Federal

[39] See President Carter's Industrial Innovation Initiatives Message to the Congress on Administration Actions and Proposals (October 31, 1979): http://www.presidency.ucsb.edu/ws/index.php?pid=31628. This message to Congress was in response to the productivity slowdown throughout the U.S. economy that began in the early 1970s.

> laboratories; and, through the State and Commerce Departments, increasing the availability of technical information developed in foreign countries.

In October 1980, Congress passed the Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96-480. This Act of 1980 states that Congress finds and declares that

> Technology and industrial innovation are central to the economic, environmental, and social well-being of citizens of the United States. Technology and industrial innovation offer an improved standard of living, increased public and private sector productivity, creation of new industries and employment opportunities, improved public services and enhanced competitiveness of United States products in world markets. Many new discoveries and advances in science occur in universities and Federal laboratories, while the application of this new knowledge to commercial and useful public purposes depends largely upon actions by business and labor. Cooperation among academia, Federal laboratories, labor, and industry, in such forms as technology transfer, personnel exchange, joint research projects, and others, should be renewed, expanded, and strengthened. … No comprehensive national policy exists to enhance technological innovation for commercial and public purposes. There is a need for such a policy, including a strong national policy supporting domestic technology transfer and utilization of the science and technology resources of the Federal Government. It is in the national interest to promote the adaptation of technological innovations to State and local government uses. Technological innovations can improve services, reduce their costs, and increase productivity in State and local governments. The Federal laboratories and other performers of Federally funded research and development frequently provide scientific and technological developments of potential use to State and local governments and private industry. These developments should be made accessible to those governments and industry. There is a need to

> provide means of access and to give adequate personnel and funding support to these means.

Thus, as stated, the purpose of the 1980 Act is:

> … to improve the economic, environmental, and social well-being of the United States by … promoting technology development through the establishment of centers for industrial technology … [and to encourage] the exchange of scientific and technical personnel among academia, industry, and Federal laboratories.

And the 1980 Act makes clear that it is the responsibility of each federal laboratory to establish an office as well as mechanisms to transfer its technology to those organizations that will benefit:

> It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal Government shall strive where appropriate to transfer Federally owned or originated technology to State and local governments and to the private sector. … Each Federal laboratory shall establish an Office of Research and Technology Applications. Laboratories having existing organizational structures which perform the functions of this section may elect to combine the Office of Research and Technology Applications within the existing organization.

Regarding the functioning of these offices:

> It shall be the function of each Office of Research and Technology Applications to prepare an application assessment of each research and development project in which that laboratory is engaged which has potential for successful application in State or local government or in private industry [and] to provide and disseminate information on Federally owned or originated products, processes, and services having potential application to State and local governments and to private industry.

To enhance the technology transfer mission of federal laboratories, Congress amended the Stevenson-Wydler Act of 1980 in October 1986 with the passage of the FTTA of 1986, Public Law 99-502. The 1986 Act states:

> Each Federal agency may permit the director of any of its Government-operated Federal laboratories to enter into cooperative research and development agreements [CRADAs] on behalf of such agency with other Federal agencies; units of State or local government; industrial organizations (including corporations, schools and partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and to negotiate licensing agreements … for Government-owned inventions made at the laboratory and other inventions of Federal employees that may be voluntarily assigned to the Government.

The 1986 Act also established the Federal Laboratory Consortium for Technology Transfer and the NBS, which later NIST) as the host agency.[40] The FLC would:

> … develop and (with the consent of the Federal laboratory concerned) administer techniques, training courses, and materials concerning technology transfer to increase the awareness of

[40] The FLC, while formalized through the Federal Technology Transfer Act of 1986, can be traced to the formation of the Department of Defense Technology Transfer Consortium. Eleven Department of Defense laboratories were involved when the FLC was formed in 1970 (Metcalf, 1994). The FLC dates its organization to 1974 https://www.federallabs.org/History The spirit of the idea behind the DoD Federal Laboratory Consortium was highlighted in President Nixon's address to Congress on March 16, 1972 (quoted from Metcalf, 1994, p. 15): "The ability of the American people to harness science in the service of man has always been an important element in our national progress. But the accomplishments of the past are not something we can rest on. They are something we must build on. I am, therefore, calling today for a strong new effort to marshal science and technology in the work of strengthening our economy and improving the quality of the American way of life. I am outlining ways in which the Federal Government can work as a more effective partner in the great task." See also www.presidency.ucsb.edu/ws/?pid=3773.

> Federal laboratory employees regarding the commercial potential of laboratory technology and innovations; furnish advice and assistance requested by Federal agencies and laboratories for use in their technology transfer programs (including the planning of seminars for small business and other industry); [and] provide a clearinghouse for requests, received at the laboratory level, for technical assistance from States and units of local governments, businesses, industrial development organizations, not-for-profit organizations including universities, Federal agencies and laboratories, and other persons.

As an additional incentive for federal laboratory scientists to be proactive in the identification and transfer of their technologies, the 1986 Act stipulated that

> … any royalties or other income received by a Federal agency from the licensing or assignment of inventions under agreements entered into … shall be retained by the agency whose laboratory produced the invention and shall be disposed of as follows: The head of the agency or his designee shall pay at least 15 percent of the royalties or other income the agency receives on account of any invention to the inventor (or co-inventors) if the inventor (or each such co-inventor) was an employee of the agency at the time the invention was made.

Thus, the Stevenson-Wydler Technology Innovation Act of 1980 made explicit the technology transfer responsibilities of federal laboratories. To enhance the ability of the laboratories to transfer their technologies to state and local governments and private industry, the FTTA of 1986 also facilitated technology transfer by permitting the laboratories to enter into CRADAs with public and private organizations.

The Technology Transfer Act of 1986 made clear that government-owned, government-operated laboratories (GOGOs) could enter into CRADAs, but the Act was not specific about government-owned, contractor-operated laboratories

(GOCOs).[41] The National Competitiveness Technology Act of 1989, Public Law 101-189 (Section 3131), amended the Stevenson-Wydler Act of 1980 to authorize GOCOs to enter into CRADAs:[42]

> The purposes of this part [of the Act] are to—
>
> (1) enhance United States national security by promoting technology transfer between Government-owned, contractor- operated laboratories and the private sector in the United States; and
> (2) enhance collaboration between universities, the private sector, and Government-owned, contractor-operated laboratories in order to foster the development of technologies in areas of significant economic potential.

A CRADA, according to the FTTA of 1986, Public Law 99-502, is

> … any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory …

CRADAs, as a mechanism for technology transfer, are advantageous to both parties.[43] A definition of CRADAs is given in the Federal Laboratory Consortium for Technology Transfer's

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[41] "Federal labs are typically managed under two general models: the GOGO model and the government-owned, contractor-operated (GOCO) model. GOGO laboratories are usually owned or leased by the federal government and staffed by Federal employees who are supported by non-Federal contract employees. GOCO laboratories are institutions where the facilities and equipment are owned by the Federal Government, but the staff is employed by a private or public contractor that operates the laboratory under a contract with the Federal Government" (FLC, 2013). See also footnote 1 in Chapter 1 above.

[42] See also Kerrigan and Brasco (2002).

[43] See Chen et al. (2017) for a systematic analysis of CRADA activity at NIST over time.

Technology Transfer Desk Reference: A Comprehensive Guide to Technology Transfer (2013):[44]

> [CRADAs] … provide Federal laboratories with an extremely flexible vehicle to facilitate the transfer of commercially useful technologies from Federal laboratories to the nonfederal sector. … An intimate working relationship between Federal and commercial researchers will allow the Federal side to understand commercial needs and allow ideas from the commercial sector to flow into Federal laboratories. (pp. 33–36)

More formally (FLC, 2013):

> A CRADA provides both parties with a number of benefits, including:
>
> - A means to leverage research budgets and optimize resources
> - A means for sharing technical expertise, concepts, and information
> - Protection from disclosure by the federal government of any proprietary information brought to the CRADA by the partner
> - Ability for federal and nonfederal scientists and engineers to work together
> - Access for the nonfederal partner to expertise in a wide range of disciplines within the federal laboratory system
> - Agreement by the partners to share IP that results from the effort or agreement to the

[44] Title 15, Chapter 63, § 3710a of the U.S. Code gives agencies authority to enter into CRADA agreements; "Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement or, if permitted by the agency, in an agency-approved annual strategic plan, the director of any of its Government-owned, contractor-operated laboratories—(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency) (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title15/pdf/USCODE-2011-title15-chap63-sec3710a.pdf).

retention by one of the partners of an exclusive license to patentable research

- Protection of information resulting from the CRADA from disclosure under Freedom of Information Act requests for up to five years. (pp. 33-36).

CRADAs offer many additional benefits to the laboratories, the laboratory scientist, and the private-sector partner (FLC, 2013).

- For the laboratory, the CRADA:
  - Allows a flexible mechanism for transferring the results of federally funded R&D to the private sector.
  - Allows private-sector parties to provide funds as well as other resources to assist with the commercialization of technology.
- For the laboratory scientist or engineer, the CRADA:
  - Affords an opportunity for federal personnel to provide expertise to private-sector parties in the commercialization of their work.
  - Allows the inventing scientists or engineers to receive a percentage of the royalties generated as a result of commercialization of any subject invention(s).
- For private-sector parties, the CRADA:
  - Allows nonfederal partners an opportunity to obtain rights to commercialize the results of government or joint R&D.
  - Provides for effective leveraging of resources through a team effort.
  - Provides access to federal expertise.

In 1990, President George H.W. Bush issued what might be regarded as the first formal statement of U.S. technology policy. Therein, he did address the importance of transferring R&D results from federal laboratories to the private sector. Specifically, in *U.S. Technology Policy* (Executive Office of the President, 1990):

> A nation's technology policy is based on broad principles that govern the allocation of technological resources … The goal of U.S. technology policy is to make the best use of technology in achieving the national goals of improved quality of life for

> Americans, contained economic growth, and national security … While the government plays a critical role in establishing an economic environment to encourage innovation, the private sector has the principal role in identifying and utilizing technologies for commercial products and processes … Government policies can help establish a favorable environment for private industry [by taking steps to]:
>
> - Improve the transfer of federal laboratories' R&D results to the private sector. Where appropriate, these laboratories should give greater consideration to potential commercial applications in the planning and conduct of R&D, and these efforts should be guided by input from potential users. To achieve this goal, there much be a closer working relationship among these laboratories, industry, and universities. Defense-related laboratories can make major contributions which still providing adequate safeguards for classified information.
> - Promote increased industry-Federal laboratory-university collaborations, including personnel exchanges, to help convert Federally-supported R&D into new technologies that the private sector can then turn into commercial products and processes.
> - Promote and encourage access by U.S. industry to Federal laboratories within the guidelines established by the FTTA of 1986 (P.L. 99-502), other existing legislation, and Executive Order 12591.
> - Expedite the diffusion of the results of Federally-conducted R&D to industry, including licensing of inventions and removal of barriers to commercialization of Federally developed computer software.
> - Encourage direct laboratory-industry interaction within broad, flexible Federal guideline, since effective technology transfer occurs at the operational level. (pp. 2-6)

Federal laboratories have traditionally transferred their technology in the form of patents, licenses to laboratory-

developed technologies, and CRADAs.[45] Specific emphasis on these measures and other measures of technology transfer gained attention in response to the October 2011 Presidential Memorandum—Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses. And, in November 2012, the IAWGTT prepared a response to the President's memorandum in which agencies acknowledged the need for an in-depth study of their technology transfer practices.

To give context to the IAWGTT's response, the origin of the Interagency Workgroup on Technology Transfer traces to President Reagan's April 10, 1987, Executive Order 12591:

> (a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy[46] shall convene an interagency task force, comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal laboratories.
>
> (b) Specifically, the report shall include:
>
> (1) a listing of current technology transfer programs and an assessment of the effectiveness of these programs;
>
> (2) identification of new or creative approaches to technology transfer that might serve as model programs for Federal laboratories;
>
> (3) criteria to assess the effectiveness and impact on the Nation's economy of planned or future technology transfer efforts; and

[45] Academics have traditionally studied patenting activity in federal laboratories, perhaps because such data were more readily available from third-party sources than licensing or CRADA data. For one example, see Link et al. (2011) for a longitudinal study of NIST's and Sandia National Laboratories' patent applications from 1970 through 2009. See Chapter 4 and the literature reviews therein.

[46] The Office of Science and Technology Policy (OSTP), created in 1976, is a department within the Executive Office of the President. See Hart (2014) for a historical overview of the OSTP.

> (4) a compilation and assessment of the Technology Share Program established in Section 2 and, where appropriate, related cooperative research and development venture programs.

Executive Order 12591 applied across federal agencies. Since 1987, the Office of Technology Policy within the Technology Administration of the Department of Commerce submitted to Congress biannual reports as required by the FTTA of 1986:

> Two years after the date of the enactment of this subsection and every two years thereafter, the Secretary shall submit a summary report to the President and the Congress on the use by the agencies and the Secretary of the authorities specified in this Act.

Currently, these reports are prepared and submitted through the Technology Partnerships Office at NIST. The source for the Technology Partnerships Office reports is each agency's report, all of which are now prepared annually. Under the Technology Transfer Commercialization Act of 2000, Public Law 106-404:

> Each Federal agency … shall report annually to the Office of Management and Budget … on the activities performed by that agency and its Federal laboratories … The report shall include … an explanation of the agency's technology transfer program for the preceding fiscal year and the agency's plans for conducting its technology transfer function … [I]nformation on technology transfer activities for the preceding fiscal year [shall include] (i) the number of patent applications filed; (ii) the number of patents received; (iii) the number of fully-executed licenses which received royalty income in the preceding fiscal year … (iv) the total earned royalty income … [and] (vii) any other parameters or discussion that the agency deems relevant or unique to its practice of technology transfer.

We refer to the Technology Partnerships Office's annual summary reports in Chapter 4. We used the agency-by-agency data therein to illustrate trends in selected technology transfer activities.

Appendix B: Academic Literature on Technology Transfer from U.S. Federal Agencies and Laboratories

Author(s)	Research Question(s)	Relevant Finding(s)	Data Description
Ham and Mowery (1995)	Is the CRADA mechanism effective in improving industry-government cooperative R&D at DOE? What limitations do CRADAs have?	▪ The "treasure chest" model of DOE labs—labs having a large amount of on-the-shelf technology ready for industry application—is somewhat unrealistic. A more realistic conceptual framework for understanding the utility of CRADAs includes three broad types of projects: (1) transfer, (2) co-development, and (3) R&D services. ▪ Limitations of CRADAs include a slow approval process, limited support from government researchers after prototype development, and lack of senior researcher engagement.	Case studies including 30 on-site interviews with engineers, scientists, and managers from DOE's Lawrence Livermore National Laboratory and five partner companies.
Ham and Mowery (1998)	How do CRADAs operate in different settings? How to improve and evaluate CRADAs?	▪ Characteristics fundamental to CRADA success include the degree of flexibility of the project, quality of relationships among partners, and the government researcher's knowledge of the outside party's needs and objectives. Unsurprisingly, companies also need to possess the capacity to absorb and apply the results of the collaboration. ▪ CRADAs closely related to the laboratory's historic mission are more likely to be successful than projects that are not closely related to their mission.	Case studies including 30 on-site interviews with engineers, scientists, and managers from DOE's Lawrence Livermore National Laboratory and five partner companies. (same data as above)
Jaffe, Fogarty, and Banks (1998)	Are patent citations useful in measuring the impact of NASA and other federal labs on commercial innovation?	▪ Trends are consistent with increased emphasis in commercializing federal laboratory technology since the 1980s. ▪ Patent citations are a valid but noisy measure of technology spillovers; two-thirds of cites to patents of NASA-Lewis' Electro-Physics Branch were evaluated as involving spillovers. Furthermore, patent citations cannot capture all spillovers. ▪ Evidence is consistent with the consensus from the literature that geographic proximity between companies and labs fosters spillovers. Yet, patent citations underestimate geographic spillovers.	Patents granted by the U.S. patent office between 1963 and 1994 were grouped into three categories: (1) 3,782 patents assigned to NASA, (2) 37,939 other federal government patents, and (3) random sample of 13,997 of all patents assigned to inventors residing in the U.S.

Author(s)	Research Question(s)	Relevant Finding(s)	Data Description
Jaffe and Lerner (2001)	Did the statutory changes of the 1980s have a significant impact on technology transfer from the national laboratories?	▪ Patenting increased dramatically after the policy changes of the 1980s without a substantial decline in patent quality. Federal labs reached parity with universities in terms of patents per R&D dollar. ▪ There is also a positive impact on patenting if a university is the lab manager. ▪ CRADAs increase benefits to industry as measured by patenting and also increase industry-funded R&D.	General information about 23 Federally Funded Research and Development Centers owned by DOE between 1977 and 1999 ranging from history, regional characteristics, lab budget, number of new CRADAs executed, new licenses granted, and license revenue. 6,479 U.S. patents awarded from 1978 to 1996 that emerged from DOE laboratories.
Adams, Chiang, and Jensen (2003)	How does federal laboratory R&D affect private-sector industrial research?	▪ The impact of federal labs on industrial patenting and R&D varies with the interaction mechanism. There is suggestive evidence that CRADAs may be more beneficial to companies than other interactions with federal labs, which suggests that intensive interaction fosters greater impact as measured by patenting. ▪ Government contractor interactions have little impact on industrial patents and R&D.	A 1996–1997 survey of private industrial laboratories with data on R&D, patents, and interactions with other R&D performers. Survey data include 220 industrial research laboratories owned by 115 companies. A 1998 survey on intramural or on-site R&D in federal labs.
Mowery (2003)	Literature review: What is known about the characteristics of CRADAs, federal support for CRADAs, and their effectiveness?	▪ The author reviewed findings and limitations of the past literature on effectiveness of CRADAs. ▪ In general, more information is needed to examine the effectiveness of CRADAs. Calls for better information about agency expenditures used to support CRADAs, characteristics of partners involved, and reasons for terminating CRADAs.	Literature. CRADA information published by the National Science Foundation and Department of Commerce.
Link, Siegel, and Van Fleet (2011)	Is there evidence of the impact of the Stevenson-Wydler Act and/or the FTTA on patenting activity at U.S. national laboratories?	The Stevenson-Wydler Act did not stimulate an increase in patenting applications by scientists at Sandia National Laboratory (SNL) or NIST. However, the FTTA and the delegation of internal resources to support technology transfer did have positive effect on patenting activity at the two labs.	Patent applications and patent applications per $R&D (billions, $2009) from 1970 through 2009 at SNL and NIST.

Author(s)	Research Question(s)	Relevant Finding(s)	Data Description
Stevens et al. (2011)	To what degree has public-sector research contributed to the applied-research phase of drug discovery?	Research carried out by public-sector research institutions can be traced forward to 153 drugs, vaccines, or new indications that were approved by FDA. These drugs are expected to have a disproportionately large therapeutic effect as indicated by their treatment areas.	Author-assembled database of successful drug discovery and development projects that derive from public-sector research. Primary sources included FDA Orange Book, U.S. Patent and Trademark Office (USPTO) database, rDNA database of Recombinant Capital, and FDA databases on approvals.
Chatterjee and Rohrbaugh (2014)	To what degree has the NIH IRP's contributed to drug commercialization relative to extramural public-sector research institutions?	NIH's IRP's contributes disproportionately to drug commercialization relative to research budgets despite roughly similar shares of budget allocated to basic versus applied research.	Data from Stevens et al. (2011) plus internal NIH records.
Chan (2014)	What is the relationship between transferring federally funded inventions to the private sector and the subsequent rate of innovation spillovers?	Technology transfer has a large positive effect on the rate of spillovers with the following evidence: ▪ Licensing increases the annual citation rate to a national laboratory patent by 31–48%. ▪ Over 75% of subsequent innovation after a licensed patent occurs outside of the licensing company.	▪ Over 800 licensed patents since 2000 at the U.S. DOE National Laboratories (Brookhaven National Laboratory, SNL, Lawrence Berkeley National Laboratory, Pacific Northwest National Laboratory, and the National Energy Technology Laboratory).

Author(s)	Research Question(s)	Relevant Finding(s)	Data Description
Popp (2016a)	What is the time lag between energy R&D and successful research outcomes (publications)? Do large increases in research funding result in marginally lower quality projects?	▪ At least a decade is needed to realize the full effect of public R&D funding. Also, public R&D funding has a strong influence on new publications, while other demand characteristics are apparently less important. ▪ There is evidence of reduced publication quality (as measured by citations) as the number of publications increases, except for in the solar energy technology area. This is consistent with previous research that showed that large R&D funding increases in short time periods result in adjustment costs for public researcher institutions because of constraints such as the pool of scientific talent.	▪ Journal publications from 1991 to 2011 for four technology areas: biofuels, energy efficiency, solar energy, and wind. ▪ Agency data on government energy R&D spending.
Popp (2016b)	▪ Are scientific articles cited frequently by other articles also more likely to be cited by patents in clean energy? ▪ Which institutions produce the most valuable research in energy? Are there differences across technologies?	▪ Scientific articles cited frequently by other articles also receive more citations by patents, so the count of journal-to-journal citations could be a good indicator for the impact of an article on technology development. ▪ Government patents are cited the most frequently by researchers among all patents. Government research articles are also more likely to be cited by future patents. Universities play a larger part in solar and biofuel research than in wind research.	▪ Journal publications for three technologies—biofuels, solar energy, and wind energy—from the Thomson Reuters Web of Science Core Collection database. ▪ Patents related to biofuels, solar energy, and wind from the online database provided by Delphion.
Chen, Link, and Oliver (2018)	Did the FTTA have an impact on CRADA activity at NIST? Is CRADA activity at NIST a cyclical phenomenon? At what frequency do private-sector companies engage in CRADA activity with NIST?	There is suggestive evidence that the FTTA began to influence NIST's CRADA activity within 2 to 3 years of after its passage, and there is suggestive evidence that CRADA activity moves with the business cycle. Finally, there is suggestive evidence that most companies that were engaged in CRADA activity were engaged only once; it was only the larger companies that continued to engage over time in CRADAs with NIST.	Data on CRADA activity at NIST over the years 1978 through 2014.

Appendix C:
Policy Literature on Technology Transfer from U.S. Federal Agencies and Laboratories

Author(s)	Description	Relevant Finding(s)	Data Description
IDA (2011)	Large-scale descriptive summary study of federal laboratory technology transfer performance.	▪ The length of negotiation time and complexity of administration are rated as top barriers to forming CRADAs with federal labs by industrial collaborators. ▪ Describes other barriers to industry-lab interaction caused by CRADA regulation such as advanced payment, indemnification, and U.S. competitiveness requirement.	Discussions with technology transfer personnel from 13 agencies and 26 laboratories.
IDA (2013a)	Identifies what the National Science and Technology Council can do to help expedite the transition of federal aeronautics R&D products to civil and national security applications.	▪ Barriers to CRADA collaboration and technology transfer include the length of time, complexity of collaboration rules, a tendency of laboratory TTOs to focus on agreements with larger companies, geographic distance, uncertainty of research outcomes, and a lack of funds. ▪ Recommendations include bundling CRADAs for several related projects to reduce administrative time, standardizing administrative procedures for CRADAs, and clarifying IP rights early.	Literature. Request for comments via the *Federal Register*. Interviews with 30 leaders from over 20 aerospace companies, two industry roundtables, and inputs from 10 aeronautics-related federal laboratories.
IDA (2013b)	What are the exemplar practices of DoD laboratories?	▪ The report selected 24 exemplar practices categorized into seven categories ranging from organizational structure to use of mechanisms to outreach and marketing. ▪ Best practices include tailoring the CRADA agreement to fit specific purposes, tracking the overall process of and status of individual CRADAs and licenses, and creating a handbook for partners.	42 interviews with DoD laboratory Office of Research and Technology Applications staff, DoD legal offices, and other stakeholders.

Author(s)	Description	Relevant Finding(s)	Data Description
Bozeman (2013)	Addresses conceptual issues in analysis of technology transfer, including definitions of technology transfer and technology. Develops a model to analyze stakeholders' role in technology transfer activity and effectiveness of technology transfer activity.	Based on previous literature, refined the following criteria for technology transfer effectiveness: ▪ Out-the-door technology transfer mechanisms. ▪ Assessment of market impact and economic development of the transferred technology, including its impact on regional and national economic growth. ▪ Political reward the technology transfer generates. ▪ Scientific and technical human capital the technology transfer builds.	Primarily published research study available in Web of Science, as well as a few unpublished, uncited papers from 2001–2013.
ITIF (2013)	How can National Laboratories better meet their mission and produce useful technologies that benefit the American economy?	Argues that DOE laboratories suffer from inefficiencies such as duplicative regulations, micromanagement, and biases against technology transfer to the private sector. Recommends greater accountability for contractors operating labs, better alignment (between funding, management, and innovation goals), and incentives and flexibility to push more technology to market.	NA
Andes et al. (2014)	How can DOE laboratories contribute to synergistic regional clusters that drive technology development?	Argues that labs should enhance their connections with the regions in which they are located to be a regional economic development asset. To enhance connection to the region, they argue that labs should open up to SMEs and increase the relevance of their work to regions. The report also emphasized the need for greater flexibility in oversight and funding.	Literature

Author(s)	Description	Relevant Finding(s)	Data Description
DoD Licensing Study (TechLink, 2016)	Evaluates the extent to which DoD license agreements active during the 2000–2014 period contributed to new economic activity and job creation in the United States.	Finds that DoD license agreements generated $20 billion in total sales of new products and services, $3.4 billion in sales of new products to the U.S. military, $49 billion in total economic output nationwide, $1.6 billion in new tax revenues, and nearly 183,000 full-time jobs created or retained.	▪ Surveyed all 602 companies with DoD license agreements active during the 2000–2014 period. ▪ Used an input-output model to estimate total economic output.
Argonne National Laboratory (2016)	Summary of national laboratory best practices for industry partnerships, technology transfer, and commercialization.	▪ Major barriers are over-centralization, lack of experimentation, mixed messages about importance of technology transfer, aversion to risk, and lack of commercialization experience/capacity for research staff. ▪ The report also discusses ways to enhance partnerships by leveraging existing programs and federal resources such as the SBIR program, the STTR program, the NNMI, and the MEP.	Literature
Federal Laboratory Consortium (2013) Desk Reference	A primer and reference document for federal TTO staff.	Comprehensive guide for practitioners that addresses issues in CRADAs and other mechanisms, IP, and marketing outreach.	Predecessor FLC desk reference guides with changes to federal technology transfer as a result of the Leahy-Smith America Invents Act of 2011.
Federal Laboratory Consortium (2017) T2 Playbook	Shares the efforts and authorities that have been used in the best practices at federal labs across the country.	There are 15 "plays" in the report; each play includes a concept of best practices, agency example, and guidance on how to implement the best practice. To name a few of the best practices: ▪ Understand the needs, goals, and tasks of all the players. ▪ Agencies can encourage entrepreneurship internally by using reinstatement rights. ▪ Ensure the effectiveness of the organization structure, staff, and resources, etc.	Experiences from federal labs in the U.S.

Appendix D: Description of the NETS Database

The NETS Database was constructed by Walls & Associates using information from Dun & Bradstreet. The starting point for the NETS Database was 25 annual snapshots (taken every January) of the full Duns Marketing Information file that followed over 58.8 million companies over the years 1990 through 2014. These snapshots were taken to determine which companies were active in January of each year in question. Other archival files (e.g., the Credit Rating file) were used to provide annual raw company data that allowed Walls & Associates to create time-series information (over 350 fields) in numerous categories.

In the NETS Database, companies are classified in three categories:

- **Headquarters:** A headquarters is a business location that has branches or divisions reporting to it and is legally responsible for those branches or divisions. If the headquarters is more than 50% owned by another corporation, it is also a subsidiary. If it owns more than 50% of another corporation, then it is also a parent.
- **Branch:** A branch is a secondary location of a business. It has no legal responsibility for its debts, even though bills may be paid from the branch location. It has the same legal business name as its headquarters, although branches frequently operate under a different trade style. A branch may be located at the same address as the headquarters if it has a unique industry and unique

operations. In such cases, the branch appears to be a second location alongside the headquarters record.

- **Stand-alone:** An organization is not a member of a legal family tree. The organization has no parent company, no subsidiaries, or no branch/division locations.

And we calculated a fourth category:

- **Aggregated:** This category was created for this study. It refers to entities that are combinations of companies of various types (headquarters, branches, and stand-alone) that are present in the NETS Database at the same physical location but have different time series for sales and employment. In these cases, we could not distinguish which company licensed the technology from the federal government, so we aggregated them into a single entity for analysis. For these entities, we added together company metrics (e.g., sales) and assigned an industry code (North American Industry Classification code) for each year based on the company with the largest sales each year.

Appendix E: Template for Case Studies of Technology Transfer and Commercialization

E.1 PURPOSE OF THIS DOCUMENT

The case study approach documented in this appendix may be used as a template to chart the progress and success of a particular occurrence of a federal laboratory's technology transfer to the private sector, and in the private sector's follow-on efforts to develop and commercialize the transferred technology. This template is intended to be a useful starting point for future case studies of technology transfer, but it would need to be tailored according to the unique objectives of future case studies.

The case studies in this report provide examples of the ways that different federal labs have achieved technology transfer success in different settings and scenarios and act as potential guideposts based on the best practices of the federal lab highlighted in the particular case study. The way that these case studies have been structured provides a model that an evaluator may follow to design their technology transfer study to investigate and report important milestones and contextual factors along the development-commercialization-adoption path and the contribution of the program/effort to observed progress and success.

This protocol aims to be useful for federal organizations that are either conducting or contracting out technology transfer case studies to document the success of their technology transfer efforts. We believe that the protocol described was used successfully in this NIST-sponsored study, as illustrated by the nine case studies included herein, completed for multiple federal agencies and about very different technologies and transfer recipients. It was important that our multiple case study principal investigators followed a common protocol for cost-effectiveness and quality assurance and to preserve reporting consistency and analysis across the case studies. For us, the case studies as conducted using the same evaluation protocol allow for easier comparison or synthesis across studies, but just as no two snowflakes are alike, no two case studies describing successful technology transfer are alike.

E.2 PURPOSE AND SCOPE OF THESE CASE STUDIES

Like any evaluation, these case studies[47] begin by defining the purpose of the particular case study. The case studies were conducted using this protocol to investigate and qualitatively describe outcomes (which some refer to as impacts) of the subject technology transfer from the federal laboratory. This includes the federal laboratory's technology development and transfer, the TTO's support, the transfer mechanisms used, and the context in which these occurred. The case studies attempt to document the observed outcomes and tell the story of how federal agency and laboratory support, as well as other factors, contributed to the observed outcomes.

We anticipated a broad range of technologies that could be transferred from federal agencies and federal laboratories and structured the case study protocol to include broad but consistent definitions of terminology and a consistent logic and line of inquiry, despite heterogeneity in the underlying technologies, agencies, and mechanisms.[48] Many scenarios are

[47] For general information, see Harrison, Helena et al. Case Study Research: Foundations and Methodological Orientations. Forum Qualitative Sozialforschung / Forum: Qualitative Social Research, [S.l.], v. 18, n. 1, Jan. 2017. ISSN 1438-5627. Available at: <http://www.qualitative-research.net/index.php/fqs/article/view/2655/4079>. Date accessed: 09 May 2017.

[48] Case studies conducted with the same evaluation protocol allow for easier comparison and synthesis across studies.

possible in federal efforts to develop and transfer technologies to the private sector for commercialization to achieve societal impact. We structured each case study so that important milestones and contextual factors along the development-commercialization-adoption path are investigated and reported. Each case study also covers the contribution of federal agency activities to observed progress and success of the technology transferred. Federal agency activities may include programs, approaches, R&D efforts, and technology transfer activities.

We attempted to use consistent terminology; it is important to ensure quality implementation of the described protocol. Common terminology is as follows.

Technology may include hardware or software; a service such as calibration or certification; a technical standard, measurement tool, or dataset; a process, practice, or business model; or knowledge or know-how. In addition to a stand-alone item, technology may also be a component that is embedded in a new or existing product, process, practice, or policy.

Commercialization is defined here as "at least one technology sold (or used) in the market." There are different ways of categorizing stages in the development of a new technology, including the stages of the Stage-Gate process (Cooper, 2008) (preliminary and detailed investigation, development, validation, and commercial launch) or the sequence of clinical trials for a new biomedical innovation.

Success may be represented in the form of improved capabilities, improved knowledge, and new hypotheses on which future innovation can build, where innovation is defined as introduction to the market of something new or improved that adds value (Organisation for Economic Co-operation and Development and Eurostat, 2005).

