Accelerating Therapeutic Innovation: A Framework for AI-Enabled and Data-Driven Pharmaceutical Public-Private Partnerships

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While the leader of Deloitte's Future of Healthcare initiative, Mr. Mehendale developed the "Wellbeing as a Service" platform, which created data-enabled ecosystems to improve patient healthcare outcomes. He also identified a $4 billion "Drug Discovery as a Service" opportunity, worked on the acquisition of an AI company, and engaged with emerging life-science clients in the midcap sector to drive growth. He forged a transformative partnership with a leading AI and internet technology firm to develop a next-generation, collaborative bio-medical research platform. He holds a Master of Business Administration from Harvard Business School, a Master of Science from the University of Wisconsin-Madison, and a Bachelor of Engineering from the University of Pune.

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Abstract

We propose a framework for transformational pharmaceutical public-private partnerships (P3s) to accelerate the movement of discoveries from the bench to the bedside and the more rapid identification and approval of secondary uses of existing drugs through a multi-sided platform managed by a trusted intermediary utilizing artificial intelligence (AI). This AI-driven platform will enable pharmaceutical firms and other innovators to share valuable data without compromising their proprietary rights. The proposed platform would be developed and managed by a technology company or other entity with deep experience in AI. This entity would, under a written multilateral contract, act as a trusted intermediary and provide participants with a readily searchable knowledge database within a secure, encrypted environment. Like the government-industry collaborations that led to COVID-19 treatments in record time, our proposed P3s would be sponsored by US governmental agencies utilizing the "Other Transaction Authority" granted by Congress to cut through regulatory "red tape" and expedite projects deemed important to the public interest. The goal of what we have called "CureFinder" would be to accelerate the transformation of scientific data into life-saving therapies in a manner that efficiently and equitably balances the interests of taxpayers, universities, patient advocacy groups, the pharmaceutical industry, and other stakeholders.*

*Aspects of this chapter are drawn from "Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside" (Bagley & Tvarnø, 2014), and "Promoting 'Academic Entrepreneurship' in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient" (Bagley & Tvarnø, 2015), and the authorities cited therein.

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I. Introduction

The pharmaceutical industry and the government agencies that allocate funds to university scientists conducting life sciences research are at a crossroads. (Unless the context expressly indicates otherwise, we use "universities" to include nonprofit research institutions and similar entities.) The traditional linear pharmaceutical business model, centered on high-cost firm-by-firm proprietary research and development and the licensing of promising, but expensive, taxpayer-funded discoveries from individual universities, has proved increasingly untenable. Historically, the National Institutes of Health (NIH) was able to rely on initiatives like the 21st Century Cures Act to fund billions of dollars in grants to support both basic and applied medical research in university laboratories (e.g., National Institutes of Health [NIH], n.d., *The 21st Century Cures Act*). Yet record budget deficits, calls for more efficient government spending,

and other policy shifts have brought into laser focus the fact that both new drugs and secondary uses of existing drugs cost too much and take too long to move from the bench to the bedside (Gaspar et al., 2012, p. 980). (Although the term "drugs" is used primarily to refer to pharmaceutical treatments designed to treat, cure, or prevent diseases or ameliorate other medical conditions, the benefits of our proposals extend equally to biologics and vaccines.)

Pharmaceutical firms face multiple challenges that impede the efficient translation of scientific discoveries into life-saving therapies. As Arslan et al. explain, "'the drug-development process in biotechnology is beset with extremely high uncertainty and occasional serendipity'" (2024, p. 560).

Pharmaceutical companies invest billions in the high-risk endeavor of developing innovative and commercially viable drugs. To recoup these substantial investments, they rigorously safeguard their discoveries and clinical data until intellectual property (IP) protection is secured. The intellectual property regimes governing pharmaceuticals, which are primarily determined on a country-by-country basis, are particularly complex and dynamic. Drugs are usually protected by patents, which generally preclude others from making or selling the patented drug in the jurisdiction that granted the patent for a specified period of time. To be patentable, an invention must be kept secret until a patent application is filed. Patent cliffs, generic competition, and the treatment of biosimilars pose significant challenges to firms seeking to maintain market exclusivity and predictable revenue streams to recoup their investments and to earn profits adequate to attract the capital necessary to fund discoveries. Once the patent expires, anyone can make or sell the drug in the country that issued the patent. A firm may elect to keep certain information, including data, perpetually confidential as a trade secret. However, if the owner of a trade secret fails to take reasonable steps to maintain its secrecy, then the information can be used by anyone, unless the person seeking to use it has agreed in advance of disclosure to keep it confidential (typically through a nondisclosure agreement signed before the information was disclosed). As a result, firms tend to closely guard their data, limiting external collaboration and fostering a culture of secrecy rather than open knowledge exchange, at least until they can secure IP protection.

The need to keep inventions secret until IP protection is secured has contributed to a culture of secrecy that hinders the free flow of valuable data and knowledge. This culture of secrecy impedes not only the development and commercialization of new compounds but also the commercialization of secondary uses for existing drugs.

Developing a new drug comprises five stages: discovery, preclinical, clinical Phase 1, clinical Phase 2, and clinical Phase 3 drug trials (Arslan et al., 2024, p. 563). The degree of technological uncertainty varies depending on the stage. The discovery and preclinical stages represent the highest levels of technological uncertainty. During the discovery stage, "scientists search for a molecule that will address an indication (a medical condition or a disease) through the intended biological mechanism of action" (Arslan et al., 2024, p. 560). "Once the research in the drug-

discovery stage converges on a specific molecule with supporting evidence for its potential usefulness, the molecule is moved to the clinical stage for human testing and eventual commercialization" (Arslan et al., 2024, p. 560).

Uncertainties, such as "a drug's toxicity, absorption, diffusion, metabolism, exertion, and intended and unintended molecular-level interactions," which can lead "to desirable or undesirable biological outcomes," are "resolved progressively" during the clinical phases (Arslan et al., 2024, pp. 560, 564). "Phase 1 tests toxicity, Phase 2 tests efficacy, and Phase 3 tests efficacy and added value" (Arslan et al., 2024, p. 564). "Although the clinical stage unfolds over multiple phases, technological uncertainty is lower because there are far fewer parameters for experimentation than in the discovery stage" (Arslan et al., 2024, p. 560).

> With fewer parameters to affect the outcome, the success of the clinical stage is heavily contingent on the appropriate execution of best practices for clinical trial operations. These processes involve determining the right clinical endpoints, selecting and monitoring patients, training and coordinating clinicians, ensuring a stable supply of the drug, and compliance with regulatory requirements. (Arslan et al., 2024, p. 560)

If the clinical trials reveal unacceptable levels of toxicity or fail to demonstrate that the compound being tested is effective in treating the primary indications of interest to the entity running the trials, then the compound tends to languish on the shelf and the data generated during the trials remains locked up in the vault of the owner (or licensor) of the compound and the data. The same holds true of potential secondary uses of an existing drug not of strategic interest to the owner of the drug and data. Data are often kept secret, "even in circumstances where it might be in the economic interests of the firm" to disclose information about technology it is not exploiting to potential licensees (Vanhaverbeke & Gilsing, 2024, p. 55). To convert clinical data into cures, there must be a mechanism whereby the information about both the compound and the clinical data can be shared with others for which the compound or data are better strategic fits without the owner's losing the ability to use IP law to recoup at least part of its research and development costs.

Addressing these challenges requires a paradigm shift to a more open, innovative approach (e.g., Chesbrough, 2003) in drug development. Sharing data and knowledge among institutions can help identify promising research leads, validate findings, and accelerate the clinical development pipeline. It also enables the owners of shared knowledge to license specific pieces of data or technology to others. Such out-licensing generates revenues for the licensor to help fund its own promising candidates while promoting more productive drug development by the licensee as it pursues the projects that "fit" with its business model (Chesbrough, 2006b, p. 9).

More data sharing will also help universities, drug manufacturers, and clinicians meet the expectations of volunteers who participate in clinical trials, as they often lack confidence in the effectiveness and safety of the drugs being tested. These patients often expect that their data will

be shared with various entities across different initiatives, so it can be reused and recycled. They are often motivated by a desire to help scientists identify the most effective treatments that may work for them and others across various conditions, thereby leaving a legacy of finding cures and advancing medical research.

However, before firms can be expected to share their proprietary data, a mechanism must be put into place that addresses firms' legitimate concerns that data sharing will unduly cut into the profits considered necessary to fund drug development costs. These include the costs associated with not only the compounds that are commercial successes but also those that never make it to market. Inventions publicly disclosed prior to the filing of a patent application can be neither patented nor protected as a trade secret. Also, they cannot be licensed to others or sold for a price sufficient to cover the costs of discovery. This is because the very disclosure necessary to match potential buyers and sellers willing to do a deal at a fair price causes the purchase price to approach zero. As explained in Kenneth Arrow's seminal work (1962), "absent property rights—a seller disclosing information for evaluation by potential buyers allows the buyer to acquire that information at no cost" (West, 2006, p. 116).

This chapter proposes an innovative form of pharmaceutical public-private partnership (P3) that would use artificial intelligence (AI) to ameliorate these concerns. Our P3 model would make it possible for scientists and firms to share their proprietary findings and other knowledge without the owners of that data having to give up the opportunity to use intellectual property law to protect their most innovative discoveries from misappropriation by others. The P3 would include, as a partner, or otherwise engage, a technology company or other entity with deep experience in artificial intelligence (AI) and open search to be a trusted intermediary responsible for operating and managing a multi-sided data-sharing platform with the P3 agreement. The trusted intermediary would receive proprietary data, safeguard it with strong encryption, and use AI to expose certain information and technology gleaned from the shared data to firms that might be interested in buying or licensing it or in collaborating with its owner.

The goal of our P3 model is to transform data into cures. By structuring their relationships as transformational pharmaceutical public-private partnerships, pharmaceutical firms, universities, government funding agencies, and patient advocacy groups will be able to "safely" pool resources, share data and expertise, and leverage complementary capabilities, thereby creating a more efficient drug development ecosystem for both new compounds and secondary uses for existing drugs. We envisage a multi-sided platform that would be developed and managed by a technology company or other entity with deep experience in AI and open search. This entity would act as or with a neutral trusted intermediary. It would use secure encryption techniques to make it possible for universities, competing firms and potential collaborators to share their discoveries concerning targets, compounds, and related matters and to learn more about the discoveries of others without sacrificing the ability of the entity owning the data to protect their truly innovative discoveries with patents or as trade secrets.

By facilitating the sharing of clinical data, the implementation of our P3 model would enhance the quality of the clinical data necessary to obtain regulatory approval of both promising new compounds and secondary uses of existing drugs. (Unless the context indicates otherwise, the terms "compound" and "molecule" are used interchangeably.) It would also increase the speed at which patient data can be collected, analyzed, and converted into treatments.

Our proposals offer valuable strategic opportunities and real options (Bower, 1970; Chesbrough, 2006b, p. 9) for pharmaceutical industry participants. This is especially the case for those willing to join such public-private arrangements early and to share aspects of their less sensitive discoveries and thereby to help train the AI programs necessary to improve the algorithms required to evaluate clinical trials and other medical data.

Our proposals build on earlier successful US public-private healthcare initiatives. The United States developed a nimble and very successful pharmaceutical regulatory regime in 2020 when it launched Operation Warp Speed (OWS), an unprecedented initiative to rapidly develop, produce, and distribute COVID-19 vaccines and therapeutics. In collaboration with pharmaceutical firms, universities, patient advocacy groups, and other stakeholders, the US government provided substantial funding and resources, streamlined regulatory processes (including use of government agencies' congressionally granted "Other Transaction Authority" (OTA) to cut regulatory "red tape"), and leveraged military logistics expertise to support the effort (e.g., D'Souza, 2023; see also Arnold, 2022a; Arnold 2022b; Bloom et al., 2021; Hall & Packard, 2022). Pharmaceutical companies partnered with research institutions to accelerate clinical trials and to scale up manufacturing capabilities. At the same time, patient advocacy groups played a crucial role in recruiting diverse trial participants and educating the public about the safety and efficacy of vaccines. During his first term, President Donald Trump called Operation Warp Speed "one of the greatest miracles in the history of modern-day medicine" (quoted in Adams, 2025).

The success of our P3 model is similarly predicated on the sponsoring government agency's use of Other Transaction Authority to tailor the regulatory regime to further the objectives of accelerating the development of promising drugs from the bench to the bedside. Eliminating unnecessary red tape does not mean abandoning the protections necessary to prevent unscrupulous "snake oil salesmen" from wasting taxpayer money or, worse yet, endangering the health of either the volunteers enrolled in clinical trials or the patients prescribed the newly approved drugs or secondary uses. Independent experts must constantly reassess risks and rewards as new data becomes available.

The regulatory environment for approving new drugs and patenting them is highly complex and time-consuming. In addition to the scientific demands, navigating the complex and varied regulatory landscape for the commercialization of pharmaceuticals across countries requires substantial resources and expertise. Ongoing harmonization efforts, even within the European Union, have yet to be fully realized. Given our expertise and the complexity and novelty of our

model for transformational P3s, we have elected to limit the scope of this chapter to entities organized under the laws of the United States or a state thereof. It is left to others better qualified to address arrangements subject to different legal or regulatory frameworks.

In light of the fierce global competition for new drugs and innovative AI, policy makers must keep in mind that the countries willing to adjust their regulatory regimes to facilitate exchanges of commercial medical data and other activities necessary for accelerated drug development may well be at a competitive advantage over the countries less willing to provide conditions conducive to more innovative types of public-private collaboration.

Given that geopolitical reality, we propose in Section II the immediate formation of a pilot transformational P3 dedicated to finding cures for pediatric neurodegenerative diseases. We would recommend that the Advanced Research Projects Agency for Health (ARPA-H), an agency within the Department of Health and Human Services with OTA, be the sponsoring agency, given its successful track record in healthcare innovation. Other participants in that project could include OpenAI, Google, Meta, or Microsoft, as a trusted intermediary to facilitate data sharing among participants by developing and operating (alone or with others approved by ARPA-H) the multi-sided data-sharing platform necessary for CureFinder. The Secretary of the Department of Health and Human Services could work with both the private sector and other governmental agencies, such as DARPA (the Defense Advanced Research Projects Agency, an agency within the Department of Defense), to select the appropriate agency (or individuals) to help structure the data analytics necessary for such a project as well as the systems required for its efficient operation and for assessing its outcomes.

