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# Bridging the translational gap: collaborative drug development and dispelling the stigma of commercialization



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**The current drug discovery and development process is stalling the translation of basic science into lifesaving products. Known as the 'Valley of Death', the traditional technology transfer model fails to bridge the gap between early-stage discoveries and preclinical research to advance innovations beyond the discovery phase. In addition, the stigma associated with 'commercialization' detracts from the importance of efficient translation of basic research. Here, I introduce a drug discovery model whereby the respective expertise of academia and industry are brought together to take promising discoveries through to proof of concept as a way to derisk the drug discovery and development process. Known as the 'integrated drug discovery model', I examine here the extent to which existing legal frameworks support this model.**

## Introduction

To the benefit of individuals and society, pharmaceutical innovations and technologies have the ability to lead to better healthcare, improve quality of life, and increase longevity. As stated in the 2009 Pharmaceutical Sector Inquiry, '[i]nnovation in human medicines has enabled patients to benefit from treatments that were unimaginable a few decades ago' [1]. However, the cost of healthcare and research and development (R&D) to bring new drugs to market is ever increasing. The average cost of bringing a new drug to market is US$2.6 billion and the average time to develop a new drug is more than 10 years [2,3]. In another study, it was reported that the economic burden to society associated with the treatment of chronic diseases, such as heart disease, diabetes, and cancer, is estimated at US$1.3 trillion or €700 billion a year [4,5]. Although the US Food and Drug Administration approved 41 new drugs in 2014 (17 of which had fast-track status and a further eight were approved under the 'accelerated approval' program) [6], in the immediate 10 years prior, the number of new drugs approved was approximately the same number of drugs approved during the 1950s [7,8]. As such, there is mounting evidence that the complexities of the current drug discovery and development process could be stalling the process of translating basic science into much-needed treatments.

## Current situation: inefficient translation of basic research into useable form

Despite significant public and private funds that have been invested into universities to conduct basic drug discovery research [9,10], there is a gap in the crucial step of translating such discoveries for development into products that can benefit the public. The nature of drug discovery and development is such that few early-stage discoveries deliver promising results [11,12]. Pharmacokinetics make it almost unpredictable as to whether promising early-stage discoveries will have the desired effect on humans. Available statistics indicate that only one in 10 000 chemical compounds prove to be medically effective to be further developed into a product and, after development, over half of those products entering Phase I clinical trials fail to advance to approval, resulting in a clinical approval success rate of approximately 10–16% [7,8,13]. According to another report, in recent years, an average of only three drugs acting on novel targets enter the market annually [14]. Many of the costs associated with drug discovery and development are related to the high risk of failure in translating discoveries into safe and effective products, demonstrating how challenging it is to move a molecule from discovery to commercialization. Given that industry is the only player in the drug discovery and development process that manufactures and makes products derived from basic research available to the public, it is understandable why industry tends to shy away from investing

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in early-stage research in favor of innovations with established indications of viability, such as proof of concept [11,15,16]. A consequence of the preference of industry to invest in later-stage technologies is that researchers potentially face increasing difficulty finding funding to translate and develop their early-stage discoveries to provide proof of concept. It is a chicken and egg scenario: investors need proof of concept to invest in the further development of basic research, but researchers need investors to invest in early-stage discoveries to have the funding to achieve proof of concept.

## Current situation: 'old school' technology transfer and the 'valley of death'

One of the major shortcomings in the current drug discovery and development process is the lack of competencies to advance innovations beyond early-stage development [17] despite large government investments in university R&D, education, equipment, and apparatus in the fields of medicine and pharmaceutical sciences [18]. The rate of commercialization of university inventions by technology transfer offices (TTOs) is slow, mainly because TTOs have limited resources and skills required to assess and market inventions that come from all the different disciplines and faculties of a university [19,20]. TTOs are given the responsibility of deciding what research to protect by way of intellectual property (IP). However, without the benefit of the necessary scientific or relevant expertise or know-how to evaluate and decide which innovations have potential and which do not, promising research potentially falls through the gap. TTOs also typically do not have pre-existing relationships or contacts with industry or potential licensees, especially in relation to highly innovative inventions with niche markets, making such inventions particularly difficult to market [21]. Furthermore, typical strategies used by TTOs in an effort to commercialize early-stage discoveries might not be based on sound business practices and could lead to undesirable results. For example, a common criticism of university TTOs is the amount of time and resources spent on negotiating royalty and/or licensing fees for access to basic research in the absence of any measures to determine what a fair fee would be [22,23]. Without proof of concept, investing in lengthy and costly negotiations over early-stage discoveries might not be the most productive and effective way to approach translation and eventual commercialization. Positional negotiations might even deter collaborative research if both sides hold fast to their respective positions. Therefore, the traditional university technology transfer model lacks the means to bridge the gap between early-stage academic discoveries and preclinical research to achieve proof of concept, which investors increasingly require to assess the risk and justify financial investment in new discoveries. Known as the 'valley of death', innovations that might be the next 'blockbuster success' could languish and be left undeveloped at the early stages because of the lack of funding and expertise to bring the discovery through to an investible commercial point [24–26].

## Current situation: negative connotation associated with 'commercialization'

The word 'commercialization' is usually associated with the concept of profit. However, in the drug discovery and development context, commercialization is a more complex word that incorporates the concept of making basic drug discovery research available for the benefit of the public. The reality is that drug discovery and development requires the involvement of both academia and industry because none of the individual players have all the necessary skills and resources to discover and develop pharmaceutical products independently. Academia is a rich source of basic research and discovery, but lacks the funding and translational expertise of how new therapies reach the market. Industry has core competencies in clinical translational activities and procedures required to convert early-stage research into new therapies, but they generally outsource the discovery of new molecules to external partners [27,28]. There is no denying the financial motive of industry, especially when, on average, only three in ten new pharmaceutical products generate revenues equal to or greater than average industry R&D costs [29]. However, as a *quid pro quo* for making life-saving products available to, and for the benefit of, the public, efficient and effective translation of publically funded research through university–industry collaborations is a necessity that should dampen any criticism and discontent relating to commercialization.

## Collaborative drug discovery and proof of concept: the solution?

Given the increasing cost of R&D and budgetary and funding challenges in the public research sector, collaborative partnerships between industry and public research organizations might be a pragmatic solution as a means to pool resources and reduce duplication efforts. Public private collaboration in product development is not a new idea and appears to be an obvious model to explore in the context of drug discovery and development, given that both academia and industry have a key role in the efficient translation of basic drug discovery research to develop commercializable products. Can public research organizations and industry forge closer ties with each other through collaborations to facilitate the drug development process while preserving academic core values and providing industry with the competitive advantage that they seek?

Currently, there are many different models that attempt to foster the translation of ideas from academia to industry as a means to bridge the translation gap. These range from strategic partnerships to joint institutes between industry and academia. My focus here is one particular model referred to herein as the 'integrated drug discovery and development model'. The integrated drug discovery and development platform is a collaborative model whereby the respective expertise of academia and industry are brought together to establish viability in early-stage technologies by way of achieving proof of concept. The premise of this platform is that both academic and industrial scientists share at least one common interest, which is to provide better treatment to, and care of, patients, and it is this mutual desire that drives the collaboration and development of partnerships to bridge the translational gap. However, despite a shared public health commitment, significant 'cultural' obstacles between academia and industry [30,31] can stand in the way of a successful partnership. Academics speak the language of science and industry speaks the language of business. Academics are motivated by research and publication to 'survive' in the academic world, whereas industry is motivated by commercial interests to keep shareholders happy. In


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