Innovation is interpreted to mean market or nonmarket adoption of a technology.

E.3 GUIDANCE ON SELECTION OF CASE STUDIES

Although there may be implicit criticism when the choice of case studies is limited to cases of success, that is, cases where there has been progress toward commercialization or actual commercial launch, there are practical reasons for choosing

successful cases. Because of the extreme variation in technologies, markets, and contexts in the possible cases to choose from, even if technology transfer failures were included, the broader study's findings and observations do not include generalized conclusions about the overall population of federal technology transfer efforts. Case studies in which a federal technology has been transferred and commercialized, generally qualitatively describe and usually quantify the social and economic benefits that the transferred technology delivers; part of the story includes the research and financial contributions of the federal laboratory that transferred the technology. The stories also educate readers on the steps and challenges involved in R&D and innovation and provide federal technology managers with ideas about what may be better methods.

The preference may be to select cases where the federally funded laboratory or university-developed technologies have had an impact on some aspect of the economy or society, if possible, in sync with the mission of that federal laboratory. Possible cases may be identified through interviews with federal managers with a view of past work.

Preferably, the mechanism for federal transfer to the private (or sometimes public) sector is clear, but the transfer mechanism can differ across the case studies. Federal transfer may occur through licenses, CRADAs, use of laboratory services or materials, entrepreneurial spin-offs/start-ups by federal scientists or external organizations licensing federal technology, or other mechanisms. It may make sense to choose a certain case for analysis because the particular transfer mechanism plays a large role in technology transfer at the organization. In this context, the case study may add richness to reported quantitative data on that federal transfer mechanism.

We used two selection criteria considered important to complete high-quality case studies with no undue expense. Ideally, 1) information for the proposed case study is readily available, and there is a good trail of historical data on the transferred technology's development and commercialization and the federal laboratory's contribution to the eventual private or public-sector use. The other important criterion is 2) information about the transferred technology's "performance" (such as speed, efficiency), cost, and how the technology compares to what it replaces (next best alternative) is also

needed. We recommend not pursuing duplicate case studies where data are available because the federal technology transfer story has been studied and reported previously. Second, they recommend that the available data should include the names of individuals or organizations who were involved in the technology transfer, their roles and timing, and how they may be contacted, whether in the federal laboratory or the transferee's premises.

E.4 FRAMEWORK FOR THE CASE STUDIES

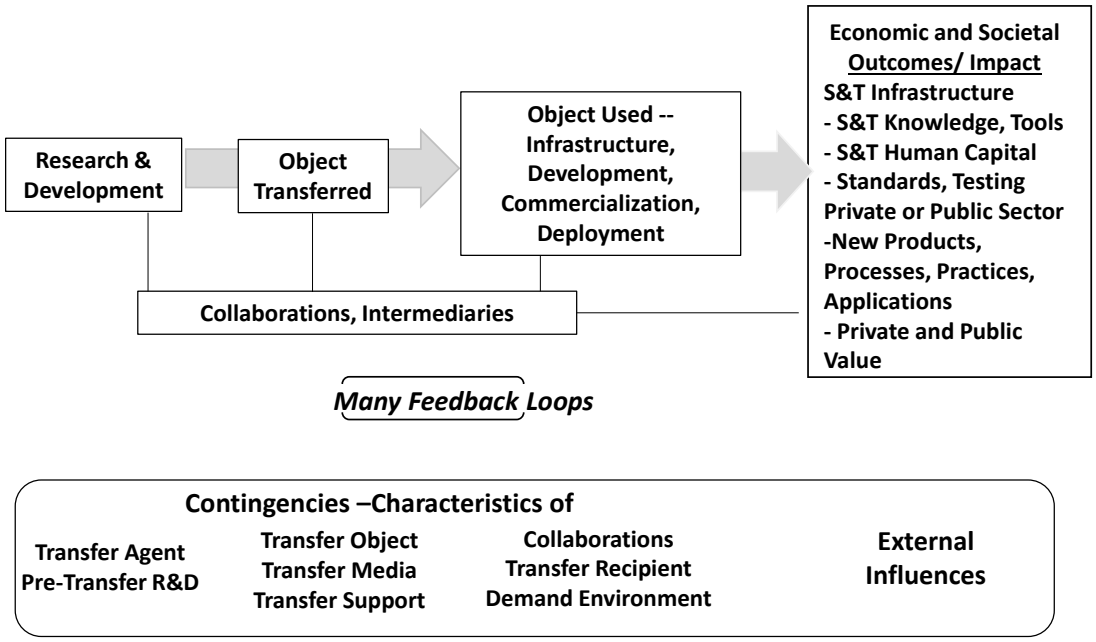
A Logical Framework Guided these Case Studies

Once the purpose of these case studies was defined, following good practice in evaluation, the next step was to develop a general logical framework to guide each case study. A logical framework includes a logic model or "theory of change" and the research questions that follow from that model. Data required to answer the research questions are then determined. Findings and observations are organized around the research questions, that is, organized along the pathway from inputs, activities, and outputs to technology transfer and from the sequence of observed outcomes and any benefits stemming from those outcomes.

The Logic Model Template

The logic model in Figure E-1 is a simple linear representation of what is generally understood to be a nonlinear process with many feedback loops, contingent on different characteristics of the transferred technology, market, actors, and context. However simplistic, it is a useful pedagogical device for researchers using this protocol to adopt for the case being studied. Hopefully using a logic model ensures a quality study, and if multiple studies are being conducted, using this generic logic model provides consistency in the approach to each case study and the reporting of multiple technology transfer efforts.

Figure E-1. Technology Transfer and Commercialization Logic Model with Contingencies



One point on terminology is important to note. The term *outcomes* in this logical framework is a sequence of short-, intermediate-, and long-term outcomes that result from reaction to and use of the outputs of activities associated with the transferred technology. *Impact* is defined several ways. Some use *impact* as only that part of observed outcomes that can be credited to the results the transferred technology produces. Often, *impact* is used interchangeably with outcomes, particularly with longer-term outcomes.

The logic model in Figure E-1 incorporates five basic elements plus contingencies that delineate possible internal and external influences on the elements of the model. The five elements are the following:

- R&D expenditures, planning, implementation, and results of that R&D from discovery to proof of application and technical disclosure within an R&D organization
- Transfer of an R&D-based object (e.g., technical knowledge and/or a prototype technology) and the process and mechanisms of transfer
- Receipt and use of that object by the recipient who adds resources to use the transferred object to further

specific technology development and commercialization or to add to the general technical infrastructure

- Collaborations and intermediaries involved before, during, or after the transfer
- Technical, social, and economic outcomes for both private and public benefits associated with using the commercialized version that stems from the transferred object

To summarize, R&D in federal laboratories may lead to an object that is transferable. After the federal transfer of the technology, the recipient company of the technology transferred adds resources (physical capital and human capital) to employ the object for use as a product, process, service, or practice and that object may have economic and/or social value. Collaborators or intermediary supporting organizations may be involved in one or more steps along the way.

Contingencies: Factors that Influence the Success of Federal Technology Transfer Efforts

Our generic logic model, developed in this NIST-funded study, was based in large part on the Bozeman (2013) published paper that proposes a logic model with contingencies, factors that differ and heavily influence the timing, parties involved, and size and type of outcome/impact of the technology transfer. We added three factors to Bozeman's five and expanded one. The additions are noted with an asterisk (*). The usefulness of these eight contingencies was established in the case study interviews completed for this NIST-funded study.

Note that contingencies have been developed for each element of the logic model; characteristics will vary depending on the federal laboratory involved and the specific R&D, the object transferred and the transfer mechanism, the transfer recipient and the demand environment, the federal agency's mission, and a broad notion of the pathways to possible economic and or social benefits. The contingencies that were considered in this study, and should be considered in developing a case study, for data collection, analysis, and reporting are as follows:

- **Transfer agent and *pretransfer R&D**: Transfer agents are the innovating institutions. The national federal laboratories (the subject of this report) vary widely and are characterized by such factors as technological niche, mission, sector, scientific and

technical human capital, resources, geographic location, organizational design, management style, and political constraints. The nature of the federal R&D leading up to the transfer varies in terms of the stage of development or presents incremental or radial change to the current state of the technology.

- **Transfer object**: Characteristics of the technology transferred vary in terms of type. It may be software or hardware, for example, or a vaccine. What are its characteristics in terms of value to potential users: comparative advantage over next best alternatives, compatibility, complexity, trialability, and observability.[49]
- ***Technology transfer support**: This category includes characteristics of federal agency and laboratory leadership, the allocation of resources for the technology transfer, and the capabilities and actions of the federal technology transfer staff.
- **Transfer media**: The way in which the federal technology is handed off to private or public entities varies. Typical for federal laboratories are cooperative research agreements, licensing, open-source software, material transfers, and occasionally business start-ups.
- **Technology recipient**: Characteristics of the entities that acquire the innovation vary in terms of resources and areas of expertise, capacity, geographic location, and size.
- ***Transfer collaborations and intermediaries**: The extent to which other entities are involved in the development, transfer, and commercialization varies, as do the characteristics of those partners, collaborators, or other entities.
- **Demand environment**: This category is the nature of the target market's demand for the federal innovation, such as the level of existing demand for a comparable technology. It may also include characteristics of the existing supply chain and any required supporting technology and infrastructure.
- ***External influences**: In addition to the other categories of contingencies, other factors outside of the federal laboratory's or its TTO's efforts or control can either drive or restrain successful transfer. For example, there may be unexpected technical breakthroughs by third parties, a competing technology may enter the

[49] E. Rogers, Diffusion of Innovation, 2005.

market first, federal regulations may support adoption, or cultural norms or an economic recession may slow adoption.

E.5 RESEARCH QUESTIONS, DATA COLLECTION, AND ANALYSIS

The objective of the case study analysis is to capture and describe successful technology transfer activities by identifying specific outcomes/impacts associated with the technology transferred from the federal laboratory. The case study protocol followed by us for these case studies, included in the broader study, involves the following seven broad research questions:

1. What is the technology to be transferred, and what does it do for whom when compared with the next best alternative it would replace?
2. What is the history of federal lab/agency involvement in the research and technology development of this technology?
3. Who else was involved in the R&D before, during, and after the federal transfer and what is known about their interactions?
4. What were the circumstances surrounding the federal transfer of the technology to the private (or public) sector?
5. What has happened since the transfer of the federal technology?
6. What benefits occurred as a result of commercialization/adoption of the transferred technology?
7. What did the federal technology development and transfer effort contribute to observed outcomes and how did contextual factors contribute to these observed outcomes?

Detailed questions within each of the seven broad questions used by us are provided here as fodder for future case studies of technology transfer. We found that interviews with knowledgeable federal personnel familiar with key aspects of the case study are key. Typically, we interviewed principal investigators, TTO staff, and companies or public-sector organizations that were recipients and follow-on investors in the technology. Because the role a federal lab, collaborating partner, or company transfer recipient plays influences

perspective, data on the role played and organization type are attached herein to the data collected. The other source of data may be from review of program documents, the extant literature, and relevant websites.

1. What is the "technology" and what does it do compared with the next best alternative?
    a. What is its function, who uses it, and for what purposes?
    b. How does it relate to the agency mission?
2. What is the history of federal lab/agency involvement in the R&D of this technology?
    a. When and how did the federal lab or agency first take up this technology (e.g., past project, stakeholder idea)?
    b. What resources did the lab and agency provide for this R&D effort?
    c. Who funded/did what portion of the R&D (at what stages of technology development) and when? It includes before, during, and after transfer.
    d. While the lab/agency was developing this technology, what improvements did they make and validate in the technology's performance and cost?
    e. At the time the lab/agency transferred the technology, how far along was the technology toward meeting the technology performance and cost goals for market entry? What was the technology transfer mechanism?
    f. If appropriate, what IP was produced (e.g., invention disclosure, patents, copyrights) by the federal lab prior to transfer?
    g. What, if anything, was done by the federal lab or TTO staff to develop a "business case" for this technology (identify markets, investor interest/funding, IP created, potential transfer agreements, market interest, attractiveness)?
    h. Was the lab/agency involved in demonstrating full-scale prototypes in realistic and/or operating settings? What was the result of this federal test/validation?
    i. What was the business case for the federal technology at the time of transfer?

j. What factors internal to the federal lab/agency enabled development and demonstration of the federal technology? This may include other enabling technologies, related past experience, etc.

3. Who else was involved in the R&D before and during transfer and what is known about their interactions with federal labs and outside parties?
   a. Who were the federal lab's R&D partners, when were they involved, and what private partner support was provided in terms of investment (funds, in kind)?
   b. Were any intermediaries such as small business assistance programs involved and, if so, what were their roles?
   c. What was the form, frequency, and continuity of interactions between the federal labs and outside parties?
4. What were the circumstances surrounding the transfer of the federal technology to the private (or public) sector?
   a. What was the mechanism of federal transfer (e.g., license, CRADA, start-up company, standard)?
   b. What was the involvement of the TTOs at the lab and agency levels?
   c. Who was the federal technology transferred to? What were the characteristics of that/those entities (e.g., organization type, size, any past experience with the lab/agency and with this or related technologies)?
5. What has happened since the transfer of the federal technology?
   a. What is the technology development and validation progress (stages, proximity to technology performance and cost goals).
   b. What is the business case progress (identified markets, investor interest/funding, IP created, transfer agreements, market interest, attractiveness)?
   c. Has the technology been commercialized, that is, at least one sold or otherwise adopted by a market? By whom? What market?
   d. Have there been post-launch technology refinements?
   e. What were the drivers and constraints to adoption on both supply (production/supply chain) and demand

(comparative advantage, compatibility, cultural norms) sides?

f. At what volume is the technology produced? What is the volume of sales over the relevant time frame if the technology is sold?

g. What technology did this technology replace (next best alternative)?

6. What benefits accrued as a result of the technology's commercialization/adoption?

   a. Who benefits from that commercialization and how?

   b. What kind of benefits/impacts are there? Economic, environmental, health, national security, other?

   c. What occurs because of the per-unit performance and cost of the new technology as compared to what it replaces (e.g., reduced energy use, emissions, cost and time to replace short-span bridges)?

   d. What benefits accrue to the producer of the technology and to the accompanying supply chain (e.g., revenue, skills, able to meet requirements or standards, advantage in new markets)?

   e. Have those personnel involved in the federal R&D and/or transfer of the technology made use of the technical or business knowledge accumulated or lessons learned about the process in later work?

   f. Have there been any unanticipated outcomes from the federal technology development, transfer, and commercialization, either positive or negative? Has it furthered follow-on technologies?

7. What did the federal technology development and transfer effort contribute to observed outcomes and how did contextual factors contribute to these observed outcomes?

   a. Did the federal laboratory and agency (1) accelerate how quickly the technology was developed and commercialized relative to what may have happened in the absence of the federal laboratory and agency? (2) Improve the quality of the technology above what others would have accomplished without the federal lab? (3) Help expand the technology into new markets?

   b. Overall, how much credit does the federal laboratory and agency deserve for the benefits/impacts that accrued from this transferred technology? Would it

have happened without them? Select one of the choices below.

i. It would not have happened without them.

ii. Much of the credit. The federal lab and agency were the main contributing factor, but there were other factors as well.

iii. About half of the credit. The federal lab and agency were a major contributing factor as were other factors.

iv. Only some of the credit. The federal lab and agency were a contributing factor, but other contributing factors played a greater role.

v. None of the credit (it would have happened without them in the same time frame).

c. Summarize who did what prior to and post-transfer, and over the development and market absorption time frame, and what was the influence of each entity as measured by funds in, timing, and degree of contributions.

d. What other plausible explanations (contributing factors) are there for the occurrence of the observed outcomes post-transfer?

e. What would have happened with this technology if the federal lab and agency had NOT been involved with it? Would it have been developed at all?[50]

Menu of Possible Indicators

One way to respond to the questions posed above is to provide indicators, qualitative as well as quantitative. To help guide data collection, We developed Table E-1, which provides a menu of possible indicators that may be collected related to these case studies of technology transfer and commercialization and their related benefits. The categories mirror Questions 1 through 6. Our underlying method is not to try to collect all these data but to be aware of what to look for depending on the specifics of the case study and on the evaluator's budget and the evaluation effort's time frame.

[50] Question 7e is best posed to a third-party technology or market expert.

Table E-1. Menu of Possible Indicators for the Evaluation Questions

Menu of Possible Indicators for the Evaluation Questions

Characteristics of the Technology and Target Market

- Technology name, sector (e.g., energy, security)
- Technology "functions"—aspects that give it comparative advantage (e.g., speed, durability, flexibility, size, efficiency)
- Who is expected to use it, for what purposes
- Expected benefits of use
- Expected time to market or date entered the market

Agency/Laboratory R&D and Demonstration History

- Lab/Agency inputs and resources; amount/source of funds for R&D
- Expenditures on research support activities, such as database development, research equipment, facilities, methods
- Depth, breadth of knowledge base and skill set of researchers and technologists, teams, TTO, organizations
- Lab R&D conducted on this technology
- Research project size, duration, stage (investigation, prototype development/scale, validation)
- New knowledge advances (publications, technical challenges overcome)
- New technology development advances (movement through stage gates or readiness levels)
- Milestones met, preferably milestones for reaching next technical readiness level
- Business case progress (e.g., interviewed potential customers, identified market and product advantage)
- Progress on goals for technology function/performance and cost, proximity to those goals
- IP created, ownership of it
  - Number of invention disclosures, number of patent applications
  - Number of patents, trademarks, copyrights, etc., received

Partners, Others Involved in R&D Before, During, and After Transfer

- Research collaborations, partnerships formed
- Industry engagement, co-funding, funding for the R&D
- Interconnections: Frequency, duration, value exchanged
  - — With other technology developers, intermediaries; potential application users
  - — Across functions with developers, manufacturers, marketing; Inter-sectoral-
- Level of integration (e.g., co-located, boundary spanners)

Development/Commercialization Since Transfer

<u>Commercial launch</u>

- Product commercialized; policy/practice implemented; attitude or behavior changed
  - New "technology" commercialization/diffusion advances (supply chain develops, adoption of new process technology)

<u>Post-launch stages:</u>

- Volume of production, sales
- Share of the target market using the technology
- Technology/product refinements in performance or cost

<u>Adoption infrastructure (potential and actual)</u>:

1. Business
2. Government procurement
3. Public groups (engagement, awareness, participation, media mentions)
4. Market readiness in four domains:

- the availability of program information (knowledge of technology or market, amount of use of decision support tools, influence on decisions)
- the improvement in economic attractiveness of technologies to the supply chain (influence on policy, codes, government entities, amount of incentives offered, taken)
- the increase in supply chain capacity (manufacturing volume, cost, total cost (installation, operating), financing availability and cost)

Menu of Possible Indicators for the Evaluation Questions

Funding received (or under discussion) for future work on the technology, source of funds

Transfer of the Technology

- Date of formal handoffs to or take up by partners, others, and transfer mechanism
- Interactions with the TTO, patent support office
- Transfer agreements underway or signed, by type
  - Number of licenses granted
  - Number of citations of patents (normalized by patent class)
  - Value of IP to company that licensed it
  - Revenue from licenses of IP generated by program

Start-up launched or contemplated (e.g., entrepreneurial leave taken)

- the improvement in economic attractiveness of technologies to end users (payback period, consumer characteristics—who is served).

Benefits of Commercialization

Specific to this technology:

- Per-unit benefit compared with next best alternative; cost savings
- Revenue, number of jobs created based on commercialization of technologies
- Tax revenue generated based on commercialization of technologies
- Competitiveness (e.g., open new markets)
- Modeled monetized benefits, benefit-to-cost ratio

Depending on the affected sector(s):

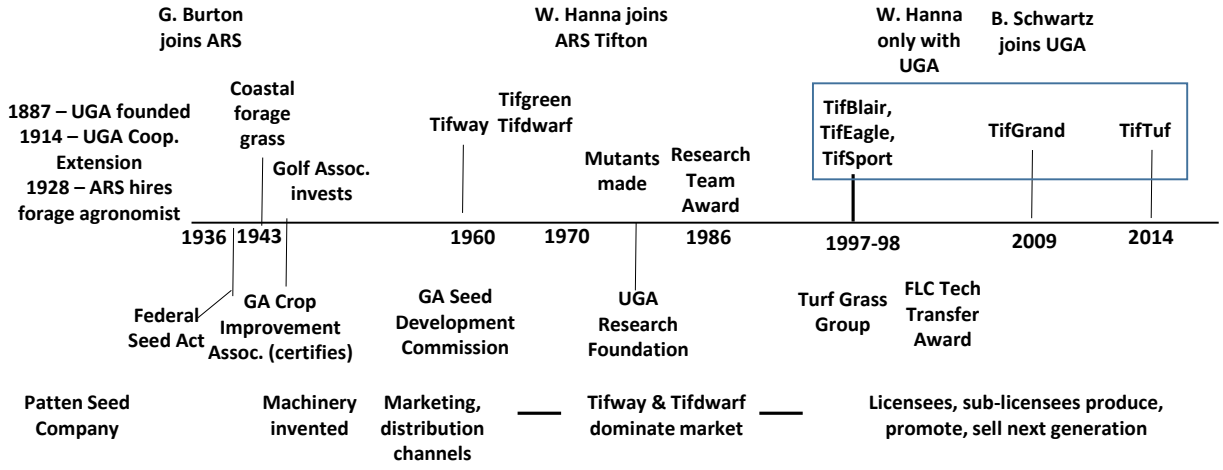
Economic (e.g., income levels, energy cost savings; for company: production levels, jobs); social (quality of life, health; environment (e.g., pollution reduced); security, safety, other

Analysis of Timeline and Contribution

We set up this protocol to conduct historical tracing analysis—who did what over a period of time that led to the benefits accrued, from the transfer of the technology from federal laboratories, and what other contextual factors were major influences. By conducting this tracing in an evaluation based on a well-founded logic model (also called a theory of change), Our protocol allows for contribution analysis. This is a form of attribution analysis that tracks progress along the logic model and investigates plausible explanations for observed outcomes other than the technology transferred being studied.[51]

A useful graphic for historical tracing is a timeline showing the major milestones in the federal transfer and commercialization of the technology. The example in Figure E-2 depicts actions of the federal agency above the timeline and the actions of partners and others below the timeline.

Figure E-2. Timeline for USDA ARS R&D on Improved Turfgrasses



[51] Mayne J, & Stern E. (2013). *Impact evaluation of natural resource management research* programs: a broader view. (ACIAR Impact Assessment Series Report No. 84). Canberra: Australian Centre for International Agricultural Research. Retrieved from: http://aciar.gov.au/files/ias84.pdf

Another helpful template that aids historical tracing and contribution analysis for technology transfer efforts is shown in Table E-2. This template is more useful for internal analysis than for reporting. Table E-2 depicts a matrix that summarizes data categories collected across the historical timeline of federal development and adoption: who did what during each phase is listed for each row.

Table E-2.Template for Collecting and Analyzing Technology Commercialization Information

Categories of Information Needed for Additionality (Attribution) Assessment	Technology Timeline →					
	Capabilities for Tech Maturation	**Preliminary & Detailed Investiga-tion**	**Develop Components, System**	**Validate/ Demon-strate**	**Commer-cialize or Utilize**	**Market Receptivity, Adoption**
History of the technology/market						
What agency did						
What others did (rival explanations—Private sector and other nations)						
What others did (rival explanations—US & state government)						
The agency effect						
Description of agency Influence and its strength						
Basis of evidence of influence						

Appendix F: Case Study of DOC NIST Transfer: Cypersecurity Framework

DOC – NIST Cybersecurity Framework	
Federal agency:	Department of Commerce, National Institute of Standards and Technology
Laboratory:	Information Technology Laboratory
Collaborating entities:	Various entities through public comment and workshops
Transfer object:	Framework for Improving Critical Infrastructure Cybersecurity: The Framework uses business drivers to guide cybersecurity activities and considers cybersecurity risks as part of the organization's risk management processes.[52]
Inventor(s):	Not applicable
Invention disclosure date:	Not applicable
Transfer mechanisms:	Framework reference guide
Key dates:	Version 1.0 released on February 12, 2014 Version 1.1 released on April 16, 2018
Transfer recipients:	Government and industry
Impact summary:	As of 2015, 30% of organizations in the United States had implemented the Framework, and that percentage is projected to increase to 50% by 2020. A recent report found that 28% of U.S. companies now require vendors to follow the Framework. The wide adoption of the Framework helps prevent and mitigate cyberattacks. Estimates of the average cost of these attacks range from $2.7 million to $21 million per event.

[52] https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf

F.1 BACKGROUND

The National Institute of Standards and Technology (NIST) established and maintains the Framework for Improving Critical Infrastructure Cybersecurity (hereafter the Framework),[53] a voluntary tool—that is, a type of reference guide—used by government and industry designed to improve cybersecurity within critical infrastructure. According to the Committee on National Security Systems, cybersecurity is the prevention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication, including information contained therein, to ensure its availability, integrity, authentication, confidentiality, and nonrepudiation.[54]

The basis for the Framework came from a presidential executive order in 2013 (Executive Order 13636) that designated NIST as the implementing agency.[55] NIST, led by its Information Technology Laboratory (ITL), convened hundreds of public- and private-sector entities, including companies, associations, standards development organizations, and government agencies, to create the Framework. The resulting Framework comprises standards, guidelines, and practices that help organizations identify, assess, manage, and communicate cybersecurity risks.

An organization can use the Framework as a key part of its process for managing cybersecurity risk, including:

1. Reviewing cybersecurity practices in an organization;
2. Establishing or improving a cybersecurity program;
3. Communicating cybersecurity requirements to stakeholders;

[53] See https://www.nist.gov/cyberframework for more information about the Framework.

[54] https://rmf.org/wp-content/uploads/2017/10/CNSSI-4009.pdf

[55] See https://www.whitehouse.gov/presidential-actions/presidential-executive-order-strengthening-cybersecurity-federal-networks-critical-infrastructure/. Specifically, the executive order states: "Effective immediately, each agency head shall use The Framework for Improving Critical Infrastructure Cybersecurity (the Framework) developed by the National Institute of Standards and Technology, or any successor document, to manage the agency's cybersecurity risk."

4. Informing decisions about buying products and services; and
5. Identifying opportunities for new or revised standards and practices.

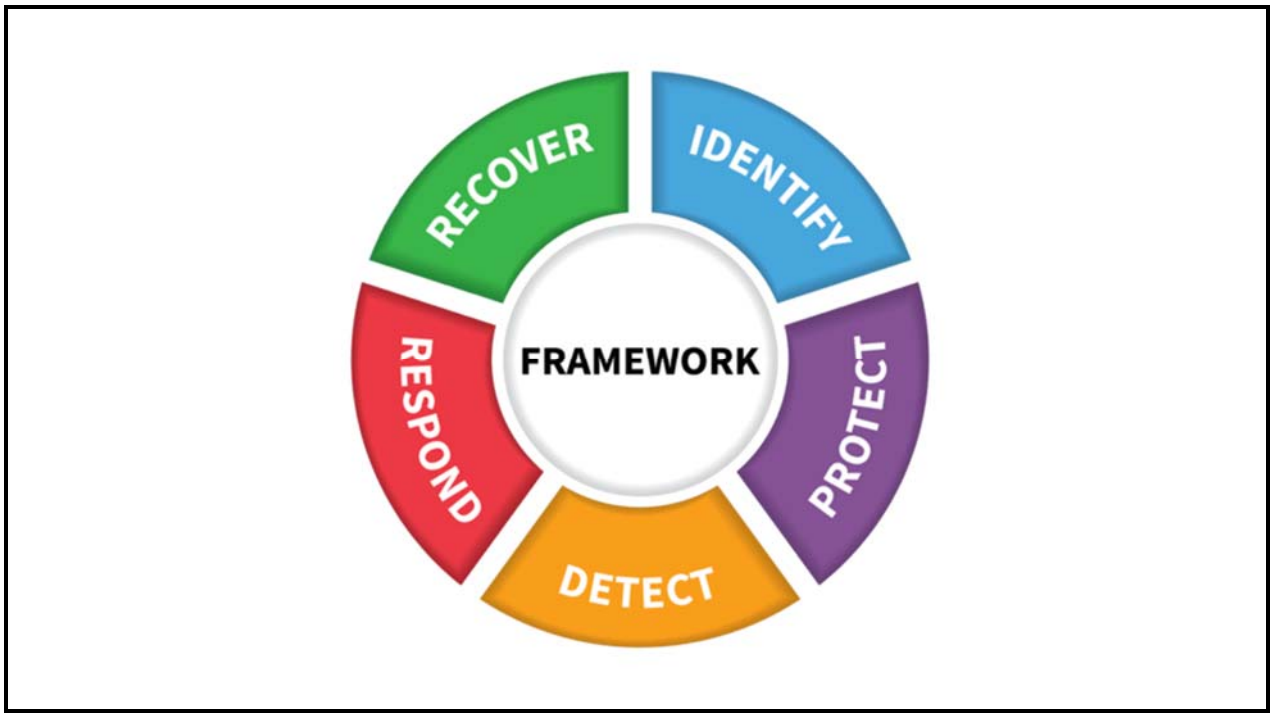
Cybersecurity threats emerge continuously and take advantage of weaknesses in large-scale online networks. For example, a cybersecurity vulnerability in one organization might be shared or create exposure in other organizations, thus weakening the strength of the overall network. The Framework was designed to help individual organizations understand and improve their own internal cybersecurity strategies. The Framework was also designed to create collective resistance to cyber threats among hundreds of organizations through the continuous exchange of knowledge. The Framework improves individual organization and collective cybersecurity using three key tools: the Framework core, Framework implementation tiers, and profile.

F.1.1 Framework Core

The Framework core provides a set of activities to achieve specific cybersecurity outcomes, as well as reference examples for organizations to achieve those outcomes. Drawing from common elements of cybersecurity across critical infrastructure sectors,[56] the core helps guide individual organizations that seek to reduce the risk of cyber-related threats. The core comprises five concurrent and continuous functions designed to protect computers and networks: Identify, Protect, Detect, Respond, and Recover (see Figure F-1). Embedded within the five functions are 23 categories—and individual subcategories—that provide specific outcomes of technical and/or management cybersecurity activities. Using simple, nontechnical language, the core enables communications not only between an organization's leadership and cybersecurity professionals, but also communication among organizations.

[56] According to the Department of Homeland Security, the 16 critical infrastructure sectors are those whose assets, systems, and networks, whether physical or virtual, are so vital that their incapacitation would have a debilitating effect on the safety and security of the United States. For more detail, see https://www.dhs.gov/critical-infrastructure-sectors.

Figure F-1. NIST Cybersecurity Framework Core



F.1.2 Framework Implementation Tiers

Framework implementation tiers provide a progressive set of characteristics that describe how an organization views cybersecurity risk and the processes in place to manage that risk. Tiers range from Partial (Tier 1) to Adaptive (Tier 4), describing the degree to which an organization's cybersecurity practices are informed by its business needs and integrated into its overall risk management practices. Tier 1 organizations typically manage risk in an ad hoc, reactive manner, whereas Tier 4 organizations generally adapt quickly to changes in the risk environment and share their lessons learned with other organizations. However, achieving a higher-level tier can be costly and challenging for an organization. Organizations can choose an acceptable level of cyber risk and craft a commensurate cybersecurity response based on their respective feasibility to implement, as well as their threat environment, business goals, current risk management practices, and legal and regulatory requirements. In other words, while organizations are encouraged to move toward higher tiers, these tiers do not represent levels of cybersecurity

protection, but are instead a tool for identifying goals and making organizational decisions about cybersecurity.

F.1.3 Profiles

A profile provides a snapshot of an organization's cybersecurity strategy relative to the desired outcomes identified by the Framework core. Two profiles, current and target, illustrate existing and future cybersecurity strategies based on organizational requirements, objectives, risk appetite, and resources. Once profiles are established, the organization compares its current and target profiles, thus providing a mechanism for identifying gaps in cybersecurity strategy. Organizations can then use these gaps to update targets for corrective action, estimate their cost, and prioritize next steps.

Viewed collectively, these three Framework elements present a prioritized, flexible, and cost-effective approach that helps promote the protection and resilience of critical infrastructure,[57] among other sectors important to the economy and national security of the United States and beyond.

F.2 TECHNOLOGY NARRATIVE

Established in 1901 as the National Bureau of Standards, the NIST mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST has a long history of advancing its mission by partnering with industry, academia, and other government agencies. Although NIST has been involved in cybersecurity since the 1970s, its role in the Framework began with Executive Order 13636, Improving Critical Infrastructure Cybersecurity, signed by President Barack Obama in February 2013. The Executive Order was issued in response to the growing cyber threat to critical infrastructure and the recognition that the national and economic security of the United States depends on the reliable functioning of the nation's critical infrastructure.