The balance of this chapter proceeds as follows. In Section II, we present our proposal for transforming data into cures—pharmaceutical public-private partnerships (P3s). In Section III, we focus on a key element of our model for transformational P3s—the use of artificial intelligence by a trusted intermediary. This section also includes two sample use cases. We discuss certain governmental incentives for participants to join CureFinder in Section IV. Section V outlines the key elements of the partnership agreement essential for transformational P3s, and Appendix A provides sample language to be included in such an agreement. We address the potential concerns and challenges of our transformational P3 model in Section VI and conclude with a call to action in Section VII.

II. Our Proposed Solution: Using Pharmaceutical Public-Private Partnerships (P3s) to Transform Data into Cures

The complexities of the human body and the intricate nature of disease pathogenesis present significant hurdles in drug discovery, development, and commercialization. Many diseases, such as cancer, Alzheimer's, and autoimmune disorders, have complex etiologies and heterogeneous patient populations, making it challenging to identify effective drug targets and to develop therapies with broad therapeutic benefits. The high attrition rates observed in clinical trials underscore the difficulty of translating promising preclinical findings into successful human

treatments. Overcoming these challenges requires a deep understanding of disease biology, coupled with advanced technologies and sophisticated data analytics.

Moreover, scientists are increasingly discovering that it takes a cocktail of pharmaceuticals to cure or control a disease, as happened with the human immunodeficiency virus (HIV). If one firm has a patent on one component and refuses to license it to another firm, no cure or treatment will be available. An individual firm may not even know who has identified and owns the other pieces of the puzzle that may be needed to develop a cure. Many potentially promising compounds and biologics never make it through the "valley of death" (Rai et al., 2008, p. 4) between discovery and commercialization.

Pharmaceutical firms often fund basic research in university laboratories and research institutes and typically have the right to license or acquire the discoveries resulting from their funding. The firms usually also maintain internal labs staffed with their own scientists or create subsidiaries that conduct research and development in disciplines ranging from chemistry, biology, pharmacology, genetics, bioinformatics, to absorption, distribution, metabolism, and excretion (ADME), as well as toxicology.

Increasingly, the larger firms have tended also to rely on smaller firms for drug discovery. These are often spin-offs founded by professors who made significant discoveries in their own university labs. The larger firms then acquire the spin-offs or license their inventions when the smaller firms lack the significant capital infusions and capabilities needed to complete the clinical trials necessary for ultimate commercialization of promising compounds and molecules.

Researchers generate various kinds of data during the different stages of drug development. During the discovery and preclinical phases, they collect information concerning indications, targets, and molecules. Sharing molecular-level data about the properties, structures, and mechanisms of drug candidates can be a valuable contribution to the broader scientific community. These data can spur further research, enable the identification of synergies, and accelerate the development of complementary therapies. To the extent that pharmaceutical companies can be assured that the proprietary aspects of their molecular entities can be adequately protected, firms might be willing to enter multi-party arrangements for the open exchange of at least certain molecular-level data. In contrast, data from clinical studies represents a more sensitive asset for pharma companies. These data, which typically include patient demographics, biomarkers, safety profiles, and efficacy outcomes, provide critical insights that inform a drug's development pathway and commercial potential. As discussed more fully below, pharmaceutical companies are generally more reluctant to share clinical trial data for potential blockbuster drugs than for those targeting less strategically important areas, such as orphan diseases. This hesitancy stems from a perception that the risks associated with data sharing outweigh the potential benefits when high-value products are involved.

We propose a transformational P3, which we call "CureFinder," to optimize drug discovery and accelerate the translation of scientific breakthroughs into life-saving therapies. This model is

designed to create a more efficient ecosystem for innovation, incentivizing data sharing and the development of shared research tools while balancing the interests of all stakeholders**.**

Our model, underpinned by a game theory-informed contract, helps participants escape the Prisoners' Dilemma created by the traditional culture of secrecy in the pharmaceutical industry. Firms are stuck in an arrangement that is not as economically efficient as it could be because they cannot effectively coordinate with others without risking their IP. By factoring in the strategic interests and potential interactions of each partner, the contract would be designed to align incentives, promote cooperation, and prevent "defection." This ensures that each party is better off by collaborating and maximizing the partnership's overall value creation and long-term sustainability, rather than acting in its own isolated self-interest.

The P3's foundation rests on multiple key elements, discussed in detail below. It will leverage strategic AI within a multi-sided platform, managed by a trusted intermediary, to facilitate secure data sharing and accelerate discoveries. The customized contract would establish the governance structure and align incentives. The partnership would be sponsored by a government agency with Other Transaction Authority (OTA), like BARDA (Biomedical Advanced Research and Development Authority) or ARPA-H, which can cut regulatory red tape and provide resources not readily available from private sources. Participation would be voluntary, with incentives for involvement from both large pharmaceutical companies and smaller start-ups. Our model would also promote a culture of trust and transparency among all partners.

A cornerstone of our model is the strategic use of an AI-driven platform that would be operated by a neutral trusted intermediary on behalf of all parties to the P3. CureFinder requires the strategic use of artificial intelligence to support multi-party shared data platforms embedded within P3s so diverse stakeholders, including pharmaceutical companies, biotechnology companies, start-ups, academic institutions, and regulatory agencies, can contribute and access data securely. These platforms would use cutting-edge AI to facilitate data integration, analysis, and interpretation, thereby accelerating the identification of novel drug targets and biomarkers as well as new secondary uses of existing drugs.

The platform would match university research, discoveries, and tools with industry compounds and clinical data while preserving the ability of the owner of the shared information to patent it. It would also facilitate the strategic sharing of clinical data. This intelligent matching process, powered by advanced data analytics and machine learning, can accelerate the translation of basic research into drug development. The intermediary's AI would provide layered technical safeguards through tiered data access. Raw data would remain siloed, with queries answered by synthetic or differentially private outputs. It would perform contextual anonymization, redacting specific trial-biomarkers or obscuring molecular structures. It would also enforce dynamic licensing through automated systems that track data usage and trigger revenue sharing only when commercial viability is achieved. This ability to dynamically adjust data granularity based on a bidder's credentials—giving less sensitive datasets to start-ups than academic researchers, for

instance—mitigates antitrust risks and ensures equitable access to data and innovation. By using AI, the intermediary transforms dormant data into a pipeline for secondary therapeutics, generating new revenue streams for data owners while safeguarding their IP. Two cases showing how this might work in practice are presented in Section III.

Yet, it is essential to appreciate AI's limitations: "AI is not designed to entirely replace human ingenuity or authority" (Zhang et al., 2025, p. 53). David Baker, a biochemist who shared the Nobel Prize in Chemistry in 2024 for using AI to "predict and create proteins," told *The New York Times* that he viewed AI "more as a tool" than as a technology "on a path to matching or surpassing all human abilities" (Lohr, 2025). Other experts concur, stating that AI is not "omnipotent" and "human input will still be needed to determine the direction of AI research and use" (Zhang et al., 2025, p. 53).

To protect the legitimate proprietary interests of the firms (and perhaps also the universities) in their most promising discoveries, the platforms would utilize trusted intermediaries to keep the innovative aspects of the discoveries secret until a match between a university discovery or target and an industry molecule or other treatment is found. If there is a match, then the owner of the proprietary data would not be required to disclose the particulars to a potential collaborator, licensee, or buyer without an enforceable nondisclosure agreement.

P3s will require public funding from a sponsoring public agency. By applying portfolio theory from the field of finance, the US government may be able to generate higher returns by pooling its investments in drug development and other aspects of biotechnology in a new US sovereign wealth fund for drug development and related biotech. As a proposed beta test of transformational P3s and their scalability, we propose the immediate commencement of a pilot P3 dedicated to developing cures for pediatric neurodegenerative diseases. The P3 would be sponsored by the Biomedical Advanced Research and Development Authority (BARDA) or the Advanced Research Projects Agency for Health (ARPA-H), as determined by the Secretary of the Department of Health and Human Services.

In addition to public funding, transformational P3s would require active public sector operational involvement. They should be sponsored or at least supported by a designated governmental agency, such as ARPA-H or BARDA, with Other Transaction Authority (OTA). OTA, which was used to power the COVID-19 Operation Warp Speed project, is a congressionally granted power that permits designated administrative agencies to cut regulatory red tape (including certain competitive bidding requirements) to facilitate high-priority, high-risk projects deemed essential to the public interest. (For exemptions from the Competition in Contracting Act and other laws, see Vadiee & Garland, 2018; Advanced Research Projects Agency for Health [ARPA-H], 2024, *Other Transactions (OTs), Overview*, p. 13.) In collaboration with the private participants, the governmental agency can provide or enhance existing private infrastructure; promote data uniformity; reduce transaction costs, including reducing the regulatory burdens and other "red tape" associated with new drug discovery; provide financing and other resources not

readily available from private sources; and promote drug safety, including the full disclosure of any adverse effects and risks, and patient confidentiality. Both ARPA-H and BARDA have OTA. The National Institutes of Health, the primary federal US agency for conducting and supporting medical and biomedical research, is another entity that could be involved, as might DARPA, given its deep experience with high technology projects.

The P3 must be structured with care to promote transparency, accountability, and effective decision-making. Transformational P3s require trust among all the participants, both in the organizational phase and during the operational stages. They also require psychological safety for the individuals working on the projects undertaken by the partnerships.

The formal governing instrument would be a customized, long-form written partnership agreement, which all the parties to the collaboration would negotiate and agree to accept as a legally binding contract. The agreement would include a mechanism to permit the admission of new members and the use of CureFinder by non-members under limited circumstances. The agreement would use a game-theoretical framework to establish the governance structure for the entity and set forth the parties' rights and responsibilities. Participants capable of negotiating and crafting such customized agreements will have a competitive advantage over those tied to more traditional contractual models (e.g., Bagley, 2008). We discuss the agreement in greater detail in Section V and in Appendix A.

Our P3 model, by design and as executed, should promote involvement by start-ups and smaller companies as well as the major pharmaceutical firms. Participation in CureFinder should be voluntary, but, as discussed further below, the NIH, the Food and Drug Administration (FDA), and other government agencies, as well as private actors, might offer firms various incentives to encourage them to participate in CureFinder. Also, firms should be given an incentive to share their data to help train AI programs in the early stages of CureFinder's development even if they elect not to become a fully participating member of a P3.

The pharmaceutical industry's traditional innovation model is often predicated on proprietary research, development, and commercialization, relying on intellectual property protections, primarily patents and trade secrets, to monetize its core innovations. This is understandable, given both the nature of the US patent system and the high costs associated with developing and securing FDA approval for new, effective, and safe drugs. In particular, because an invention cannot be patented if it was publicly disclosed or sold before a patent application was filed, firms tend to jealously guard their proprietary inventions.

Once a firm elects to patent an invention, then it must describe the invention in detail in the patent application and explain how to make it. Thus, once the patent for a drug or biologic expires, anyone can manufacture and sell a generic or biosimilar (non-branded) version of the product by simply following the instructions outlined in the patent application after receiving FDA approval through a streamlined process. The generics or biosimilar manufacturer is not

required to pay anything to the firm that patented the drug or biologic. In short, the patent system promotes innovation and the dissemination of new knowledge by incentivizing inventors to create new and useful inventions that will, after a limited period, become part of the public domain.

Understandably, the patent holder will seek to maximize its revenues from the patented invention during the period of exclusivity, in part to recoup its R&D costs and the cost of capital. In the case of branded drugs and biologics, these costs include not only the expenses associated with bringing a particular successful, patented drug or biologic to market, but also the costs incurred for all the compounds and molecules that failed.

In addition to the period of exclusivity granted by US patent laws, various regulatory regimes might prohibit third parties from using specific data generated by others. For example, the FDA grants periods of data exclusivity for certain new drug approvals, during which competitors cannot rely on the originator's clinical trial data for their applications. Even after patents eventually expire, these data exclusivity regulations can provide separate, time-limited protection.

Instead of viewing the sharing of clinical data during periods of exclusivity as a binary decision, a P3 offers a more nuanced choice whereby a participant in a P3 could elect to share anonymized or synthetic data by using a trusted intermediary's secure AI-powered platform. Our model makes it possible for firms to license others to conduct research for secondary uses unrelated to the owner's core products without compromising its competitive advantage in its core markets.

Although understandable from a strictly legal standpoint, pharmaceutical firms' traditional insular approach to knowledge exchange has far-reaching negative consequences. It ultimately hinders the overall pace and cost of innovation, as well as the development of new therapies.

When information is siloed within individual organizations, there is a heightened risk that researchers will independently pursue similar research questions, leading to wasted resources, time, and effort. This duplicated effort not only hampers efficiency but also diverts valuable resources from the exploration of novel therapeutic avenues. Forcing researchers to operate in isolation also makes it more difficult for them to build upon existing knowledge. This hinders the pace of innovation industry-wide, leading to poorer patient outcomes than would be the case if the firms could find a way to collaborate more effectively. Other impediments to data sharing include pharmaceutical firms' concerns about exposure to legal liability for "unvetted" data generated by third parties.

Another impediment to data sharing is the absence of uniform data standards for measuring toxicity and efficacy. This includes not only the lack of uniform patient data standards but also clinical biomarkers, including assessment of biological activity of a particular drug candidate against its target and the like, which are essential to assessing proof of principle as well as

clinical endpoints. This makes it particularly challenging for firms to collaborate in collecting and sharing the data generated during clinical trials. The increased use of electronic medical records and the utilization of contract research organizations (CROs) have helped alleviate some of these problems. Yet, the lack of standardized data formats and normalized data, as well as inadequate data sharing infrastructures, still pose significant challenges to effective collaboration. We propose a process for generating standards for CROs later in the section.

