Innovation Ecosystems in Pharma: Collaboration at the Boundaries between Disciplines

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Clinical Pharmacology and Translational Research section submitted this article.
Collaboration at the Boundaries between Disciplines

Innovation Ecosystems in Pharma: when the shortcomings of the creative spirit and suggests speaking to the best of our programs. All of this has led to the rising costs of R&D continues to escalate, reflecting the productivity of the pharma R&D effort. We can increase innovation. Each year brings new tools and techniques that offer high-throughput screening, for example, but this has not led to a greater number of successful new programs. We can use in silico techniques like modeling and simulation to estimate the probability of success in phase 3, but we have not seen a substantial improvement in the productivity of the pharma R&D effort. We just seem to arrive at failure more often and at greater expense.

INVENTION VERSUS INNOVATION

The geniuses of the early 20th century—such as Thomas Edison, Henry Ford, and the Wright Brothers—are often remembered as bicycle repairmen who tinkered with an airplane, they were, in fact, serious scientists who systematically performed experiments to understand the aerodynamics of mechanized flight. The work of these innovative geniuses helped define the concept of excellence in R&D.

But the genius of these inventors is not in their invention themselves. Their genius is in the recognition and development of the systems required to fully implement their ideas and enable society to realize the benefits of their inventions. Before the light bulb could shine over the family dinner table, Edison had to conceive of an infrastructure for generating, distributing, and utilizing electricity. Ford’s Model T was a marvelous invention, and Ford’s efforts at designing and optimizing the assembly line dropped the production time for a Model T from 12 hours to 90 minutes. This allowed a reduction in price that resulted in a cultural revolution.

And while the Wright brothers are often remembered as bicycle repairmen who tinkered with an airplane, they were, in fact, innovators. The result can be identified with their iconic inventions. The light bulb, the Model T, and the flight at Kitty Hawk are widely recognized as fruits of years of experimentation and tinkering.

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INNOVATION ECOSYSTEMS

With its origins in biology, the term “ecosystem” conveys the idea of the complex and intricate relationships between all the organisms found in a particular physical environment. This definition of ecosystem has since been extended to include any complex system that resembles an ecosystem from a biological systems, such as pharma R&D.

Within the pharma R&D ecosystem, there are many constituent components, including the companies that supply the organizational structure and funding, the departments within the company that execute specific tasks and functions, and the scientists who, by virtue of their training and interest, gravitate toward different areas of specialty. All these components function within the cultural and economic milieu that their home country has established. Adverse events are governed by governmental and regulatory policies.

The distinction between an invention (the implementation of a useful product or process based on the ideal) and innovation (the introduction of new and better processes and introduce new technologies that can translate into new approaches for dealing with old challenges.

But cross-functional, interdisciplinary knowledge synthesis is lacking in many R&D programs. Instead, various functional areas are assigned to write separate and distinct sections of investigator brochures, team presentations, and early R&D plans.

Each section reflects the group that prepared it. “Synthesis” is merely a collection of separate facts and study results from the various disciplines.

This lack of cross-functional synthesis has two important consequences: knowledge gaps between disciplines are not identified and rectified, and research plans are developed based on experimental intuition rather than an analytical synthesis of interdisciplinary knowledge. The result can be biased study designs that are not powered to new medicines. This knowledge synthesis is essential for the proper design, analysis, and interpretation of studies; the development of effective research and development plans; and the assembly and presentation of evidence for successful regulatory submissions. In other words, knowledge synthesis is needed for all the activities required to successfully deliver innovative medicines to the marketplace.

EXCELLENCE IN SCIENCE

Not all have a sense, or definition, of excellence that we bring to our work. For example, a scientist may have personal expectations of what it means to do a good job, such as meeting certain standards for professional behavior. These expectations are likely guided by the community of practice and reinforced by fellow scientists’ behavior patterns. These standards and norms are welcomed because they provide guidelines for improving the personal, institutional, and organizational behavior.

EXCELLENCE IS ONE OF THE MAIN DRIVERS OF INNOVATION

In short, the pursuit of excellence involves so does the instrumentation that uses that technology. But in seeking to increase the speed of throughput and accuracy of results, the nature of the fact which is being measured may also change or the interpretation of the result may change in significant and important ways. For example, the value of in vitro potency generated by high-throughput screening may not be directly useful in predicting concentration-response relationships.

DISTANCE BETWEEN DISCIPLINES

Three changes occur as the knowledge base in a specialty area of science expands in complexity and sophistication. First, an entirely new language may arise to facilitate communications between knowledgeable practitioners.

Second, as technology evolves, so does the instrumentation that uses that technology. But in seeking to increase the speed of throughput and accuracy of results, the nature of the fact which is being measured may also change or the interpretation of the result may change in significant and important ways. For example, the value of in vitro potency generated by high-throughput screening may not be directly useful in predicting concentration-response relationships.