The Executive Order sought to develop a Framework to reduce cyber risks to critical infrastructure. It recognized that much of

[57] The Framework was developed originally to help owners and operators of critical infrastructure understand and manage cybersecurity risk. There are 16 defined critical infrastructure sectors.

the nation's critical infrastructure is owned, operated, and managed by the private sector. The Executive Order directed NIST to engage in an open consultative process with diverse public and private stakeholders to develop the Framework. NIST was chosen to lead the creation and implementation of the Framework given its track record of establishing and managing public-private partnerships, rapport with industry, and flexibility in responding to government mandates. The Executive Order required NIST to construct and implement the Framework within 1 year.

When the Executive Order was released on February 12, 2013, it established the following objectives for the Framework that NIST, in turn, used as design criteria:

- Identify security standards and guidelines applicable across sectors of critical infrastructure;
- Provide a prioritized, flexible, repeatable, performance-based, and cost-effective approach;
- Help owners and operators of critical infrastructure identify, assess, and manage cyber risk;
- Enable technical innovation and account for organizational differences;
- Provide guidance that is technology neutral and enables critical infrastructure sectors to benefit from a competitive market for products and services;
- Include guidance for measuring the performance of implementing the Cybersecurity Framework; and
- Identify areas for improvement that should be addressed through future collaboration with particular sectors and standards-developing organizations.

Tasked with these objectives, NIST needed to establish a Framework that was applicable to 16 different critical infrastructure sectors and that could be customized to fit a variety of industries and perspectives. NIST leaders architected and executed an open, transparent, and inclusive process to understand the mission and business objectives of critical infrastructure owners and operators, understand their cybersecurity needs and challenges, and use this information to inform development of the Cybersecurity Framework.

The first step in this process was to send a request for information in the *Federal Register* to help identify, refine, and

guide the many interrelated considerations, challenges, and efforts needed to develop the Framework. In response to their request, NIST received 250 written responses.[58] NIST staff then planned and hosted facilitated open and public workshops in Washington, DC; Pittsburgh; San Diego; Dalla; and Raleigh, every 6 weeks for 8 months. Workshops were all announced publicly through the *Federal Register* and were open to the public. These meetings were well attended by industry; nonprofits; federal, state, and local governments; international governments and industry; standards-developing organizations; and other interested stakeholders. NIST's prior work in cybersecurity and its strong relationship with industry enabled NIST to attract interest and eventual support for the Framework.

The workshops provided a mechanism to iteratively gather stakeholder ideas and feedback to guide the establishment and refinement of the Framework. The purpose and result of the workshops include the following:

- Workshop 1: The purpose of the first workshop was to present NIST's objectives for the Framework, understand the cybersecurity challenge, and understand possible features of the Framework.
- Workshop 2: This workshop introduced participants to the facilitated group discussion format and allowed them to provide some general ideas about what the Framework should include. Further, the workshop provided a forum for them to express concerns that included the possibility that the voluntary Framework might become mandatory, sensitivities related to privacy, and previous frustrations of working with government.
- Workshops 3 and 4: After the second workshop, NIST staff created a working draft of the Framework, posted it for online comment, and presented it at Workshops 3 and 4. The draft not only provided an opportunity for industry and government stakeholders to see how the Framework was taking shape, but also provided another opportunity—during Workshops 3 and 4—for comment, additions, and edits.

[58] See https://www.nist.gov/cyberframework/rfi-framework-reducing-cyber-risks-critical-infrastructure-2013 for original RFI comments.

- Workshop 5: The fifth workshop provided participants with a final opportunity to provide refinements to the working Framework document.

At the end of this iterative, year-long process—through multiple workshops, versions, comments, and rounds of edits—NIST finalized and released the Cybersecurity Framework, Version 1.0, on February 12, 2014. After its release, NIST personnel worked with associations, companies, and government agencies to raise awareness regarding the Framework and provide education as to its possible uses. NIST also created a guidance document (IR-8170) in May 2017 that describes approaches to using the Cybersecurity Framework within federal agencies.

NIST released Version 1.1 of the Framework on April 16, 2018. Cybersecurity is a constantly changing field in response to continuously evolving threats. Specifically, the update provides new areas for inclusion in the Framework, including management of risk in supply chains, identity and authentication, and self-assessment of cybersecurity risk with the Framework.

F.3 IMPACT OF COMMERCIALIZATION

The creation, development, and dissemination of the Cybersecurity Framework have led to several benefits for industry, government, and society. The case study illustrates the importance of long-standing agency connections with industry, providing mechanisms to receive stakeholder feedback and incorporate it into a solution, and continuously updating solutions within rapidly changing technological environments—in this case, cybersecurity. The sections below describe benefits of the Framework in greater detail.

Growing Adoption: The Cybersecurity Framework and its growing adoption improve overall cybersecurity. NIST has had strong public engagement from external organizations with over 10,000 webcast participants and over 500,000 downloads of the Framework spanning 30 countries as of January 2019.[59] Not only is their engagement, there are also signs of adoption. A report finds that 28% of U.S. companies now require their

[59] https://www.nist.gov/cyberframework/cybersecurity-framework-impacts

vendors to follow the Cybersecurity Framework.[60] In short, while organizations can customize the Framework to their unique contexts, the Framework provides a common benchmark among all sectors and encourages the integration of these sectors into robust information-sharing networks. Through these networks, organizations can rapidly share and learn lessons about various cyber threats and the efficacy of efforts to mitigate them.

Improved Communication: One of the biggest challenges for cybersecurity professionals was the lack of a common language between them and noncybersecurity professionals. The Framework gives cybersecurity professionals a common language to communicate with their organization's leaders and, importantly, a plan for implementing that strategy. The Framework also enables stakeholders to have cross-organizational and cross-sector communication, thus strengthening herd resistance. The Framework has elevated the importance of cybersecurity and, as a result, cybersecurity has become a strategic priority in many organizations.

Industry Benefits: A typical U.S. firm experiences 130 cybersecurity breaches each year. While many breaches are thwarted, the cost to the firm of successful breaches is significant. Cyberattacks disproportionately affect larger companies, and estimates of the average cost of an adverse cyber event for a larger company range from $2.7 to $21 million per event.[61] Cyberattacks are also growing among small and medium-sized companies, with average damages to them ranging from $7,000 to $32,000, although researchers believe cyber events are underreported among these companies.[62]

Given the substantial costs of cyber events, the Framework has been of value to sectors, industries, and individual organizations. For example, the U.S. Telecom Association facilitated the involvement of companies from the communications sector in the development and update of the Framework and has promoted the use of the Framework among its member companies since its release.[63] Further, the National

[60] https://newsroom.cisco.com/press-release-content?articleId=1818259
[61] https://www.whitehouse.gov/wp-content/uploads/2018/02/The-Cost-of-Malicious-Cyber-Activity-to-the-U.S.-Economy.pdf
[62] Ibid.
[63] https://www.ustelecom.org/news/oct-2017-cscc-letter-gao

Association of Insurance Commissioners endorsed the Framework given its emphasis on risk management and mitigation.[64] According to NIST officials, the Framework process allows organizations to provide input to the Framework while benefiting from the systematic way of viewing cybersecurity and from input of others. This works much in the same way the standards process works between NIST and standards development organizations (SDOs).

According to interviewees from industry, the Framework provides an approachable way for stakeholders to conduct security and privacy assessments. Most importantly, it allows users to customize their cybersecurity strategies based on their specific needs and contexts. The adoption of better cybersecurity practices among businesses in the long-term means protecting their brand, maintaining customers, decreasing the cost of cybersecurity, and working with others to solve complex cybersecurity challenges.

Through the Multi-Association Framework Development Initiative (MAFDI), 32 industry associations are working together to focus on ways to maintain and promote the Framework, demonstrating its importance. Specifically, MAFDI seeks to (1) engage multiple stakeholders in the maintenance, improvement, and use of the Framework; (2) share information across sectors on specific NIST framework activities, including experiences with regulators and other stakeholders; (3) promote the Framework as an international model; and (4) bring key influencers from government to hear association and industry perspectives on cybersecurity and the Framework.[65]

State, county, and local governments have adopted the Framework to guide their cybersecurity decisions and anecdotally have begun to require that responding companies possess knowledge and experience with the Framework. This trend in public sources is also driven by the adoption of the Framework by third-party public- and private-sector auditors as "best practice" in cybersecurity strategy.

Benefits Among Governments: The Cybersecurity Framework gives governments a way to standardize and put

[64] https://artemissecure.com/cybersecurity-guidance-from-the-insurance-industry-endorses-nist-Framework/

[65] https://www.fcc.gov/files/csric5-wg5-finalreport031517pdf

into place measures that could prevent and reduce the impact of cyberattacks. The Framework has not only provided federal agencies an important benchmark, but it has also given weight to resource requests in terms of cybersecurity budget and staffing. State, country, and local governments have also adopted the Framework, which has significantly contributed to building stronger network-based protections among all levels of government. With some modification, the Framework has also been adopted in other countries such as Israel, Italy, Japan, and Philippines.

Interestingly, it may be among local governments where future opportunities for implementation of the Framework may lie. For example, many county governments run hospital systems. When establishing a cybersecurity strategy, most local government officials not only focus on ways to protect against cyberattacks and diminish the impact of cyber events, but they must also concern themselves with privacy requirements associated with the Health Insurance Portability and Accountability Act.

Improves the Visibility and Reputation of NIST: The creation and implementation of the Framework led NIST to deeper engagements with industry and other organizations on a variety of technical issues relating to cybersecurity. Increased NIST engagement with the public results in better public participation in other forms of NIST cybersecurity guidance and development of better practice guides at the National Cybersecurity Center of Excellence. Further, NIST's role as an effective honest broker, growing trust that the Framework was not a prelude to regulation, and the quality of NIST's engagement with industry have added to the reputation of NIST and heightened awareness of its work among industry. In short, the Framework resulted in benefits to the private and public sectors as well as to NIST.

Extended Mechanisms for Industry Engagement at NIST: When creating the Cybersecurity Framework, NIST built on its long-used model of industry engagement. Regarding technical issues, NIST frequently hosts public workshops to create a draft publication, issues and provides a period of open comment from the public on the publication, and then publishes the final product. During the creation of the Framework, NIST built further on this model by:

- Hosting multiple meetings in various locations around the country, thus increasing the substantive and geographic range of stakeholder participation;
- Facilitating group discussions at the workshops to give participants a voice and reconcile different suggestions;
- Using the *Federal Register* notices to transmit all related requests for information (RFI) and requests for comment (RFC), publicly posting all RFI and RFC responses, and publicly posting all related analyses and responses to public comments, all to improve transparency; and
- Hosting follow-up workshops to ensure that NIST's analysis was accurate and to provide a venue for additional stakeholder input.

Although these additional mechanisms are not always used for NIST or government initiatives, they were used because the Framework development required substantial private-sector involvement and needed to be voluntarily adopted by a myriad of organizations to ensure national impact.

Appendix G: Case Study of DoD Air Force Technology Transfer: Attenuating Custom Communications Earpiece System

DoD – Air Force Attenuating Custom Communications Earpiece System (ACCES®)

Federal agency:	Department of Defense, Air Force
Laboratory:	Various NIH researchers, universities, and research centers
Collaborating entities:	Westone Laboratories, Inc. (a hearing protection technology company)
Transfer object:	Airforce Attenuating Custom Communications Earpiece System (ACCES®)
Inventor(s):	John Allan Hall (HPW) Karl Cartwright (Westone) Kris Cartwright (Westone)
Invention disclosure date:	Information not provided
Transfer mechanisms:	CRADA Exclusive license
Key dates:	Patent filed April 24, 2006 Commercialization in 2007
Transfer recipients:	Westone
Impact summary:	ACCES earpieces were used by 10,000 Air Force users between 2007 and 2018 with an estimated market penetration of 11% within the Air Force. ACCES protects and reduces hearing loss and aids pilot retention and user effectiveness. From 2007 to the end of 2017, Westone sold 13,755 ACCES units.

G.1 BACKGROUND

In 2006, the Federal Lab Consortium (FLC) awarded Air Force Research Laboratory (AFRL) 711th Human Performance Wing (711 HPW) an award in Excellence for Technology Transfer for its Attenuating Custom Communications Earpiece System (ACCES®). The FLC recognized the 711 HPW for its effective use of federal investment through a CRADA to commercialize a high-impact product to both military and nonmilitary users. ACCES addresses the pilot's need for enhanced hearing protection and facilitates operational effectiveness in high-noise environments in times where safety, awareness, and communication are of paramount importance. Finally, the low-cost ACCES device saves the federal government money by proactively protecting its most important investment—the men and women who serve and use ACCES.

ACCES was developed by the AFRL's (AFRL) 711 HPW and Westone Laboratory (now Westone, a hearing protection technology company) through a Collaborative Research and Development Agreement (CRADA). Since being commercialized in 2007, Westone has sold nearly 14,000 ACCES units to the U.S. Air Force (USAF), foreign air forces, commercial pilots, and law enforcement.[66] For the purposes of this study, the research, development, commercialization, and adoption of ACCES are discussed in the context of USAF usage, which makes up 91% of the current ACCES user base.

In the absence of the ACCES technology, pilots and crew typically use hearing protection that has remained unchanged for decades—a combination of foam ear plugs and earmuffs. The ACCES technology addresses the shortcomings of the foam ear plugs by providing both a better fit and a channel for unimpeded radio communications.

G.1.1 Technical Details

ACCES is a hearing protection device that integrates a voice communications cable into a pair of custom-molded earpieces created from silicone to precisely fit a user's ears. The molded earpiece (see Figure G-1) extends into the ear canal to provide an isolating seal and to deliver audio to the user.

[66] Aggregated, de-identified sales data provided for this case study, courtesy of Westone.

Figure G-1. The ACCES Custom-Molded Earpiece Attached to a Speaker Cable

Source: Westone

The 711 HPW U.S. Air Force School of Aerospace Medicine[67] designed ACCES using an existing Westone technology. Westone has been designing and manufacturing custom earpieces for hearing protection, hearing aids, audio for musicians, and communications systems since 1959. Their existing earpieces, however, could not be used by the USAF for three reasons:

1. Changes in altitude during flight can cause dangerous levels of pressure in the ear, damaging the eardrum.
2. The audio cable needed to connect securely to the earpiece but at the same time be able to disconnect rapidly from the rest of the aircraft equipment in the event of an emergency ejection.
3. Existing earmold products did not extend far enough into the ear to provide adequate and consistent sound isolation for the USAF's use cases.

The 711 HPW solved the pressure problem by adding small capillary vents (Item 26, Figure G-2) to what became the ACCES earmolds to allow for pressure in the ear to adjust to changing conditions outside the ear. The 711 HPW received a patent for the venting device in the ACCES earpiece and an additional patent for designing a connection mechanism that allows for ACCES to be quickly disconnected from the rest of the aircraft in the event of an emergency ejection (Item 14,

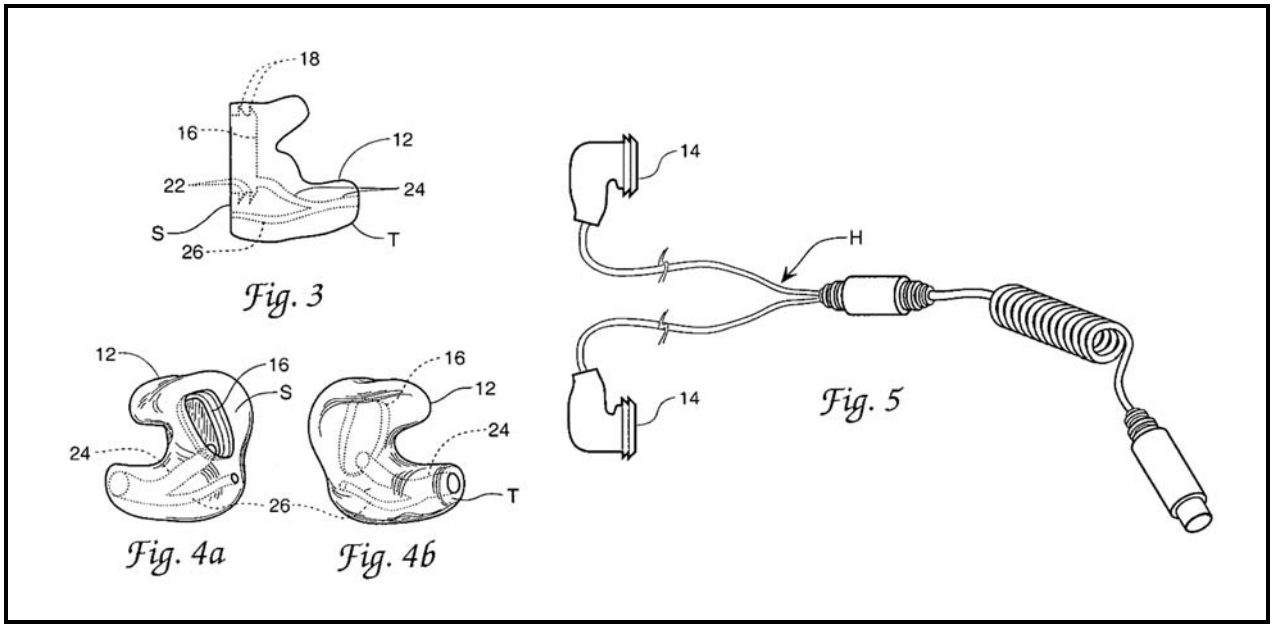
[67] The 711 HPW U.S. Air Force School of Aerospace Medicine is the premier institute for research, education, and worldwide operational consultation in aerospace medicine.

Figure G-2). Finally, the ACCES earpiece extended three-quarters of the way into the ear canal, as opposed to one-quarter of the way for earpieces that Westone produces in other applications.

Because the ACCES earpiece is customized, the earpiece component is sold in raw material form to create an impression of the user's ears. Outside of the USAF, ACCES users can go to a Westone-authorized dealer to have the earpieces fitted. Within the USAF, Westone's primary market for ACCES, Westone provides training to aviation physiologists on base, who create the ear impressions for service members.

ACCES, like other hearing protection technologies, is more effective at protecting users against certain frequencies, particularly high-frequency sounds. Mid- to high-frequency sounds are the most commonly experienced noises by user pilots, the settings for which the ACCES earpiece is designed.

Figure G-2. Illustration of ACCES from Patent Filing (Adapted from U.S. Patent Filing US7784583B1)



G.2 TECHNOLOGY NARRATIVE

The seeds of ACCES were planted in 2000 at the National Hearing Conservation Association (NHCA) conference. John Hall, a 711 HPW research audiologist, attended the conference and shared that the USAF had identified a need for pilot and crew equipment that both protected hearing from aircraft noise and facilitated clear communications between pilots, air crew, and ground crew.

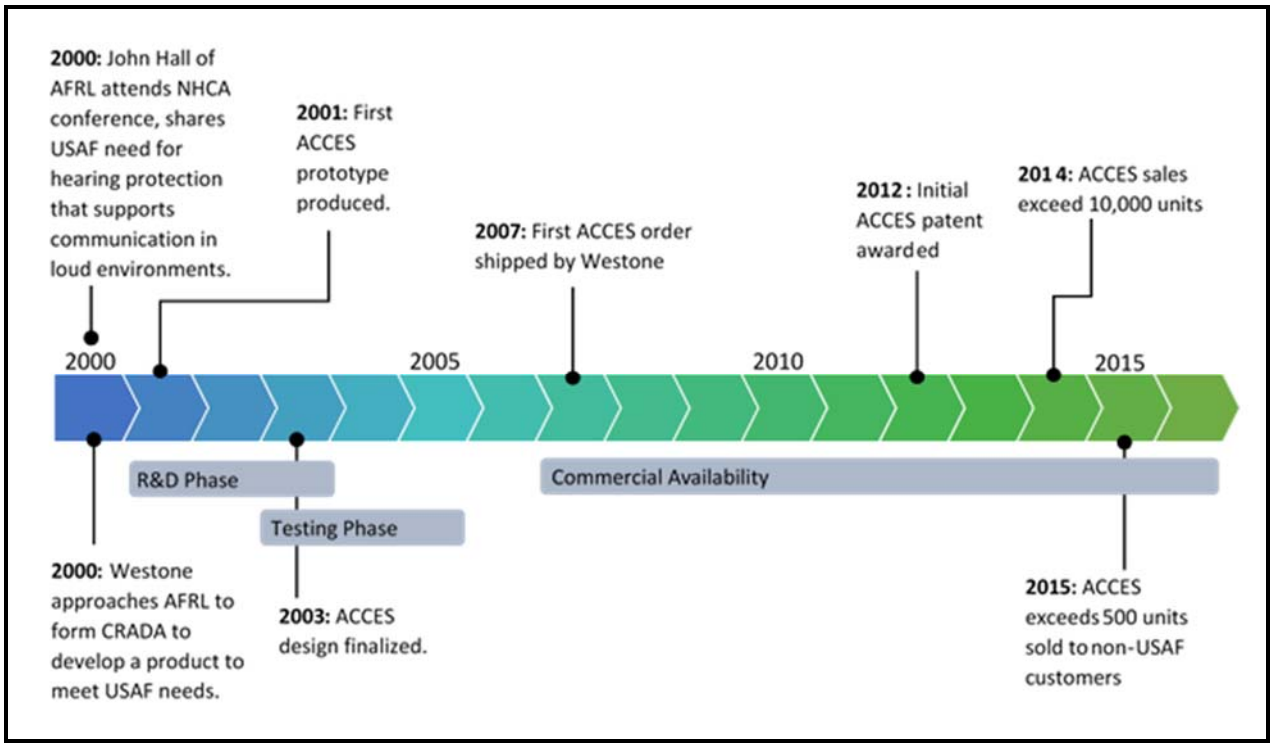
John Hall's presentation at the NHCA conference amounted to a request for help from the private sector to generate ideas that would solve their problem. After the fact, Westone approached 711 HPW and proposed a collaboration with the Air Force Medical School to develop technology that met USAF's needs using existing Westone earpieces as a starting point. 711 HPW and Westone formed a CRADA. By 2001, the first ACCES prototype was developed.

As described in the background section above, the design modifications to create an earpiece that would meet the needs of pilots and crew members focused on the following:

1. Testing of different ear depths to enhance protection from the extreme noise levels created by military aircraft while maintaining user comfort,
2. Provision for easy detachment of speaker cables in the event of an emergency ejection, and
3. Accommodation for rapid changes in pressure experienced by pilots by adding a capillary vent to each earpiece.

In 2003, the design of ACCES was finalized and 711 HPW began testing the unit. By the end of 2006, test pilots were using ACCES, and it was ready to be marketed commercially by Westone. The first production units shipped in early 2007 to the USAF.

Figure G-3. Timeline of ACCES Technology Research, Development, and Commercialization



As part of the CRADA between 711 HPW and Westone, 711 HPW owns the patents on the ACCES technology but granted exclusive license to Westone to manufacture and market ACCES technology. Initially, use of ACCES earpieces within the USAF was limited to pilots' use in fighter jets, starting with the F-22. However, over time ACCES technology became certified for use across a variety of airframes within the USAF. In addition, use of ACCES technology by USAF pilots spread to other aircraft crew members and ground crew.

Although the USAF remains Westone's dominant purchaser of ACCES, accounting for 91% of sales, the company does market the product to other branches of the military, friendly foreign militaries, law enforcement, and the commercial space industry. From 2007 through 2017, Westone sold a total of 13,755 ACCES units. At a cost of $300 per unit, the USAF has spent an estimated $3.75 million providing ACCES to service members.

Currently, the USAF uses ACCES in a limited number of airframes and some ground crew operations. The USAF and Westone have the opportunity to expand adoption through the certification of ACCES technology on other airframes and its use

in more roles on the ground. Other service members who experience excessive noise on the job may find use of ACCES effective, including:

- Fighter pilots and crews across *all* airframes,
- Bomber pilots and crews across *all* airframes,
- Training pilots and crews,
- Air mobility command pilots and crews, and
- All flight line ground crew and maintainers.

Using data provided by the USAF, we estimate this population of potential users in the USAF to be over 88,000 individuals, suggesting an estimated market penetration of 11% within the USAF.

Alternatives to ACCES

As previously mentioned, foam earplugs are the most common form of hearing protection for individuals working around aircraft. Users find them difficult to insert reliably every time, and foam ear plugs block all noise equally, including radio communications. To hear the communications in their helmet clearly, some users cut the plugs in half, keep them loose in the ears, or turn up the volume of the speaker (CNN, 2006). Other crew members remove ear plugs altogether to communicate, thereby exposing their ears to loud external noises in the process (Schutte, 2005).

ACCES technology provides significant improvements over foam earplugs, but it does have some shortcomings. For users, Westone custom makes the ACCES earplugs; for Westone to make them, they must make personal ear impressions of the customer. This product cannot be bought off the shelf. Results may vary across individuals, and the ear impressions require manual refining in some cases. These limitations reduce the rate of adoption.

Some R&D efforts have focused on active noise cancellation and reduction (ANR) technology for hearing protection. ACCES does a good job of attenuating noise across a broader range of frequencies, whereas ANR is mostly effective at reducing noise from low-frequency energy.

G.3 IMPACT OF COMMERCIALIZATION

Based on interviews with individuals involved with the development and marketing of ACCES, We found it unlikely that this product would have been developed without interest and investment by the USAF, in part because the application addressed a problem specific to the USAF; therefore, the market was relatively narrow (i.e., pilots, air crew who experience rapid pressure changes at altitude, and ground crew around military and commercial aircraft exposed to unsafe noise levels over extended periods). ACCES provides service members clear communications experience, while protecting them against hearing loss and related injuries.

Clear communications and operational effectiveness: A fighter pilot interviewed for this study noted that before using ACCES he had to turn the volume up on his communications equipment to its maximum level and still struggled to hear. With ACCES, the user is able to maintain volume at approximately half the maximum level and can hear very clearly.

To address the service members' need to hear radio communication traffic, the ACCES the earpiece incorporates a communications speaker into the design, so all audio communications are fed directly into the wearer's ear canals. This feature allows users to hear much more clearly at a significantly lower radio volume. The built-in speaker not only reduces strain on the users' ears and allows them to maintain full hearing protection, but also improves operational effectiveness by helping them hear more clearly, which could save lives during combat situations. The user interviewed for this study noted that it was "almost impossible" to hear at all while flying in an F-22 without the ACCES earpiece.

Hearing protection and enhanced quality of life: Military aircraft pilots, crew members, and ground crews are often exposed to dangerous levels of noise over extended periods of time. Military aircraft lack the same level of sound insulation as civilian aircraft; combat aircraft in particular have louder engines operating relatively close to the pilots compared with civilian aircraft. Additionally, ground crews operate in closer vicinity to military aircraft during peak noise periods, such as takeoff, than ground crews working in commercial settings.

In 2016, over 2.8 million U.S. veterans reported suffering a hearing-related disability caused by their service. Tinnitus and hearing loss were the two most commonly reported disabilities, affecting over 227,000 new veterans in 2016 alone (VBA, 2016).[68] Hearing-related injuries can limit a service member's ability to serve, can affect his/her long-term quality of life, and also represent a significant expense for the Department of Veterans Affairs (VA), which supports disabled service members with disability compensation payments in retirement.

One common cause of hearing-related injuries experienced by USAF service members is the engine noise from military aircraft. Noise levels above 85 dB can cause hearing-related damage, and jet engine noise can reach as high as 150 decibels (dB) (OSHA, 2017; Schutte, 2005). ACCES technology has the potential to reduce noise by an average of 30 dB (Westone, 2016). The decibel scale is logarithmic, so 150 dB is eight times louder than 120 dB. Earmuffs, used over the ear with the ACCES earpiece inserted, provide extra protection.

Ultimately, users of ACCES technology protect against hearing-related injuries, which has the potential to improve their quality of life over the long term.

Cost savings to the government: Between 1977 and 2007, the VA spent an estimated $6.7 billion on disability payments for service-related hearing loss. In addition to the cost of caring for veterans with a hearing-related disability, such injuries can shorten the career of a service member, which lessens the value of the investment that the military made in training that individual. Although service training costs vary across roles, the USAF expends $6 million to train one fighter pilot. In addition, the USAF is currently facing a severe fighter pilot shortage, which makes pilot retention an even greater priority (Pawlyck, 2017).

[68] Breakdowns of disability claims by branch of service were not available for this study

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Appendix H: Case Study of DoD Army Technology Transfer: Japanese Encephalitis Virus Vaccine

DoD – Army Japanese Encephalitis Virus Vaccine

Federal agency:	Department of Defense, Army
Laboratory:	Walter Reed Army Institute of Research (WRAIR)
Collaborating entities:	CheilJedang Corp (CJ Corp), VaccGen International, Valneva (formerly Intercell AG)
Transfer object:	IXIARO®, Japanese encephalitis virus (JEV) vaccine
Inventor(s):	Hyun Su Kim (CJ Corp) Wang Don Yoo (CJ Corp) Soo Ok Kim (CJ Corp) Sung Hee Lee (CJ Corp) Sang Bum Moon (CJ Corp) Sun Pyo Hong (CJ Corp) Yong Cheol Shin (CJ Corp) Yong Ju Chung (CJ Corp) Kenneth H. Eckels (WRAIR) Bruce Innis (WRAIR) Joseph R. Putnak (WRAIR) Leonard N. Binn (WRAIR) Ashok K. Srivastava (WRAIR) Doria R. Dubois (WRAIR)
Invention disclosure date:	Information not provided
Transfer mechanisms:	CRADA
Key dates:	Patent US6309650 filed June 15, 2000; approved October 30, 2001. FDA approves IXIARO® JEV vaccine on March 30, 2009. DoD begins purchasing IXIARO JEV vaccine in 2011.
Transfer recipients:	Intercell AG (merged with Vivalis SA in 2013 to form Valneva)
Impact summary:	IXIARO is the only JEV vaccine approved for use in the United States and for many of its allies, including the European Union and Canada. The IXIARO vaccine is safe, effective, and has lower risks of adverse allergic reactions than its global competitors. The DoD uses IXIARO to vaccinate U.S. service personnel and their families who are assigned to JE endemic areas of Asia. In January 2019, Valneva signed a new $59 million contract to supply IXIARO JEV vaccine to the DoD.

H.1 BACKGROUND

The development, technology transfer, and commercialization of IXIARO, a Japanese encephalitis virus (JEV) vaccine, in the 1990s and 2000s highlights the unique expertise of federal research laboratory assets and how the public and private sectors can work together to develop new health technologies. Ixiaro was invented by researchers from the Department of Defense (DoD) Walter Reed Army Institute of Research (WRAIR) and scientists from CheilJedang Corp (CJ Corp). The limited North American market for the vaccine, mainly military personnel and their families, meant that a public-private partnership was essential for its development and deployment to the market.