Our pharmaceutical public-private partnership model builds on the open innovation paradigm first articulated by Henry Chesbrough (2003, 2006a, 2020). It also promotes open science. As Collins et al. remarked in *Science*:

> Perhaps the most valuable lesson that COVID-19 has taught the research community—and hopefully society more broadly—is the importance of collective effort and continuous investment in basic and applied research. It takes more than individual ingenuity and hard work for biomedical research to respond swiftly and effectively to a rapidly emerging public health challenge. For [the COVID-19] pandemic, it required the coordinated efforts of thousands of creative researchers, administrators, and community partners who were supported by much needed resources and provided with rapid, free access to decades of discoveries made by their scientific forebears. (Collins et al., 2023)

The White House Office of Science and Technology Policy cited the importance of open innovation and science as a matter of public policy when it required the more expeditious free and public access to federally funded scholarly articles and data resulting from government-funded research by the end of 2025 (McCabe & Mueller-Langer, 2024; Nelson, 2022). Scientific productivity is positively associated with adherence to "the FAIR principles (i.e., to publish data in such a way that they are **f**indable, **a**ccessible, **i**nteroperable, and **r**eusable)" and other tenets of open science (Poetz et al., 2024, p. 455). Research shows that academic scientists benefit from openness and collaboration among different stakeholders, including, for example, "companies, citizens, researchers from other disciplines" (Poetz et al., 2024, p. 455). Funding agencies and universities can promote open innovation and open science by sponsoring multi-disciplinary research, encouraging scientists to publish research findings in open-access journals, sharing data, reagents, and tools with the broader scientific community, and participating in collaborative research projects.

The open innovation paradigm views "R&D as an open system" (Chesbrough, 2006b, p. 1), and its proponents encourage managers of for-profit firms to use both internal and external knowledge to advance their innovations and thereby increase realizable value for the firm (Chesbrough, 2006b, p. 1). For example, Chesbrough cites Merck as a pharmaceutical company that both is "widely respected for its excellent internal research" and, as evidenced by its annual report for 2000, is well aware of the fact that it "must actively reach out to universities, research institutions and companies worldwide to bring the best of technology and potential products into Merck" (p. 9).

Although advocates of open innovation promote collaboration and certain types of data sharing among firms, they do not expect for-profit firms to give their innovations away for free unless there are good strategic reasons for doing so. Instead, open innovation scholars acknowledge the need for companies to use intellectual property protection both to defend against claims of infringement by others and to monetize the value of the firm's own innovations through the revenues generated by its branded products and the licensing fees available from others eager to use innovations that do not "fit" with the licensor's business model (Chesbrough, 2006b, pp. 9–10).

As discussed further below, our transformational P3 model promotes the practice of open innovation by, among other things, providing novel data stewardship and sharing mechanisms, including the use of AI-powered platforms operated by trusted intermediaries. It also has the potential to unlock opportunities for new applications of compounds that may have failed in clinical trials for their original intended use or that may have gone off-patent, enabling so-called "drug repurposing." Also discussed are certain changes in US law and government regulations that may help promote open innovation, not only for new drug compounds but also for the repurposing of drugs for secondary uses (see Chesbrough & Chen, 2013).

Our model also creates dynamic IP boundaries. For instance, an established pharmaceutical company working with a start-up could not only keep full rights to a drug's original intended use (such as treating diabetes) but could also license the start-up to use the compound for a new use (such as cardiovascular disease). This is AI Sample Use Case 2 in Section III.

Another critical element of our model is the use of trusted intermediaries, such as Alphabet (Google), OpenAI, Meta, or Microsoft, or an entity working with such a firm, to provide AI-driven mechanisms whereby for-profit pharmaceutical firms and university technology transfer offices seeking to license discoveries by academic researchers or others can confidently expose their molecules or treatments for possible matching with targets without having to disclose their proprietary characteristics. Depending on the scope of the projects, the Wellcome Trust or the Bill and Melinda Gates Foundation (or perhaps Bill Gates personally) may also play a role, as may the Pew Foundations, given their work in maintaining the Shared Platform for Antibiotic Research and Knowledge (SPARK). (SPARK is a publicly available, interactive database designed to help scientists around the globe identify new drugs to combat antibiotic-resistant bacteria.) In some cases, independent research organizations or academic consortia might be best suited to serve as neutral custodians of certain types of especially sensitive data, such as data from clinical trials.

Our model enhances the value provided by intermediaries, which "many innovating companies" now retain as a matter of "standard practice" to facilitate open collaboration (Diener et al., 2024, p. 382). Diener, Piller and Pollok characterized the challenge of balancing the value creation and capture opportunities for the buyers and sellers of innovations as "perhaps the most significant task for open innovation intermediaries" (2024, p. 382). Through "open search," intermediaries

can (1) identify potential partners or technology unknown to the innovating organization and (2) orchestrate exchanges using proprietary information-technology-based platforms and other mechanisms (Diener et al., 2024, pp. 371–375). "[O]pen innovation can only be maintained over time if value is generated for all involved" (Chesbrough et al., 2018, p. 936, quoted in Diener et al., 2024, p. 382), thus "innovation intermediaries must actively shape collaborations through communication, transparency, and interaction opportunities" (Diener et al., 2024, p. 382). This type of trusted intermediary is appropriate for our P3 model, and the functions and tasks assigned to that participant offer a novel and effective means of meeting that challenge.

The trusted intermediaries should endeavor to provide participants with a readily searchable knowledge database while protecting each participant's legitimate IP and research interests. It should also, to the extent possible, strive to offer access to secondary outcomes, all within a secure, encrypted environment. If there is a match between a target and a molecule, for example, then unless the parties agreed to another arrangement in advance, the firm (or university) owning the proprietary technology would typically have the option of disclosing more information to the matching party under the protection of a nondisclosure agreement or deciding not to proceed further trying to do a deal with that matched party.

Secure and dedicated data sharing platforms, created by trusted intermediaries and supported by robust governance frameworks, could serve as centralized repositories for preclinical research findings, clinical trial data, and other relevant information. The parties could use smart contracts to establish the terms and conditions for data sharing, thereby automatically ensuring the secure and controlled exchange between parties. Smart contracts are legally binding provisions embedded in "computer code that automatically executes all or parts of an agreement [that] is stored on a blockchain-based platform" (Levi & Lipton, 2018). They eliminate the need for the parties to meet again, often with attorneys as intermediaries, to execute the provisions necessary to make the agreement fully enforceable, thereby denying either party the ability to exert "hold-up" power. Knowledge graphs can help de-identify data and create a structured representation of the data, compromising proprietary information. The participants can also craft data use agreements to help ensure that data are used ethically and responsibly. The goal of this approach is to build trust among partners and to encourage greater openness in sharing knowledge.

Although some level of clinical data transparency is essential for validating scientific findings and building trust, manufacturers and universities should have the ability to retain specific datasets that give them a competitive edge. A tiered data sharing model, whereby scientists contribute an initial package of less sensitive clinical information but maintain more proprietary datasets, at least until they agree that a stage-two disclosure makes sense, can strike the right balance between openness and protecting intellectual property.

Thus, the data sharing arrangements should permit pharmaceutical manufacturers and others to structure their data contributions into distinct packages. The first package includes histories, responses to prior treatments, diagnostic results, and compliance metrics. This level of data

sharing can provide valuable insights into other market participants without compromising the manufacturer's competitive edge. The second, more proprietary data package might include follow-up data, additional therapy permutations, and detailed patient phenotypes information that the manufacturer believes holds the key to developing future molecules.

A well-qualified, trusted intermediary or its designated agent could validate the quality, statistical significance, and authenticity of the clinical data packages, reducing risk for both purchasers and potential sellers. Additionally, such an intermediary or its agent could handle legal and compliance aspects of the data transfers, expedite the process, and make the platform more attractive to participants.

Speed is of the essence in the competitive pharmaceutical industry, where getting new drugs to patients as soon as possible drives profitability. Even a few months' advantage can translate to significant market share and revenue. Being first to market can secure a product's inclusion on formulary lists, influence prescribing behavior, and establish it as the standard of care. By enabling faster and more efficient transactions, a well-chosen intermediary can provide substantial value to manufacturers seeking to compress their development timelines and reach the market ahead of competitors. Implementing a tiered data-sharing model, backed by a trusted neutral intermediary, can help strike the right balance between transparency and proprietary protection.

Government funding, primarily through federal agencies like the National Institutes of Health, has for decades played a pivotal role in supporting collaborations between academia and industry in the development of new drugs. Grants, contracts, cooperative agreements, and other arrangements have provided the financial resources necessary to initiate and sustain multiple successful joint research projects deemed too risky for funding by the private sector. By offering incentives and reducing financial barriers, government funding has encouraged the exploration of novel ideas, helping to bridge the "valley of death."

Government agencies can serve as intermediaries, connecting potential partners and facilitating collaboration. By providing matchmaking services and networking opportunities, they have helped to identify complementary expertise and resources. Additionally, government funding has successfully been used to establish shared research facilities and infrastructure, providing a platform for collaboration and knowledge exchange.

Government agencies have also successfully leveraged their purchasing power to stimulate innovation and support collaboration. By procuring new products and services through academic-industry partnerships, government agencies have created market demand for innovative drugs and vaccines and incentivized the development of new solutions. This approach has also helped to accelerate the commercialization of research findings and brought new technologies to market (e.g., Quinn, 2013, discussing the collaboration of government, industry, and academia to mass-produce penicillin during World War II).

Research by MIT Professor Andrew Lo and his colleagues concerning successful investments in high-risk, high-potential-reward biotechnology companies (e.g., Kumar et al., 2024) offers powerful insights into how those structuring P3s might leverage portfolio theory from the finance literature to create more efficient and successful P3s, that is, P3s more likely to result in new, effective, and safe drugs at reasonable costs. Portfolio theory posits that investors are more likely to earn a higher return on their investments over time when they invest in a diversified portfolio of securities instead of trying to select a few "winners" (e.g., Fama, 1970). This strategy enables the investor to both diversify risks and maximize potential returns across the entire portfolio.

For example, Flagship Ventures, known for its innovative approach to biotech investment, created a portfolio of companies that leveraged cutting-edge science to address unmet medical needs. Similarly, BridgeBio focused on developing treatments for genetic diseases by identifying and advancing promising drug candidates. Both organizations demonstrated that a diversified investment strategy can yield substantial returns while driving significant advancements in healthcare. Another biotech company, Roivant Sciences, created a successful business model that focused on the secondary uses of failed and off-patent drugs. By employing a portfolio theory approach, Roivant has successfully identified and acquired drug candidates that had shown potential but were not fully developed or commercialized by their original owners. As explained below, the Biomedical Advanced Research and Development Authority (BARDA), a US funding agency involved in multiple successful P3s, has also taken a portfolio approach when funding drug discovery.

To jumpstart the technical work necessary to create the underlying AI-powered data-sharing platform necessary for CureFinder, and to demonstrate the feasibility and value of the transformational P3s in which CureFinder would be embedded, we recommend the immediate commencement of a pilot P3 project, perhaps under the auspices of ARPA-H, to accelerate the development of treatments for pediatric neurodegenerative diseases. This pilot will serve a dual purpose: validating the core P3 concept, especially the AI technology behind CureFinder, and assessing the scalability needed for inclusion of projects like this in a future sovereign wealth fund dedicated to drug development. By focusing on a targeted pilot, participants can begin constructing a funding and investment framework that could lay the groundwork for the creation of a full-fledged US sovereign fund dedicated to drug discovery and perhaps biotech more broadly. This streamlined approach would enable rapid implementation, potentially even inviting tech experts from relevant government organizations to contribute to the development of the CureFinder platform. This pilot can be initiated promptly, minimizing administrative hurdles, and allowing for immediate progress in validating data-driven drug discovery.

Following the successful pilot, the US government could apply an expansive portfolio approach by establishing a sovereign wealth fund dedicated to creating ecosystems for drug development and other forms of biotechnology innovation. (For a discussion of the power of innovation-related ecosystems to create new knowledge and transform it into valuable products and services,

see West and Olk, 2024.) The fund could invest in a wide range of projects, ranging from the specialized science and technical education required for drug development (including experiential learning techniques and evaluation metrics) to establishing geographic centers of excellence in underserved areas to creating the data platforms and analytics necessary for the successful exploitation of existing drugs for secondary uses. By diversifying investments across multiple projects, the fund could balance the high-risk nature of drug-discovery research with the potential for significant breakthroughs. This approach would not only provide a stable funding source for innovative projects, it would also ensure that promising secondary uses of drugs are adequately supported and brought to market efficiently. It would also make it possible for American taxpayers, who fund a significant portion of the research that leads to new, and typically very expensive, drugs, to share in the rewards.

The fund could facilitate the creation of a pharmaceutical public-private partnership focused on orphan diseases, which big pharmaceutical companies often neglect due to the low economic returns from small markets. By branding this initiative as an accelerated program, perhaps under the auspices of ARPA-H or BARDA, the government could, for example, accelerate the development of treatments for rare conditions affecting children or diseases endemic to specific geographic regions in the United States. As discussed above, we recommend that a pilot P3 addresses pediatric neurodegenerative diseases. At the same time, such a P3 pilot would be an essential proof of concept for many of the yet untested proposals in this chapter, especially those related to data standardization and the use of trusted intermediaries armed with cutting-edge AI. Given the Trump administration's recent embrace of OpenAI as an American leader in AI, that firm would seem a logical candidate to help lead the AI aspects of such a high-profile project, along with potentially X-AI, Palantir, Alphabet (Google), Meta, and Microsoft. Thus, this could be an early "win" for OpenAI (and other firms chosen by ARPA-H or other sponsoring agencies) if they can work together as partners to create the AI-driven data-sharing platform. ARPA-H or the other sponsoring agency could use a truncated competitive bidding process to help ensure that the most capable firms are selected to do the cutting-edge AI work required for successful transformational P3s. Most likely more than one firm will be required.

To promote more efficient public-private collaboration in drug development, we recommend that either BARDA or ARPA-H (both housed within the Department of Health and Human Services) serve as the government party for the transformational P3s. Both entities have successfully utilized the congressionally granted streamlined governmental contracting power, known as Other Transaction Authority (OTA), to create and operate P3s. OTA allows them to eliminate competitive bidding requirements and cut other regulatory "red tape" to facilitate high-priority, high-risk public-private projects deemed essential to the public interest (Vadiee & Garland, 2018; ARPA-H, 2024, *Other Transactions (OTs), Overview*, p. 13).