Third, innovations that arise in a specialty area that could significantly benefit an adjacent specialty may not be recognized as such. Consequently, these innovations may be implemented as a partial solution such that the larger enterprise does not realize the full benefit of the innovation.

The limited utilization of microdosing studies enabled by exploratory investigational new drug guidance3 across companies because of internal hurdles in defining the value of this option is an example of the latter.4 Developing scientific and innovative excellence in pharma R&D requires attempts to bridge these distances between disciplines with a structure that firmly definitions that all team members can understand and use. A TEAM SPORT

A comprehensive, interdisciplinary synthesis of available data and expertise plays a central role in the innovation that leads to new medicines. This knowledge synthesis is essential for the proper design, analysis, and interpretation of studies; the development of effective research and development plans; and the assembly and presentation of evidence for successful regulatory submissions. In other words, knowledge synthesis is needed for all the activities required to successfully deliver innovative medicines to the marketplace.

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Innovation Ecosystems in Pharma: Framework for Interdisciplinary Collaboration

In a world where rapid progress is required, the ability to synthesize knowledge and translate insights into action is crucial. A conceptual schema (see Figure 1) is used to compile and structure (preferably in a process flow format) the current knowledge and drug effects, and all available data regarding the disease process and drug effects, including any existing in silico models and results from prior investigations. It draws data and analyzes results from all functional areas and provides strategic guidance, which will allow data to be integrated across functional areas to yield new results or insights. The conceptual schema for an R&D program defines the known elements of the disease process, the hypothesized interrelationships between disease process and drug effects, and the assumptions required to generate results, plans, analyses, and experiments that will validate or invalidate the hypotheses. The hepatitis C viral kinetic model is an example of a comprehensive conceptual schema. On developed, the first and most critical use of the conceptual schema is to first define the gaps in knowledge, including gaps between disciplines, that the R&D team must investigate. The therapeutic area managers and scientists then utilize this management guidance to develop their analytical and experimental investigation plans and models. Additionally, the in silico team members utilize the conceptual schema to identify key interfunctional parameters and develop data for the therapeutic areas to use to design their analyses and experiments in a manner that will be most useful to downstream collaborators and stakeholders.

There are many challenges to achieving effective team collaboration. Not the least of which is the difficulty in realizing a shared vision of the challenges to be overcome and a commitment to finding common ground for developing solutions. Some people have extraordinary talents in accomplishing these tasks. Most often, though, the complexity of the problems in biology and drug development require the talents and experience of a broad range of individuals. The shared responsibility for developing a clear conceptual schema of what is known and unknown will allow teams to better coordinate their efforts to improve productivity. However, the critical importance of interdisciplinary collaboration and coordination requires a new definition of excellence.

Three Dimensions of Excellence

Scientific excellence—asking the right question, then designing and conducting a valid study that answers that question and influences future research—is widely accepted as a benchmark for success in research. However, excellence of a more complicated sort is required to enable innovation.

In this setting, there are at least three dimensions to excellence: strategic, operational, and technical excellence. Strategic excellence is demonstrated when existing knowledge about the disease and the drug is used to formulate goals and objectives, specify decision criteria for new reviews, and provide a rationale for proceeding with a development program. Operational excellence is a result of careful study design, precise data selection and definition, and attention to detail in preparation of high-quality, error-free experimental results. And scientific results when scientists use their training and experience to identify cross-disciplinary relationships in the data, formulate and test hypotheses, and accurately represent the data in management reviews.

An obstacle in the pursuit of these three dimensions of excellence is the difficulty of creating a team with the requisite strategic, technical, and operational skills. The best teams include scientists with diverse skills and perspectives who have a shared sense of ingenuity and who trust and appreciate the skill that each brings to the project.

Metrics of Innovation

What metrics can be used to measure the productivity of the R&D ecosystem? At present, we can readily track the financial inputs to the system. We can also measure output by the extent to which components under development are progressing through the phases of clinical testing and the extent to which they have gotten through the regulatory process. In the future, new measures related to the impact of those products on health will likely become important if we are to move beyond blockbuster drugs and justify the effort toward discovering personalized therapies.

Measuring our progress toward the cultural changes needed to encourage interdisciplinary collaboration will also require metrics of a different sort. Perhaps one day we will measure the extent to which teams are meeting the conceptual schema-based decision criteria and by the extent to which they have generated the data necessary for effective decision-making.

The pharmaceutical R&D ecosystem is remarkably complex, and it can be intimidating to think that individuals can have an impact on the many different components and interactions between stakeholders. The pursuit of excellence is a strong tradition in science, and harnessing this desire for excellence in the service of interdisciplinary collaboration to achieve real transformative innovation could be the key to achieving measurable gains in R&D productivity, which would ensure the future of the industry.

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What does successful innovation in the pharmaceutical sciences look like you?