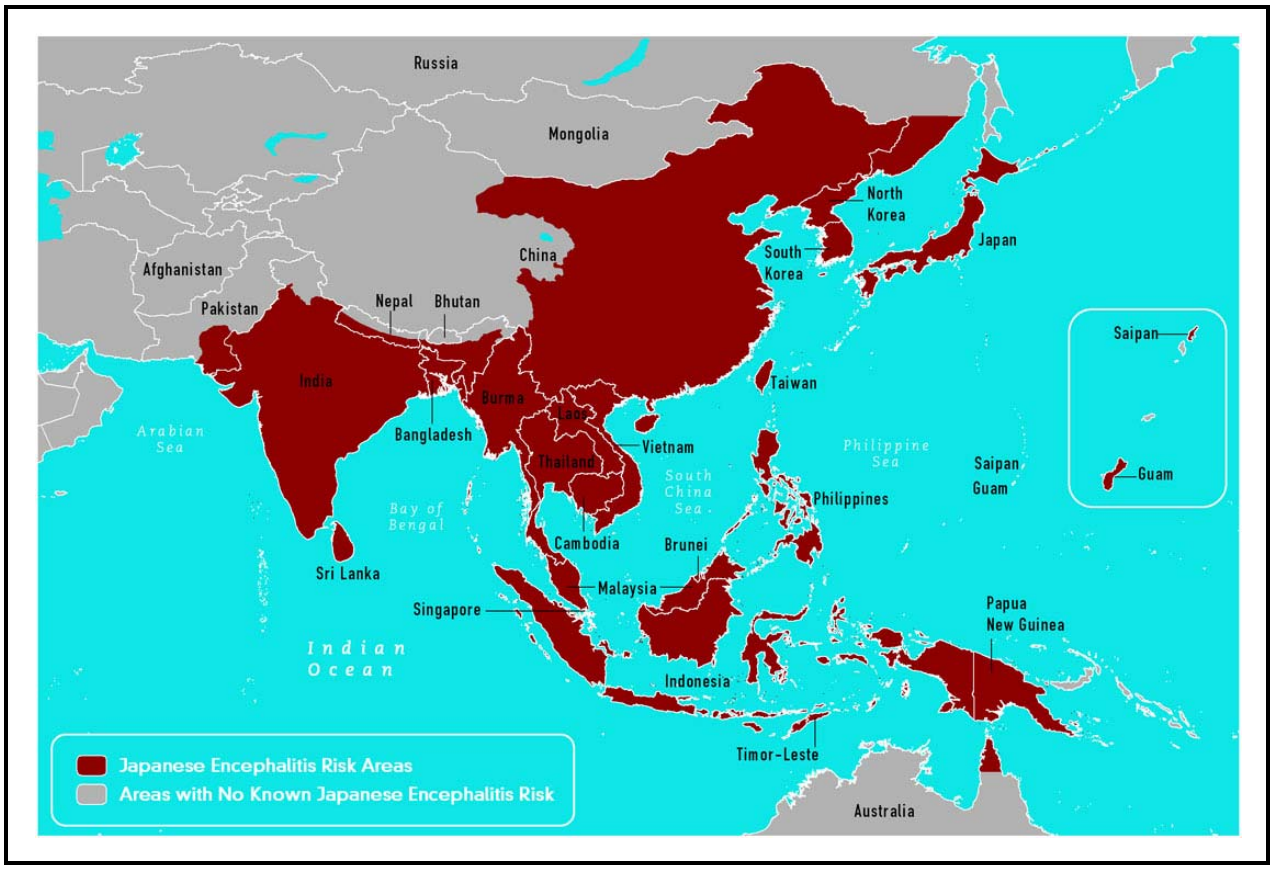
JEV is a mosquito-borne virus in the same family as West Nile, dengue, yellow fever, and Zika viruses. Symptoms of JEV include fever, headache, and seizures. In rare cases, the virus progresses to encephalitis, an infection of the brain that kills about one in four people who get it and often leaves those who survive permanently disabled (Fischer, 2010).

There are more than a dozen JEV vaccines available worldwide, but the WRAIR vaccine is the only vaccine currently approved by the U.S. Food and Drug Administration (FDA). Although there was a JEV vaccine on the U.S. market when research began in 1995, IXIARO is a second-generation JEV vaccine that helped address specific U.S. military needs by protecting personnel living in Asia (see Figure H-1) or for longer-term travelers likely to visit rural or agricultural areas[69] (Defense Health Agency, DoD, 2017).

The IXIARO JEV vaccine, a Vero cell-derived, inactivated vaccine, offers an incremental improvement to other vaccines on the market. It shows similar levels of efficacy as other JEV vaccines, along with a lower likelihood of mild or severe adverse allergic reactions. As this case study shows, improved safety and a reliable supply chain made its development valuable to DoD.

[69] JEV is more common in rural areas than urban ones, likely because those areas are more conducive to mosquito breeding, survival, and transmission.

Figure H-1. Geographic Distribution of Japanese Encephalitis



Source: Centers for Disease Control and Prevention. (2015). https://www.cdc.gov/japaneseencephalitis/maps/index.html

The limited market for a JEV vaccine in the United States meant it was unlikely that a public-sector or private-sector entity alone would have pursued the development of an FDA-approved product. This case illustrates how public-private collaboration brought the vaccine to market to address a specific military need and a niche U.S. civilian need.

H.2 TECHNOLOGY NARRATIVE

The IXIARO JEV vaccine is neither the first nor the only FDA-approved JEV vaccine, but it is a significant advancement in safety and efficacy over previous technologies. Researchers in Japan first developed a JEV vaccine in the 1930s derived from virus grown in mouse brains. The FDA approved a mouse brain–derived JEV vaccine in 1992 under the commercial name JE-VAX®, manufactured by Biken in Japan. U.S. and Canadian clients, including the DoD, used JE-VAX until the early 2000s. The mouse brain–derived vaccine was effective, but its

composition made it more likely to provoke mild to severe allergic reactions in vaccine recipients. Although the DoD recommended the use of the Biken vaccine, it was not mandatory to be administered to military personnel serving in JE endemic areas because of the risk of such allergic adverse events.

In the 1980s and 1990s, DoD WRAIR conducted extensive vaccine research. Its experience in developing military vaccines dates to work on typhoid immunizations in World War I, and its work on Flavivirus vaccines (the variety needed to combat JEV) has its origins in the first dengue vaccines in World War II.

As shown in Figure H-2, in 1995, CJ Corp, a large South Korean conglomerate with expertise in vaccines, entered into a Cooperative Research and Development Agreement (CRADA) with WRAIR to develop a purified, inactivated JEV vaccine. In addition to their complementary research expertise, there were several motivating factors for the CJ Corp-WRAIR CRADA:

- WRAIR obtained an attenuated strain of JEV (SA14-14-2) virus from researchers in China in the 1980s.
- Although WRAIR was given a green light from DoD to conduct research, they did not receive direct funding from DoD and needed to recruit a commercial partner.
- WRAIR had the necessary infrastructure and know-how to work within FDA regulations and DoD, thus providing a less risky pathway for a commercial partner to access the military as a potential customer.

Although WRAIR researchers in the 1990s articulated a military need for a new JEV vaccine because of allergic reaction risks and reliable production and quality issues associated with JE-VAX, a JEV vaccine was not a top DoD R&D priority at the time. WRAIR was given the green light to pursue development in its own facilities but had to find financial support elsewhere. As part of the CJ Corp-WRAIR CRADA, CJ Corp provided all the funding for the early-stage development from 1995 to 1998. WRAIR researchers explained that the project would not likely have advanced without a private-sector partner during these early years.

In 1998, CJ Corp and WRAIR filed for a U.S. patent. The same year, CJ Corp abandoned the CRADA with WRAIR and sublicensed their rights to the vaccine and its patent to VaccGen International, a small pharmaceutical brokerage with

considerable expertise in development, regulatory approval, and commercialization of vaccines. WRAIR and VaccGen continued the development program under a new CRADA between the parties to move the vaccine through Phase 1 and Phase 2 clinical trials. All vaccine supplies for these clinical trials were produced at WRAIR's Pilot BioProduction Facility under Good Manufacturing Process (GMP) conditions. Furthermore, all subjects in the trials were recruited at the WRAIR Clinical Trials Center, and clinical samples were tested by WRAIR personnel. The U.S. Patent and Trademark Office (USPTO) granted a patent to WRAIR and CJ Corp as assignees for the vaccine as developed (USA Patent No. 6309650B1, 2001). WRAIR and VaccGen published preclinical results in 2001 showing the efficacy of the new JEV vaccine in mice (Srivastava, 2001).

Both Phase 1 and Phase 2 results showed excellent safety and immunogenicity of the vaccine in a small sample of human subjects (Lyons, 2007). The parties believed these results justified that the vaccine was ready for a larger Phase 3 evaluation, pending FDA consent. Because Phase 3 trials and subsequent manufacturing required significant capital investment and infrastructure, VaccGen recruited Intercell AG, an Austrian biotechnology firm, into the project in 2003 to help with vaccine manufacturing and the large-scale clinical trials. With the prospect of FDA approval for the vaccine becoming increasingly likely, Intercell AG purchased a GMP-compliant vaccine production facility in Scotland.

Because results from Phase 1 and Phase 2 trials were strong and there was a clinical correlate for efficacy in humans already established from previous trials with JE-VAX, FDA allowed Intercell and WRAIR researchers to use immune biomarkers to show clinical efficacy in humans, in lieu of conducting a full-scale efficacy Phase 3 trial. Furthermore, FDA permitted Intercell AG and WRAIR to do a passive transfer experiment, where they transferred serum produced by vaccinated individuals into mice and demonstrated its efficacy. The research team believes that the combined use of a clinical correlate in Phase 3 trials and the passive transfer experiment saved approximately 5 years and $100 million of the development process.

Meanwhile, the manufacturer of JE-VAX removed the product from the U.S. market in 2006 for undisclosed reasons. This

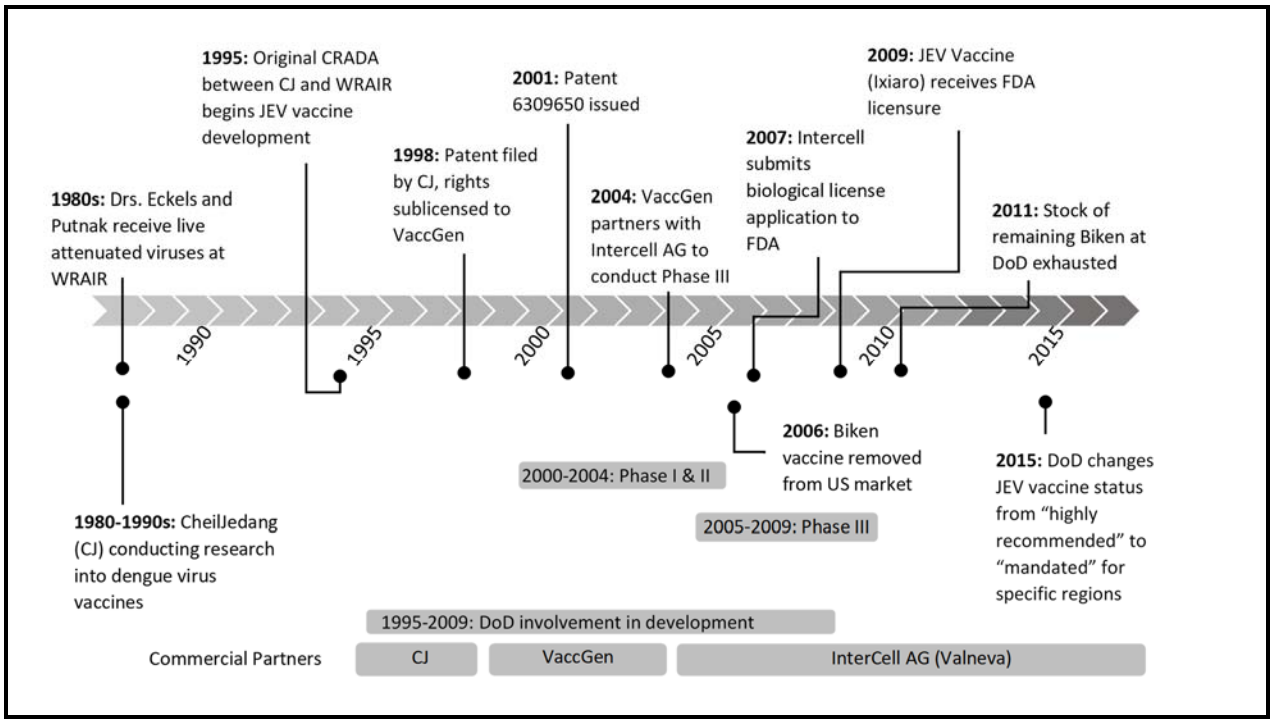
meant that once existing stocks of JE-VAX were exhausted, there would be no other available FDA-approved JEV vaccine option. This circumstance made the vaccine availability issue more pressing for DoD, which eventually guaranteed the vaccine's purchase immediately upon FDA approval of the WRAIR/VaccGen/Intercell AG product. DoD's selection of the WRAIR group's product was due in no small part to a promise by Intercell AG to expedite the process and bring the vaccine to market ahead of schedule. In 2007, 1 year later, Intercell AG applied for a biologics license application from FDA. This was a request for permission to introduce or deliver for introduction a biologic product into interstate commerce. The application was approved by FDA in March 2009 under the brand name IXIARO.

DoD's remaining stock of Biken lasted until 2011, 5 years after the manufacturer removed it from the market, at which point they began purchasing IXIARO. The delay in purchasing by DoD caused a significant financial impact for Intercell AG, which had incurred the cost to expedite the process for DoD. In 2013, shortly after DoD began purchasing IXIARO, Intercell AG and Vivalis merged to form Valneva, and Valneva has manufactured the vaccine since then.

With IXIARO on the market and steady purchasing by DoD, Intercell, with support from WRAIR, encouraged DoD to re-examine their recommendations for use of the vaccine.[70] Specifically, they advocated for expanded use of IXIARO by modification of occupational risk assessments of service members and no dependent recommendation for JEV immunization to "required" for service members and "highly recommended" for dependents. In 2015 to 2016, all branches of the military updated their JE vaccination policies to require the JEV immunization for service personnel, service members' families, and other government service travelers heading to east and southeast Asia (Defense Health Agency, DoD, 2017).

[70] Although Biken had been highly recommended, it was not mandated because of concerns about adverse reactions to the vaccine.

Figure H-2. Product Development Timeline



Notes: Phase I—testing of drug on healthy volunteers for dose-ranging; Phase II—testing of drug on patients to assess efficacy and side effects; Phase III—testing of drug on patients to assess efficacy, effectiveness, and safety. Abbreviations: CJ—CheilJedang; CRADA—Collaborative Research and Development Agreement; DoD—Department of Defense; FDA—Food and Drug Administration; JEV—Japanese encephalitis virus; WRAIR—Walter Reed Army Institute of Research.

H.3 IMPACTS OF TECHNOLOGY TRANSFER

The health and commercial impacts of the IXIARO vaccine are significant but small in the broader context of JEV vaccines across the globe. As of 2014, 12 different JEV vaccines were on the global market, with most coming from China, Japan, Korea, and India. Although half of the global vaccines are inactivated vaccines like IXIARO, IXIARO is the only JEV vaccine approved for use in the United States and in many of its military ally countries, including the European Union and Canada (World Health Organization, 2014), partly because of the strict FDA standards for biologics, which, while allowing Ixiaro to be the only JEV vaccine available in the United States by keeping out noncompliant competitors, also makes it more expensive to produce and less able to compete outside of the primary U.S. market. It is more expensive to produce an effective JEV vaccine that complies with FDA regulations than one that does not, and in a small market any efficiency gains from economies of scale are unlikely.

Commercial impact: The commercial impact of the JEV vaccine, although small compared with many blockbuster pharmaceuticals, is still significant. After waiting a couple of years after FDA approval for DoD to exhaust their inventories of JE-VAX, Intercell began selling the IXIARO vaccine to DoD in 2011. In 2013, Intercell merged with Vivalis to form Valneva, which took over sales of the vaccine. In 2019, following several years of growing sales to DoD and a 2015 change in military recommendations that required JEV vaccination, Valneva signed a 1-year $59 million contract with DoD to supply IXIARO to DoD (Valneva SE, 2017). Since the private market for the vaccine in the United States is small, DoD purchasing is a critical source of sales for Valneva. Today, DoD requires that all military personnel spending over 30 days in Japan and the Korean Peninsula be vaccinated with IXIARO against JEV.

Human health and risk reduction: The JEV vaccine has had a beneficial impact on human health through increased immunization and lower risk of adverse reactions. On that front, WRAIR's careful development of a safe, efficacious vaccine deserves credit. The local tolerability profile of IXIARO was more favorable than its mouse brain–derived predecessors in clinical trials with fewer risks to vaccine recipients. Previous vaccines had shown 91% efficacy, along with low but significant occurrences of side effects including anaphylaxis and neural tissue damage (Lyons, 2007). To that end, IXIARO has a broader population reach, making immunization against JEV possible in virtually all populations that are at risk for JEV, including children and seniors. Efficacy trials in the vaccine's development, for example, demonstrated the product to be safe and efficacious in young children as of 2 months, healthy adults, and older adults alike (Chowdhury, Lin, & Horne, 2013).

The risks of using the IXIARO vaccine proved lower and the benefits higher than using other vaccines, leading to DoD's change in the designation for the IXIARO vaccine, making its use required in military overseas populations in vulnerable areas. As of 2017, use of the vaccine is considered safe not only for U.S. service personnel, but for their families as well, lowering the risk of JEV infection for relevant military families in Asia.

H.3.1 Conclusions

The successful development of the IXIARO vaccine by WRAIR, CJ Corp, VaccGen, and Valneva was the result of several factors, including the prior experience of WRAIR working with both Vero cell and Flavivirus vaccines; the successful collaboration between WRAIR and private-sector partners; and the bottom-up leadership from the research team at WRAIR, who continued to move the project forward in the early years despite limited DoD support. The IXIARO vaccine project lasted approximately 15 years at WRAIR: from the initial research and development through clinical trials and licensing to DoD's agreement to purchase and widely use the vaccine. The process of develop IXIARO highlights the role of public-private collaboration under WRAIR's CRADA arrangement to overcome market obstacles in the lengthy, complex, and expensive process of vaccine development for a niche use.

In total, 16 WRAIR researchers worked on the product, all of whom leveraged considerable experience with Flavivirus vaccines and long histories of developing military vaccines. Moreover, without the WRAIR research team's interest in developing a new JEV vaccine, it is unlikely that DoD would have shown any interest in another JEV vaccine until the Biken vaccine was no longer available with no ready substitute. Thus, WRAIR's foresight was as crucial as their research.

Today, the IXIARO vaccine is a success story because it addresses a specific need for a JEV vaccine for U.S. military personnel stationed in Asia, who are vulnerable to the JEV virus, and replaces the prior vaccine, which is no longer available on the U.S. market. It has a more favorable local tolerability profile and is at least as effective than its mouse brain–derived predecessor, providing a public health benefit to U.S. military personnel, their families, and U.S. military allies including Canada, the European Union, and Israel. This vaccine was able to be brought to market through joint contributions from public and private players throughout the development process. WRAIR's extensive vaccine development experience was a major contribution to the vaccine's success as was the private-sector commitment and funding.

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Appendix I: Case Study of DoD Navy Technology Transfer: Port Security Barrier System

DoD – Navy Port Security Barrier System	
Federal agency:	Department of Defense, Navy
Laboratory:	Physical Security Equipment Program, later the Anti-Terrorism Force Protection-Ashore Naval Facilities Engineering Command
Collaborating entities:	Harbor Offshore (a marine construction firm), Truston
Transfer object:	Port security barrier (PSB) system
Inventor(s):	Laurence G. Nixon (Navy) Stephen Slaughter (Navy) Robert J. Taylor (Navy) William Seelig (Navy)
Invention disclosure date:	Information not provided
Transfer mechanisms:	Exclusive licenses
Key dates:	Patent US6681709B1 filed March 12, 2003 Patent US7401565B2 filed November 6, 2006 Exclusive licenses with Harbor Offshore through 2006. Harbor Offshore's license became nonexclusive, and Truston negotiated a co-exclusive license with the Navy in 2009.
Transfer recipients:	Harbor Offshore, Truston
Impact summary:	Between 2004 and 2012, the Navy replaced Dunlop systems at Naval facilities with PSB systems. The PSB system is a maritime barrier security system suitable for military and civilian use. The PSB system provides physical security protection to Navy facilities and is designed to protect against attacks on them. PSB is also used to protect other high-value assets like cruise ships, nuclear power plants, dams, and oil rigs. Harbor Offshore and Truston have developed portfolios of products related to PSB technology, resulting in cumulative sales of approximately $185 million.

I.1 BACKGROUND

The Port Security Barrier system (PSB), a heavy-duty surface water fencing barrier system, was developed by Navy researchers in the early 2000s in response to the USS Cole terrorist attack that killed 17 U.S. Navy sailors and injured 39 others in Yemen in October 2000. This case study explores how the Navy developed the technology, transferred it to Harbor Offshore and other private companies by patent licensing agreements, and Harbor Offshore commercialized the PSB, selling it to the Navy to protect waterside assets. These included both military—Navy ships, port infrastructure—and nonmilitary assets—cruise ships, nuclear power plants, dams, offshore oil rigs—from waterborne craft terrorism threats. This example highlights how technologies originally developed for military security can also be deployed to protect commercial assets.

Data, research tools, and expertise from previous Navy research programs combined with PSB's abrupt increase in priority level and associated research funding provided the fertile grounds from which the Navy was able to rapidly develop and pilot the PSB technology between 2000 and 2001. Over time, the Navy, through its ongoing procurement relationships with small marine construction businesses and existing programs, licensed the technology to them also for production of PSB to protect cruise ships, dams, nuclear power plants, and offshore rigs. The Navy has continued to use the PSB technology for military purposes and bid out PSB installations to various vendors. The movement of key people among the various organization involved played an important role in transferring know-how.

I.2 TECHNOLOGY NARRATIVE

Through its PSB technology, a floating barrier system, the U.S Navy protects its assets and vessels from potential waterborne attacks. Acting as a physical and visible deterrent, the PSB system reduces the likelihood of unauthorized access to waterfront assets by small surface watercraft,[71] thus discouraging attacks. It can also dissipate the kinetic energy from a high-speed small surface watercraft collision through

[71] Based on analyses of stopping force.

specially designed netting connected to an underwater mooring system.

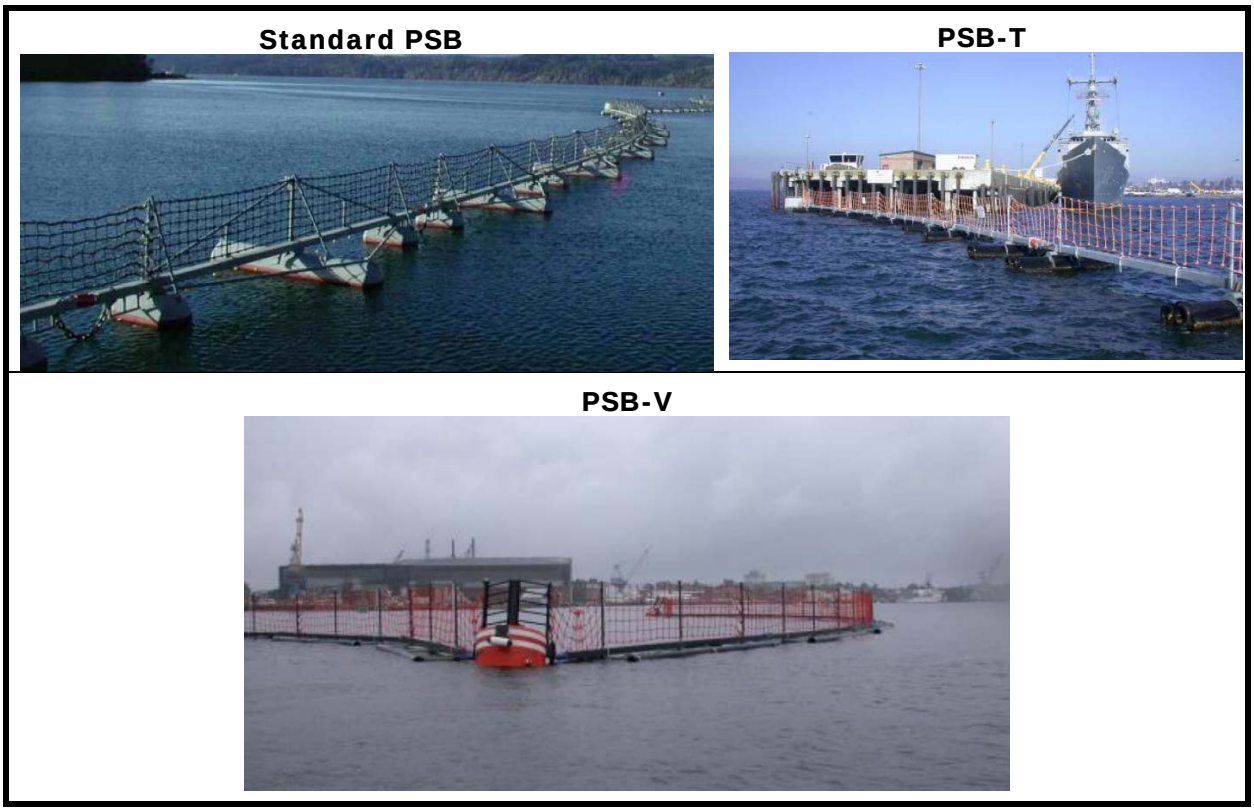
According to one of its inventors, the PSB technology as a physical floating barrier is a key component of an integrated port security system, involving high-value military assets. Waterfront military bases and assets have historically been vulnerable to threats, especially bases located near civilian/pedestrian boat traffic. Vulnerable areas like these make it difficult to monitor potential threats from small, high-speed watercraft. However, military bases with land-based access have multiple layers of security and closely controlled access points. Port security vulnerability gained public awareness in October 2000: the USS Cole was attacked by a small watercraft, manned by terrorists, packed with bulk explosives, which killed 17 servicemen (Carter, 2017). The port in Yemen, where the USS Cole was attacked, had no physical barrier system installed.

Before the PSB technology, to prevent unauthorized access by water, the Navy and harbor masters employed techniques largely involving harbor security boats, sensors and detection systems, lines of demarcation (made up of buoys, rope, and warning signs), and inferior inflatable barrier systems.

The PSB technology is composed of a nylon capture net attached to a urethane plastic pontoon base, vertical steel pylons, underwater moorings, and deadweight anchors (Report to Congress on DoD Office of Technology Transition, 2005). Initially, an individual section of PSB fencing measured about 50 feet across. The original design is capable of stopping a large incoming 10,000-pound boat (the equivalent to an offshore racing boat), traveling about 50 to 60 knots, and delivering the equivalent of over 1 million-foot pounds of energy (Nixon, n.d.). The PSB technology is able to dissipate such high levels of force because of its pontoon design, with its above water netting connected to an underwater mooring system.

On average, the PSB construction costs about $1,000 per foot of barrier, including manufacture and installation, according to two interviewees. Thus, a PSB quarter-mile system would cost about $1.3 million. Of course, the cost of PSB installation varies based on specific features of the installation, and the natural and built environment where it will be installed. The Navy has

Figure I-1. PSB and PSB Variants

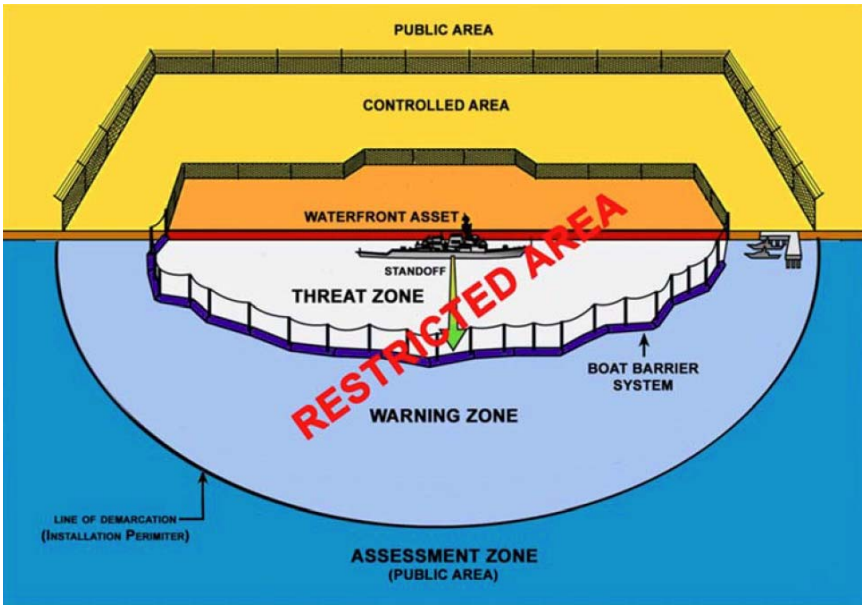


Source: PSB, PSB-T, and PSB-V images from Nixon.

several PSB variants with different specifications, dependent on use and location (see Figure I-1 for images). The low-cost PSB (PSB-T) and very low-cost PSB (PSB-V) are cheaper and easier to deploy than the standard PSB. The PSB-V is designed to act as a temporary barrier to protect lower value assets.

The Chief of Naval Operations had a specific overarching design requirement for the system: "to prevent direct unauthorized access to vessels and critical assets in ports." This was a shortcoming of existing port security measures. The PSB technology complements and reinforces other forms of port security such as water patrol, short-range radar, active use of security camera footage, other sensors, lines of demarcation, and signage. Figure I-2 depicts how the PSB technology factors into overall port security. A line of demarcation buoys and often warning signage indicate the edge of the "warning zone," and the boat barrier system marks the edge of the "threat zone." One PSB inventor described the idea behind the PSB was to have a layered system akin to the various security perimeters that are common in terrestrial military bases.

Figure I-2. Waterfront Zones and PSB



Source: Reproduced from Cofer (2017)

According to one lead Navy inventor, another important PSB requirement was that the system would not be lethal. Thus, the barrier was designed to arrest watercraft with some damage possible, while avoiding fatalities in the case of a hypothetical accidental civilian boating collision with the PSB.

Another key design feature is that the structure is passive; the PSB technology has no sensors, motion detection radar systems, cameras, artillery, or other active technology incorporated. This reduces the initial investment and ongoing operations costs of PSB. In addition, for most installations, the PSB technology allows for a gating function. Thus, connection points can be manually disconnected, and the PSB can be moved by a tugboat for ingress/egress of Navy ships. Furthermore, the PSB technology has significant advantages over the predecessor physical barrier system that the Navy phased out once the PSB gained traction.

I.2.1 Alternative to PSB: The Dunlop Barrier

The only other readily available technology at the time the PSB was invented was the Dunlop antiboat barrier.[72] Developed in the United Kingdom, the Dunlop barrier was an inflated cylinder-shaped barrier that measured 82 feet long by 8 feet in diameter. It was designed to be deployed around waterside facilities and assets regarded as vulnerable to maritime attacks (Navy, 2003). However, the Dunlop barrier systems had some key deficiencies. First, boats are able to go over cylinder-shaped barriers. During the 1860s Civil War, the Union was able to get a steam launch over a Confederate log boom (Elliot, 1994). Full-scale boat attack tests conducted by the Navy in the 1980s demonstrated that when a boat hits a cylinder-shaped object, like the Dunlop barrier, the cylinder starts to roll and acts like as a conveyor belt carrying the boat over the barrier. Second, the Dunlop barrier was prone to deflating and had to be regularly reinflated when it lost air. Third, because of its cylindrical design and large surface area above the water, the Dunlop barrier was susceptible to high-wind loading and thus to being moved from its intended position. Fourth, security personnel were unable to see through the Dunlop barrier, which greatly reduced their situational awareness and operational effectiveness. Table I-1 summarizes these Dunlop barrier shortcomings and how the PSB technology addresses them. Various design features make the PSB superior to the Dunlop at a roughly similar cost.[73] The PSB is a solid structure, for instance, that does not require regular inflation. Second, the PSB links and connectors are robust to withstand a variety of wind and wave conditions, including hurricane-force winds of 100 to 125 knots. Third, PSB testing shows that it can dissipate the energy of 99.9% of pedestrian watercraft (U.S. Navy, 2003). Finally, the PSB's design and netting allow patrols to retain the visibility of any potential security threats on the other side of the barrier.

[72] Since the PSB has been developed, other alternatives have emerged such as the Halo Barrier system marketed by Halo Maritime Defense Systems, which the Navy also played a role in developing. For more information, see https://www.onr.navy.mil/en/Media-Center/Press-Releases/2014/Halo-Barrier-Protect-Navy-Port.

[73] A report by Targosz (2003) listed the cost for the Dunlop at $951 per foot, while the PSB was only $800 per foot. But later expert interviews indicated that the true cost of the PSB was closer to $1,000 per foot.

Table I-1. Dunlop Barrier vs. PSB Technology

Shortcomings of the Dunlop Barrier	Features of the PSB that Address Shortcomings
▪ Low boat stopping ability.	▪ Solid material construction (noninflatable). Able to stop 99.99% of boats with lengths less than 65 feet in the United States.
▪ Regular deflation.	▪ Withstands hurricane conditions. ▪ Net allows wind to pass through, reducing loads.
▪ High wind loading resulting in movement from intended position.	▪ Solid construction helps reduce maintenance.
▪ Limits visibility, which poses a security risk.	▪ Netting allows visibility.

I.2.2 Commercialized Versions of the PSB Technology

After negotiating licenses with the Navy at different points in time, Harbor Offshore and Truston became the Navy's two commercialization partners who brought the PSB technology to market for all nonmilitary uses. Harbor Offshore, for its part, offers three versions of the barrier:

- The Floating PSB-T U.S. Navy Model
- Floating Barrier PSB 600™
- The Floating Barrier PSB 5500™

The PSB-T is the main variant used by the U.S. Navy. Although both the PSB 600 and the PSB 5500 are continuous net capture systems supported on a pontoon structure, the PSB 5500 has an ultimate stopping energy of 9.1 million foot-pounds of force, whereas the PSB 600 has an ultimate stopping energy of 5.9 million foot-pounds of force. The PSB 5500 is regarded as heavy-duty ready, while the PSB 600 is considered the global standard (Harbor Offshore Factsheet, undated).