Congress originally gave OTA to the Defense Advanced Research Projects Agency (DARPA), an agency within the Department of Defense created after the Soviet Union shocked the United States by successfully launching Sputnik, the first human-made object put in Earth-orbit, so the

United States could rapidly marshal public and private resources to mount a response. Known for its high-risk, high-reward research projects, ranging from radar to self-driving vehicles, DARPA also uses P3s to drive innovation in life sciences. DARPA's ongoing investments in various biotechnologies and medical technologies, along with its support for research in synthetic biology, continue to pave the way for innovative approaches to drug discovery and development. DARPA may have relationships with AI experts who might be engaged to fill out or advise the P3 team on challenging AI issues.

The Biomedical Advanced Research and Development Authority has played a pivotal role in fostering P3s for the development of countermeasures against emerging infectious diseases and chemical, biological, radiological, and nuclear threats. It used its OTA to fund public-private partnerships with GlaxoSmithKline, AstraZeneca, and other companies to develop vaccines, therapeutics, and diagnostics for influenza, Ebola, Zika, the COVID-19 virus, and other diseases (Administration for Strategic Preparedness & Response [ASPR], n.d., *BARDA's Programs to Combat Emerging Infectious Diseases*). As of early 2025, BARDA had been involved with ninety-five Food and Drug Administration approvals, licensures, or clearances for pharmaceutical products. They include an enzymatic debridement agent for burn victims, a nasal spray for the emergency treatment of opioid overdoses, and a "rapid test" that identifies individuals infected with inhalation anthrax (Biomedical Advanced Research and Development Authority, n.d.). BARDA can take a "portfolio approach" to fund a company's effort to "simultaneously and in parallel develop multiple drug candidates," which allows for the "reallocation of resources across activities and among drug candidates if technical or business risks materialize" (Houchens & Larsen, 2017).

Another agency candidate with OTA is the Advanced Research Projects Agency for Health (ARPA-H). Established by Congress in 2022 within the Department of Health and Human Services, ARPA-H is charged with improving the "U.S. government's ability to speed biomedical and health solutions" (ARPA-H, n.d.). One goal of ARPA-H is to promote public-private partnerships (P3s) to speed technology and transition through the formation of a Partnership Intermediary Agreement (PIA) with a "nonprofit partner with deep commercial sector and transition expertise, to engage academia and industry on behalf of the government" (ARPA-H, 2023). Like our model P3, benefits of the PIA structure include flexibility and speed, as well as facilitating "novel approaches that mirror commercial practice to get solutions to market" (ARPA-H, 2023). Through its 2023 Defeating Antibiotic Resistance through Transformative Solutions (DARTS) project and its 2024 Transforming Antibiotic R&D with Generative AI to Stop Emerging Threats (TARGET) project, ARPA-H is seeking solutions to address the rise of antibiotic-resistant bacteria, including the development of new medications (ARPA-H, 2024). It is also involved in projects related to optic nerve regeneration and methods for targeting and treating cancer (Adams, 2024).

As the primary US federal agency for conducting and supporting medical and biomedical research, the National Institutes of Health (NIH) can also catalyze P3s by providing funding,

infrastructure, and scientific expertise. The NIH's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have been instrumental in supporting early-stage drug development by small businesses and academic institutions. NIH has allocated more than $1.4 billion annually from its Research and Development funding for these two programs (NIH, n.d., *Understanding SBIR and STTR*).

Individuals with mission-critical expertise are already housed within some of these agencies, in private firms, and in public universities. Consistent with the norms of open science and the standards of open innovation, we encourage the Trump administration and Congress, when authorizing P3s, to urge the leaders of the sponsoring OTA agency to search for and seek to engage the most qualified researchers from government agencies, universities, and the private sector to work collaboratively on P3s.

Public funding agencies, drug manufacturers, and the FDA each have an interest in ensuring that clinical trials are run properly and appropriately at a reasonable cost by qualified firms with well-trained staff. To this end, many pharmaceutical companies hire contract research organizations (CROs) to assist in running their clinical trials. Currently, there is no transparent and systematized way for drug manufacturers or governmental agencies to assess the quality of the various CROs involved in drug testing. Quality-control failures can be as fundamental as a CRO staff member's failure to maintain the integrity of data samples at a single site.

An easy and cost-effective first step to improve the quality of services offered by CROs is to ensure greater transparency. To that end, if it is not already required, then the FDA should require all drug manufacturers to identify, when submitting their clinical trial data for drug approval, any CROs that worked on any aspect of the clinical trials and to specify what activities the CRO performed. This information should be collected and analyzed using AI to generate more information about CRO usage, standards, and capabilities. Armed with this information, the FDA or another sponsoring agency could, at a minimum, work with healthcare companies to help determine which CROs might be particularly well-suited for facilitating data harmonization and de-identification within P3s, thereby ensuring that shareable data are properly structured while maintaining confidentiality.

A sponsoring agency (such as BARDA or ARPA-H) should solicit grant proposals for a methodical study of CRO best practices, which would include recommendations regarding the standards that CROs should be required to meet, including quality control (which initially might be relatively modest), data management, patient confidentiality, and the disclosure of pricing alternatives available to clients. An alternative is that the agency works with another agency (such as the NIH) with staff qualified to perform such an assessment. De-identified data collected by the FDA should be made available for this assessment.

Suppose such a study reveals significant variations in the quality of the work performed by different CROs, when measured against the recommended standards, as modified by the agency that funded the study. In that case, it might signal the need for the licensing of CROs by a

government agency or their inclusion as members of a new self-regulatory organization (SRO). An SRO would typically be established by a private firm, including potentially a non-governmental organization.

CROs currently work for the drug manufacturers under opaque standards and conditions, so imposing a new governmental licensing requirement for CROs at this juncture would appear both unworkable and frankly overly heavy-handed, especially given the current Trump administration's articulated desire to reduce the size of government, not to expand the remit of its agencies. However, a proposal whereby the private pharmaceutical sector could be "nudged" to better police itself would be wholly consistent with the goal of reducing government bureaucracy and ensuring that taxpayer money on drug research and development is better spent. To put it bluntly, everyone suffers when the clinical trial of a promising compound fails or is delayed because a CRO staffer failed to refrigerate a tissue sample properly.

Thus, ARPA-H or another sponsoring agency could solicit grant applications to study CRO best practices and to recommend standards that CROs should be required to meet, including quality control, staff training, and data management. Such a study will help inform the data standardization already identified as key to our transformational model working effectively. After the results of that study are submitted and analyzed, the sponsoring agency should, at a minimum, circulate the study results so drug manufacturers can decide whether to include specific performance requirements and metrics in their contracts when they hire CROs.

In addition, the sponsoring agency should solicit a second grant proposal for a project dedicated to the creation of a self-regulatory organization (SRO) that would (1) recommend more detailed standards than outlined in the first study that a CRO should have to meet, including staff education and testing, as well as supervision, to be qualified to engage in designated activities in connection with clinical drug trials and (2) set forth a business plan for creating an SRO with a sustainable membership model that would limit membership to CROs that met those standards. The request for proposals would stipulate that, initially, at least, a CRO would not have to be a member of the proposed SRO to be eligible to work on clinical trials. However, to encourage drug manufacturers to use CROs that are members of our hypothetical new SRO, the FDA could, at some future date, require drug manufacturers to indicate in their FDA submissions whether they used any CRO in connection with their clinical studies that was not a member in good standing of the SRO. As a further "nudge" down the road, the drug manufacturer could be required to explain why it did not consider CRO membership in the SRO prudent to ensure the quality of work by the CRO. Furthermore, CROs willing to dedicate the extra resources necessary to gain expertise in specific areas, such as data harmonization, would have the means to signal this to both potential clients and regulatory authorities through potential specialty designations offered by the SRO.

The securities laws employed a variation of this model when they entrusted self-regulatory organizations, overseen by the Securities and Exchange Commission (SEC), to manage the

licensing and conduct of securities broker-dealers and national securities exchanges, thereby significantly reducing the governmental bureaucracy required to regulate the securities markets. At some point, membership in an SRO for CROs could encompass the activities the CRO performs for its clients. For example, to be a securities broker-dealer licensed to buy and sell securities on a national securities exchange, a broker-dealer must almost always be a member in good standing of the Financial Industry Regulatory Authority (FINRA) (Goedtel, 2024).

Similarly, the London and Toronto Stock Exchanges did not require the directors of listed companies to separate the roles of chair of the board and chief executive officer (CEO); however, regulators did require the firms to disclose whether they had done so and, if not, explain. Scholars recommended that the SEC adopt a similar rule that would require companies listed on a US exchange to separate the roles of chair and CEO or to appoint a lead independent director with the authority to call board meetings and add items to the agenda or to explain why the board of directors had decided it was not in the best interests of the firm to do either (Bagley & Koppes, 1997).

To ensure the long-term success of a P3, it is essential to establish a governance structure that promotes transparency, accountability, and effective decision-making. A collaborative governance body, representing the interests of all stakeholders, should oversee the partnership and ensure that its objectives are met. The governing body could be an independent technology company, organized, perhaps, if in the United States, as a B corporation, so it can have a purely social purpose, or as a non-governmental organization (NGO).

Consistent with the partnership agreement for the P3 (discussed in Section V and Appendix A), the P3 structure should be adaptable and responsive to the evolving landscape of drug development and to changes in the external environment. These include technological advancements, regulatory shifts, and evolving disease landscapes, as well as the possible inclusion of new players.

To ensure the long-term success of the P3, a robust monitoring and evaluation framework is essential. The participants should set forth explicit milestones and benchmarks, as well as key performance indicators (KPIs), all tailored to the project at hand, in the P3 agreement. By tracking key performance indicators and assessing the P3's progress against explicit milestones and benchmarks, the participants and other stakeholders can identify areas for improvement. The parties should also agree to work together in good faith to make necessary adjustments to achieve their common goals.

Implementation of advanced data analytics and AI systems could automate much of the oversight process. At the same time, standardized templates for at least specific provisions in a typical P3 agreement could minimize the need for extensive legal reviews. Clear, quantifiable performance metrics would allow for more objective and efficient evaluation of P3s. These measures would not only reduce the number of personnel required to manage partnerships but also make them more self-sustaining by lowering administrative costs, thereby freeing up more resources for the

research and development needed to attain the partnership's drug discovery and commercialization goals. The increased efficiency and reduced bureaucracy could make these P3s more attractive to private sector partners, leading to increased participation and investment, ultimately creating a more dynamic and responsive government-industry collaboration ecosystem.

For projects that show promise but lack resources, we propose establishing an incubator-style support system. (Bagley & Alon-Beck, 2018, pp. 862–866). This would include offering equity-based incentives to original researchers, providing infrastructure and expert support, and implementing a flexible management approach that allows for team changes if necessary.

To ensure that start-ups and research teams can participate effectively, we propose providing mentorship and funding support for promising projects. We suggest implementing a "short leash" approach with clear milestones, utilizing a venture capital-style model for funding allocation, while leveraging existing mechanisms, such as the Other Transaction Authority, to streamline processes. This support system would help level the playing field and allow innovative ideas from smaller players to compete with larger pharmaceutical companies.

In-Q-Tel, the CIA's successful venture capital fund, provides valuable lessons in this regard (see Bagley & Alon-Beck, 2018, pp. 838–840). By establishing an agency-level fund that takes equity stakes in companies, the government can incentivize data sharing and the development of innovative solutions. This model enables the creation of spin-out entities that can commercialize the insights derived from pooled data, providing economic incentives for pharmaceutical companies to contribute their data. The government's unique access to information and its ability to optimize public investments could be a powerful driver for this type of collaborative approach.

Participation in CureFinder should be voluntary, not mandated by the regulatory agencies responsible for approving new drugs. A voluntary participation model is crucial for fostering a collaborative environment that encourages organizations to join the partnership based on their specific capabilities and needs.

Although no private pharmaceutical firm seeking to license government-funded university discoveries would be required to participate in CureFinder, we hope that many firms will find it economically advantageous to do so. To incentivize participation, the federal government and P3s could offer a range of benefits, including access to shared resources, expertise, and data; opportunities for co-development and commercialization; and shared risk and reward mechanisms. By creating a compelling value proposition, governmental agencies and P3s can attract a diverse range of partners and foster a culture of collaboration.

Before a firm could obtain a license for at least certain types of government-funded research, the NIH or other funding agency could require the firm to indicate whether it would be willing to participate in CureFinder. Funding agencies might require universities to consider giving preference to participating firms. Still, the university should have the right to elect to work with a

non-participating firm if it could demonstrate why it believed in good faith that a non-participating firm would be a superior partner; that is, better equipped to commercialize the discovery faster at a lower cost.

Similarly, funding organizations could require universities to indicate in their grant applications whether they would be willing to share their research data, including their models and tools, with others. This could include their desire to permit other researchers to use the test animals they have created, all under a mutually acceptable nondisclosure agreement. Cancer research was significantly hindered when Harvard University, whose scientists had created the oncomouse, granted an exclusive license to DuPont. DuPont refused to license this powerful tool to other cancer researchers on acceptable terms (see Eisenberg, 2008, pp. 1072–1075). The mouse was genetically engineered so it could grow human tumors, providing an innovative and handy way for researchers to test new drugs. Sometimes, a university technology transfer office may prohibit academic scientists from sharing even those discoveries or tools that lack clear proprietary value in unrealistic hopes of securing a highly lucrative patent years later. Such discoveries or tools may not have the value of an oncomouse but may still be helpful to a start-up or biotechnology firm doing early-stage work. Funding agencies could give universities an incentive to share such discoveries and tools by offering to expedite review of grant applications or signaling a willingness to look more favorably upon those containing a commitment to share data and tools with appropriate third parties.

Building trust among participants is essential for the successful implementation of P3s. During the negotiation phase of the P3, it is critical for the parties to be honest about their capabilities, aspirations, vulnerabilities, and concerns. Research indicates that the process of negotiating and drafting long-form written contracts can enhance trust and improve each party's satisfaction with the ultimate outcome of the collaboration (Poppo & Zenger, 2002, p. 712).

Fostering trust requires time, effort, and a willingness to listen to differing viewpoints. Leaders at the firm, university, agency, and team levels should lead by example and strive to create an atmosphere of openness, transparency, and mutual respect so that all stakeholders feel valued and heard. This can be achieved through regular communication, shared decision-making processes, and a willingness to address conflicts constructively.

Amy Edmondson's research (1999, p. 354) on successful innovative teams highlights the importance of what she calls "psychological safety," creating an environment in which team members feel comfortable taking interpersonal risks, such as speaking up, sharing ideas, and admitting mistakes. If someone makes a mistake, supervisors and coworkers should encourage that individual to speak up so the error can be corrected before it becomes a bigger problem that may jeopardize the entire project (see Edmondson, 2023). In the context of P3s, this concept can be extended to the relationships between different organizations and sectors. By prioritizing psychological safety, P3s can cultivate an environment that encourages innovation,

collaboration, and the free exchange of ideas, ultimately leading to more effective and sustainable partnerships and accelerated discoveries and better patient outcomes.

III. The Use of AI by Trusted Intermediaries and Sample Use Cases for AI-Driven P3s Seeking Secondary Uses of Existing Drugs

The extensive and appropriate use of artificial intelligence by a trusted intermediary with in-depth knowledge of AI and open search is a critical element of transformational P3s. In Section III, we discuss in more detail how the trusted intermediary would use AI to facilitate data sharing and the licensing of technology, both among the members of the P3 and with certain specially invited outsiders. We also present two use cases designed to show the reader how our model might work in practice to facilitate secondary uses of existing drugs.

The AI-savvy intermediary would be a party to the P3 agreement and perform several key functions, including using cutting-edge AI, which may be proprietary, to implement and monitor robust data protection and access controls, as well as to validate the quality, statistical significance, and authenticity of the clinical data packages. (If the AI used by a proposed trusted intermediary is proprietary, then the AI should be evaluated for its suitability by a third party to a nondisclosure agreement to protect the owner's proprietary elements.) The intermediary would maintain and operate (and modify as needed on an ongoing basis) the AI-driven CureFinder data-sharing platform, which would be accessible to both P3 members and those seeking to enter into transactions with the P3 or its members. Non-members would only be granted access to CureFinder if invited by a stated percentage of the P3's existing partners, as outlined in the partnership agreement (see Section V for further discussion of the P3 partnership agreement). The platform would be designed to permit tiered data access, thereby ensuring that raw data remains siloed while providing synthetic or differentially private outputs for queries. The intermediary would employ contextual anonymization to redact trial-specific biomarkers or to obscure molecular structure correlations, thereby safeguarding sensitive information. Dynamic licensing systems (such as smart contracts), automated by AI, would be used to track data usage and trigger revenue sharing only upon achieving commercial milestones. This layered approach would ensure data security and controlled access.

The partnership agreement (or an ancillary agreement) would require the intermediary to employ AI tailored to the project described in the agreement to facilitate the delicate balance between transparency and protection. In the case of pre-revenue trials, the intermediary would share only aggregated efficacy and safety trends, masked biomarker correlations, and synthetic patient profiles; raw genomic data and proprietary assays would be withheld. In post-market data scenarios, treatment outcomes and comorbidity patterns would be accessible, but molecular structures, manufacturing processes, and trial-specific protocols would be redacted.

As a guiding principle, the intermediary should strive to ensure that all participants are granted equitable data access, to convince antitrust regulators that the use of our P3 model will make the drug innovation market more efficient. This will be achieved in part by encouraging existing

firms and new entrants to develop entirely new products for indications not adequately addressed by existing drugs, or to identify secondary uses for existing products.

The intermediary could also use AI to dynamically adjust data sharing on a granular level based on the bidder's verifiable credentials. For example, access to sensitive data sets should be gated depending on the ability of potential partners to ensure the use of sophisticated and secure crypto-protected data management systems. Companies lacking the ability to keep sensitive data secure should almost certainly be granted more restricted access to sensitive data sets than companies with effective systems. Although differential data sharing based on a party's credentials may prompt closer scrutiny by the antitrust regulators, it is far more justifiable when based on legitimate needs, such as the importance of keeping sensitive data secure pending the filing of a patent application, than a general refusal to share with small companies or start-ups that may prove to be more nimble competitors.

By using AI to control the allocation of valuable innovation assets and the potential division of innovation markets among existing and potential competitors, the intermediary should be able to mitigate antitrust risks compared to what they would be if individual firms agreed to work together in a transparent manner. Advice from antitrust experts will be needed concerning both the role of the intermediary and other aspects of our model. We would encourage the sponsoring agency for the P3 to insist that the parties seek guidance from the Department of Justice and the Federal Trade Commission when negotiating and before finalizing the partnership agreement and any ancillary agreements, such as agreements with AI providers.

Indeed, because the antitrust laws are themselves a creature of Congress, Congress can amend them at will. Accordingly, Congress can include exceptions for P3s sponsored by public agencies with OTA from the antitrust laws. For example, part of the 2006 Pandemic and All-Hazards Preparedness Act, under which BARDA was formed, "set up limited anti-trust exemptions to help pharmaceutical companies collaborate with each other and with the government in the development of medical countermeasures" (Marty, 2007, p. 444). BARDA has already "taken advantage of a countermeasure-based antitrust exemption to support collaborative studies among competing vaccine manufacturers" (Plitsch, 2018). Congress, when authorizing a sponsoring agency to pursue P3s based on our model, should consider exempting them from certain antitrust laws and regulations when warranted by specific circumstances.

More broadly, we encourage potential participants in the first transformational P3s (and their counsel) to work proactively with elected representatives in Congress and the White House, together with Cabinet members and other members of the executive branch, to resolve potential conflicts between the existing regulatory regime and what might be necessary for the smooth operation of a transformational P3, especially its data-sharing platform. Given the strength of biotech ecosystems in the geographical regions of Cambridge, Massachusetts, and San Diego, California, regional efforts incorporating our ideas might prove fruitful as well.

The AI-powered platform would effectively transform dormant data into a pipeline for new and secondary therapeutics, generating potential revenue streams for data owners while safeguarding core intellectual property. This process would enable the efficient repurposing of valuable data, ultimately accelerating the development of new therapies and benefiting patients and society in general.

The next two sample use cases are designed to show how our AI-driven model could work in practice.

Sample Use Case 1: Sharing of Clinical Trial Data A university conducts a Phase 2 clinical trial for a novel oncology compound, generating valuable data on patient responses, biomarker levels, and adverse events. To maximize the data's potential, the university employs a trusted intermediary's AI-powered platform embedded in a P3 of which the university is a partner.

First, the intermediary anonymizes the data by masking patient identifiers and creating statistically valid synthetic datasets. Next, using machine learning, the intermediary analyzes the data and matches it with biotech start-ups or pharmaceutical companies possessing relevant expertise in specified areas, such as immunology or neurology, as well as experience with specific biomarker analysis. This matching process would go beyond just identifying companies involved in any aspect of the therapeutic areas of immunology and neurology. Instead, the AI identifies explicitly companies that also have proven experience in analyzing the *precise types* of biomarkers present in the dataset. Such companies are more likely to be a good match as a potential collaborator or licensee when paired with the university that conducted the clinical trials and owns the associated clinical data. For example, if the data includes detailed cytokine profiles, the platform will prioritize companies with expertise in analyzing cytokine storms or inflammatory pathways. If genetic markers were prominent, the platform would favor companies with experience in genomic analysis and personalized medicine.

The intermediary would also be expected to utilize AI to evaluate a potential collaborator's success in identifying correlations between specific biomarker changes and patient outcomes, thereby demonstrating the company's ability to extract meaningful insights from complex data. This granular matching ensures that the right expertise is applied to the data, maximizing the chances that the company doing the data analysis will be a good candidate both to safeguard the shared data and to identify new therapeutic applications successfully.

In this case, note that the AI platform facilitates a secure data exchange, enabling secondary developers to identify potential new therapeutic uses for the compound, while ensuring that the university retains control over its core intellectual property and receives licensing fees for any discovery efforts by others resulting in drugs for indications not core to the research agenda of the primary investigator in the laboratory that ran the clinical trials.

Once a match is made, any potential licensor or licensee that is not currently a member of the P3 would be required to pay a transaction fee stipulated in the P3 agreement. Non-members might

also seek membership in the P3 in accordance with the provisions of the partnership agreement governing the admission of new members.

Sample Use Case 2: Sharing Post-Market Data for Secondary Indications Imagine a patented diabetes drug that also seems to help patients with cardiovascular issues, based on real-world patient data collected by clinicians. The diabetes drug manufacturer, which may or may not be a member of a P3, is not focused on cardiovascular conditions but is aware of the potential benefits for cardiovascular health. The diabetes drug company reaches out to an AI-savvy tech company that, either alone or in partnership with a firm, specializes in handling sensitive data, in hopes of licensing the drug for cardiovascular conditions. With the approval of the governing body of a P3 dedicated to such secondary uses, the P3's trusted intermediary enters into a contract with the diabetes drug manufacturer and the tech company whereby the tech company will work together with the trusted intermediary to strip away any information that could identify patients, keeping only the data that are relevant to cardiovascular health. That data will be input into CureFinder in accordance with the terms and conditions agreed to by the diabetes company at the outset, either when it first joined the P3 or sought to use CureFinder. The intermediary would then use CureFinder to allow a non-member, cardiac-focused start-up approved by the P3 members to analyze the data without giving them direct access to it or identifying its source. Instead, they send the start-up's scientists encryption keys and data analysis tools that keep the sensitive data secure.

Suppose the start-up finds something helpful and develops a new cardiac treatment. In that case, if the start-up develops a new cardiac treatment, the start-up would notify the intermediary, and negotiations would ensue for a licensing agreement giving the start-up (or its successor) the right to use the unredacted clinical data to help secure FDA approval of the new cardiovascular treatment. Better yet, once the market for the sharing of clinical data becomes more mature, the AI would include in its code "smart" digital contracts that would protect each party's intellectual property and set forth the terms on which any such property is available for licensing. In either case, if the start-up and the diabetes company can consummate a deal, the diabetes drug maker gets a new revenue stream from royalties paid by the start-up (or its successor) based on sales of the cardiovascular treatment; the cardiovascular-focused start-up can develop and help bring to market a new cardiac therapy in exchange for a reasonable royalty to the diabetes drug maker; cardiac patients obtain access to potentially life-saving therapies faster; and the P3 is paid adequate data-sharing and other transaction fees by non-members to keep it self-sustaining.

IV. Promoting Governmental Efficiency Goals and Providing Government Incentives for Parties to Join P3s

The use of a public entity with Other Transaction Authority to serve as the public sponsor of transformational P3s, together with many of the other proposals in this chapter, would, we assert, further the foundations of the 21st Century Cures Act and the 2020 Coronavirus Aid, Relief, and

Economic Security Act (CARES Act). By investing in data analysis, impact assessment, and knowledge translation activities, an agency with OTA can help to maximize the return on investment in collaborative research. It can also inspire and inform future joint efforts by publicly sharing the results of successful partnerships, thereby contributing to a culture of innovation and collaboration within the broader research ecosystem. The sponsoring agency can also create more streamlined and favorable regulatory environments for start-ups, sparking disruptive innovation. Finally, by implementing advanced data analytics and AI systems, the sponsoring agency can collaborate with the participants in the P3 to automate much of the oversight process, thereby reducing the need for costly government oversight requirements.

We proposed a pilot project in Section II for a transformational P3 dedicated to curing pediatric neurodegenerative diseases. The Secretary of the Department of Health and Human Services could designate the appropriate agency to be involved in the structuring, analytics, metrics, data collection and sharing systems, and evaluation of such a pilot project. In short, utilizing a public entity with Other Transaction Authority can help maximize the return on collaborative research, create a favorable regulatory environment for start-ups, and automate part of the oversight process, thereby reducing the need for costly government oversight.

The US Constitution granted Congress the power to authorize the granting of patents "[t]o promote the Progress of Science and useful Arts" (U.S. Const. art. I, § 8, cl. 8). As the US Supreme Court explained, "[P]atent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention'" (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 2013). Congress has the power to amend the patent laws as it deems necessary to tweak that balance to foster the public good.

Carefully crafted amendments to the patent laws could make more compounds available for potential matches with targets and more clinical data available for collaborations, without removing the incentives drug manufacturers need to bring new compounds to market and to license existing compounds for secondary uses. To accomplish this, Congress can accept the recommendations made by various experts to amend US patent laws to allow for more flexible patenting and licensing of drugs for new applications and secondary uses. Hence, taxpayers and other funders get "more bang for their buck" and patients have access to a broader range of medical treatments. This may be a particularly opportune time for such a change since President Trump's administration has recommended that the NIH drastically reduce the rate at which it will reimburse universities for the "indirect" costs associated with their medical research.

Another approach to encourage greater data sharing by manufacturers would be to have Congress amend patent laws to extend the term of certain intellectual property protections in exchange for increased data transparency. Even several additional months of exclusivity could shift the risk-reward calculation. In summary, by providing a more apparent upside for sharing data, in the form of extended market exclusivity or faster regulatory review (discussed further

below), the US government may be able to persuade drug manufacturers to voluntarily agree to take on more of the risks and administrative burdens associated with data sharing.

We believe that a critical first step to promote widespread clinical data sharing is to establish industry-wide data standards. By creating common data formats and terminologies, researchers from different organizations can more easily share and analyze data. This standardization would facilitate data integration and enable the identification of trends and patterns that might otherwise go unnoticed.

Specific private arrangements for sharing medical data exist but have not resulted in widely accepted uniform data standards. For example, Qualified Health Information Networks (QHINs), organized under the Trusted Exchange Framework and Common Agreement (TEFCA), facilitate the secure exchange of electronic health information between healthcare providers. TEFCA is a national framework that establishes the rules and standards for securely sharing patient data across health information networks nationwide. The QHINs have demonstrated the value of interoperability standards and trust frameworks for secure data exchange in healthcare; however, they have been unsuccessful in generating widely accepted, uniform data standards. This may be due in no small part to private firms' antitrust concerns.