Truston offers different models of PSB systems and customizes them to the unique locations of their buyers. Different versions of the system are designed for and endure environmental factors such as soil conditions, tidal ranges, and currents. Other factors taken into consideration when designing and choosing a PSB model, include ship traffic, barrier terminations, and gates (Truston, 2018).

I.2.3 Technology Timeline

The PSB technology evolved over 15 to 20 years from a set of ideas and principles to a superior port security product and a

commercially viable product through several (somewhat overlapping) phases of activity, as described below.

Early Testing, Conceptualization

The origin of the PSB technology can be traced back to the late 1980s. No similar port security barrier existed at the time the Navy began PSB-related R&D in the late 1980s. According to one Navy inventor of the PSB, other U.S Navy engineers had completed initial investigations on barriers and were wrapping up their work when the Navy conceived of a subsequent full-scale project test of a system designed to stop a high-speed boat. In the 1990s, Navy researchers Dwayne Davis[74] and Chip Nixon developed the basic idea of a capture net capable of stopping a high-speed boat. The Navy conducted testing and data collection in the San Diego Bay. This earlier testing of the PSB predecessor provided critical data and insight used in developing the later PSB version in the early 2000s.

The Mobile Offshore Base Program

In addition to the early testing of the PSB predecessor, the Navy had a separate experimental research program to develop a large semisubmersible floating series of connected platforms called a Mobile Offshore Base (MOB). These connected platforms were developed to support military operations and receive aircraft in parts of the world without fixed U.S. bases.[75] The MOB program's chief engineer, Bob Taylor, was later one of the lead inventors for the PSB. Although no MOB was ever built, this naval research program delivered many spillover benefits for PSB development. One of the most important challenges both mobile offshore bases and the PSB technology faced was the ability to withstand the ocean environment and storm conditions.

The Navy MOB program involved experts from over 50 commercial, academic, and government agencies, whose purpose was to establish the feasibility and cost of an MOB (MOB Project Team, 2000). Although the Navy found that the

[74] Although Dwayne Davis was involved in initial testing of capture nets, he was not an inventor on last patents.

[75] The MOB program was sponsored by the Office of Naval Research from FY1997 to FY2000 and built on a DARPA project called Maritime Platforms Technology Program that was funded from FY1993 to FY1995. The initial concept emerged as early as the 1970s when the U.S. began losing key aspects of its overseas logistical network (MCA Engineers, 1999).

MOB was technically feasible, it was never built probably because the estimated price tag was $4 billion to $8 billion (MOB Project Team, 2000). Nevertheless, the Navy developed a set of powerful modeling tools and expertise under the MOB program that provided for the rapid development of the PSB technology.

Rapid Development and Piloting

Nearly a decade after the U.S. Navy initially tested the full-scale boat impact in the San Diego Bay, they showed renewed interest in developing a PSB system, following a terrorist attack on the USS Cole on October 12, 2000. The Navy destroyer was rammed by two al-Qaida members piloting a small boat containing explosives, which blew a hole in the ship's hull. Seventeen American sailors were killed, and nearly three dozen more were injured (Burns and Meyers, 2000).

The Navy began full-scale development of the PSB system in the early 2000s. They assembled a team that aimed to refine the basic floating security concept, prototype it, test it, and pilot it. Originally part of the Physical Security Equipment Program, the PSB program later became the Anti-Terrorism Force Protection-Ashore program[76] when the Naval Facilities Engineering Command (NAVFAC) took over the project and accelerated its pace of development.

Chip Nixon, William Seelig, and Robert Taylor, designated team leader, constituted the engineering team and were all from the Naval Facilities Engineering Service Center (NAVFAC NFESC). Steve Slaughter, a commercial structural engineer brought on under the contract, was a key team member and the fourth patent holder of the PSB technology. Other support staff rounded out the team.

Development of the PSB technology by the team proceeded rapidly during this starting phase in late 2000. The team was able to take the PSB system from the conceptualization stage to detailed design in just 10 months. The Navy conducted initial testing at the base in Norfolk, VA. The U.S. Naval Academy even got involved and performed a variety of scale-model tests to validate key design features and performance.

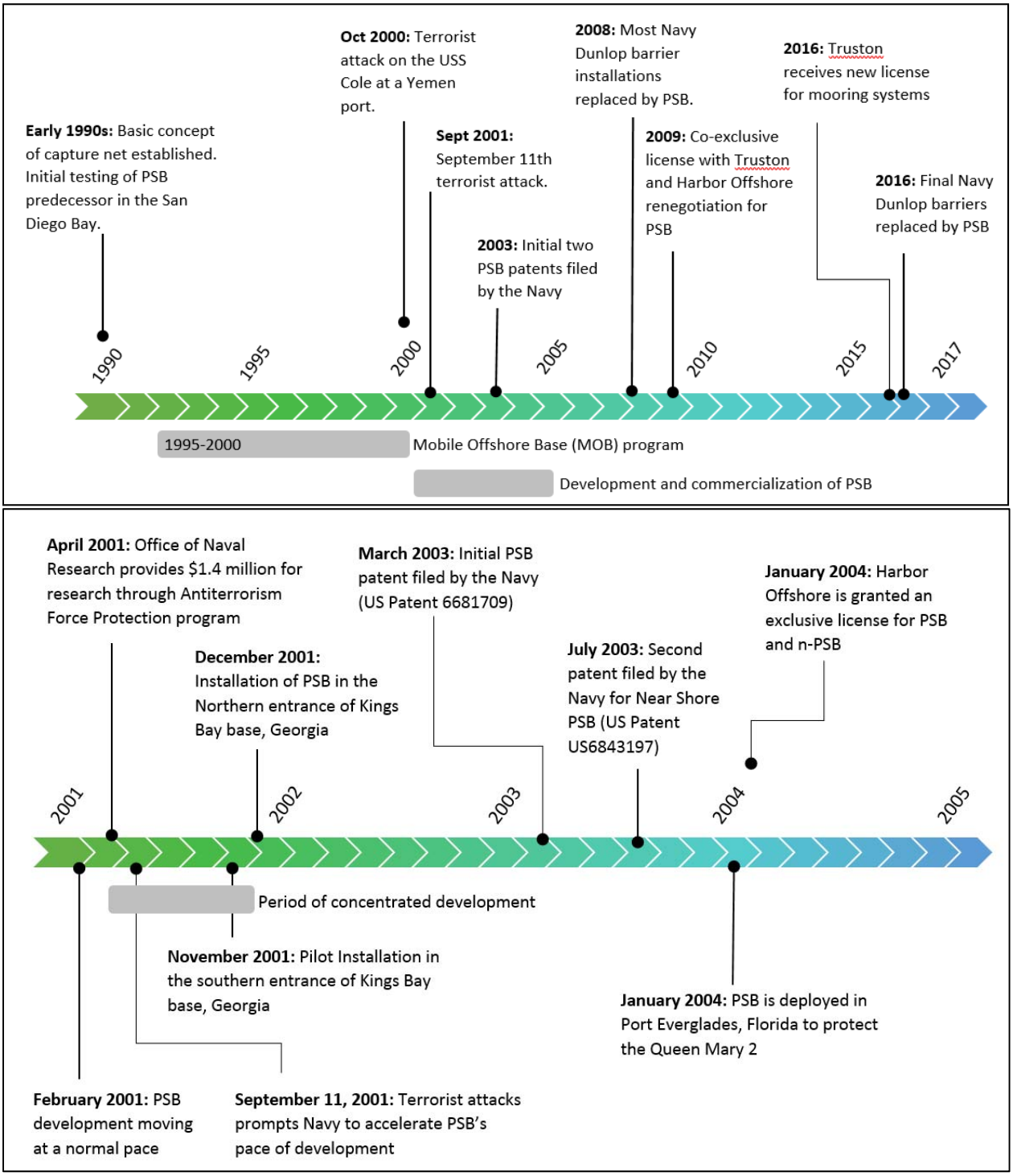
[76] The ATFP-Ashore program requirements were given by Commander Fleet Forces Command and Commander Navy Installation Command.

The Office of Naval Research provided substantial funding in April 2001, and the Navy installed the first PSB system at the southern entrance of the U.S Navy Submarine Base in Kings Bay, Georgia, in November 2001 (Report to Congress on DoD Office of Tech Transition, 2005). In the interceding months, the 9/11 terrorist attacks further exacerbated the public interest and policy imperative to find better measures against all kinds of potential terrorist attacks. The Navy's initial testing and piloting successfully demonstrated the effectiveness of PSB technology.

Navy Deployment

Once the Navy installed the PSB at several sites and demonstrated its superiority to the Dunlop barrier, it began phasing out the Dunlop barriers at homeports around the world. According to one PSB inventor, the Navy faced some initial challenges with securing buy-in from leadership who controlled the deployment of barrier systems, but they were won over by the PSB's superior performance. Between 2002 and 2008, the Navy phased out most Dunlop barriers. All 24 U.S. Navy homeports around the world currently have some variant of the PSB system installed, making them substantially more secure than before.

Figure I-3. The Evolution of Navy Port Security Barriers



Licensing and Commercialization for Nonmilitary Uses

Once the Navy piloted and installed the PSB system, they filed for the initial set of two patents in 2003 to protect their intellectual property. Prior to the development of the PSB system, the Navy had limited physical barrier options available to adequately defend against boat-based terrorist attacks in both military and nonmilitary settings. These vulnerabilities were glaringly obvious. The Navy partnered with outside companies to make the PSB technology available to nonmilitary sectors.[77]

Harbor Offshore, a marine construction company, initially catalyzed the licensing discussions with the Navy for the PSB technology. Harbor Offshore was familiar with the Navy because of Harbor's participation in the Navy's small business set-aside procurement program for marine construction. The Navy and Harbor Offshore negotiated a patent license agreement in 2004, which gave Harbor Offshore the exclusive rights to market the patented PSB technology for commercial uses. The Navy retained the rights over the technology for their own use.

In 2009, the Navy's original license with Harbor Offshore, after the first 5 years, converted to a nonexclusive right for Harbor to continue selling the PSB technologies; Truston, a second firm, negotiated a co-exclusive license with the Navy in 2009. Two major players were selling the PSB technology for commercial applications. The patents included in the Navy's license agreements with the two firms included U.S. patent 6,681,709 and U.S. patent 7,401,565.[78]

Although the Navy's entering into co-exclusive licenses may have created some challenges, it ensured that two companies would be deploying PSB technology into the marketplace.

Additional Development

Over time, the Navy and its private partners have made additional improvements to the PSB technology. The Navy and

[77] According to our interviewees, technology transfer efforts had little to do with the Navy's needs for procuring the system for its own use. The Navy was able to solicit bids for fabricating and deploying the Navy-developed PSB technology through existing procurement mechanisms regardless of whether it licensed the technology.

[78] Truston also licensed two patents in 2016 related to mooring systems: U.S. patent 8,453,590 and U.S. patent 8,726,826.

its licensees switched to plastic for the pontoon base, replacing the steel, to limit the corrosion of the steel with constant contact with salty ocean water. Additionally, the parties replaced the original 50-foot PSB model with a 40-foot variant, because these fit more easily into standard shipping containers, reducing transport costs.

I.3 IMPACTS OF TECHNOLOGY TRANSFER

Deployment of the PSB technology at Navy homeports around the world, accompanied by its commercialization by private firms, has resulted in a variety of impacts.

Protection of waterside military assets: First and foremost, the Navy's deployment of the PSB technology at U.S. homeports has provided national security benefits. As one Lieutenant Commander said, "the fence makes us a harder target" (Taylor, 2005). The PSB system serves as a physical obstacle that acts as a deterrent for a malicious person or group of persons considering a waterside attack. The PSB technology also signals the specific area beyond which access is restricted. Military personnel are able to be more certain about the potential intentions of someone attempting to breach the barrier. The PSB system provides clear national security benefits over the predecessor Dunlop barrier, once the standard.

Quantifying the risk reduction the PSB provides from attack is a speculative exercise, so we relied on existing literature. According to Taylor (2005),[79] the PSB is capable of stopping 99.99% of small watercraft, relative to the Dunlop barrier system, which is capable of stopping about 97.00% of small watercraft (Taylor, undated). Thus, the marginal benefit in probability terms is a reduction in the probability of failure of 0.299%.[80]

[79] Taylor (2005) cites Bhattracharya and Basu (1999) who in their paper describe the annual probability of failure and the monetary consequences of failure in different settings. In this framework, some risks are deemed acceptable, while other risks are marginally acceptable or unacceptable.

[80] The annual probability of an attempted attack is 10%. The difference in probability of failure conditional on an attack between the Dunlop barrier and the PSB is 2.99%. Thus, the marginal benefit of PSB per year is 10%*2.99% (0.10 * 0.0299) or 0.299%.

Reduction of economic risks: Similarly, economic risks are associated with potential waterside attacks on high-value nonmilitary economic assets such as cruise ships, nuclear power plants, dams, and offshore oil rigs. The total monetary impact from risk reduction is beyond the scope of this analysis but would depend on the expected magnitude of lives lost in a failure and the expected economic costs from a failure. Fortunately, there is not much historical data on small watercraft attacks, but a couple of prominent examples include the Iraqi oil terminal attacks in which three lives were lost and the USS Cole attack referenced earlier in which 17 lives were lost. The estimated cost of the USS Cole attack was $250 million.

Reduction of risks posed to human safety: Deterring or physically stopping waterborne attacks helps us protect our most important asset—human capital—reducing the risk of the lost human life or serious injury in both military and nonmilitary settings where the PSB is deployed.

Economic impact on licensees: Harbor Offshore and Truston have developed portfolios of products around the PSB technology, resulting in cumulative sales of about $185 million. The Transportation Security Administration commissioned the first nonmilitary use of the PSB to protect the Queen Mary 2 cruise ship when it arrived in Port Everglades, Florida, from its maiden voyage. Harbor Offshore installed the PSB technology under the Navy license (Zynsys, 2004). The Iraq Coalition Provisional Authority commissioned Harbor Offshore to install the PSB technology to protect two key Iraqi oil platforms. The U.S. Navy provided the site design. Harbor Offshore provided the following high-level sales data to us: Overall, Harbor Offshore has earned about $100 million in cumulative sales of PSB products.[81] They also segmented sales based on whether the installation was for Navy or non-Navy[82] purposes. Based on this high-level data, Harbor Offshore has deployed at least $25 million of PSB technology for nonmilitary purposes. This is equivalent to nearly 5 miles of PSB technology. An additional benefit to DoD comes in the form of dividends; the commercial sales of PSB yield licensing revenues to it.

[81] Profit margins were not available.

[82] Non-Navy sales may include other military sales, but detailed data were not available.

Table I-2. Harbor Offshore PSB Sales

	Navy Marine Barrier Revenues	Non-Navy Marine Barrier Revenues
PSB technology licensed from the U.S. Navy	65–75%	Less than 2%
PSB technology proprietary to Harbor Offshore	0%	Greater than 25%

Source: Harbor Offshore

Truston did not provide data directly to us. Truston's global military and commercial sales of the PSB are more than $85 million (Carter, 2017).[83] Truston has sold over 20 miles of their barriers at dozens of locations worldwide.

I.3.1 Conclusions

The Navy developed the PSB technology in rapid response to terrorism crises in the early 2000s, and it has been deployed for both national defense purposes and nonmilitary commercial applications. The individuals interviewed had slightly different perspectives about the role of the federal laboratory and agency in the benefits that have accrued from the PSB technology. According to the inventors that we interviewed, the Navy's development of the PSB and the transfer of the technology were the primary reasons why this technology was developed when it was. One inventor thought that it could have eventually been developed by a private company but not within the compressed schedule that the Navy was able to accomplish:

> It probably would have happened otherwise, but it is very doubtful that it could have been done in the extremely compressed schedule that we had. It is also likely that the configuration would have differed.

One of the licensees stated that the PSB technology simply would not have happened without the Navy invention. A representative from the other licensee agreed that the Navy was critical in the initial PSB development. Specifically, the initial development would not have occurred or occurred as rapidly if not for the Navy's compressed schedule. Once the PSB product was introduced to the commercial market, this licensee believed that further adaptations, upgrades, and variations occurred as his firm addressed the marketplace needs.

[83] Contract awards to Truston under the Navy IDIQ MAC contract have been in excess of $30 million since January 2010.

Despite these slight differences interviewees made in describing the Navy's contributions, the Navy's intramural research program was clearly the party responsible for the first patented pontoon barrier for port security and the period of PSB accelerated development. Based on our primary and secondary research, three primary factors enabled the rapid development and piloting of PSB technology in 2000 and 2001. First, prior Navy research and testing on PSBs in the early 1980s and 1990s provided it with information critical to the focused development efforts of the early 2000s. Second, naval research on the MOB program created fundamental knowledge and simulation tools for wave and current modeling, instrumental to understanding how different floating structures and connections between them behave in a variety of conditions. Finally, the Office of Naval Research provided a new stream of funding after the USS Cole attack, which recatalyzed research efforts, expanded the team working on the PSB, led to the piloting of PSB technology in a very short time frame, and eventually led to the ultimate installation of PSB technology in Navy ports around the world. The Navy's licensing of the PSB technology to private-sector companies made its commercial applications available to the public and enabled additional development by the licensees.

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Appendix J:
Case Study of DOI U.S. Bureau of Reclamation Technology Transfer: Flexible Fluxprobe Diagnostic Tool

DOI – USBR Flexible Fluxprobe Diagnostic Tool

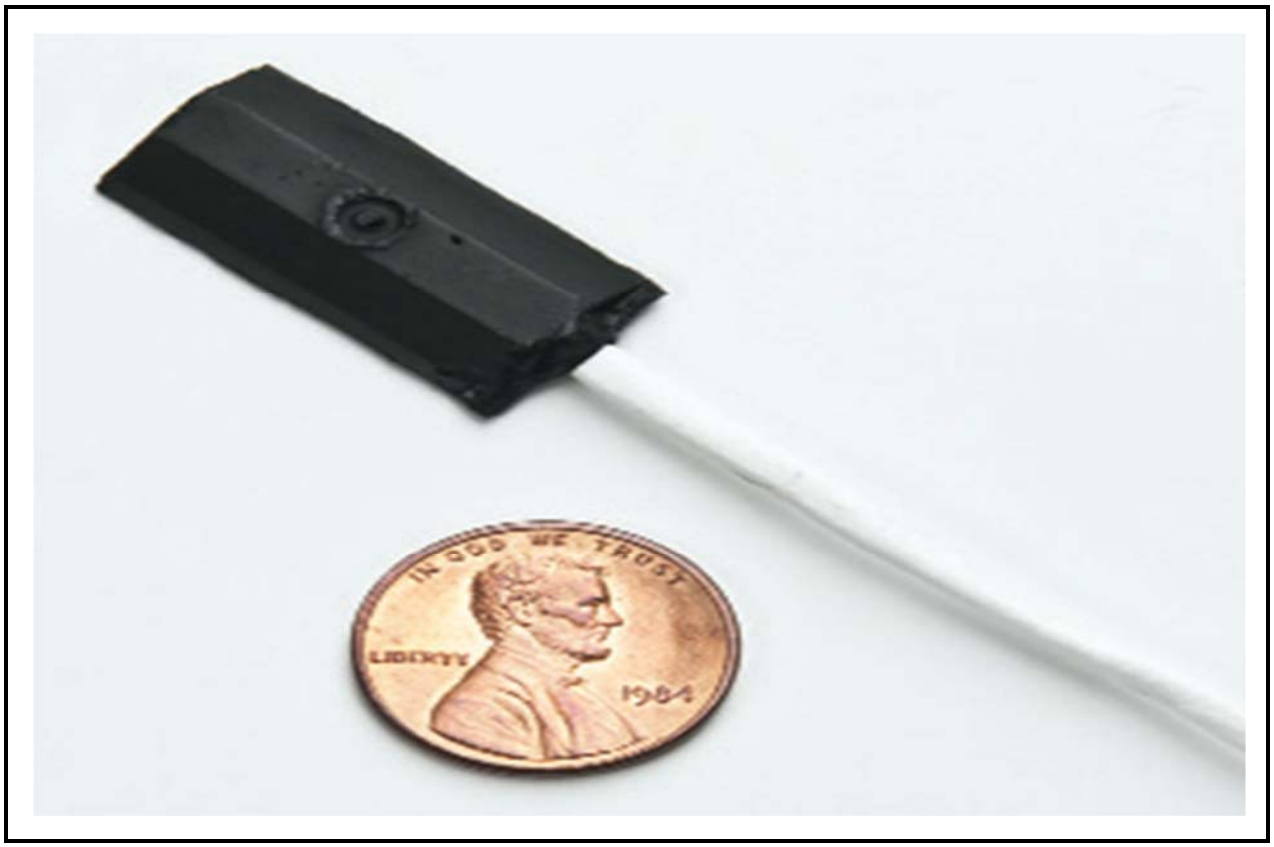
Federal agency:	Department of the Interior—U.S. Bureau of Reclamation
Laboratory:	U.S. Bureau of Reclamation
Collaborating entities:	Iris Power LP (company focused on managing and maintaining large-scale power equipment)
Transfer object:	Fluxprobe diagnostic tool
Inventor(s):	Jim Dehaan (USBR) Umberto Milano (USBR) Malin Lester Jocobs (USBR)
Invention disclosure date:	2000
Transfer mechanisms:	CRADA Exclusive license converted to nonexclusive license after 3 years
Key dates:	Patent US6466009B1 filed June 6, 2001 Iris Power LP enters into a license agreement and CRADA in 200.
Transfer recipients:	Iris Power LP
Impact summary:	The flexible fluxprobe reduces offline time for component evaluation, improves diagnosis accuracy, maintenance schedules, and reduces the risk of catastrophic component failure. DOI also received nearly $40,000 in licensing fees as of 2015. Although the flexible fluxprobe is a low-volume product, with 366 units sold by 2016, it enhances the products and services Iris Power offers. Iris Power has made functional improvements to the technology and developed complementary services, and it offers the device as part of larger product and service bundles to companies around the world.

J.1 BACKGROUND

The flexible fluxprobe is a technology invented in 2000 by Jim DeHaan, Umberto Milano, and Malin Lester Jacobs, electrical engineers at the Bureau of Reclamation (USBR) within the Department of Interior, that detects magnetic fields within the generators that generate power in hydroelectric dams. The device is relatively inexpensive, small, flexible, and light and can be installed relatively easily (see Figure J-1). As water flows through a hydroelectric dam, it turns a turbine which, in turn, turns the generator rotor. The generator comprises two main elements: 1) the rotor consisting of field poles, the rotating portion of the generator, and 2) stationary coils mounted to a stator, the stationary portion of the generator, that surrounds the field poles. Direct current is applied to the field poles generating a magnetic field. When the turbine turns the rotor, the field poles move over the stator coils that generate electricity. Generators are connected to power lines that transmit electricity to surrounding regions.

Over time, thermal and mechanical stresses cause components within the generator rotor and stator, including the electrical insulation that is a part of the rotor field poles, to degrade. As components degrade, electrical shorts occur. These electrical shorts affect the magnetic fields in the generator and eventually lead to significant vibrations in the rotor. If unaddressed, these rotor vibrations may increase and lead to an unscheduled shutdown of the generator or, worse, failure of components within the generator. Repairing failed generators can run into millions of dollars for the owners. Unscheduled generator downtime means less power generation capacity and, according to USBR officials, an estimated $100,000 of lost revenue is possible per large generator per day for a large hydroelectric power plant generating unit.

Figure J-1. The Flexible Fluxprobe



In the past, the most common way for a power plant worker to evaluate the condition of the rotor winding insulation associated with hydroelectric power generation was the pole-drop test. A pole-drop test can only be employed by the worker when the generator is shut down for maintenance. The test is time consuming to perform and may not detect some shorts only present when the rotor is spinning at normal speeds. Further, plant owners may have planned maintenance shutdowns for large generators every 5 years, at which time a pole-drop test would be administered. Given that degradation can occur rapidly to rotors, regular maintenance intervals may not be scheduled often enough to allow for technicians to predict future failures.

The invention of the flexible fluxprobe in 2000 enabled USBR to evaluate the condition of the rotor winding when the unit is in operation. Thus, USBR is better able to understand the electrical/mechanical condition of its more than 200 generators located in 53 hydroelectric power generation facilities.

According to USBR officials, it has thus helped to reduce the cost of power generation for the United States by identifying potential rotor failures before they lead to an unscheduled generator shutdown. Furthermore, the licensing of the flexible fluxprobe to industry by USBR allowed the technology to be used by other public and private hydroelectric power generation organizations and helped reduce overhead costs for the USBR itself. This led to further savings for the American taxpayer.

J.2 TECHNOLOGY NARRATIVE

The USBR is one of a number of bureaus within the Department of Interior. It was established in 1902 to promote the economic development of 17 states in the American West. The mission of USBR is to manage, develop, and protect water and related resources in an environmentally and economically sound manner. USBR has advanced this mission over time by constructing and operating canals, dams, and power plants within these 17 western states. In addition to channeling water to farms and rapidly growing cities, USBR is also the second largest producer of hydroelectric power in the United States, operating 53 hydroelectric power generation facilities.[84]

In the early 1900s, USBR was a pioneer in the design and construction of hydroelectric dams. Faced with challenging geographies and climates, USBR developed unique technologies that could efficiently and reliably produce electricity. It did so by establishing the Research and Development Office in Denver, Colorado. Today, the Research and Development Office works with USBR engineers to create technical solutions to help Reclamation better fulfill its mission. In the case of hydroelectric power generation, USBR engineers work with the Research and Development office to find, develop, and deploy technical solutions for current hydropower issues, such as how to extend the service life of generators that were installed in the early to mid-1900s. The Research and Development Office is staffed with scientists who focus on technical solutions and engineers who spend much of their time in the field where they are learn about operational problems and can test potential solutions. They also spend time working with other engineers

[84] The Army Corps of Engineers, which operates approximately 700 dams, is the largest single dam operator in the United States.

and scientists from similar agencies around the world, as well as private-sector scientists and engineers.

Reducing generator downtime evolved as an important USBR objective in the late 1990s. This goal was driven by increasing demand for power from growing western populations and the aging of power generation equipment, much of it installed in the 1930s and 1940s. Facility operators were especially concerned about the degradation of hydroelectric generators including the rotor components. Although the condition of the rotor components was able to be evaluated during scheduled 5-year maintenance cycles, there was concern about the age of the generators and the potential for degradation between maintenance cycles. The inability of work crews to monitor the operational conditions of field poles inside a generator with greater frequency decreases generator reliability that may result in more frequent generator breakdowns and prolonging generator downtime. Although techniques such as the pole-drop test were available to evaluate component degradation in the early 1990s, these approaches were not 100% accurate and could only be performed by plant staff when generators were offline for maintenance.

Jim DeHaan, an electrical power engineer who joined USBR in 1991, along with other USBR engineers, sought to create an inexpensive way to sense rotor component failure and developed the flexible fluxprobe. The fluxprobe comprises a flexible substrate—a material on which the circuits are embedded—and a sensor. The flexible fluxprobe is placed into the hydroelectric generator between the field poles and stator coils. The flexible fluxprobe does not affect the performance of the generator but detects the change in the magnetic field caused by shorts in the rotor pole insulation. Once the fluxprobe is attached to the generator, engineers and technicians can manually record the signal with data acquisition equipment and visually interpret the results while the generator is running.

After the flexible fluxprobe was developed, DeHaan filed an invention disclosure report to the Research and Development office in 2000. USBR filed for a patent, which was awarded in 2002 (U.S. Patent No. 6,466,009: "Flexible Printed Circuit Magnetic Flux Probe"). As the fluxprobe was being patented,

USBR manufactured several flexible fluxprobe prototypes for use in the field.

J.2.1 Partnership with Iris Power

After the flexible fluxprobe was developed in the late 1990s and patented in 2002, Iris Power LP played an important role in the further development of derivative technologies that used the fluxprobe and eventual commercialization of the device. Iris Power was established in 1990 to develop sensors and instruments to help clients understand the condition of large electrical machines, manage maintenance schedules, and extend the operational life of those machines. Engineers from USBR, including Mr. DeHaan, had experience working with Iris Power personnel and the products and services they provide. Through this relationship, Iris Power learned of the development of the fluxprobe.

After the patent for the flexible fluxprobe was granted in 2002, USBR personnel approached Iris engineers with their invention to see if they would be interested in licensing the technology to improve the monitoring of generator rotors. In addition to legislative mandates, beginning with the Stevenson-Wydler Act in 1980 and the Technology Transfer Act in 1986, to transfer government-developed technologies to industry, USBR was also seeking to take advantage of manufacturing capabilities and efficiencies in the private sector. If USBR could not find an industry partner, it would need to further develop and manufacture the generator rotor monitoring equipment at relatively high cost. USBR staff thought that their partnership with Iris Power might offer a potential solution.

Iris Power was indeed interested in the flexible fluxprobe and agreed to work with USBR to transfer and further develop the government-owned technology. It did so by signing a licensing agreement[85] with USBR for the flexible fluxprobe and establishing a CRADA with USBR. The CRADA was meant to enable USBR staff to continue to work with Iris Power to further develop the flexible fluxprobe. USBR and Iris Power were motivated to enter into these agreements based on their prior

[85] Iris Power enjoyed an exclusive license for 3 years specifically related to use of generator and motor conditioning monitoring. The license was then converted to a nonexclusive license for the same field of use. This arrangement is specific to the field of turbines and large or small generators. USBR is currently receiving royalties.

technical cooperation. In addition, the flexible fluxprobe fit into Iris's line of commercial products and services that were designed to help clients maintain large electrical equipment. Given that Mr. DeHaan and his colleagues had already constructed schematics for the flexible fluxprobe as part of their patent and used these to produce prototypes to monitor generator rotors, it was relatively easy for USBR to transfer the underlying technology to Iris Power through licensing agreements.

As Iris Power began to develop a similar technology in the early 1990s, under the USBR-Iris Power CRADA it worked with Mr. DeHaan and other USBR staff to develop and refine their generator rotor monitoring system. In the process, Iris Power made several functional improvements to their system that helped automate detection within hydroelectric generators. First, Iris Power developed a portable instrument and accompanying software that digitize the voltage signal from the fluxprobe and then display high-resolution interpretations of the data. As part of its development efforts in the 1990s, Iris Power also added a rotational sensor that allows identification of poles with a short. Finally, Iris Power included flexible fluxprobe installation in its client service offerings and packaged those installations with other diagnostic solutions. Today, Iris Power continues to offer these products and services to its customers, companies, cooperatives, and governments that possess large-scale hydroelectric generation facilities.

J.3 IMPACT OF TECHNOLOGY TRANSFER

The transfer, development, and commercialization of the flexible fluxprobe technology have led to several benefits for industry, government, and society. This case study illustrates the importance of public-private partnerships to solve technical problems that have both economic and social benefits. The sections below describe these benefits in greater detail.

Lowers Development Costs for Industry: By inventing the flexible fluxprobe to improve the operation and lifespan of government-owned hydroelectric power facilities, USBR created a new technology that not only benefited publicly owned hydroelectric power facilities and thus its customers, but also helped lower the development costs for industry. Technical change occurs slowly in the power generation industry; thus,

market-driven incentives for innovation, including industry investment in R&D, are lower compared with other, more rapidly changing industries. For example, representatives from Iris Power indicated that if USBR had not invented the flexible fluxprobe, it was unlikely that they would have developed the device on their own, or if they had, it would have taken a significantly longer period of time.

Benefits to Industry and the Economy: Iris Power agreed to license the flexible fluxprobe from USBR because the technology aligned well with Iris Power's corporate mission to help its clients manage and maintain large-scale power equipment. Although flexible fluxprobes are a low-volume product (about 366 units were sold by 2015), its addition to Iris Power's product offerings enhanced the product and services of Iris Power. Iris Power has developed complementary services, such as installation of the flexible fluxprobe, and offers the device as part of larger product and service bundles to power generation companies around the world.

Industry Technology Development and Commercialization: Iris Power not only licensed the flexible fluxprobe and established a CRADA with USBR, but also worked with USBR staff to further develop and manufacture the rotor monitoring technology. In the process, Iris Power made several functional improvements to the technology, including the addition of a monitor and analytical software to allow its clients to automate the detection of rotor component problems in large hydroelectric generators. Although Iris Power may not have funded the initial development of the flexible fluxprobe, USBR staff who were interviewed said that they would not have been able to make such substantial improvements to rotor monitoring technology and were not in a position to market and sell it.

Improved Power Generation Efficiencies: The invention and subsequent further industry development of the flexible fluxprobe and generator rotor monitor have enabled government, industry, and cooperatively operated hydroelectric power generation facilities to run more efficiently. Specifically, the flexible fluxprobe provides facility operators with diagnostic capabilities that allow them to detect component degradation among generators. This capability reduces the time required by plant staff for offline component evaluation, improves the

diagnosis accuracy and maintenance schedules, and reduces the risk of catastrophic component failures. These benefits collectively reduce generator downtime, resulting in operational savings and more reliable power generation to government, co-op, and industry-run facilities. Although Americans who receive their electricity from hydroelectric facilities have enjoyed indirect benefits from the transfer and development of the technology, so have residents of other nations, such as China, Canada, and Brazil whose power operators have purchased the flexible fluxprobe and generator rotor monitor from Iris Power.

Benefits to USBR: The transfer, development, and commercialization of the fluxprobe enabled USBR to fulfill its agency and Congressional mandate (i.e., the Stevenson-Wydler Act) for transferring technologies developed through publicly funded R&D. Through its CRADA with Iris Power, USBR worked with Iris Power to develop its invention further, the flexible fluxprobe and generator rotor monitor that, in turn, allowed the agency to benefit from improved diagnostic capabilities from the devices it purchased for its hydroelectric power generation facilities. In addition, USBR was able to take advantage of the development and manufacturing capabilities of Iris Power, thus reducing overhead costs for the agency; in the absence of Iris Power, USBR would have needed to develop and manufacture the flexible fluxprobe and rotor monitor itself. The agency also received modest licensing revenues (nearly $40,000 as of 2015) from Iris Power that were used to continue its technology transfer activities and provide incentives to USBR inventors to further develop new, useful technologies.

Appendix K: Case Study of DOT Federal Highway Administration Technology Transfer: Mobile Solution for Assessment and Reporting

DOT Federal Highway Administration – Mobile Solution for Assessment and Reporting

Federal agency:	Department of Transportation, Federal Highway Administration (FHWA)
Laboratory:	FHWA
Collaborating entities:	Various state DOTs
Transfer object:	Mobile Solution for Assessment and Reporting (MSAR)
Inventor(s):	Sergio Mayorga (FHWA)
Invention disclosure date:	Not applicable
Transfer mechanisms:	Licenses
Key dates:	Texas DOT acquired 50 MSAR licenses in 2016 MSAR piloted in six states as of 2017 Texas DOT has used MSAR for six separate events as of early 2018
Transfer recipients:	State DOTs (FL, GA, MI, MN, TX, WV)
Impact summary:	MSAR helps officials provide near real-time assessments of damage to infrastructure, allowing federal and state governments to assess damages more quickly and cheaply. Faster assessment and repair mean less social and economic disruption. Pilot testing of MSAR has demonstrated a total labor savings of 17.5 hours (reduced from 18 hours to 0.5 hours) per damage assessment.

K.1 BACKGROUND

This case study reviews the Federal Highway Administration's (FHWA) Mobile Solution for Assessment and Reporting (MSAR), a cloud-based mobile software solution that is used when disasters cause unexpected damage to the U.S. transportation infrastructure. MSAR was conceptualized by FHWA federal staff, who performed a detailed user needs assessment and researched solutions in the market. FHWA adapted a commercial off-the-shelf solution to speed up delivery timelines. Run Consultants, the private-sector IT solutions provider, adapted their solution to address FHWA workflow requirements and deployed it within 6 months. MSAR was licensed to state partners and made available to federal lands management agencies free of charge.

In this case study, we outline how FHWA program staff brought the concept to reality and the impacts the MSAR had on emergency response operations for FHWA. FHWA had and continues to have a key champion for this technology in Sergio Mayorga, Emergency Relief for Federal Owned Roads (ERFO) Program Manager. From a previous role at Caltrans, Mr. Mayorga was very familiar with emergency relief (ER) processes required to document damages and request federal aid. Mr. Mayorga pushed for technology that would transform the data capture, approvals, and oversight for the ER and ERFO programs. FHWA leadership supported technology development through the Accelerating Market Readiness program.

MSAR allows field users to capture information in a streamlined fashion using ubiquitous smartphone and tablet technology, thus providing near real-time accessibility to damage assessments and intelligent and flexible routing for approvals. MSAR has yielded significant efficiencies compared with the status quo—a cumbersome process relying on paper forms, scanned documents, and emails and FTP sites. Additionally, MSAR enables precise, rapid reporting and visibility into the scale of transportation damages resulting from events ranging from flooding, to earthquakes and forest fires, and even to manmade natural disasters.

K.2 TECHNOLOGY NARRATIVE

MSAR is a cloud-based mobile platform that allows field personnel to rapidly perform Damage Inspection Reports

(DDIRs) and Damage Survey Reports (DSRs)—henceforth damage assessment reports unless specifically noted—in the field to assist federal lands management agencies and states in the event of a disaster. It provides several primary functions that benefit both FHWA and its partners:

1. Streamlined data collection at damage sites, including photos and GPS locations, while disconnected from the internet;
2. Streamlined, flexible approvals routing; and
3. Real-time reporting features.

These functions are significant improvements over the old way of doing business and have yielded a variety of benefits for DOT FHWA and its partners who are responsible for coordinating ER efforts within the federal highway system. Benefits include the following:

- Increased government efficiency in terms of labor hour savings for each damage assessment report,
- Increased data quality and transparency
- Improved turnaround time between when the event occurs and when funding for repairs is authorized (particularly important for large events or smaller jurisdictions), and
- Improved real-time situational awareness across all stakeholders at all levels (i.e., for ER state DOT and local agency officials, FHWA division office, and FHWA headquarters. For ERFO, federal lands management agency units, regional offices, Federal Lands Highway Division, and FLH headquarters).

MSAR was developed because there was a critical need that FHWA program manager—Mr. Mayorga—recognized after a few years working in the realm of ER. Mr. Mayorga recognized a need for a completely new way of approaching damage assessment.

K.2.1 Illustrative Example: The Old Damage Assessment Reporting Process

Imagine capturing information about flood damage to a federal highway after waters have receded to a safe enough level to promote entry to the specific site. You have a camera, a global positioning device, a notepad, a laptop, and several other devices. You take 10 to 20 pictures of the site from different angles, record the geolocation of the site, make handwritten

notes and sketches, and take measurements of various aspects of the site alongside a co-inspector. Later that evening, after having inspected five other sites in the area, you set up shop in your hotel room, and you seam everything together manually: upload the pictures to the computer and type up handwritten notes, measurements, and geolocation. You also have to make some new sketches because your sketches from the field were rough and then scan and upload the new sketches.

The process has just begun. Additional information needs to be captured by your colleagues in the office. Once that is complete, your office emails the documents to your counterparts at the FHWA division office. The FHWA division office notices some discrepancies, provides markups of the pdfs, and sends them back. You have to then revise the documents and resend them. Once the package is finally approved, the documents are signed by the division office and further routed via email to the appropriate state and federal signatories. Several months later, the FHWA has reimbursed the appropriate partners for the damage repair. The state had decided to proceed with the necessary repairs instead of waiting for reimbursement and drew down from its reserve maintenance funds. In this hypothetical, they ended up delaying repair of other maintenance projects on secondary state-owned roads, also damaged during the flooding.

The hypothetical above presents a common situation states face, although some of them do outsource their damage assessment and reporting process. With a paper-based system or one managed by a contractor, the FHWA would have had difficulty responding quickly to a congressional request for damage estimates by county, congressional district, or roadway over the past 10 years. Until MSAR was rolled out at FHWA, FHWA had to pull together these types of damage estimates in an ad hoc fashion.

MSAR has been making the old way of doing things quickly obsolete as federal lands partners and states adopt it. Stakeholders throughout this process gain substantial efficiencies during the course of their ER efforts. Leveraging ubiquitous smartphone and tablet technology, MSAR has streamlined the old way of doing business by centralizing data capture on mobile devices and storing all data in the cloud so that field users, system administrators, and FHWA program

managers have simultaneous real-time access to damage assessment information from a variety of computing platforms.

Without action by FHWA, it would have taken significantly more time for states to develop their own software solutions, and even then those solutions would not be standardized.

K.2.2 The Scale of Transportation Emergency Relief Efforts

FHWA receives approximately $100 million per year in regular appropriations for ER. It also receives special congressional appropriations from year to year depending on the frequency and scale of weather and other events affecting the transportation infrastructure.

Two ER programs—the ER program with state partners and the ERFO program with federal lands partners—have been implementing MSAR to streamline the data capture, approvals, and reporting of transportation infrastructure damages. MSAR has been piloted and fully adopted in a handful of states through the ER program (see Section K.3) and has been rolled out to most federal lands agencies[86] through the ERFO program.

K.2.3 Use and Adoption of MSAR

The FHWA has not mandated the adoption of MSAR; they have focused on educating state and federal lands partners about the technology through piloting and training activities. To date, MSAR has been piloted in 12 states and 7 federal lands agencies. The outreach program also engaged over 10 states that are interested in piloting MSAR.

States are still learning about MSAR and are in the early adoption phase. States that tend to be prone to emergency events have shown the most interest to date. Texas has been the lead early adopter and has completely phased out their old process in favor of MSAR.

In FY 2017, MSAR was used across 32 events to document over $714 million in damages. There are over 2,840 assessments in

[86] Tribal transportation facilities, federal lands transportation facilities, and other federally owned roads that are open to public travel such as Bureau of Reclamation, Department of Energy, Department of Defense (Military Installation roads), and Surface Deployment and Distribution Command (Defense Access roads).

MSAR for the year, which translates into a savings of over 52,540 labor hours and $4.2 million in cost avoidance.[87]

Texas Department of Transportation (TxDOT)

Texas' experience as an early pilot state for MSAR was positive. As a result, TxDOT acquired 50 MSAR licenses at a cost of $1,000 per license in March 2016 for use throughout the state.

The prior practice in Texas, according to the FHWA Emergency Relief coordinator there, was to conduct services through emails and SharePoint sites, an inefficient process. As of early 2016, TxDOT had used MSAR for six separate events, including two major flooding events. This includes 418 damage assessments, $51 million in damages for permanent repairs, and $57 million in damages for emergency repairs. Texas is having its local government partners, such as Houston, use the platform.

TxDOT stressed the high value of the MSAR reporting functionality; its ability to provide real-time information at one's fingertips rather than having to pull data together manually.

TxDOT has also experimented with MSAR use for FEMA-related reporting, which would be a potential future application of this platform.

Federal Lands

Federal lands agencies have implemented MSAR rather quickly compared with their counterpart states because, as part of the federal government, they incur no license fees.

K.3 IMPACTS FROM TECHNOLOGY DEVELOPMENT AND DEPLOYMENT

Through MSAR implementation, the FHWA DOT has experienced various operational improvements, as have regional and location stakeholders. MSAR has also delivered improved reporting and situational awareness for all parties involved and faster turnaround times for reimbursement decisions for damage assessments.

Operational improvements for FHWA: The primary impact from MSAR is a streamlined damage and assessment reporting process, driven by streamlined data collection at damage sites,

[87] Personal communication. Lisa Seyler, Run Consultants.

flexible and smart routing, and access to synchronized data from all parties involved.

While no methodology was provided to us, pilot testing of MSAR demonstrated labor savings of 18.5 labor hours per DDIR/DSR for public-sector employees to process applications for FHWA funds (a reduction from 63 hours to 44.5 hours). Although the process in every state is different, we were able to establish manual clerical activities performed by each stakeholder group and identify the tasks that are automated by MSAR, which frees up staff time for higher-value activities.

For Hurricane Harvey alone, TX DOT and local agencies documented over 900 sites in under 5 weeks. FWHA and TxDOT reported 17,500 labor hours of savings for this event alone. If we conservatively assume an average hourly wage rate of $80 per hour,[88] the resulting "soft" cost savings thus far have been $1.4 million. Projecting MSAR cost savings 10 years into the future, if there continue to be 1,750 DDIRs/DSRs per year in future years, cumulative cost savings over the next 10 years in present value terms would be more than $25.9 million.[89]

Improved reporting and situational awareness: Another major benefit MSAR implementation provides is the improved reporting functions for FHWA across regional boundaries. States have developed their own tools for damage assessment and reporting processes that have not been interoperable. Although most states have not adopted MSAR, FHWA is using MSAR as an information management tool and entering and/or uploading data from states themselves.

Once data are in the platform, MSAR provides standardized, digitized information stored in an easy-to-query way. Two system administrators pointed to this as a significant benefit for responding to ad hoc requests such as congressional inquiries about the impact and financial needs of states affected by recent natural disasters like Hurricane Harvey, Maria, and Irma. The ability to provide leadership and appropriation committees

[88] The hourly rate is based on Federal GS 11/12 project reimbursable employees and/or equivalent state-level employees who commonly collect disaster data in the field and/or manipulate the data in an office environment following its manual collection. The $80 rate includes management overhead and leave reserve.

[89] Personal communication. Lisa Seyler, Run Consultants.

timely and accurate damage estimates enables them to effectively advocate for disaster relief needs.

Improved information quality: Because of its ease of use and design as an all-in-one application, MSAR generates fewer data quality issues by field staff, who in the past would have had to translate data from handwritten field notes and other data collection methods into forms back at the office. Not only does MSAR improve ease of data collection, but it also ensures minimum standards for data entered into the system.

Faster response times for FHWA reimbursements: Another major benefit MSAR provides to state and federal land partners is faster response times from FHWA. Because MSAR streamlines damage assessment and reporting for these partners, they are able to obtain federal funding to repair infrastructure in a timelier manner.

If something is incorrect in a damage report, it can quickly be returned under the MSAR platform, thus avoiding the additional printing, signing, and scanning of documents that prior processes required. The MSAR platform also provides greater transparency in the routing process, and problems and bottlenecks can more easily be identified. Where MSAR is implemented, faster reimbursement from FHWA to the state or county for repairs occurs, leading to faster repairs even in those states with inadequate transportation budgets to front the cost of repairs. This may result in fewer hardships for the people and businesses affected by damaged highway infrastructure and fewer losses for drivers who are forced to use detours.

K.3.1 Conclusions

Without the development of MSAR, it is likely that most states and federal lands agencies would still be relying on old systems. Although FHWA has licensed MSAR to a handful of states that are actively using MSAR for damage assessment and reporting, FHWA's use of MSAR to centralize data management of all DDIRs/DSRs expands its importance. By using MSAR in this way, FHWA is able to provide near real-time reporting for stakeholders like Congress.

The importance of a champion for this technology cannot be understated—an FHWA program manager identified the clear need for a software platform and guided the technology from concept to development by working with private-sector

partners. Another primary factor for MSAR's success has been FHWA's collaborative approach to its planning and development: this has involved key stakeholders from ER and ERFO programs, as well as FHWA's internal IT department (to ensure compliance with federal cybersecurity guidelines). FHWA and its partners involved users early on for up-front needs assessments, and the platform has been further refined with ongoing usage feedback from pilot states.

MSAR's expanding adoption has benefitted from the fact that the federal government itself is the customer—for instance, the ERFO program.[90] For the ERFO program, the cost of adoption is reduced because there are no licensing fees. The FHWA's close working relationships with its partners—state partners and federal lands management agencies—has inspired a level of trust between the parties and an understanding of their mutual needs.

There are also two major technology characteristics that made MSAR successful. First, MSAR is interoperable across common personal computing platforms from desktop computers to mobile devices. The interoperability feature mitigated a major potential barrier to adoption. Second, MSAR leverages the Salesforce.com Government Cloud platform, which is highly scalable and FedRAMP approved. The platform undergoes regular security assessments by FHWA as well as other federal agencies leveraging the platform.

Overall, MSAR as a technology is still early in its life cycle but appears to be quite promising based on cumulative experiences with the platform. MSAR's rate of adoption promises to increase, should the cost model be adapted to different state partners' financial, budgetary, and event risk constraints. Continued technology transfer activities include outreach, training, and refining of the system with early user feedback will encourage adoption by the next round of states.

[90] https://flh.fhwa.dot.gov/programs/erfo/

Appendix L:
Case Study of HHS Center for Disease Control Technology Transfer: Human Microvascular Endothelial Cell Lines (HMEC-1)

HHS – CDC Human Microvascular Endothelial Cell Lines (HMEC-1)

Federal agency:	Department of Health and Human Services, Centers for Disease Control and Prevention
Laboratory:	CDC—Atlanta campus
Collaborating entities:	Research collaborator: Emory University
Transfer object:	Human Microvascular Endothelial Cell Lines (HMEC-1)
Inventor(s):	Paco Candal Edwin Ades Thomas Lawley
Invention disclosure date:	Disclosed to CDC November 1990
Transfer mechanisms:	Material transfer agreements and licenses
Key dates:	Discovery of HMEC-1 published in 1992
Transfer recipients:	Various institutions, universities, and companies
Impact summary:	The HMEC-1 is a faster and lower cost process for producing endothelial cells that researchers use to understand how diseases spread in the body. The cell line improves the capability and productivity of researchers studying diseases and testing new drugs. The cell line allows CDC to better serve its public health mission, and the dissemination of this technology has led to improved research productivity and health outcomes.

L.1 BACKGROUND

In 1990, researchers at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, invented a new way to grow endothelial cells, what they termed the Human Microvascular Endothelial Cell Line (HMEC-1). Invented by Francisco J. (Paco) Candal, Edwin Ades, and Thomas Lawley, the HMEC-1 is the first immortalized human microvascular endothelial cell line that retains the morphologic, phenotypic, and functional characteristics of normal human microvascular endothelial cells. CDC selected the cell line for this study as an example of transferring foundational knowledge to society.

Endothelial cells are critical to the function of the human body; they line the interior surface of blood and lymphatic vessels. Vascular endothelial cells, which function as endothelial cells that maintain direct contact with blood, have several unique functions including fluid filtration, maintenance of vessel tone, and repair of damaged vessels (hemostasis).

Production of endothelial cells is important for scientific research. Endothelial cells are used in research that seeks to understand basic body functions. Further, these cells are used to test the impact of various diseases and viruses on the human body, especially tissue structure. For example, researchers use endothelial cells to understand how diseases are spread through the body, such as the spread of tumors through the bloodstream or lymphatic vessels. Industry researchers use endothelial cells to test the efficacy of new drugs on disease targets, such as cancer.

Scientists typically produce endothelial cells by extracting cells from human foreskin, as well as lung and brain materials and bone marrow, and then grow the cells under laboratory conditions. Unfortunately, traditional methods for reproducing endothelial cells taken directly from cell donors—termed *primary cells*—are relatively slow and labor intensive. Further, endothelial cells produced using traditional techniques die relatively quickly and vary in quality and uniformity, thus creating challenges for controlled experiments and follow-on efforts to reproduce scientific results.

HMEC-1 continues to be an important contribution to science because the cell line—that is, the source material and techniques for reproducing it—results in cells that multiply

uniformly and rapidly, providing researchers with endothelial cells that satisfy their research requirements. The development of the HMEC-1 cell line provided an important research breakthrough to allow CDC to better serve its public health mission of protecting the American public from the spread of communicable diseases and other public health threats. Further, CDC's dissemination of the HMEC-1 cell line to other government laboratories, universities, and companies—through both academic publications and material transfer agreements (MTAs)—similarly led to increased research productivity and improved health outcomes. Today, researchers can purchase the HMEC-1 cell line on the market through purveyors such as Thermo Fisher Scientific[91] and American Type Culture Collection.[92]

L.2 TECHNOLOGY NARRATIVE

CDC works 24/7 to protect America from health, safety, and security threats, both foreign and in the United States. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. To accomplish its mission, CDC conducts critical science, provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

Today, CDC is administratively located within the U.S. Department of Health and Human Services (HHS). Its contemporary mission includes health security, occupational health, the identification and surveillance of threatening diseases both domestically and abroad, and responses that help halt their spread. CDC employs thousands of talented researchers and clinicians to support this mission; their response times and research productivity are critical enabling factors.

Paco Candal worked as section chief for CDC's Scientific Resources Division for 18 years. His research group was responsible for producing different types of cell lines—including

[91] https://www.thermofisher.com/us/en/home/technical-resources/cell-lines/h/cell-lines-detail-159.html

[92] https://www.atcc.org/en/Products/All/CRL-3243.aspx#generalinformation

endothelial cells—to grow parasites and viruses to support CDC's mission. As mentioned, traditional techniques grow endothelial cells from human tissue. Not only are techniques for growing endothelial cells difficult and costly, Mr. Candal also realized in the 1980s that the technique had not advanced for decades. In discussions with his supervisor, Dr. Edwin Ades, and Thomas Lawley, an academic researcher at the nearby Emory University, Mr. Candal thought of different ways to speed up production of endothelial cells. Further, he and his colleagues sought to "immortalize" endothelial cells, that is, find ways for these cells to live longer because these cells are difficult to isolate in pure culture, are fastidious in their in vitro growth requirements, and have a very limited lifespan.

Mr. Candal experimented with different ways to produce endothelial cells in the 1980s. His first experiments focused on inserting various types of DNA into cells to change their genetic structure. However, these cells only lived 2 to 3 weeks. He then tried a different approach: he inserted cells with DNA from viruses known to cause cancer. The modified cells reacted by dividing faster and living longer. The researchers also noticed that the cells were forming colonies surrounded by a monolayer, which meant that the cell colonies could be isolated and reproduced. In other words, the cells could be produced quickly and effectively for research purposes.

After the invention of the HMEC-1 line, the National Institutes of Health (NIH), also administratively located within HHS, filed patents on behalf of CDC. In the process, the agency learned that the prior publication about HMEC-1 invalidated its ability to patent the invention, and further patent prosecution was ceased. Nonetheless, CDC published the results of its discovery and distributed the HMEC-1 cell line widely to hundreds of groups, especially nonprofit research organizations, through MTAs. A representative list of institutions and universities that received HMEC-1 under MTAs include the University of Edinburgh, the Cleveland Clinic Foundation, Rega Institute for Medical Research, The Heart Research Institute, and the University of North Carolina. These organizations not only used the cell line in various types of research, but they also improved on the cell line to create new, unique cell lines that better fit their research needs.

CDC also facilitated sharing of HMEC-1 with a variety of companies for use in drug discovery and research and development. This sharing was subject to Biological Material Licenses (BMLs), which provided back to CDC revenues to support additional research at CDC and to reward the inventors who created HMEC-1. CDC used the substantial proceeds from the BML revenues to maintain the cell line and continue to make it widely available. For example, CDC earned nearly $18 million in royalties from licenses with a representative list of licensees including Bristol-Myers Squibb, Cryptome Pharmaceuticals, and Lexicon Genetics, Inc.[93]

In all, sharing of HMEC-1 with institutions, universities, and companies shows that even nonpatented research tool technologies can have a positive impact on the research community. Taking into account all sharing paradigms (MTAs and BMLs), a total of 360 transfers of the HMEC-1 cell line have occurred since April 2018.

L.3 IMPACT OF KNOWLEDGE TRANSFER

CDC's development and issuance of the HMEC-1 cell line provide an example of a foundational knowledge transfer, benefitting several aspects of society.

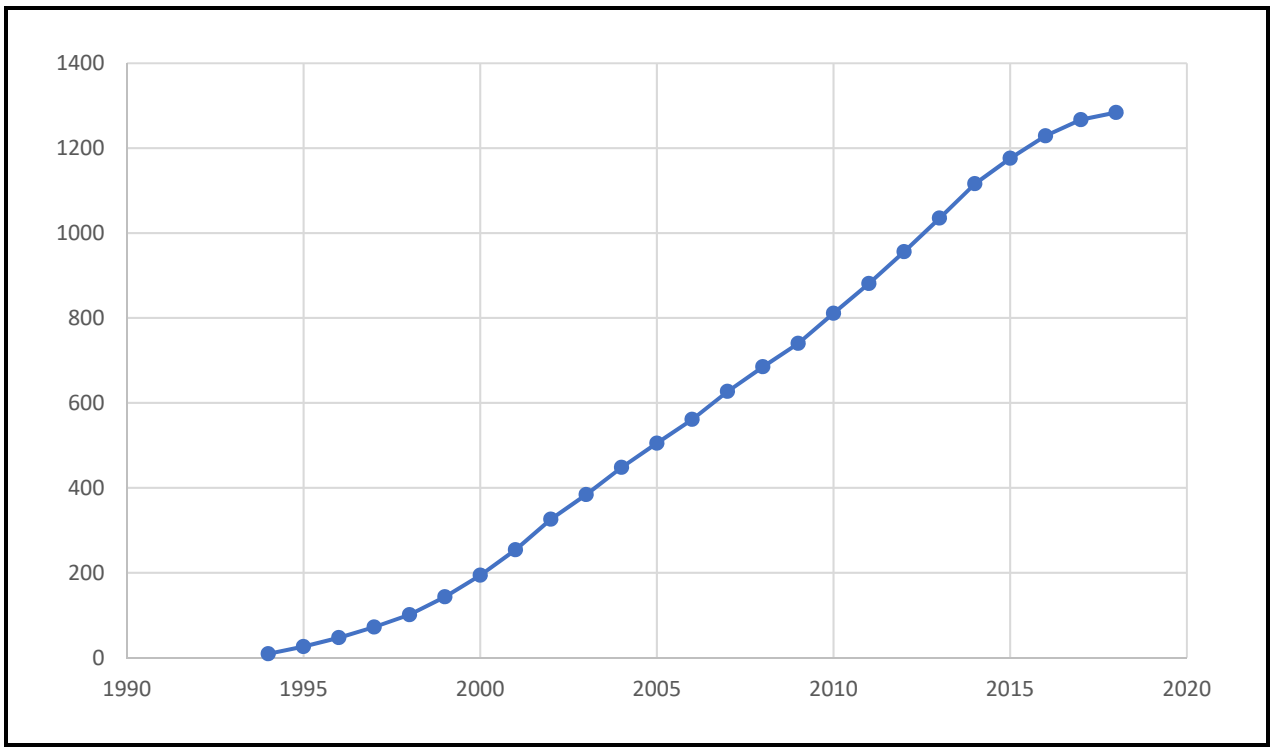
Contributions to scientific knowledge: The discovery by the CDC researchers of the HMEC-1 cell line was first published in 1992 in the *Journal of Investigative Dermatology*. Entitled "HMEC-1: the establishment of an immortalized human microvascular endothelial cell line,"[94] the publication has been cited 1,292 times (see Figure L-1), as of mid-2018 representing an effective transfer of knowledge. Other related articles that discussed the HMEC-1 cell line were published in esteemed journals that were also often cited. These include such academic journals as *Proceedings of the National Academy of Sciences* (157 citations), *Infection and Immunity* (129 citations), *The Journal of Immunology* (92 citations), and

[93] A portion of this revenue is for patent prosecution cost reimbursement (for the time the patents were still under prosecution).

[94] Full citation is Ades, E.W.; Candal, F.J., Swerlick, R.A.; George, V.J.; Summers, S.; Bosse, D.C.; Lawley, T.J., 1992. HMEC-1: establishment of an immortalized human microvascular endothelial cell line. *Journal of Investigative Dermatology.* 99(6): 683-690.

Microvascular Research (72 citations), and further illustrate the reach of this discovery.

Figure L-1. Cumulative Citations to Paper Over Time



Contributions to research practice: CDC's HMEC-1 line provides researchers from universities, government agencies, and life science companies with uniform, reproducible endothelial cells that, compared with primary cells, are less expensive, reproduce more quickly, live for longer periods of time, and retain their primary cell characteristics for a greater duration.

Cell lines such as HMEC-1 are unlikely to replace research and medical use of primary cells completely. According to experts interviewed for this case study, universities and companies continue to use primary cells for advanced drug research. However, CDC's discovery of the HMEC-1 cell line provided an important complement to primary endothelial cells and allowed researchers to expand the scope of their experiments and validate experiments using primary cells at a relatively lower cost.

Economic and social benefits: Although data are not available to quantify the economic and social benefits of the HMEC-1 cell line, experts interviewed for this case study indicated that there are such benefits. These economic and social returns of the cell line include greater research productivity in university, government, and industry laboratories, leading to the greater scientific understanding of the human body. By enhancing research productivity, the HMEC-1 cell line likely leads to faster diagnoses of diseases that affect microvascular endothelial cells and accelerates their treatment.

Appendix M: Case Study of HHS National Institutes of Health Technology Transfer: Human Papillomavirus Vaccine

HHS - NIH Human Papillomavirus Vaccine

Federal agency:	Department of Human and Health Services, National Institutes of Health
Laboratory:	National Cancer Institute, various universities, and research centers
Collaborating entities:	Merck & Co., Medimmune, SmithKline Beechem (later GSK)
Transfer object:	Human papillomavirus vaccine
Inventor(s):	John T. Schiller (NIH) Douglas R. Lowy (NIH)
Invention disclosure date:	Information not provided
Transfer mechanisms:	Nonexclusive licenses converted to co-exclusive licenses
Key dates:	A valid method for producing HPV VLPs developed and patent application filed in 1992 by NIH NCI NIH NCI nonexclusively license NIH VLP technology in 1997 to Merck and Medimmune Merck presents results of HPV vaccine clinical trials in 2001
Transfer recipients:	Merck & Co., Medimmune, SmithKline Beechem (later GSK)
Impact summary:	HPV causes an estimated 610,000 cancers each year, with 80% of these occurring in less developed countries. Today, at least one HPV vaccine is licensed in more than 100 countries. In addition to health benefits, this vaccine has reduced medical costs and provides significant income to providers/suppliers.

M.1 BACKGROUND

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States, infecting 42% of people aged 15 to 59 in 2008 (Satterwhite et al., 2013). Although most infections cause no symptoms and go away on their own within a few years, some last longer and can progress to genital warts or cancer, depending on the HPV type. Among the more than 200 identified HPV types, 15 are linked to cancer. Of those, HPV type 16 (HPV-16) and HPV-18 are the most common, accounting for 70% of cervical cancers. HPV-6 and HPV-11 cause 90% of genital warts but do not cause cancer.[95]

HPV causes an estimated 610,000 cancers each year worldwide, 80% of these in less developed countries; in North America, 26,000 of the 1.6 million new cancer cases each year are attributable to HPV.[96] Cervical cancer, the most common type attributable to HPV and the fourth leading cause of female cancer mortality, causes an estimated 528,000 new cases and 266,000 deaths per year worldwide.[97] In the United States, the American Cancer Society estimates that in 2018 about 13,000 women will be diagnosed with invasive cervical cancer and about 4,000 women will die from the disease.[98]

In June 2006, Gardasil, developed and manufactured by Merck, became the first HPV vaccine approved by FDA; the vaccine covers HPV types 6, 11, 16, and 18. Later that year, the HPV vaccination was added to the U.S.'s routine vaccination schedule for girls 11 or 12 years old and recommended for women aged 9 to 26. A second vaccine, Cervarix, developed by Medimmune and GlaxoSmithKline (GSK) and manufactured by GSK, was approved in Europe in September 2007 and in the United States in October 2009; it covers HPV types 16 and 18. Merck's Gardasil 9, approved by FDA in October 2016, covers

[95] See Bosch et al. (1995) and Kyrgiou and Shafi (2009). HPV-16 also accounts for approximately 95% of HPV-positive oropharyngeal cancer, a subset of head and neck squamous cell cancers including tumors in the mouth, sinuses, and throat; 22,000 new cases are diagnosed every year (Forman et al., 2012). Incidence of HPV-positive oropharyngeal cancer is on the rise in the United States and Europe (Berman and Schiller, 2017).

[96] These estimates, from Forman et al. (2012), are for 2008.

[97] These estimates, from Bruni et al. (2017), are for 2012.

[98] See https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html.

an additional five HPV types linked to cancer: 31, 33, 45, 52, and 58. Today, at least one of these vaccines is licensed in more than 100 countries.

Clinical trials and registry-based observational studies have shown HPV vaccines to be safe and highly effective in preventing HPV infections.[99] Among young women in the United States, the prevalence of HPV types 6, 11, 16, and 18 has declined by more than half since the introduction of Gardasil.[100]

These vaccines and their profound public health impacts are the product of inspired and inspiring efforts by numerous scientists in university, government, and industry settings. The principal players include scientists at the German Cancer Research Center, NIH's National Cancer Institute (NCI)), Georgetown University, and the University of Rochester in the United States; Queensland University in Australia; and the pharmaceutical companies Medimmune, GSK, and Merck.[101] To highlight policy considerations concerning public investment in medical research and technology transfer from federal laboratories, this case study describes NCI's role in the context of the entire body of work on HPV: a global collaboration among government, universities, and industry.