Instead, a governmental regulatory body, such as the Food and Drug Administration (FDA), would seem a logical candidate to take the leading role in establishing uniform medical data standards. The FDA already sets standards for drug development and approval processes, which provides it with a strong foundation for establishing data-sharing guidelines. Additionally, the FDA has the authority and expertise to ensure data quality and integrity, facilitate regulatory review, and promote public trust. The FDA can also leverage its existing collaborations with industry, academia, hospitals, clinicians, and patients' advocates, as well as with other regulatory bodies, including the National Institutes of Health (NIH) and the Centers for Medicare & Medicaid Services (CMS), to establish a comprehensive framework for data sharing.

The private "experiments" by the QHINs and other successful Health Information Exchanges (HIEs) provide the FDA with helpful information on how to address challenges, such as high implementation costs and inconsistent adoption. The private data sharing arrangements have demonstrated the importance of transparency, strong governance, privacy protections, and participant alignment for successful data sharing as well as the need for sustainable funding, clear accountability, and adaptable data-sharing protocols.

Establishing generally acceptable data-sharing standards will require a public-private collaborative approach to ensure that the standards are:

- Comprehensive: Address the diverse needs and priorities of all stakeholders.
- Workable: Not be overly burdensome for clinicians or hospitals and preferably be interoperable with at least some of the larger legacy medical record systems, such as EPIC.

- Flexible: Be adaptable to the evolving landscape of drug discovery and development, including new ways of collecting tissues.
- Innovative: Leverage the latest programming languages that have made it easier for those without data management skills to utilize apps and remote electronic devices, such as iPads, for data entry and analysis.
- Transparent: Use clearly defined protocols, rules, and procedures that are communicated in plain language to all participants.
- Ethical: Prioritize data privacy, security, and patient consent.

Given recent US Supreme Court cases regarding the need for more explicit congressional authorization for regulatory action than has historically been the case (e.g., *Loper Bright Enterprises v. Raimondo*, 2024; *Securities and Exchange Commission v. Jarkesy*, 2024), we recommend that Congress enact legislation explicitly giving the FDA the responsibility for establishing uniform medical data standards and provide dedicated funding and resources for this purpose.

In some cases, drug companies may view the strategic and financial risks associated with sharing their data and receiving data from others as outweighing the potential upside of receiving clinical data gathered by others. One concern about receiving clinical data from "unvetted" treatments conducted by third parties is that it could expose previously unknown side effects or safety issues with their compounds or drugs. This opens firms to significant legal risks, as any adverse events or safety problems that come to light could lead to lawsuits, regulatory actions, and damage to the product's reputation. It may ultimately turn out that the adverse results reported by others were due to their clinicians' failures to follow the strict protocols for subject selection (such as excluding candidates with certain preexisting conditions, for example), but ferreting out those explanations can be exceedingly difficult and take valuable time to tease out, potentially derailing an otherwise promising first-out-of-the-gate treatment. As noted later in this chapter, certain limitations of liability may be necessary to mitigate these risks.

Finally, pressures to deliver financial returns to shareholders can lead managers to focus on maximizing profits from existing products rather than investing in high-risk, long-term research projects, especially those that may cannibalize existing offerings. This short-term perspective can discourage companies from engaging in data-sharing initiatives that may not yield immediate financial benefits but could lead to higher returns in the long term.

In summary, the current pharmaceutical development model, characterized by a focus on government-funded research, high regulatory costs, competitive pressures, regulatory hurdles, and economic incentives, is not conducive to data sharing and knowledge exchange. Overcoming these challenges requires a fundamental shift in mindset and the adoption of new business and regulatory models that prioritize collaboration and open innovation.

Notwithstanding the challenges, the CEO Roundtable on Cancer, a nonprofit organization established in 2001 by former President George H.W. Bush to inspire corporate leaders to take meaningful action in the fight against cancer, provides an encouraging example of how the right combination of political will, private commitment, and leadership can change attitudes and behavior. One of its key initiatives, Project Data Sphere, focuses on advancing cancer research through data sharing and big data analytics (RTI International, 2023). This platform allows researchers, pharmaceutical companies, and academic institutions to access and analyze aggregated clinical trial datasets from over 100,000 patient lives. By fostering collaboration across the healthcare ecosystem, Project Data Sphere aims to accelerate innovation in cancer prevention, diagnosis, and treatment. Additionally, the CEO Roundtable promotes the CEO Cancer Gold Standard accreditation and other workplace health initiatives that encourage companies to implement evidence-based practices to reduce cancer risk among employees.

Through Project Data Sphere, major pharmaceutical players have contributed anonymized clinical trial data to create a centralized repository for research. This initiative has enabled groundbreaking studies, including the development of AI models for tumor assessment through the Images and Algorithms Initiative (CEO Roundtable on Cancer, n.d.).

By 2018, these collaborative efforts had affected millions of lives, particularly in underserved communities disproportionately affected by cancer. Their impact underscores the transformative power of cross-sector collaboration in addressing complex health challenges and highlights the critical role of data sharing in driving progress against cancer.

Some experts have suggested that if the FDA were to give an expedited review of an application for a new drug indication for an existing drug, then a firm might be more willing to share more of its compounds, including those that may have failed clinical trials. That carrot would be especially valuable if the right to expedited review were transferable to other drug candidates. If the carrot proves inadequate, then, at least for discoveries funded with government grants, the NIH or other funding agency could require a pharmaceutical company that owns a compound that it has decided not to pursue for further commercialization to offer to license it on a nonexclusive basis to other firms for new applications not being pursued by the drug company, in exchange for a reasonable royalty.

Especially when ARPA-H, BARDA, or the other designated agency sponsoring the first P3 is working with the trusted intermediary to create and operate the first iteration of the AI-driven data-sharing platform CureFinder, the sponsoring agency could encourage data sharing to help train the AI program by offering the pharmaceutical firm, university, or other entity willing to share their data a tradeable right to expedited FDA review of an application for a new drug or a new drug indication.

Another regulatory lever that could incentivize data sharing is adjustments to pricing policies, such as those permitted by the Inflation Reduction Act of 2022 (IRA) in the United States. The IRA introduces new constraints on drug pricing, particularly for products later in their lifecycle. If policymakers were to offer manufacturers some relief from these pricing restrictions—for example, by delaying the onset of IRA-mandated price cuts or by reducing the magnitude of those cuts—in cases where the manufacturer has participated in data-sharing partnerships, that too could create a powerful incentive. This type of carrot-based approach, where data sharing is rewarded with more favorable pricing policies, may be more effective and politically achievable than trying to mandate data sharing through regulation.

An additional regulatory incentive may involve a Food and Drug Administration waiver, similar to the one granted for compassionate-use approval, also known as "expanded access." This waiver enables a patient with a serious or life-threatening condition to access an experimental therapy (drug, biologic, or medical device) that has not yet been fully approved by the FDA, when no other satisfactory treatment options are available, thereby providing access outside of clinical trials. The law limits the liability of drug manufacturers for such experimental therapies. Similar safe harbor protection might be provided to pharmaceutical companies that share clinical data.

Under certain circumstances, the US government has also limited the liability (other than for willful misconduct) for the manufacture of certain vaccines and medications related to diseases, threats, and conditions that constitute a present or credible risk of a future public health emergency (ASPR, n.d., *Public Readiness and Emergency Preparedness (PREP) Act*; see also Hickey et al., 2023, p. 3; Holland, 2018, p. 447). Providing this type of immunity is sometimes needed to induce a pharmaceutical firm to develop a drug when the risks to certain patients cannot be adequately quantified or eliminated. In such a case, the government may set up a fund to compensate patients harmed by the drug.

It is essential for pharmaceutical companies to maintain complete transparency regarding adverse toxicity data related to their drugs. To ensure this, a mechanism could be implemented whereby an independent panel of experts is responsible for validating the quality and integrity of clinical trial data, especially safety data collected by others. This panel would assess whether reported adverse events are legitimate or if they stem from flawed protocols. It must be noted that this will be a difficult and challenging task. Healthcare institutions, physicians, or CROs that consistently produce substandard or questionable data could face exclusion from future trials, creating an iterative process that improves overall data quality. Additionally, artificial intelligence programs could be trained to evaluate whether clinical trials conducted by third parties meet the rigorous standards required for FDA approval.

To create an efficient market for the commercialization of drug compounds for new applications, we recommend creation of a public-private auction-based system for the licensing of drugs that failed in clinical trials or went off-patent for new indications. Congress could facilitate such an

auction by designating an appropriate governmental agency with OTA, such as BARDA or ARPA-H, to oversee them and provide antitrust guidance.

Again, the use of AI platforms would permit the sharing of clinical and other data without the loss of IP protection. The open innovation literature posits that firms can increase both the value they can create and the value they can capture from their innovations when they are able to buy innovations relevant to their core business from others (be an in-licensor) and to sell non-core innovations to others (be an out-licensor) (West, 2006, p. 116). Scholars caution, however, that the licensing of innovations "requires significant disclosure to match buyers and sellers" (West, 2006, p. 116). They further note that when it comes to deciding how much information to disclose concerning the innovation for sale, the potential parties to the exchange will have conflicting interests. The potential buyer will want as much information as possible "to evaluate [the innovation], judge its value," and make its build-or-buy calculation (West, 2006, p. 116). In contrast, the potential seller wants to disclose enough information to close the deal, but "at the same time, it must be concerned about providing enough information to customers (or rivals) to invent around and bypass the seller" (West, 2006, p. 116).

Our P3 model creates more selective information disclosure options by making it possible for potential sellers to expose more data related to their innovations to a larger set of potential buyers, even if all aspects of the innovations are not protected by IP law, without forgoing the possibility of attaining IP protection later. Similarly, our model makes it possible for potential buyers to see more data that might be of interest to them from more potential sellers, even if the sellers have not yet secured IP protection for the data or such protection has lapsed. This is made possible by the creation of a novel mechanism whereby the seller of the innovation can "safely" use neutral AI-powered platforms, operated by trusted intermediaries, to share *masked and protected sensitive data* with potential buyers. Although the shared information is incomplete, it may be sufficient to narrow down the potential bidders to a single entity willing to sign a mutually acceptable nondisclosure agreement in exchange for more complete information. For example, instead of sharing raw clinical trial data, the owner of the data participating in the P3 can provide "synthetic" datasets that hide patient details and proprietary information to the trusted intermediary. This makes it possible for start-ups or biotechnology firms to explore new uses for a drug (like repurposing it for another disease) without risking the original company's trade secrets or sacrificing its ability to demand licensing fees if, after further disclosures, this time, pursuant to a nondisclosure agreement embedded in a smart contract, a particular start-up or biotechnology firm agrees to license the drug on the specified terms. In short, AI is a valuable tool that skilled intermediaries can utilize to facilitate secure data transfers and transform data into actionable insights.

The pharmaceutical companies would, in exchange for a designated fee and perhaps also the sharing of certain of their own data, be able to subscribe to access a new-drug database, thereby gaining the option to participate in a time-bound bidding process for licensing rights. Companies could then bid on different indications for a drug that had failed in clinical trials or had gone off-

patent. This would eliminate the current situation, whereby a government-funded drug owned by Company A, which failed a clinical trial for Indication 1, cannot be used by Company B for Indication 2 because Company A has elected not to pursue Indication 2. To prevent firms from unfairly overbidding to drive out competitors, the auctions would be guided by the principle of "use it or lose it." Accordingly, licensees would be required to use reasonable efforts to commercialize the licensed drug within a specified timeframe. Perhaps after seeking input from the NIH and the FDA, the agency running the auctions could mandate data sharing or require the grant of a nonexclusive license at a reasonable rate to other firms if the drug is not brought to market for the new indication within a certain timeframe. The goal is to prevent a firm from being a "dog in the manger" and seeking to prevent others from exploiting an invention funded by the government, indicating that the firm currently owning the drug has elected not to exploit a specific indication. In certain respects, this is similar to the "march-in" rights granted to the US government under the Bayh-Dole Act if the owner of a discovery funded by the government fails to commercialize it.

To expedite the process, the agency running the auctions should have the authority to make decisions, so bidders have limited appeal rights. Additionally, we propose a mechanism whereby other companies can petition to secure license transfers or co-licensing rights if the current holder of the rights is not making adequate progress commercializing a compound. This approach is designed to ensure that compounds with promising applications for new indications are developed efficiently and do not languish due to strategic inaction.

Our model aims to strike a balance between encouraging innovation and ensuring access to potentially life-saving treatments. We suggest considering both financial bids and scientific capabilities in licensing decisions, implementing a "quality override" mechanism for high-potential but less-funded teams, and encouraging participation of smaller players and start-ups. This approach is inspired by DARPA, which supports innovative small businesses engaged in federal research and development projects with the potential for commercialization.

Tradeable tax credits or vouchers, similar to carbon credit systems, could also incentivize companies to share data for less compelling commercial indications or alternative uses. This would help offset potential market losses from sharing the data. Additionally, the tax laws could be changed so companies that share their data concerning failed compounds and agree to auction the compounds off for other indications are not required to mark down or depreciate assets or take a charge against earnings even when they receive less in an auction than they invested in the compound.

V. Key Elements of a Pharmaceutical Public-Private Partnership Agreement

Fostering a culture of trust, collaboration, and innovation is essential for the success of a P3. Negotiating and crafting a well-drafted written pharmaceutical public-private partnership agreement that spells out the parties' rights and responsibilities can help create such a culture and prevent misunderstandings. Both the business and government leaders involved in

making the deal and their lawyers must remember that the primary goal is to create a supportive environment that encourages knowledge sharing, risk-taking, and experimentation, allowing participants to maximize their potential in delivering breakthrough patient therapies. At a minimum, as stated by Ferid Murad, Nobel Laureate in Physiology and Medicine, "the collaborating parties must plan carefully, take the project seriously, define who does what, and honor their commitments" (Murad, 2014, pp. xvii–xviii).

As with the Information Commons contemplated by the 21st Century Cures Act, we recommend that a government agency, such as ARPA-H or BARDA, with Other Transaction Authority, be a party to the contract. Thus, the contract would establish multi-lateral arrangements among universities and other research institutions, private pharmaceutical and biotechnology firms (and potentially private investors), the trusted intermediary, and governmental actors. Patient advocacy groups might be represented on an advisory board but would typically not be a party to the contract itself.

Entities and other persons who are not initially parties to the P3 agreement (what we call non-members) would not be granted access to the CureFinder data-sharing platform unless they either are subsequently admitted as members of the P3 under the P3 agreement terms or they (1) were invited to participate by a stated percentage (say 2/3) of the members of the P3; (2) agreed to abide by a standard data-sharing agreement attached to the partnership agreement as an exhibit; and (3) paid stipulated data-sharing and transaction fees to the P3 in addition to any licensing fee or other payment due if there is a match between the non-member and a buyer or seller who is a member of the P3 or who agreed to be bound by the provisions applicable to non-members. The partnership agreement should include explicit, workable provisions making it easy for qualified new members to join after approval by a supermajority vote of the governing body or similar mechanism.

As discussed in Bagley and Tvarnø (2014, 2015), parties can use long-form P3 agreements to promote mutual trust, transparency, and fair dealing, as well as to achieve more economically efficient outcomes. To optimize the structure and dynamics of P3s, the parties should employ a game-theoretic framework when drafting the written contract to promote fruitful cooperation by aligning incentives, preventing free-riding and defection, and addressing information asymmetries concerning the value of resources and likelihood of potential outcomes (for a detailed discussion, Bagley and Alon-Beck, 2018, pp. 886–889; Bagley and Tvarnø, 2014, pp. 386–390).

In brief, game theory is the study of strategic interactions among different actors engaged in a common enterprise, where each actor's decisions affect the outcomes for all. Game-theoretic contracting comprises three basic steps: analysis, modeling, and design. One begins by carefully *analyzing* the incentives and concerns of each participant in the proposed undertaking, paying particular attention to any respects in which the participants may have conflicting interests. For example, in the case of a P3, a junior university scientist may seek academic advancement of the

early publication of novel research findings concerning a new drug. In contrast, the university itself and the pharmaceutical firm may seek the profits attainable years later when that drug is patented. The agency funding the university research will typically want the most effective and safe new drug available to patients in the shortest period at the lowest cost. The next step is *modeling*—using game theory tools to map out possible scenarios and to determine how different contract terms (such as data sharing, IP rights, revenue sharing, or expedited regulatory review) would influence each party's choices. The third step is *designing*—crafting contract terms that promote transparency (to deter cheating) and align incentives to the extent possible to create a "win-win" so that each participant benefits more by cooperating, that is, by abiding by the P3 agreement, than they would by "defecting" and violating the contract at the expense of the other participants. The design might include trust-building techniques, shared risks and rewards, clear IP management, and transparent processes. The application of game theory can help ensure the fair distribution of costs and benefits, and it can also help promote the long-term sustainability of the partnership. The focus on maximizing joint value creation and preventing "defection" is what makes the game-theoretic contracting approach to crafting P3 agreements particularly powerful.

A critical aspect of our proposed P3 model is the creation of explicit mechanisms for sharing risks and the right to use the knowledge created by collaborative effort. By pooling resources and sharing the financial burden of drug development, partners can reduce the overall risk associated with research and development. This can encourage investment in high-risk, high-reward projects that might otherwise be avoided. Accordingly, the agreement should set forth which resources will be shared and establish the framework for determining who will own or otherwise have the common or exclusive right to exploit the shared knowledge or information resulting from the collaboration.

Another key concern is the sharing of development costs—the agreement should clearly define each party's responsibilities and investments. This is important for both the private firm and the public partner, as it outlines the financial commitments and risk-sharing arrangements.

The P3 agreement should incorporate mechanisms for intellectual property (IP) sharing, ownership, licensing, and management. Clear IP guidelines will facilitate collaboration and help prevent disputes. Given the legitimate interests both funding agencies and universities have in promoting basic research, funding agencies and university technology transfer offices should seek to limit overly burdensome provisions, such as reach-back licenses and other provisions that would prohibit university researchers from utilizing tools they have developed in the course of one project when doing research in another, unrelated project (see Bagley & Tvarnø, 2015, pp. 47–52).

Negotiating the terms around when, where, and how data and results can be published is often a point of debate, as it impacts the professional success and recognition of the researchers involved. Although many industrial participants may be less concerned about this, academic and

research institutions place a high value on the ability to publish findings from the collaboration. Yet, with planning, publications, and academic presentations can be timed to avoid forfeiting patent rights.

Any joint project should have clear milestones with associated timelines, along with provisions that establish the process for determining whether these milestones have been satisfied. The contract should delineate who has the power to make that determination. If a project does not meet a milestone, it should be considered a failure. In that case, there should be a mechanism to determine whether the original objective was unrealistic or unworkable and potentially needs to be modified through an amendment to the partnership agreement or the entire arrangement should be terminated to prevent the creation of "'zombies'" (Arslan et al., 2024, p. 559).

The agreement could contain a provision permitting the parties, by perhaps a supermajority vote, to agree to modify the original objective if the parties conclude that it was unrealistic or unworkable as originally conceived but still warranted further collaborative work on a modified basis. That way, if a compound has failed to perform as expected, the disappointed party will have the option of cutting its losses and moving on to another more promising therapeutic candidate. But if others wanted to pursue other indications or delivery options, they would have a right to do so.

The P3 agreement should require regular communication among the participants and within the participating entities themselves, so that the research scientists are kept informed. The agreement should also establish feedback mechanisms to facilitate knowledge sharing and address any challenges that may arise. The agreement itself should encourage the participants to be honest about their vulnerabilities and objectives so they can develop ways to identify issues before they sour the working relationships necessary for success (see Edmondson, 1999, p. 354). The participants should agree to work together in good faith to make any modifications required to their working relationships to achieve their common objectives. This could include bringing in coaches to help resolve interpersonal conflicts.

Our model assumes that a party will not be required to disclose proprietary data unless an enforceable nondisclosure agreement (NDA) is in effect. To enable the smooth sharing of data and consummation of licensing transactions, the forms for NDAs and for assignments of inventions and licensing agreements should, whenever possible, be agreed upon in advance and appended to the P3 agreement as exhibits with blanks for terms like the description of the invention and the licensing fees.

A critical component of a successful P3 is often the deployment of a skilled workforce with the expertise to drive innovation and collaboration. To the extent that training and education programs are necessary to build or maintain the necessary capabilities within the partner organizations, the contract should require that they be provided and evaluated regularly. The contract should also specify who is responsible for providing and paying for such training.

Sample clauses to consider including in a P3 contract to reinforce the importance of relational governance to the successful operation of a P3 are included in Appendix A.

VI. Addressing Additional Concerns and Challenges Associated with P3s

Although pharmaceutical public-private partnerships offer significant potential benefits, it is essential to acknowledge and address potential concerns. For universities, the primary concerns include maintaining academic freedom and ensuring that commercial interests do not unduly influence research priorities. Government agencies are focused on ensuring that public investments lead to accessible and affordable treatments while safeguarding public health. Industry partners are concerned with protecting their intellectual property and receiving fair compensation for their contributions. Patient advocacy groups prioritize the availability of safe, effective, and affordable treatments. By acknowledging and addressing these diverse concerns, P3s can create a balanced and collaborative environment that benefits all stakeholders.

Another concern is the potential for unfair pricing of drugs developed through P3s. If pharmaceutical companies capture excessive profits from these collaborations, it could undermine the public interest in supporting such partnerships. There is a risk that the benefits of public funding and expertise may primarily accrue to the private sector, while patients bear the burden of high drug prices.

To address this risk, government partners should have a significant say in P3s. For instance, in the case of developing bacteria-resistant antibiotics, the government could offer a substantial prize, such as $1 billion, to firms that successfully create such a drug. However, this prize could come with conditions, such as mandating the sparing use of the antibiotic to prevent the development of resistance. This approach ensures that public investment leads to public benefit.

Additionally, the government could negotiate pricing agreements or implement tiered pricing structures to ensure affordability and accessibility of the developed drugs. The COVID-19 vaccine development provides valuable lessons on government involvement in P3s. Operation Warp Speed, the public-private partnership initiated by the US government, provided substantial funding and resources to accelerate vaccine development. The government invested billions of dollars in research, development, and manufacturing, effectively de-risking the process for pharmaceutical companies. In return, the government secured millions of vaccine doses at pre-negotiated prices. This model demonstrated how government involvement could expedite critical drug development while ensuring widespread access. Similarly, in the case of Hepatitis C treatments, government-funded basic research played a crucial role in the development of curative drugs. However, the high prices of these drugs upon market entry highlighted the need for better mechanisms to balance innovation incentives with affordability. These examples underscore the importance of government partners having a strong voice in P3s to ensure that public investments translate into accessible and affordable treatments for patients.

Furthermore, there is a concern that P3s may lead to the erosion of academic freedom and the commercialization of university research. If educational institutions become overly reliant on industry funding, there is a risk that research priorities may be unduly influenced by commercial interests rather than scientific merit. This could compromise the integrity of academic research and erode public trust in higher education.

Research suggests that these concerns may be overblown: "Overwhelmingly, the evidence suggests that academic inventors are very highly productive scientists" (Lissoni, 2012, p. 202). Similarly, Grimaldi et al. (2011, p. 1046) report: "Academic research has found little systematic evidence of a destruction of the open culture of science or to support the assertion that universities are performing less basic research." Instead, "the published evidence suggests that patenting is followed by an increase in scientific productivity" (Lissoni, 2012, p. 202).

Finally, as discussed in Section II, drug manufacturers are legitimately concerned that by participating in P3s, particularly by sharing their proprietary data, they will lose the value of innovation assets that could have been monetized had they kept the data secret until IP protection could be secured.

To address the parties' concerns and improve P3 outcomes, the partnership agreement should include strong transparency and accountability provisions. Regular reporting on research progress, decision-making processes, and funding allocations can help to ensure that public interests are protected. Additionally, the parties should have the ability to appoint (as a partnership expense) independent oversight bodies and auditors to monitor partnership activities and prevent conflicts of interest. Additionally, the partnership agreement should include mechanisms for implementing public input. Such mechanisms can help ensure that the priorities of patients and the broader community are considered in research and development decisions.

To safeguard academic freedom and integrity, universities can establish clear guidelines for industry collaborations, including conflict-of-interest policies and data-sharing protocols. Research ethics committees can play a crucial role in reviewing and approving research projects to ensure that academic values are upheld. Additionally, funding mechanisms can be designed to prioritize basic research and fundamental discoveries, thereby reducing the pressure on universities to focus solely on commercially viable projects.

Suppose junior academic scientists seeking tenure are precluded from publishing their work due to patent concerns. In that case, universities will need to create alternative mechanisms by which they can assess the scholarship of their junior faculty for promotion purposes. This may require the use of a peer-review process akin to what a top journal would use when deciding whether to publish an article, supported by air-tight nondisclosure agreements satisfactory to the industry participant in the P3. Given the amount of time a de novo review of the junior scientist's research would most likely require, the university should expect to compensate the reviewer or their home university in a mutually acceptable form of reimbursement, such as money. Under no circumstances should the compensation be affected by the outcome of the reviewer's assessment

of the research. It may be appropriate for the P3 to bear at least some of the cost of that external review, at least when the industry participant has insisted that the discovery not be disclosed or published.

To mitigate concerns that P3s will skew the appropriate balance in academia between basic research and commercial applications, innovative funding mechanisms can be designed. One approach could be implementing a royalty flow-back system, where a portion of the royalties from successful commercial products is redirected to universities to fund laboratories and support postdoctoral researchers. This would create a sustainable cycle of funding for fundamental research. Additionally, government agencies could establish dedicated grant programs specifically for basic science, with a requirement that a percentage of any resulting commercial success be reinvested in foundational research. Another potential policy could involve creating research consortia where multiple universities and private companies collaborate on pre-competitive research, sharing both costs and benefits. Tax incentives could also be offered to companies that invest in university-based basic research programs. These mechanisms would help prioritize fundamental discoveries while still maintaining the benefits of P3s, ensuring a pipeline of innovation that ranges from basic science to applied research and commercial development.

As noted earlier, under the US Constitution, Congress has the authority to legislate patent terms, which could be leveraged to create a framework that incentivizes innovation within P3s while promoting broader access to treatments. This framework could offer stronger patent protection for firms that agree to license their inventions on a non-discriminatory basis for reasonable fees, ensuring that improvements and applications for other diseases are not blocked. Additionally, Congress could extend patent protection for off-patent drugs that are found to cure different diseases, encouraging research into new applications for existing compounds. Thalidomide serves as an example of this potential. Scientists found it to be effective in treating leprosy and cancer after its initial use as a sedative was discontinued due to horrific side effects when given to pregnant women. The proposed framework could also address long-standing patent reform issues. This might include measures to combat patent trolls, promote patent pools with antitrust protection, and prohibit agreements between patent holders and generic manufacturers that delay the sale of biosimilars. Such reforms could help strike a balance between the interests of innovators, patients, and public health. By implementing these and other measures, it is possible to mitigate many of the risks associated with P3s and create a more equitable and sustainable partnership model.

The cultural shift to more open innovation in drug development and repurposing will require strong leadership from both the private and public sectors. Traditionally, pharmaceutical companies, and many university technology transfer offices, have operated in a competitive environment characterized by secrecy and proprietary research.