M.2 TECHNOLOGY NARRATIVE

Establishing a causal link between HPV and anogenital cancers was a critical first step in developing a vaccine. Dr. Harald zur Hausen at the University of Heidelberg and Dr. Alexander Meisels at Saint-Sacrement Hospital in Quebec City, Canada, are credited with providing the earliest strong evidence of such a link (Schmeck, 1985); for his work, Dr. zur Hausen was awarded a Nobel Prize in 2008.[102]

By the mid-1980s, following the seminal work of Meisels and zur Hausen, a consensus was building among scientists that papillomaviruses were involved in the development of anogenital cancers, notably cancers of the cervix and vulva, with some researchers already saying the evidence "comes as

[99] See Muñoz et al. (2010), Lehtinen et al. (2012, 2013, 2015, 2017), Rana et al. (2013), and Luostarinen et al. (2017).
[100] See Markowitz et al. (2013, 2016) and Hariri et al. (2015).
[101] *Deutsches Krebsforschungszentrum* is referred to throughout as the German Cancer Research Center.
[102] For an excellent review, see zur Hausen (1991).

close to proving a cause and effect relationship as is possible short of developing a vaccine against the virus and proving that it prevents the cancers" (Schmeck, 1985, C1). In the United States, laboratories studying the links between papillomaviruses and cancer were set up at the NCI (headed by Dr. Peter M. Howley and Douglas R. Lowy), Georgetown University (led by Dr. A. Bennett Jenson, Dr. Wayne D. Lancaster, Dr. Robert J. Kurman, and Dr. Gregorio Delgado), and the University of Minnesota (led by Dr. Anthony J. Faras and Dr. Ronald S. Ostrow). Abroad, the German Cancer Research Center was one of several laboratories studying the potential linkage. By the end of the 1980s, these laboratories' research efforts—together with case-control and longitudinal epidemiology studies conducted by NCI, the National Institute of Allergy and Infectious Diseases (NIAID), International Agency for Research on Cancer, Danish Cancer Society and others—had further strengthened the evidence of a causal link, but a vaccine was still more than a decade away.

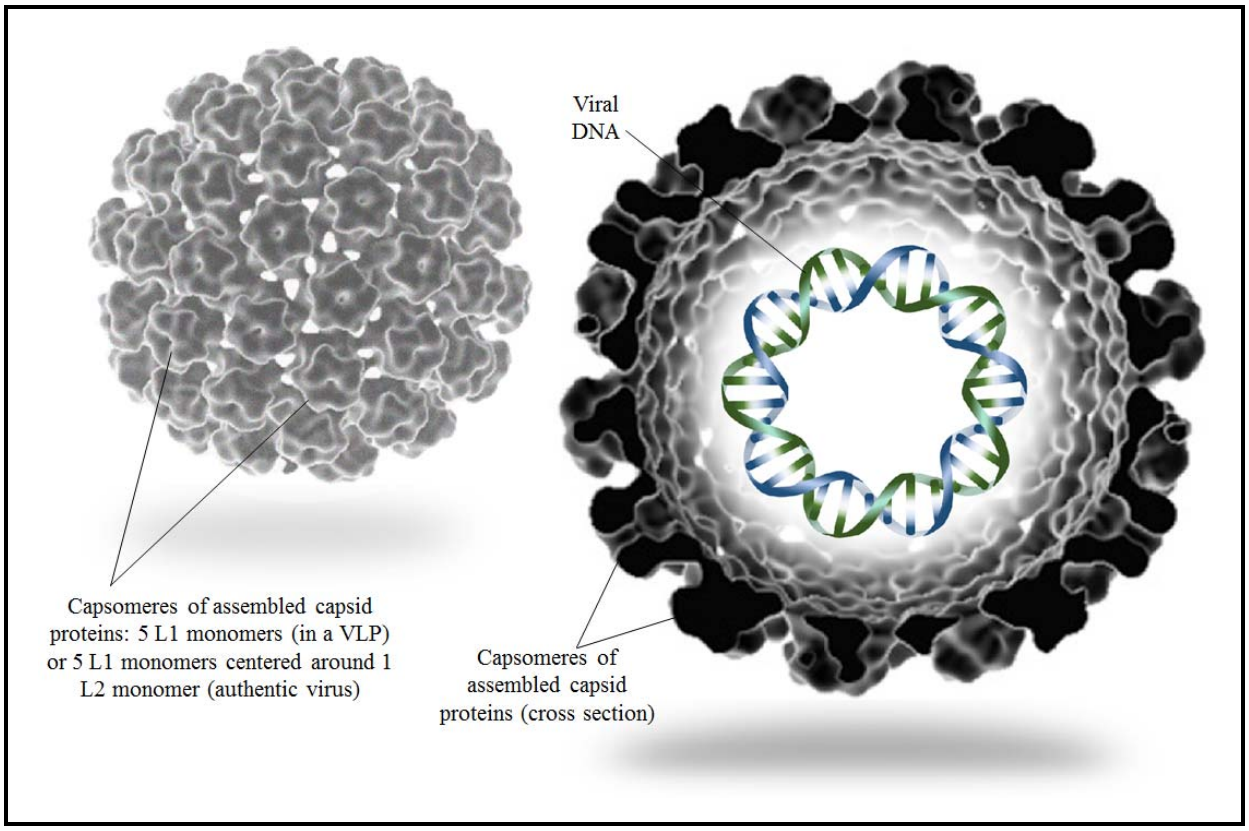
M.2.1 Virus-like Particles: Production and Immunogenicity

With HPV as with other viruses, viral DNA is surrounded by a protein coat, or capsid (Figure M-1). HPV vaccines work by presenting a person's immune system with virus-like particles (VLPs) made only from assemblages of one capsid protein without the harmful DNA inside. The immune system learns to produce antibodies that bind the capsid proteins; if presented with the actual virus, these antibodies then bind the actual virus if exposed to it in the future.

In the early 1990s, this mechanism was still unproven. The problem facing researchers who believed it could work was to develop a practical method of producing capsid proteins and show that capsid proteins produced by that method could stimulate the production of antibodies capable of neutralizing the actual live virus from causing an infection. There was a flurry of basic research on this mechanism in the early 1990s:

- At the International Papillomavirus Workshop in Seattle, in July 1991, Ian Frazer and Jian Zhou of Queensland University presented a method of producing HPV-16 VLPs by expressing the capsid proteins L1 and L2 in a vaccinia virus system; their results were published later that year (Zhou et al., 1991).

Figure M-1. Stylized Depiction of HPV Virus: Capsid Exterior (left, background) and Capsid Cross Section and Interior (right, foreground)



Source: Artistic rendering by the author. The depictions of the capsid are based on the cryo-electron microscopy images of Cardone et al. (2014). The stylized viral DNA molecule was composed using Microsoft PowerPoint. This figure is released under the terms of the Creative Commons Attribution-Noncommercial-ShareAlike 3.0 Unported license, https://creativecommons.org/licenses/by-nc-sa/3.0/ (CC BY-NC-SA 3.0).

- In September 1992, Shin-Je Ghim, A. Bennett Jenson, and Richard Schlegel of Georgetown University reported having produced the L1 protein of HPV-1 and shown that it shared antigenic characteristics of the actual HPV-1 virus in that it reacted selectively with certain kinds of antibodies (Ghim et al., 1992).
- In December 1992, a multidisciplinary team of NIH researchers reported having produced VLPs of bovine papillomavirus (BPV) and HPV-16 using only the viruses' L1 capsid proteins; using an in vitro assay, the BPV VLPs were shown to stimulate the production of unexpectedly high levels of neutralizing antibodies; the HPV-16 VLPs were shown to react selectively with HPV-16 antibodies (Kirnbauer et al., 1992). The NIH team included NCI researchers, including Doug Lowy and John Schiller, and structural biologists from the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS).

- In 1993, Robert Rose, William Bonnez, and Richard Reichman of the University of Rochester and Robert Garcea of the Dana Farber Cancer Institute reported having produced HPV-11 VLPs from the virus's L1 capsid protein that reacted selectively with HPV-11 antibodies (Rose et al., 1993); Rose, Reichman, and Bonnez (1994) then showed that these VLPs could stimulate the production of neutralizing antibodies.

Unresolved questions surrounded HPV-16 and the feasibility of sufficient production of capsid protein VLPs for use in vaccines.[103] Answers came from the NCI group in 1993 with the help of Matthias Dürst and Lutz Gissmann of the German Cancer Research Center (Kirnbauer et al., 1993): the HPV-16 L1 gene used for the earlier research was found to have a mutation that inhibited self-assembly. The DNA had been isolated from a cervical carcinoma; the researchers theorized that a mutation was possible, obtained a new sample from a precancerous lesion, and compared the DNA to confirm and characterize the mutation. The L1 capsid proteins expressed from the new DNA sample assembled more efficiently as a result of the mutation, increasing the VLP yield 1,000-fold and achieving results comparable to those observed with BPV previously.[104]

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[103] Zhou et al. (1991) had reported needing both L1 and L2 capsid proteins for particle formation; the particles they produced appeared smaller than ordinary HPV-16 capsids and were differently shaped, and Zhou et al. (1991) were silent on the particles' immunogenicity (i.e., their tendency to bind with or stimulate the production of neutralizing antibodies). Kirnbauer et al. (1992) had been able to produce HPV-16 VLPs with L1 alone, although in much smaller numbers compared with the analogous BPV VLP production system. The lower yield was both perplexing and concerning, presenting practical difficulties for the production of HPV-16 VLPs in sufficient quantities to be useful as a vaccine or as a research tool.

[104] Kirnbauer et al. (1993) speculated that the discrepancy between Zhou et al. (1991) (i.e., no VLP production without L2) and Kirnbauer et al. (1992) (i.e., VLP production with L1 only, albeit lower-yield) may be attributable to differences in the expression systems used: the baculovirus system used by Kirnbauer et al. generally produces more recombinant protein than does the vaccinia virus system used by Zhou et al.; in the vaccinia system, the concentration of L1 proteins expressed alone may have been insufficient for VLP formation, while the concentration of L1 and L2 proteins, when coexpressed, may have been sufficient. Adding to the mystery, the HPV-16 DNA used by Zhou et al. (1991) was later discovered not to have been the mutant strain used by Kirnbauer et al. (1992) but rather a strain identical to that used by Kirnbauer et al. (1993), according to Frazer and Cox (2006). Frazer and Cox (2006) maintain that the particles produced by Zhou et al. (1991)

With methods established to produce HPV VLPs from L1 proteins and encouraging indications that vaccines made from these particles might be effective at neutralizing HPV, researchers still needed to prove the concept in animal models and develop the research tools necessary for human testing.[105]

N.2.2 Early Commercial Interest and Licensing

At the same time as the VLP research in the early 1990s, biopharmaceutical companies were intrigued by the possibility of developing a vaccine to prevent cancers and had begun to and invest in early-stage research and acquire intellectual property (IP) rights related to the development of cancer vaccines:

- Kathrin Jansen and other Merck scientists returned from the 1991 Seattle workshop impressed with the presentation by Zhou and Frazer and asked for resources to begin developing a commercial vaccine for HPV using VLPs. Merck had previously developed a yeast expression system and purification technology to produce a VLP-based vaccine against hepatitis B, and scientists familiar with that technology believed it could be adapted to produce an HPV vaccine. In 1995, Merck acquired IP rights from CSL, an Australian biotechnology company that had licensed the Queensland University team's technology.[106] In late 1997, Merck also obtained a nonexclusive license to the NIH VLP technology.
- In the United States, Medimmune licensed L1 vaccine technology from Georgetown University in 1995 and (nonexclusively) from NIH in early 1997. Medimmune was familiar with the VLP approach, having previously licensed VLP technology from NIH to develop a parvovirus vaccine. Praxis Biologics, a small biotechnology company in the Rochester area, had licensed VLP technology from the University of Rochester but relinquished those rights after being acquired in 1994; Medimmune licensed the Rochester team's technology in 1995. In late 1997, Medimmune partnered

would therefore have been immunologically equivalent to those produced by Kirnbauer et al. (1993), notwithstanding their different size and shape; no immunological tests confirming this assertion were ever published.

[105] Namely, serological assays to determine whether antibodies produced in response to vaccination could neutralize HPV.

[106] Aforementioned method of producing HPV-16 VLPs by expressing the capsid proteins L1 and L2 in a vaccinia virus system.

with SmithKline Beecham (later to become GSK) to develop HPV vaccines.

These IP rights would eventually come into conflict. The USPTO declared initial interferences in 1997 and declared six two-way interferences among the claims of the four teams—NIH, Queensland, Georgetown, and Rochester—in 2001, setting up a series of hearings to determine which of the claims in the four teams' patent applications would ultimately be afforded protection. At issue was which of the four teams had been first to invent a method for producing HPV VLPs suitable for an HPV vaccine.[107]

At least one valid patent was needed to bring the technology to market. Under the first-to-invent rule then governing the U.S. patent system, this required all four parties to present their best case: a valid, enforceable patent required a solid rationale for who most deserved the patent on a given claim. Under the final judgements entered into 4 years later on September 20, 2005, each of the four teams was entitled to a patent for some but not all of its claims.[108]

After the decision in 2005, everyone cross-licensed their rights; under the cross-licensing agreements, future revenues from HPV vaccines would be shared among the four teams and the German Cancer Research Center.[109] By this time, the vaccines were outperforming all expectations in clinical trials; the compelling clinical evidence of the vaccines' effectiveness

[107] The interference proceeding that ensued would have unfolded differently today. With the America Invents Act of 2011, the United States switched its patent system from a first-to-invent rule to a first-to-file rule, where priority is given to whomever files a valid application first, bringing the United States in line with international standards. Under a first-to-file rule, disputes may still arise over whether the application filed first satisfied the enablement requirement: whether it described the claimed invention in sufficient detail to enable a person skilled in the art to carry out the claimed invention (35 U.S.C. § 112).

[108] Papers 263 and 264 in interference 104,776, accessed on January 5, 2018, through the USPTO interference web portal: https://acts.uspto.gov/ifiling/. On August 20, 2007, part of the 2005 ruling was overturned, awarding the Queensland team (Frazer) priority over Georgetown (Schlegel), based on the earlier filing date of Frazer's first provisional patent application in Australia instead of the later international filing date. The effect of the 2007 ruling on the claims to which the respective teams were entitled patent protection was not investigated for this report.

[109] Personal communication, Shmilovich.

helped to motivate the parties to reach agreement and so remove a major obstacle to bringing the vaccines to market.

N.2.3 Animal Challenge Studies: Proving the Concept

Successful proof-of-concept studies carried out in the mid-1990s were pivotal to unlocking the next level of private investment. In these, termed *animal challenge studies*, VLPs made either from L1 proteins or both L1 and L2 proteins of papillomaviruses specific to rabbits, cows, and dogs were used to vaccinate those animals. The animals were then tested for a protective immune response, either by exposing the vaccinated animals to the live virus or by transferring the serum of vaccinated animals to unvaccinated ones and then exposing those animals to the live virus to test whether the serum that had been passively transferred contained functional antibodies.

NCI-led teams published rabbit and cow studies (Breitburd et al., 1995; Kirnbauer et al., 1996), a Merck team published a rabbit study (Jansen et al., 1995), and a Medimmune and Georgetown University team published a canine study (Suzich et al., 1995).[110] All four studies showed the vaccines worked to stimulate a protective response in the animals' immune systems. The concept was proven.

One principal barrier to human testing remained. Researchers needed a means of testing the effectiveness of an HPV vaccine without exposing people to a live virus that could cause cancer; they needed an in vitro assay in which serum from vaccinated people could be tested for its ability to neutralize the live virus. That assay was developed by Richard Roden at NCI. Using this assay, NCI researchers showed that antisera[111] raised by vaccination against specific HPV types in mice were highly protective against the HPV type in the vaccine but did not neutralize other HPV types, suggesting that VLP vaccines would

[110] Suzich et al. (1995) was unique among these four studies in showing protection against mucosal as opposed to skin infections. This was significant because it more closely modeled the most dangerous mode of infection in people: high-risk HPV types induce cancer at mucosal sites, not skin sites.

[111] Blood fluids containing antibodies against specific antigens.

be type-specific and highlighting the importance of developing multivalent vaccines (Roden et al., 1996).[112,113]

With the concept of a VLP papillomavirus vaccine proved in animal challenge studies and a quantitative in vitro HPV assay available, the researchers were set for vaccine development to begin in earnest—moving into clinical trials.

N.2.4 Clinical Trials: Making History

In September 1998, Medimmune reported the success of a first-in-human study of a VLP vaccine against HPV-11 in 65 healthy adult volunteers; Richard Reichman of the University of Rochester Medical Center and the principal investigator of the vaccine trial presented the results at the 38th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Diego, California. Injections of the vaccine were well tolerated. HPV-neutralizing antibodies were induced in nearly all volunteers at the higher doses and in all 10 volunteers receiving all three injections at the highest dose (Evans et al., 2001).

The first-in-human study of a VLP vaccine against HPV-16 soon followed. NCI researchers partnered with Johns Hopkins University to perform the study in 72 healthy adult volunteers. The HPV-16 L1 VLP vaccine was well tolerated and found to be highly immunogenic even without an adjuvant, a substance typically added to vaccines to enhance their effectiveness; most volunteers who received the vaccine produced levels of neutralizing antibodies roughly 40 times higher than is observed in response to natural infection (Harro et al., 2001).

Larger clinical efficacy trials followed. In September 1999, Merck launched a pilot trial of monovalent HPV-16 vaccine in 2,409 volunteers (ClinicalTrials.gov Identifier: NCT00365378); in May 2000, Merck launched the first trial of its quadrivalent

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[112] We are grateful to William Bonnez for pointing out the earlier development of an in vitro neutralization assay for HPV-11 by Smith, Foster, Hitchcock, and Isseroff (1993).

[113] In a personal communication, a lead epidemiologist involved in the Gardasil clinical efficacy trials explained that at this time most available vaccines were developed and initially used prior to having the tools needed to determine whether effective neutralizing antibodies had been generated; thus, although serological neutralization assays enabled first-in-human dose-finding trials of the HPV vaccines, helping to gain regulatory approval for the larger clinical efficacy studies that followed, a regulatory pathway to approval could have existed even in their absence.

vaccine in 1,158 volunteers (NCT00365716). After launching two smaller trials in 1999 and 2000, GSK launched a trial of its bivalent vaccine in 1,113 volunteers in January 2001 (NCT00689741). The success of these and subsequent trials led to the regulatory approval of Gardasil and Cervarix in 2006 and 2007.[114]

The results of Merck's monovalent HPV-16 efficacy trial were the first to be announced. Dr. Laura Koutsky of the University of Washington, a lead epidemiologist on the study, told no one beforehand that she planned to present the results as part of her talk at the 19th International Papillomavirus Conference in Brazil in September 2001, then she stunned the audience: 41 cases of HPV-16 infection were observed in that clinical trial; 41 cases in the placebo group and zero in the vaccinated group (Neill, 2018). In a recent interview, John Schiller, who moderated the session, recounts the impact of the talk: "We were all . . . dumbfounded when she was finished. I remember afterwards saying, 'Ladies and gentlemen, you've just seen history'" (Neill, 2018, p. 3).[115]

Today, Gardasil is among Merck's largest revenue generators: from 2015 through 2017, Gardasil (including both the quadrivalent and 9-valent versions) was Merck's third-highest-selling pharmaceutical preparation, generating roughly $2 billion per year.[116] Cervarix accounted for 15% of GSK's £3.5 billion global vaccine sales in 2011; in 2017, Cervarix contributed £134 million to GSK's £5.2 billion global vaccine sales.[117]

[114] See Koutsky et al. (2002), Harper et al. (2004), Future II Study Group (2007), and Descamps et al. (2009).

[115] The initial trial of the quadrivalent Gardasil was so successful it was stopped early so that participants in the placebo group could also be offered the vaccine (https://www.cancer.gov/research/progress/discovery/hpv-vaccines). Grady (2003) provides some insight into the close collaboration between Dr. Kathrin Jansen and Dr. Laura Koutsky behind the vaccine development effort by Merck. The pivotal Gardasil trial included 12,000 patients (Future II Study Group, 2007).

[116] Merck's 2017 Form 10-k, accessed at https://www.sec.gov/edgar.shtml.

[117] GSK's 2011 and 2017 annual reports.

M.3 IMPACT OF HPV VACCINES

The NCI summarizes the effectiveness of HPV vaccines:

> HPV vaccines are highly effective in preventing infection with the types of HPV they target when given before initial exposure to the virus—which means before individuals begin to engage in sexual activity.
>
> In the trials that led to the approval of Gardasil and Cervarix, these vaccines were found to provide nearly 100% protection against persistent cervical infections with HPV types 16 and 18 and the cervical cell changes that these persistent infections can cause. Gardasil 9 is as effective as Gardasil for the prevention of diseases caused by the four shared HPV types (6, 11, 16, and 18), based on similar antibody responses in participants in clinical studies. The trials that led to approval of Gardasil 9 found it to be nearly 100% effective in preventing cervical, vulvar, and vaginal disease caused by the five additional HPV types (31, 33, 45, 52, and 58) that it targets. In a 2017 position paper, the World Health Organization stated that the HPV vaccines have equivalent efficacy. The Cervarix vaccine has been found to provide partial protection against a few additional HPV types not included in the vaccine that can cause cancer, a phenomenon called cross-protection.
>
> To date, protection against the targeted HPV types has been found to last for at least 10 years with Gardasil, at least 9 years with Cervarix, and at least 6 years with Gardasil 9. Long-term studies of vaccine efficacy that are still in progress will help scientists better understand the total duration of protection. (National Cancer Institute, 2018)

M.3.1 NIH Contributions

It is impossible to know when or whether an HPV vaccine would have been developed without the contributions of NIH researchers and the transfer to the private sector of the technology they developed. Reading only recent accounts by Merck-affiliated scientists (Bryan et al., 2016; Scolnick, 2018),

one could be forgiven for thinking public research investment played only a minor role. A broader assessment points to a different conclusion: public investment—in both the NIH Intramural Research Program and extramural research funding of university faculty—likely had profound impacts.

Although Merck and Medimmune both licensed NCI technology—their nonexclusive licenses being converted to co-exclusive licenses in the agreements following the patent-interference proceedings—the vaccine GSK brought to market relied more directly on the NCI method of producing VLPs: the HPV VLPs in Cervarix are produced in what is essentially a scaled-up version of the baculovirus expression system developed by the NCI team in the early 1990s, while Merck's Gardasil uses a yeast expression system. For argument's sake, say that without the NCI efforts only Gardasil would have been developed. In this case, the NCI efforts could be credited with creating competition, plausibly spurring faster development of Gardasil by Merck, making it available to patients sooner, and helping to contain prices once both vaccines were launched—not only saving patients and payers money but also increasing patients' access to vaccination as health systems base coverage decisions on cost-effectiveness.

Much is made of the high rates of attrition among drug development projects—the large number of projects that are abandoned for every new drug approved. Some of this attrition is due to technical failure—a drug candidate that is discovered to have unacceptable side effects or be ineffective; some is due to the changing priorities and market strategies of companies. Had either Merck or Medimmune/GSK faltered or decided to stop or delay their development programs, the NCI team was prepared to move all the way through Phase III with its own vaccine; that was in fact the longer-term goal when NCI partnered with Johns Hopkins for the first Phase I trial.

Perhaps this backstopping proved unnecessary in this case—the net below a trapeze artist who does not fall. But perhaps it was more than that. Given NCI's commitment to pursue its own vaccine development program through to the end, Merck and Medimmune/GSK would have known that if they encountered problems in their own development programs, they would be able to compare with the NCI results to diagnose whether the problem was unique to their vaccine candidate (a poorly

tolerated adjuvant, say) or fundamental to an HPV VLP vaccine. In either case, the companies would have a capable partner to help overcome the problem. This knowledge would have made the development programs appear less risky and therefore more attractive to the companies. It is impossible to know whether at any point in the development of Gardasil or Cervarix this difference was pivotal to sustaining the private-sector efforts; similar considerations surely are pivotal in many other drug development programs.

Similar speculation applies to the major milestones in the vaccines' development. Between 1991 and 1994, four research teams produced HPV VLPs by similar but not identical methods; three of the teams showed that the L1 protein they produced shared antigenic properties of the live virus. Would Merck and Medimmune have continued to invest if NCI had not shown BPV VLPs could stimulate the production of remarkably high levels of neutralizing antibodies and that VLPs of HPV-16 specifically (the most common HPV type linked to cancer) reacted with neutralizing antibodies? In 1995 and 1996, four animal challenge studies proved the concept of VLP papillomavirus vaccination. Given the other two, how important were the NCI rabbit and bovine studies? Having four studies with the same positive result is more convincing than having two, but did it make a difference to private investment decisions in this case?

Likewise, one can only speculate about the impact of the Roden et al. (1996) in vitro neutralization assay, used for the first clinical trial of an HPV-16 VLP vaccine, conducted by NCI and Johns Hopkins University. Merck almost certainly would have used this assay to validate the higher-throughput neutralizing antibody competition assays it developed for its clinical trials—alternative assays were either much more cumbersome or, in the case of HPV-16, nonexistent—although publications do not confirm the link between Roden's assay and Merck's (Yeager, 2000; Smith et al., 2008). Pseudovirus neutralization assays developed later at NCI (Pastrana et al., 2005) were used to develop Merck's competitive Luminex assay (Smith et al., 2008). To be sure, the development of progressively more convenient and flexible neutralization assays involved numerous incremental contributions from many researchers.

M.3.2 Summary and Emerging Research

The HPV vaccines now licensed and saving lives in more than 100 countries are the product of global collaborative efforts among scientists in academia, federal laboratories, and industry. While there are multiple research entities involved and attribution nearly impossible, NCI had prominent contributions to the development of the first two commercial vaccines against the cancer-causing HPV-16 and HPV-18 at every major milestone:

- NCI researchers were the first to demonstrate production of VLPs from papillomavirus L1 capsid proteins;
- they were the first to show, using the BPV model, that papillomavirus VLPs could stimulate the production of antibodies that prevented infection by the live virus;
- they were the first to demonstrate production of HPV-16 L1 VLPs and show that they reacted with and generated neutralizing antibodies;
- they licensed VLP technology to both Medimmune and Merck;
- they were among the first to prove the concept of a VLP vaccine with animal challenge studies;
- they developed the first in vitro HPV-16 neutralization assay; and
- in partnership with researchers at Johns Hopkins University, they conducted the first clinical trial of an HPV-16 VLP vaccine.

In addition to NCI's formal technology transfer efforts, NCI's research collaborations with academic and industry colleagues are credited with contributing to a rapidly evolving HPV knowledge base at a critical time for the vaccines' development. A lead epidemiologist in the Gardasil clinical efficacy trials stated:

> Of great help to the rest of us was their timely sharing of methods and results from both completed and ongoing work. I always learned useful and intriguing information from my discussions with them.[118]

[118] Personal communication.

In turn, Dr. Schiller is full throated in his acknowledgement of the basic research contributions of the academic teams and the "invaluable contributions of Merck, Medimmune, and GSK in bringing these vaccines to market."[119]

Doug Lowy and John Schiller attribute the success of NCI teams in large part to features of the NIH Intramural Research Program (IRP). The IRP affords researchers considerable autonomy: review is mostly retrospective, so researchers can pursue opportunities without having to ask for permission or resources in advance. In the case of the HPV vaccine development effort, this meant that NCI teams were able to stay involved with successive stages of development: from the production and immunogenic analysis of VLPs, through animal challenge studies and the development of clinical research tools, through clinical trials, through efforts today to transfer VLP production and vaccine manufacturing technology to drug manufacturers in developing countries.

The autonomy afforded by IRP also enabled the researchers to take a broader view of the impact of their work. They were able to be less focused on expedient publication than most academic researchers, and they were able to be less focused on licensing a specific product than industry researchers. From the beginning, they chose the baculovirus expression system to produce VLPs because it was an established production system, several clinical trials having already been done with materials produced in such systems, and they reasoned there would be a regulatory path forward if VLPs worked as they hoped. In clinical trials, they were able to pursue questions in the broader public interest: How is the cost-effectiveness of vaccination likely to vary with age?[120] How effective is a vaccine without an adjuvant?[121] How effective is a single dose compared with the recommended three? In general, NIH clinical trials can explore questions company-sponsored trials would not and consequently place richer sets of information in the public domain.

[119] Personal communication with Dr. Schiller.

[120] The older a person is the more likely they are to have been exposed to HPV and already be producing antibodies.

[121] An adjuvant is a (typically proprietary) substance added to vaccines by the manufacturer to increase their effectiveness and extend the duration of protection.

Another helpful feature of the IRP was ready access to multidisciplinary expertise. NCI researchers were able to collaborate with NIH researchers outside their institute—particularly at NIAID and NIAMS—and partner outside NIH, for example with Johns Hopkins University for the HPV-16 Phase I trial.

The ongoing impact of the NCI technology transfer related to HPV VLPs becomes even more apparent when one looks beyond Gardasil and Cervarix. Doug Lowy and John Schiller at NIH, in particular, have championed HPV vaccine implementation in a global public health arena, facilitating technology transfer to vaccine manufacturers in developing countries (Lowy and Schiller, 2006; Schiller and Lowy, 2006). The long-time collaborators are working with emerging-country manufacturers to produce the current-generation vaccine and with companies in India to take less-expensive next-generation vaccines into clinical trials.

NCI researchers have also shown that, unlike L1 VLPs, short chains of HPV L2 capsid proteins can stimulate the production of antibodies that neutralize a wide range of papillomaviruses, raising the possibility of a pan-HPV vaccine (Pastrana et al., 2005). Finally, NCI, along with researchers in Costa Rica, is exploring lower dosing options for low-resource settings that provide similar protection against HPV (Safaeian et al., 2018). Doug Lowy and John Schiller continue to ask the question: "what's next?"

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Appendix N: Case Study of USDA Agricultural Research Service Technology Transfer: Tifton-Bred Turfgrasses

USDA – ARS Tifton-Bred Turfgrasses	
Federal agency:	U.S. Department of Agriculture, Agricultural Research Service
Laboratory:	Agricultural Research Service Tifton
Collaborating entities:	University of Georgia (UGA) College of Agricultural and Environmental Sciences (CAES), the UGA Research Foundation and Innovation Gateway, Georgia Seed Development, Georgia Crop Improvement Association, New Concept Turf, and The Turfgrass Group, Inc.
Transfer object:	Tifton-bred turfgrasses
Inventor(s):	Glenn Burton, USDA-ARS, 1936–2003 Wayne Hanna, USDA-ARS 1971–2003, UGA 2003–date
Invention disclosure date:	TifSport®, TifEagle, TifGrand®, and TifTuf® were patent protected; while TifBlair was protected by Plant Variety Protection Certificate.
Transfer mechanisms:	Licenses
Key dates:	TifBlair, TifSport, and TifEagle were released for sale in 1997 and 1998. TifGrand was released in 2009 and TifTuf in 2014.
Transfer recipients:	Licensed sod producers, golf course and athletic field owners, associated businesses, homeowners, and all users of the turf
Impact summary:	Total royalties collected by USDA-ARS and UGA on just five varieties of certified quality turfgrasses between 1998 and 2017 was $9,700,000, nearly triple the federal share of costs of all research on all grasses at Tifton.

N.1 BACKGROUND

Turfgrasses are the primary vegetative covers for home lawns, schools, parks, roadsides, sports fields, golf courses, and commercial and public buildings and spaces. Turfgrasses have aesthetic and recreational value that generates physical and mental health benefits as well as economic and environmental value. Scientists at the Agricultural Research Service (ARS) of the U.S. Department of Agriculture (USDA) in Tifton, Georgia, developed the first seedless warm weather Bermuda grasses with characteristics that made them best sellers for their various uses. Before the ARS Tifton research took place in the 1940s, little was known about producing, planting, and managing grasses that produce little or no seed. This case study covers five turfgrasses developed collaboratively and released by ARS and the University of Georgia between 1998 and 2014 that are descendants and improved versions of those initial grasses, including the very popular TifWay released in 1965. The new turfgrasses are replacing the initial versions, generating improved private and public value. These turfgrasses were extensively tested for important characteristics in a variety of real-world conditions that researchers knew were important to different users, as well as for safety and the environment. This emphasis on research that serves the agricultural industry and the public is aligned with USDA's research and extension mission.

The study also describes a systems approach to technology transfer and market promotion that is perhaps unique to U.S. agriculture. This system is a collaboration of the ARS Tifton, University of Georgia (UGA) College of Agricultural and Environmental Sciences (CAES), the UGA Research Foundation and Innovation Gateway, Georgia Seed Development, Georgia Crop Improvement Association, and Georgia sod producers. The technology transfer system integrates plant breeding research, IP protection and strategic licensing, product quality control, and cooperative marketing to customers in Georgia and around the world. The five Tifton turfgrasses are selling well, as indicated by more than $9 million in royalty payments. While quantitative data on the economic and environmental impact of the five specific Tifton turfgrasses are not available, aggregate studies show large benefits where the five turfgrasses clearly play a role. Environmental benefits of turf from reduced erosion, carbon dioxide reduction, reduced rainfall runoff, and

reduced sports injuries have been documented. The golf industry in the United States generates $20 billion in net income annually and more than 480,000 jobs, as reported in a 2008 study. A 2014 study of the turfgrass production and related industry in Georgia calculated that the industry contributed $4 billion in output into Georgia's $700 billion economy. While not all of these impacts are attributable to USDA, the golf industry in particular likely would not have grown without the new turf. This case study documents the history, outcomes, and impact of technology development and transfer of "Tifton turf" from the USDA-ARS research laboratory through the Research Foundation of their collaborators at the UGA to sod producers and the context in which these occurred.

N.1.1 Tifton Turfgrasses

Before the ARS Tifton research took place in the 1940s, little was known about producing, planting, and managing grasses that produce little or no seed. Four of the five turfgrasses that are the subject of this study are warm-weather sterile bermudagrasses that stem from ARS-Tifton research on bermudagrasses going back to 1928 and improve upon them. The other is a warm-weather centipede grass that can be sold as seed or sod. Sterile grasses are vegetatively propagated from sprigs, produce no pollen, and result in a vegetative cover that stays very uniform over time. These grasses propagate by rhizomes, the creeping underground stems forming new roots and shoots, and stolons, horizontal branches from the base of a plant that produces new plants from buds at its tip or nodes. When cut from the parent plant, the rhizome or stolon forms a new plant, unlike many roots that die.

For vegetative turfgrasses including the five that are the subject of this study, there are no federal or state standards. The purity of seeds is regulated and can be tested in a laboratory, but the purity of vegetative grasses can only be seen by visual inspection of the grass over multiple years. Uniformity of color, resistance to weeds and drought, and other traits are not usually visible immediately upon planting. According to the people who were interviewed, certification of the quality of the Tifton turfgrasses became important starting in the 1980s when more alternative grasses came on the market.

The five turfgrasses central to this study are listed below in the order in which they were released for sale.

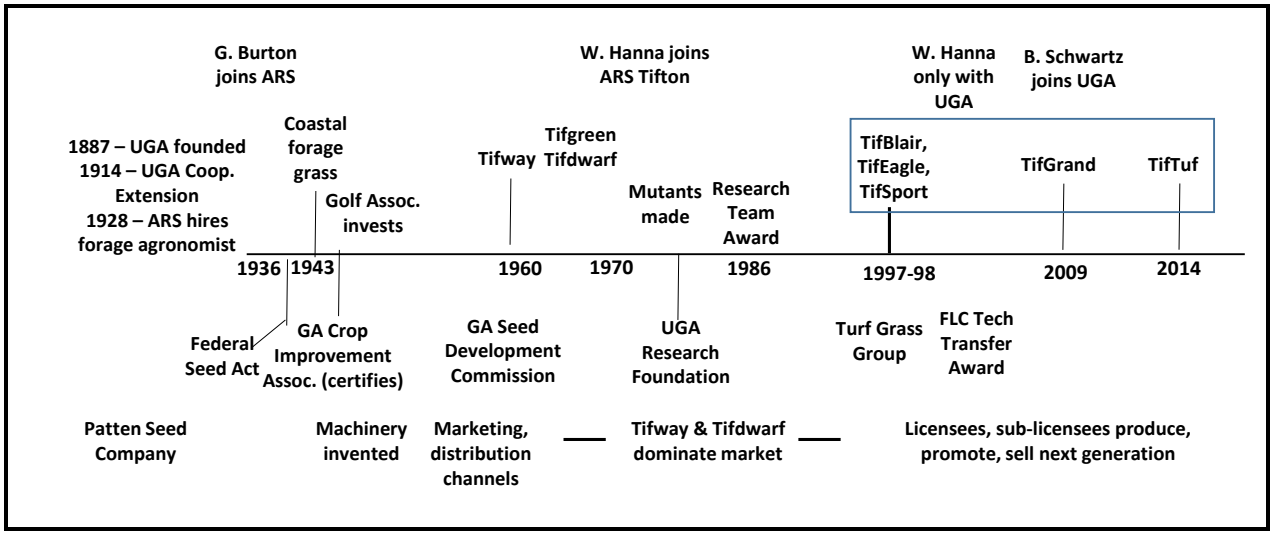
- **TifBlair** centipedegrass, a warm-season grass that forms a thick sod, was released by USDA-ARS in 1997. It does well on highway roadsides or commercial and residential lawns.
- **TifEagle** third-generation hybrid bermudagrass, developed exclusively for golf greens, was released by ARS in 1998. It can tolerate two to threw mowings per day at heights as low as 1/8-inch with no loss of stand density. Research shows TifEagle also recovers more quickly from mechanical injury, has better color, and is extremely cold hardy, drought tolerant, and disease resistant.
- **Tift 94 TifSport®** hybrid bermudagrass was released by ARS in 1998. Athletic field managers and golf course superintendents report outstanding regrowth from normal play and injury to the grass. TifSport has good drought tolerance, stays green longer but also recovers faster in the spring, and has shown to be a nonpreference by mole crickets, which damage turf in warm weather.
- **ST-5 TifGrand®** hybrid bermudagrass, developed to produce a superior turf cover in full sun and to thrive in limited light environments, was jointly released by ARS and UGA in 2009. It has a significantly reduced fertilizer requirement, reduced water requirement, and an increased cold tolerance. Three of the stadiums for the World Cup for Soccer held in Brazil were planted with TifGrand.
- **DT-1 TifTuf®** hybrid bermudagrass, a drought-tolerant bermudagrass using 38% less water than its predecessor, was jointly released by ARS and UGA in 2014. It also exhibits wear resistance, persistence in the shade, and widespread adaptability. The Federal Specialty Crop Research Initiative has identified TifTuf® as the most drought-tolerant bermudagrass, becoming the new standard. TifTuf greens up early and maintains its color well into the fall.

N.2 TECHNOLOGY NARRATIVE

The 90-year timeline in Figure N-1 summarizes when important people and organizations began their involvement in the technology's development and when the five turfgrasses and their significant predecessors were released. The research and

development are above the timeline, and market players and actions are below the timeline. Tracing the history of development and technology transfer shows how initial research discoveries require corresponding inventions of technology to plant sprigs and new organizations to grow initial sod for sale and to certify and promote its origins and quality. The following sections describe this history in more detail.

Figure N-1. Historical Development of Tifton Turf and the Turf Industry in Georgia and Beyond



N.2.1 History of Lab/Agency Involvement

Background on Research Organizations and Researchers

This study demonstrates well how research builds on past research. In 1895, USDA established the Division of Agrostology to study native and foreign grasses and appointed Frank Lamson-Scribner as the first agrostologist. In this role, he expanded the number of species in the grass garden on the National Mall in Washington, DC. He also hired field agents to collect grasses throughout the United States. In the Division's first annual report, Mr. Lamson-Scribner listed 16 species that the Division's research determined had the most potential for lawns.[122]

In 1916, USDA established a turf garden in Arlington, VA. The goal of the turf garden was to study turfgrass diseases,

[122] T.T. Taylor, 1957. Turfgrass- Its Development and Progress. USGA Journal and Turf Management 10:30.

fertilizers, propagation, and selection of superior types. Research focused on creeping bentgrass because of its tolerance to heavy traffic and low mowing, which makes it an ideal grass for golf courses and sports fields.[123]

In 1919, the Georgia state legislature created a 206-acre agricultural experiment station in Tifton, affiliated with the University of Georgia. As an integral component of the Tifton Campus research, extension, and teaching efforts, the Coastal Plain Experimental Station now includes 7,000 acres in south Georgia with four research farms and centers. Both UGA and USDA-ARS scientists are based at the station, a partnership that dates to 1924.[124] In 1928, USDA-ARS established the initial bermudagrass introduction nursery with Tifton bermudagrass they had discovered growing in a nearby cotton field.

In 1936, when Glenn Burton, a USDA-ARS geneticist, came to the Tifton Station, "little if anything was known about breeding and improvement of bermudagrass" (Hanna and Anderson, 2008). Glenn Burton spent his nearly 70-year career at ARS in Tifton. He authored 777 publications from 1936 to 2003. Another prolific researcher, Wayne Hanna, was at ARS Tifton from 1971 to 2003, an adjunct faculty at UGA from 1980 to 2002, and part-time faculty there since 2003. Dr. Hanna is author or coauthor of over 670 scientific papers and holds 24 plant patents.

USDA-ARS has consistently collaborated with researchers in the UGA College of Agricultural and Environmental Sciences (CAES). Dr. Hanna moved his employment to UGA in later years. Initially the IP for new turf varieties belonged to the USDA-ARS, but eventually new varieties developed at UGA by UGA researchers from experiments initiated at ARS were jointly owned by USDA-ARS and UGARF. The IP for TifBlair, TifSport, and TifEagle are 100% owned by ARS. UGARF had (still has with TifBlair) exclusive license to ARS's rights in those varieties until patents expired, including the right to sublicense. The IP is owned jointly between ARS and UGARF for TifGrand and TifTuf

[123] F. Lamson-Scribner, 1896.Useful and Ornamental Grasses. USDA, Division Agrostology, Grass and Forage Investigations, Bulletin 3.

[124] http://www.caes.uga.edu/research/experiment-stations/coastal-plain-station.html

because the researchers that developed the grass were employed by UGA CAES and ARS.

USDAARS Tifton and the UGA CAES continue to work together and collaborate on turf research, with individuals from either organization having different specialties. ARS still does crop genetics and breeding research in Tifton, Georgia, with funding from USDA. Their objective is to improve the productivity, quality, and persistence of warm-weather grasses grown for forages, bioenergy, and turf, as well as develop improved production strategies to meet life-cycle objectives including carbon sequestration.[125]

The CAES Institute of Plant Breeding, Genetics and Genomics was approved by the Georgia Board of Regents in 2008 and includes 19 plant breeders located on UGA campuses at Athens, Griffin, and Tifton. Along with North Carolina State University, the University of Florida, Texas A&M University, and Oklahoma State University, the Institute has 2009–2014 and 2016–2019 grants from USDA to develop drought- and salt-tolerant grasses. UGA also received funds for turf research under the USDA Specialty Crop Research Initiative in 2017. According to UGA researcher Brian Schwartz, "Over 81 laboratory, greenhouse, and field evaluations were underway at UGA in 2017 to maintain the pipeline that has provided leading turfgrass cultivars for over half a century."

Development of New Grasses

Glenn Burton, the USDA-ARS geneticist, developed the initial new hybrid grasses from Tift bermudagrass and two hay-type bermudagrasses from South Africa. One of the plants that emerged from his research in 1943 was called "Coastal." In the testing process it became evident that it might be possible to vegetatively propagate bermudagrass commercially, which has advantages of uniformity. Burton and others invented tools for the planting, including a two-row planter. Coastal was widely used for hay and grazing.

The success of Coastal set the stage for development and use of all the Tifton sterile vegetative turfgrasses (Hanna and Anderson, 2008). In 1946, the U.S. Golf Association (USGA) Green Section gave USDA-UGA a $500,000 grant[126] to

[125] https://www.ars.usda.gov/research/project/?accnN=434018
[126] Equivalent to $6,300 in 2017 adjusted for inflation.

supplement forage grass research to develop a better bermudagrass to replace existing sand greens or seeded bermudagrass greens. Plugs from the best parts of the best greens were planted along with by-products of the pasture-breeding program, and plots were tested and visually inspected and rated for sod density, color, frost and drought tolerance, resistance to weeds and diseases, and overall turf quality. Tiflawn bermudagrass was released in 1952, and it was crossed with a more fine-leafed grass, the best of which was Tifline, which was completely sterile. Better bermudagrass kept coming with Tifgreen and then Tifway, which was released to the public in 1960. Tifdwarf, a natural mutant of Tifgreen, was discovered and tested in this same time period and proved to tolerate lower mowing than Tifgreen and thus worked well as faster putting greens (Burton, 2005). Tifway covers more golf courses, athletic fields, and lawns than any other turf variety in the world[127] but is being rapidly replaced by TifTuf.

The growth of the turf industry involved a collaborative effort between research and industry. As reported in a 2008 historical account, "What we have in turf today did not just happen. It took hard work, cooperation, invention, risk, entrepreneurship, financing, promotion, and so on" (Hanna and Anderson 2008). Important players were Patten and Roquemore of Patten Seed Company and Jensen of Southern Turf Nurseries, who from the mid-1950s promoted the grasses traveling by car, advertising and promoting to Sears and other garden stores (Hanna and Anderson, 2008). Out of necessity, the industry invented machinery in the late 1950s for digging, planting, and fumigation for golf courses and sports fields. In the 1950s and 1960s, USDA-ARS completed numerous dies on mowing heights and fertilizer types, and this information was used by industry and helped them attain healthier grasses.

The ARS continued turfgrass research, and the results are the varieties that are the specific focus of this case study. The sterile triploid hybrids cannot be improved through conventional plant breeding methods. They can be modified using more sophisticated methods, which was done in Tifton in the late 1970s and in the 1980s by Wayne Hanna: it resulted in the release of TifBlair, TifSport, and TifEagle. TifSport had improved

[127] http://extension.uga.edu/topic-areas/field-crop-forage-turfgrass-production/turfgrass.html

cold resistance and density and began to replace Tifway. TifEagle, which can be mowed daily, began to replace Tifdwarf. TifTuf, released in 2014, is expected to quickly be a best seller in large part because it uses 38% less water to maintain quality turf.

N.2.2 Transfer of the Turfgrasses to the Turf Industry

A Systems Approach

As the turfgrass ecosystem matured in Georgia, the entities involved developed a systems approach for the transfer of new ARS-UGA cultivars to the private sector, reflecting the nature of the product and the market. This ecosystem integrates plant breeding research, IP protection, quality control certification, and marketing to customers in Georgia and around the world.

This ecosystem is shown in Figure N-2. Researchers at USDA-ARS and UGA CAES develop and test the new varieties of turfgrasses and give them to UGARF to patent or otherwise protect the IP. UGARF works with Georgia Seed Development (GSD) to grow the initial fields of grasses that can be sold, and the Georgia Crop Improvement Association inspects and certifies those foundation fields and all fields grown by licensed sod producers. As the GSD website states, "By working together, these four entities advance the knowledge of plant genetics, address anti-piracy issues and ensure the very best varieties are available to satisfy increasing global demand for crop output." A description of the players and the process follows.

- **UGA CAES** The University of Georgia College of Agricultural and Environmental Sciences (including USDA-ARS collaborations) has a peer-reviewed process during which data are reviewed on a potential new plant cultivar. If the data support the claims of improvement over available cultivars, then the release committee recommends to release the cultivar for commercialization.
- **The University of Georgia Research Foundation Inc**. (UGARF) was established in 1978. Located on the UGA Athens campus, UGARF owns the IP developed by all UGA employees.[128] It is responsible for protecting IP and for strategically managing UGA-CAES plant material licenses. USDA-ARS licenses its rights to the plant

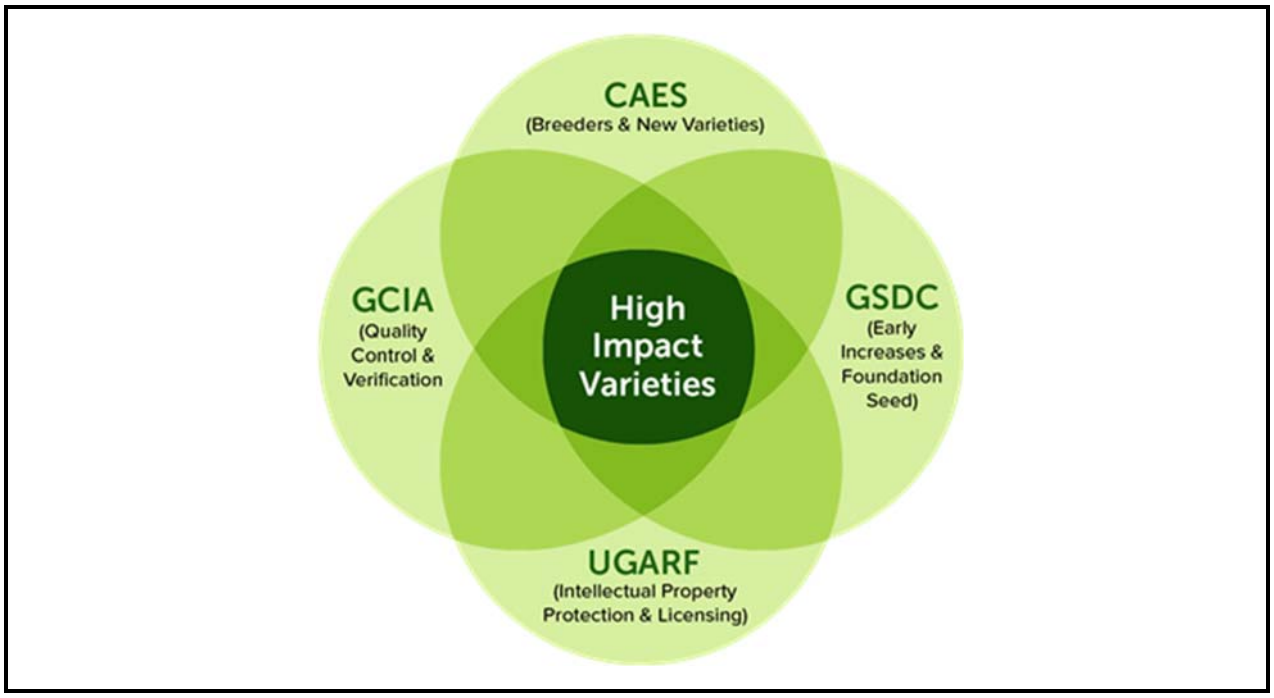
[128] https://research.uga.edu/ugarf/

material it has developed collaboratively with UGA employees to UGARF to license and manage. Through Innovation Gateway,[129] UGARF protects, markets, and licenses its IP portfolio throughout Georgia, the United States, and across the globe.

- **Georgia Seed Development** (GSD) was created in 1959 by the Georgia state legislature as a state commission to produce seed and plant stock from improved plant varieties developed by scientists at UGA-CAES and provide the seed and sprigs for commercial use. In 1997, the same year the first of the five grasses in this study was released for license and sale, UGARF and GSD developed an agreement on the licensing and distribution of plant varieties developed by USDA-ARS and UGA plant breeders. GSD now manages royalty assessment and fee collection for plant varieties licensed by UGARF/GSD. In 2008, the Georgia state legislature amended the GSD's charter to allow them to be a nonprofit public corporation and to offer services to plant breeding operations in other states.[130]
- **The Georgia Crop Improvement Association** (GCIA) was established in 1946 to provide a quality assurance program that maintains the varietal quality and purity in Georgia, including certain UGARF-licensed varieties. GCIA is a member of the Association of Seed Certifying Agencies. GCIA developed the standards for certification that turfgrass contains no noxious weeds, common bermuda, and other contaminating turfgrass varieties. They train inspectors in Georgia and other states. UGARF turfgrass licenses require that licensees sell only certified turfgrass to customers. GCIA does the inspections in the state of Georgia, and out-of-state licensees have their turf fields inspected by their respective state's certifying agency.

[129] https://research.uga.edu/gateway/
[130] http://gsdc.com/about-us/systems-approach/

Figure N-2. Systems Approach Integrates Research, Licensing, Quality Control, and Marketing



Source: Georgia Seed Development website

Certification

Certification of the quality of the turf became important to sellers and customers starting in the 1980s when alternative grasses came on the market. The quality of the turf can only be seen by visual inspection over more than a year of growth. This is unlike verifying the quality of seeds, which can be done immediately and where there is regulation for seeds such as cotton and wheat under the Federal Seed Act, as well as many other state regulations. The Federal Seed Act, P.L. 76-354 (August 9, 1939) requires accurate labeling and purity standards for seeds in commerce and prohibits the importation and movement of adulterated or misbranded seeds.[131] The Act also requires that all agricultural states establish crop improvement associations. These crop improvement associations inspect and certify the quality of vegetative crops, as discussed earlier.

Certified grasses provide the end consumer with the assurance that they are receiving varietal purity, although they may pay more for this assurance. Especially when planting large areas

[131] https://www.ams.usda.gov/rules-regulations/fsa

that are used for generating revenue such as golf courses and athletic fields, planting the wrong turf can be a very costly error. "When told of the benefits of certified sod, consumers we have surveyed say they would be willing to pay $20 to $25 more per 500-square-foot pallet," according to the Annual Georgia Sod Producers Inventory Survey conducted by Clint Waltz, University of Georgia Cooperative Extension turfgrass specialist, and the Georgia Urban Ag Council.

Licensing and Marketing

TifSport, TifEagle, TifGrand, and TifTuf discussed in this case study have been patented, while TifBlair has been protected by Plant Variety Protection Certificate. The more recent varieties have also been trademarked to protect them when the patent runs out. The IP for the first three varieties introduced belongs to USDA-ARS. TifGrand and TifTuf are jointly owned by USDA-ARS and UGARF. UGARF is the owner of IP for UGA inventions or co-inventions. USDA-ARS has consistently collaborated with UGA researchers. Dr. Hanna moved his employment to UGA in 2003.

UGARF licensing was very new when TifEagle and TifSport were released in 1998–1999. UGARF exclusively licensed ARS's rights to these early varieties and then sublicensed their rights nonexclusively to multiple sod producers to maximize the opportunity for broad market penetration. In addition to requiring certification as a part of their licenses, a small percentage of the sales royalty was set aside by UGARF for a coordinated advertising campaign for the variety to benefit all the growers. UGARF employed an outside company to coordinate the advertising efforts, which were voted on and directed by the growers themselves. This worked well at the time. As more competition came from other turf cultivars, UGARF switched to an exclusive licensing model for the new ARS-UGA varieties TifGrand and TifTuf because extensive advertising expenditures are necessary in the current marketplace and that was most effectively done by a single licensee rather than by group decisions of multiple licensed producers. Everyone interviewed agreed that this model has been successful thus far.

After release in 2009 and 2014, TifGrand and TifTuf were both exclusively licensed to New Concept Turf by UGARF in a competitive RFP process. New Concept Turf is a company

formed and owned by successful sod producers of the earlier "Tif" turf cultivars. New Concept Turf has a contract with an affiliated company, The TurfGrass Group (TTG), to market and sublicense TifGrand and TifTuf to producers. The Turfgrass Group, Inc. was founded in 1997 by two men who had been in the sod business in Georgia since the mid-1980s and were committed to its growth and development. Each producer within the New Concept Turf license has a separate sublicense to produce. The Turfgrass Group chooses to limit the number of licensed certified producers in each geographic area to help ensure each is profitable.[132] The Turfgrass Group provides oversight of the sublicensed growers to ensure quality and genetic purity, along with UGARF's continued requirement that UGA turf cultivars only be sold as certified turfgrass. According to one of its founders, TTG has come up with a unique model for structuring sublicenses that helps licensees manage the capital costs, time to establish a new field, and other risks of growing a new crop.

Marketing by TTG is "intense, widespread and continuous," addressed to professionals and professional associations across the country at the national, regional, state, and sometimes local levels. Media include print advertising, direct mail, press releases, articles, e-mail campaigns, trade show exhibits, web sites, and participation in online forums. TTG also asks all licensed growers to use a label they provide on every invoice setting forth the patent and the prohibition of unlicensed propagation. TTG offers all marketing designs to licensed growers for their own marketing purposes at no charge.

Recognition for Excellence

This systems approach yielded recognition and awards. To name a few:

- Researchers at ARS Tifton were recognized for all their innovative work by the USDA Forage and Turfgrass Research Team Award in 1986. The development and testing were not just done in Georgia. To test in different soils and climates and to receive opinions from other experts, the ARS and ARS-UGA teams tested the cultivars across the southern half of the United States on university test fields and private properties such as golf courses.

[132] http://theturfgrassgroup.com/

- USDA-ARS researchers in Tifton received the Federal Laboratory Consortium Award for Excellence in Technology Transfer in 2001 for developing greener, more durable Bermuda grasses for athletic fields and golf courses.
- ARS researchers in Tifton also received the USDA Outstanding Technology Transfer Award in 2002.

Current Status of Market and Research

If turf growing on home lawns, parks, golf courses, athletic fields, and sod farms are counted, estimates are that between 40 million[133] and 50 million acres[134] of turf are grown in the United States. This compares to between 72 million and 75 million acres of soybeans and corn and 64 million acres of hay/forage crops. For the state of Georgia, facts put out by CAES on the Georgia Turf website state that at 1.8 million acres, turfgrass is one of the largest agricultural commodities in the state of Georgia.

According to the lead Bermuda grass researcher at UGA, Brian Schwartz, in 2017 there were 22 farms producing TifGrand on about 1,000 acres. TifTuf production has expanded rapidly, and there were 47 producers in the United States and internationally growing it on approximately 4,000 acres (Schwartz, 2017). The 2014 Center for Agribusiness and Economic Development Farm Gate Value Report compiled by UGA reported nearly 24,562 acres used for producing sod/stolens. The value of the production was $104.3 million, a 15% increase from 2013. In 2016, the Georgia Crop Improvement Association reported 7,530 acres of certified grass in production, which is a 15% increase from 2015. This 7,530 acres in production represents four warm-season species (bermudagrass, centipedegrass, seashore paspalum, and zoysiagrass) and one cool-season species (tall fescue).[135]

N.3 IMPACT OF TECHNOLOGY TRANSFER

Beyond the well-established link between crop research and agricultural productivity improvements, the following describes the impact of USDA turfgrasses on consumers, the environment, the public sector, and industry.

[133] http://gsrpdf.lib.msu.edu/ticpdf.py?file=/2000s/2006/060926.p
[134] USDA NASS Census of Agriculture 2002
[135] http://caes2.caes.uga.edu/commodities/turfgrass/georgiaturf/Industry/1420_Facts.htm

Consumer benefits: Turfgrasses are the primary vegetative covers for home lawns, schools, parks, roadsides, sports fields, golf courses, and commercial and public buildings and spaces. Turfgrasses have direct benefits for the people using them and involved in producing and selling the grasses and related products and services. As stated above, estimates are that this is between 40 million and 50 million acres of turf in the United States.

Environmental impacts: Turfgrasses also produce considerable environmental benefits. In a 2013 article reviewing the literature on the benefits and issues of turfgrass, Steir et al. stated that turf research emphasis has changed from improving aesthetic quality to improving the environmental impact of turf management. Turfgrasses have a proven ability to mitigate runoff from urban environments, absorb atmospheric pollutants, provide evaporative cooling that translates into energy savings and improved comfort, remediate contaminated soils, increase property values, deter pests, and enhance mental health.

At the same time, there are some environmental concerns with turf management practices regarding water consumption and pollution, human and environmental risks from pesticide application, fossil fuel use and emissions, mowing injuries, lack of suitable habitat for most wildlife species, lack of land application for crop production, and the potential of turfgrasses to invade natural areas.

Direct public returns from royalties paid by licensees: One measure of economic impact of turfgrass research is the comparison of the research expenditures to the royalties received from licensing products of the research. Because this turfgrass research, which initially was done at USDA-ARS Tifton, then collaboratively by USDA-ARS and UGA, and then by UGA building on the initial and collaborative work, it is not possible to separate public benefits between federal and state effort. Licensing royalties are shared for each of the five cultivars in proportion to the employment of the developers of that cultivar.

Managers of the ARS program estimate that about 20% of USDA funding for research on grasses in Tifton went to research on turfgrasses, including the five of interest in this study. This funding totaled $1,186,000 for the fiscal years

between 1994 and 2000 and $2,574,000 between 2001 and 2012 for a combined total of $3,760,000. According to UGARF, total royalties collected on just the five turfgrasses between 1998 and 2017 was $9,700,000.[136] Therefore, royalties for the five turfgrasses were almost triple the federal cost of all research on all grasses at Tifton. The UGA expenditures are not included in this calculation. Note that about half of the royalties that UGA receives go back into CAES research programs, as do a percentage of royalties received by USDA-ARS.

Impact on the sports and recreation industry: We find that the Tifton turfgrasses are used widely in golf courses across the southern United States as well as in other sports, such as in soccer fields, including some fields where the World Cup has been played. The golf industry was an early adopter of these licensed and certified turfgrasses for economic reasons.

N.3.1 Conclusions

Two exceptionally productive USDA-ARS researchers and their ARS and UGA colleagues pioneered the worldwide success of Bermuda turfgrasses starting in the 1950s. Tifway bermudagrass, one of the initial sterile hybrid bermudagrasses developed at the Coastal Plain Experiment Station in Tifton, Georgia, covers more golf courses, athletic fields, and lawns than any other turf variety in the world.[137] TifBlair is a warm-weather centipede grass that thrives in poor soil with little maintenance and is very useful for roadside planting. Further, in the last 20 years, ARS and UGA researchers have developed third-generation sterile hybrid bermudagrasses including the four highlighted in this case study that have improved on characteristics that made the initial vegetative turfgrasses very successful. The newest of these introduced in 2014, TifTuf is expected to be a best seller in large part because it uses 38% less water to maintain quality turf. TifEagle has replaced Tifdwarf because it provides the fastest putting green surface available anywhere. TifSport provides exceptional turf for athletic fields, as does TifGrand, which does well in the shade. These grasses have been extensively tested for important characteristics in a variety of real-world conditions that researchers knew were important to the different users, as well

[136] All figures in this paragraph are in nominal dollars.
[137] http://caes2.caes.uga.edu/commodities/turfgrass/georgiaturf/Industry/1420_Facts.htm

as for safety and environmental considerations. This emphasis on research that serves the agricultural industry and the public is aligned with the USDA research and extension mission.

The turf industry in Georgia invented new equipment to dig, plant, and fumigate the vegetative turf, and the industry developed distribution channels and sales. The acres planted and the number of sod producers and geographic distribution of sod producers for these Tifton turfgrasses have expanded substantially over the years. Growers have formed producers' groups for each variety to combine forces to promote that variety in the market. The federal- and state-supported institutions that are part of the agricultural market also played important roles. Georgia Seed Development, originally a state commission and now a nonprofit public corporation, is the intermediary that grows the initial fields of turf that will then be sold to licensed producers 2 years later. The Georgia Crop Improvement Association and similar associations in other states employ experts to inspect and certify turf of all licensed producers prior to sales. This is important because the quality of turf sold to a customer is only determined by visual inspection over multiple years.

UGA's Research Foundation and Innovation Gateway handles all the IP protection and licensing for cultivars developed by USDA-ARS Tifton and UGA CAES researchers. UGARF has the expertise, years of experience, and relationships with the other actors to be highly effective in transferring the new cultivar releases to industry so they achieve the broadest possible benefits to all stakeholders. The technology transfer system integrates plant breeding research, IP protection, quality control, and marketing to customers in Georgia and around the world.

The royalties of $9.7 million received by ARS and UGA between 1998 and 2017 from licensing the five turfgrasses are almost triple USDA research expenditures of $3.7 million on all grasses at Tifton between 1994 and 2012. These royalties go back to the ARS and UGA Tifton in percentages dependent on where the inventers were employed. Although quantitative data on the economic and environmental impacts of the five specific Tifton turfgrasses are not available, aggregate studies show large benefits to turfgrass producers, turf users, associated businesses, and the general public where the five turfgrasses

clearly play a role. Environmental benefits delivered by turfgrasses from reduced erosion, carbon dioxide reduction, reduced rainfall runoff, and reduced sports injuries have been documented. As of 2008, the golf industry in the United States generated $33 billion in gross output and $20 billion in net income annually, and more than 480,000 jobs, as reported in a 2008 study. Without the unique turfgrasses that enhance golfing where they are used, golfing as an industry would generate fewer revenues. A 2014 study of the turfgrass production and the related industry in Georgia calculated that the industry contributed $4 billion in output to Georgia's $700 billion economy.

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