Adopting more of an entrepreneurial mindset may help individuals and institutions make the necessary cultural shift. As any good book on entrepreneurship teaches, it is critical for entrepreneurs divvying up ownership rights in their start-up to focus on not just their slice of the pie but on the size of the pie itself. As Alex Edmans states in *Grow the Pie: How Great Companies Deliver Both Purpose and Profit*, when all members of an organization work together, "they create shared value in a way that enlarges the slices of everyone," thus "growing the pie for the benefit of all" (Edmans, 2020, p. 3). So, it is typically in the best interests of an entrepreneur seeking venture capital to select the venture capitalist with deep experience and strong contacts in the industry rather than the one who may offer the highest pre-money valuation (Bagley & Dauchy, 2018). While teaching entrepreneurship for decades at Stanford, Harvard, and Yale, the second author has seen firsthand that many great ideas never come to fruition because the inventor insisted on owning all the IP rights and holding onto the lion's share of the equity. As a result, the venture lacked the motivation of a team and the funding sources necessary to overcome the inevitable obstacles to commercialization. By fostering the open exchange of ideas among bright, talented, and motivated individuals and the sharing of economic risks *and* rewards, P3s can make possible discoveries that no one group of scientists, or one institution, might have even imagined.

Our model will also require many firms to assess and potentially change their organizational structure to foster the development of new competencies. Although large pharmaceutical firms often have staff dedicated to managing alliances, they may need to create new or expanded departments or divisions dedicated to working with transformational P3s, particularly with trusted intermediaries, given the related data sharing and collaboration requirements. This may require significant new investments in human resources, technology, and infrastructure. Additionally, employees may require specialized training and development to acquire the "soft" skills necessary for effective collaboration in a team environment.

The alignment of incentives between academic institutions and industry partners can also be challenging. Educational researchers may prioritize knowledge generation and dissemination, while pharmaceutical companies (and certain university technology transfer offices) focus on commercialization and profitability. Finding common ground and developing shared objectives can be a complex process.

Moreover, balancing the need for intellectual property protection with the desire to promote open innovation can be challenging, especially as more university technology transfer offices strive to offset the rising costs of higher education through royalties from technology licensing arrangements. As mentioned earlier, we recommend that the NIH consider requiring universities receiving NIH funding to share more pre-clinical data, including engineered models demonstrating efficacy and safety, unless the university can provide a compelling reason not to do so. This would include sharing assays, know-how, and prior research, ideally under NDAs. Technology transfer offices should be "nudged" to prioritize patient benefits from data sharing over what can be the speculative gains of delayed publication until patent applications are filed.

Furthermore, we acknowledge that even with OTA, the regulatory landscape will continue to pose challenges for P3s, especially those involving start-ups. Navigating complex regulations and obtaining approvals for collaborative projects is time-consuming and resource intensive. Addressing these challenges will require close collaboration among industry, academia, and regulatory agencies, including a sincere willingness to understand the counterparties' concerns and to find mutually acceptable ways to achieve joint wins. It will also be necessary to evaluate and measure the success of the P3s so that public policymakers, industry participants, academics, patient advocacy groups, and other stakeholders can decide whether the benefits of the types of P3s we propose outweigh their costs.

Performing such evaluations will be a daunting task. Armed with AI and perhaps assisted by experts or consultants of their choosing, the Bill and Melinda Gates Foundation or the Wellcome Trust might be an excellent candidate to carry out such tasks for a P3 undertaking a project within the foundation's area of dedicated interest. If so, their work developing appropriate metrics and KPIs could be applied to P3s in a variety of areas, including cancer, to track their progress and to determine the value and limitations of our model. Ideally, such assessments would also include suggestions for improvements in structure, operations, and contract design.

VII. Conclusion

The pharmaceutical industry and the government agencies that fund academic research stand at a critical juncture. The escalating costs and extended timelines of drug development have created an increasingly challenging environment for academic researchers, pharmaceutical companies, and agencies dedicated to translating scientific discoveries into new life-saving therapies for patients. The emergence of drug resistance and the need for combination therapies, as well as the increasing prevalence of chronic diseases, further exacerbate these challenges.

Drugs are developed within a complex, high-cost, and stringent regulatory system. Before a drug can be brought to market, the manufacturer must demonstrate to the FDA, through expensive clinical trials, that it is both safe and effective for its intended use. The rare exception is for promising drugs that may be prescribed to individuals facing near-certain death, given available treatments, even if the clinical trials for the new drug have not been completed, under the compassionate-use exception. The traditional, linear approach to drug development, with its sequential phases, often results in prolonged timelines and high rates of failure. Even if a drug company identifies a compound that appears to match a target identified by an academic researcher, most compounds prove to be unsafe or ineffective.

Identifying the cause of a disease can take decades or more of basic research by academic scientists working in university laboratories, which typically rely on government funding from agencies, such as the National Institutes of Health, to support their grant applications. Such applications are usually only approved after rigorous (and time-intensive) peer review. Record US government deficits have prompted calls for dramatic cuts to agency staffing levels and the

federal funding for drug research and development, threatening to cut off the flow of resources for discoveries. Cuts to FDA staff will almost certainly further delay the drug approval process.

Moreover, the traditional focus on proprietary drug research and development for profits protected by patents makes it extremely difficult for talented individuals working in different laboratories, fields, and institutions to share their discoveries and know-how and to collaborate on promising new approaches. This results in duplicated efforts and gross inefficiencies in terms of both resource allocation and the time it takes to move discoveries from the bench to the bedside, whether the discovery is a new compound or a new indication for an existing drug.

To break out of the Prisoners' Dilemma created when firms are unwilling to share their valuable information and other resources with potential collaborators in a joint project, firms need a mechanism to align the parties' incentives so that they stand to gain more by working together than by "defecting" and pursuing their own self-interests. A P3, supported by a well-crafted partnership agreement, accomplishes that.

Central to the success of the transformational P3s we propose in this chapter is the secure and effective sharing of data and knowledge. As previously discussed, the pharmaceutical industry has historically been reluctant to share proprietary information, duplicating research efforts. Implementing AI-supported data sharing platforms, establishing data standards, and fostering a culture of open science are crucial steps towards overcoming this challenge.

Utilizing artificial intelligence, at both the participant and the entity level, will almost certainly enhance the efficiency and effectiveness of P3s. Scientists can use AI to analyze vast datasets (including radiological data) and to identify potential drug targets, thereby accelerating the drug discovery process. Additionally, AI can be utilized to optimize clinical trial design and patient recruitment, resulting in faster and more informative studies.

Trusted intermediaries can utilize AI to create encrypted repositories of systematically collected and organized sensitive data, fostering trust and cooperation among P3 participants by facilitating data sharing while safeguarding proprietary information. By creating a secure environment for collaboration, trusted intermediaries can encourage greater openness and exchange of knowledge.

A voluntary participation model is crucial for the success of P3s. By allowing organizations to join the partnership based on their specific goals and capabilities, it fosters a more inclusive and collaborative environment. Providing both private and public incentives for participation, such as access to shared resources, expertise, data, and tax incentives, can encourage broader engagement.

Concerns about undue corporate influence, predatory drug pricing, threats to academic freedom, and overly broad intellectual property protection are valid, and P3 sponsors must address them through robust governance, transparency, and accountability measures. By establishing clear

guidelines and mechanisms for oversight in the partnership agreement, these risks can be mitigated.

Similarly, we acknowledge that overuse of OTA can lead to corruption and unsafe or ineffective drugs or other medical treatments if the usual protections against insider dealings, such as competitive bidding or proper clinical drug testing, are bypassed in the purported higher interests of speed and efficiency. Policymakers should keep in mind Lord Acton's adage, "Power tends to corrupt and absolute power corrupts absolutely" (1887), as well as President Ronald Reagan's admonition, "'Trust, but verify'" ("The President in Venice," 1987). Independent inspectors general, safe from retaliation by the political party in power, will play essential roles ensuring that relaxed government regulations do not lead to a repeat of, for example, the abuses that led to the sale of unsafe food and drugs in the early 1900s, resulting in the 1906 Pure Food and Drug Act, the creation of the Food and Drug Administration, and the 1938 Food, Drug, and Cosmetic Act.

Under the second Trump administration, the participation of government agencies in various types of healthcare research is undergoing significant change. We hope that this chapter will help inform the policy debates underlying these changes. Scholars, government officials, executives, patient advocacy groups, nongovernmental organizations, and other stakeholders will need to pay particular attention to the evolving landscape of federal research funding and the decisions of both the NIH and the FDA regarding staffing. New mandates and responsibilities emerge, sometimes daily, not only through traditional governmental regulatory channels but through social media, like Truth Social and X (e.g., Johnson & Achenbach, 2025; Stelter, 2025). Several executive orders have been successfully challenged in the trial courts. Still, their fate may well be determined by the US Supreme Court (e.g., *Department of State v. AIDS Vaccine Advocacy Coalition*, 2025, US Supreme Court order denying request by US State Department to cut off funds for work completed, including clinical trials underway in Africa).

For a platform like CureFinder to be successful, policymakers in both the executive branch and Congress will need to work together to select the appropriate government agency to spearhead the initiative and to ensure that Congress passes legislation that gives the sponsoring agency apparent authority to act within articulated guidelines. This must include the scope of the designated agency's Other Transaction Authority when managing P3s. This is especially important in light of recent US Supreme Court cases limiting the power of regulatory agencies to regulate certain economic activities without a clear congressional mandate (e.g., *Loper Bright Enterprises v. Raimondo,* 2024; *Securities and Exchange Commission v. Jarkesy*, 2024).

In conclusion, transformational P3s hold the potential to revolutionize drug discovery and development, as well as drug repurposing, but P3s must be designed, established, and operated with care, in good faith, and in a responsible manner by talented and dedicated individuals in the private and public sectors if they are to succeed. To achieve the ultimate goal of accelerating the translation of scientific discoveries into life-saving therapies, governmental actors, leaders in the

drug and AI industries, entrepreneurs and emerging biotechnology firms, university leaders and academic researchers, and other stakeholders will need to work together to create a P3 ecosystem that fosters transparency, honesty, open innovation, collaboration, and shared resources, as well as a respect for law and a fair return on investment. Enlightened self-restraint will be key.

A Call to Action

It is imperative to act with urgency. The global burden of disease continues to rise, and the need for innovative solutions has never been greater. The next global pandemic may be just around the corner.

The United States and China are already fiercely competing to establish dominance in AI and in the development of new drugs. Both countries can be expected to try to show the rest of the world why they are better equipped to protect their friends from the next pandemic due to their superior use of AI and other techniques to develop new drugs. By embracing transformational pharmaceutical public-private partnerships, US political and industrial leaders can help unleash the creative power of the scientists and other skilled individuals working here. In so doing, they will also demonstrate America's ability to use taxpayer money and private capital efficiently to protect people from antibiotic-resistant bacteria and other life-threatening diseases that know no national boundaries.

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Appendix A: Sample Terms to Be Included in a Pharmaceutical Public-Private Partnership Agreement

The P3 agreement should include clauses to the following effect:

1. The parties to this Pharmaceutical Public-Private Partnership Agreement (the "Agreement") have each decided that, by working together as partners to develop new drugs and other medical treatments, they can maximize the likelihood of success and create greater realizable value than would be attainable if they worked alone.
2. The parties recognize that the provisions in this section of the Agreement are contractually binding and that adherence to them is essential to the successful completion of the Project identified in Section [insert section number] and to meeting each party's objectives.
3. The parties agree to work together in a cooperative manner, conducting research and development, with the common goal of completing the Project successfully, characterized by openness, trust, and collaboration.
4. Separate copies of both the entire Agreement and this Section [insert section number] shall stay on the table in the lab and other shared places where joint work on the Project is done. The parties shall utilize the contract on a daily basis and educate the relevant staff, researchers, and legal back-office personnel regarding its provisions, in the spirit of joint optimization. The parties acknowledge that knowledge of, and adherence to, the contract is a necessary tool to create added value and complete the Project successfully on time.
5. The parties shall take the necessary steps to complete the Project. Accordingly, all parties shall have the obligation to warn each other of any error, omission or discrepancy of which they become aware and shall immediately propose solutions designed to jointly optimize completion of the Project.
6. In general, all relevant information concerning the Project, including the books, records, research tools, and patient data, shall be made available to all parties because it generates transparency, trust, confidence, and mutual collaboration. Provided, however, that the parties recognize that a party may have legitimate reasons to keep certain information private. Moreover, certain data, such as patient records, must be kept confidential as a matter of law. The provisions regarding the sharing of information and data set forth in Section [insert section number] set forth the agreed-upon rules for the sharing of information and data. The parties acknowledge that sensitive or proprietary information may be shared with the Trusted Intermediary identified in Section [insert section number] of the Agreement.
7. The parties must ensure each other a healthy business case and optimal research conditions and recognize that they will attain different economic yields from the Project.
8. In light of the above clauses and in accordance with the other provisions in the Agreement, the parties shall establish, develop, and implement a strategic alliance

relationship in the lab and other shared facilities with the objectives of achieving:

-Mutual cooperation
-Joint research
-Common goals
-An understanding of each other's values and the joint value of the Project
-Psychological safety
-Innovation
-Improved efficiency
-Delivery in accordance with Key Performance Indicators (KPIs) and timetables.

9. Any unanticipated research burdens, added value, risk, pain and gain identified by the parties shall be subject to negotiation regarding potential additional incentive payments.
10. The parties shall investigate, and remain open to considering, all possible positive incentives to create the value-added attainable by the successful completion of the Project. To the extent possible, the parties shall be rewarded for and encouraged to maximize their joint efforts for the benefit of the Project and allocate any unexpected added value in accordance with the key factors in paragraphs 8 and 9.
11. Any dispute shall be resolved as soon as possible in accordance with the following strategic alliance guidelines: When a problem arises, the first responsible director shall gather the parties and, based on the objectives set forth in the Agreement, launch a procedure to solve the problem in light of:
    -Common goals
    -Optimization of the Project
    -Trust and cooperation
    -Openness, open books and calculations

    If the problem persists, the next director in the hierarchy shall be given responsibility for the problem, then a mediator, and finally an arbitrator shall be retained. At every stage, the above points shall be observed. All parties recognize that even when they experience conflict, common goals and optimization lead to added value for the parties engaged in the Project.

12. All parties to the Agreement agree, on behalf of themselves and their employees, agents, and contractors, not to make any oral or written statements to non-parties concerning the Project or any other aspect of the Agreement, without first obtaining written approval of said statements from the communications oversight committee comprising representatives from all involved parties.

    Source: Adapted from Bagley and Tvarnø, 2014, pp. 396–397.