

Building the relationship between industry and academia: Benefits and the general landscape of accomplishing research

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Abstract

Drug development (*i.e.*, the discovery, testing, and development of new pharmaceuticals) continues to result in substantial improvements in disease prevention and treatment. Clinical research, a cornerstone of drug development, occurs in both the private (*e.g.*, pharmaceutical and biotechnology companies) and the public sectors (*e.g.*, university academic medical hospitals, centers and institutes). Although differences in methodologies, oversight, motivations and other important domains can impede collaboration, productive private-public research efforts can be achieved. In this article we highlight many of the important differences, describe some of the difficulties commonly encountered, and provide valuable insights that may help forge symbiotic collaborative efforts among private and public clinical research investigators/entities.

The academic world has freedom that attracts many scientists. Discoveries in basic science are often made in academia and lead to the subsequent development of practical uses. Drug discoveries such as finding a new activity of a compound (*i.e.*, pleotropic effect) may be an unexpected discovery of a study with a different purpose. Such exploratory work in basic science can ultimately lead to much scientific progress. As the work is done in a transparent environment, academics traditionally enjoy not only the discovery of these results but also dissemination of the results in the form of peer-reviewed publications. In spite of the many positives of academic research, finding and obtaining funding for basic science is difficult, so researchers spend substantial time writing grants and seeking out collaborations with researchers to bring in new areas of expertise and to improve the odds of obtaining funding. These researchers are savvy about collaborating within their institution and frequently with other institutions to find resources and further their scientific cause. Even so, achieving the funding required to conduct research can be one of the most difficult obstacles to overcome in the academic world. It would seem that collaboration with industry could provide an avenue through which the breadth of research expertise on a particular area of study could be expanded and funding for the research could be obtained. These benefits could be obtained along with an additional benefit, which is that the industry partner would bring experience in moving a discovery through the various phases necessary to obtain market approval.

Traditionally, early academic discoveries are prized for the discovery itself and the publications that follow. Many researchers in academia are then motivated to move on to the next great discovery. Often industry then buys the potential drugs and begins investing its resources in completing pre-clinical research to further explore the possibilities of drug development. Universities today are recognizing the value of these findings in building relationships with industry. Faculty are encouraged to patent these inventions, including molecules or chemicals that may later become marketable medications, in order

to protect the intellectual property developed. The university then works to help find a partner or buyer in industry that would actually develop and ultimately bring a drug to market.

As a potential drug shows promise with pre-clinical testing, clinical research is urgently needed. Pharmaceutical companies have a desire to move as quickly as possible to move a drug forward through the process, since trials are expensive and many potential drugs are found to be ineffective or unsafe as testing progresses. Industry seeks clinical sites that can work effectively and efficiently to collect clinical data. Data has shown that less than 12 percent of drugs that begin clinical testing actually achieve FDA approvals [1,2]. Industry looks to clinical sites that can efficiently recruit large numbers of patients in order to move through the process as quickly as possible.

Despite the fact that universities are large sources of patients, there has been a movement on the part of industry away from using academia for clinical research due to the extensive ethics and contracting process that guides a university through participating in research [3]. Historically, the amount of time to get approval by an academic Internal Review Board (IRB) was often weeks longer than a for-profit IRB. In the pharmaceutical world, a matter of weeks can amount to costs of millions of dollars, which is unacceptable in a world in which the average drug making FDA approval costs an average 2.6 billion dollars [1].

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Many universities have recognized that industry needs faster turn-around time for IRB approval than they can provide in house. The Ohio State University has responded to this problem by offering to cede sponsored research projects to an external review board. The university has an agreement with this IRB so that the necessary language is inserted into the consent forms to protect the university, and both parties can cooperate with the IRB to get the project initiated as quickly as possible. As universities see the opportunities available by working with industry, offices of sponsored research have been developed to funnel these projects through a more efficient contract negotiation processes, often using master agreements that allow for multiple studies to be conducted under one large contract.

In our experience of working with new sponsors, there is often a misunderstanding of the academic use of charging an “overhead” expense to the costs of a clinical trial, with industry fearing this is an added fee. Truly, this line item is not an additional cost, but rather the manner that universities allocate the expenses of keeping a building open and the heating and power bills, for example, paid. In fact, costs of using university clinical sites are often lower due to the lower pay scale of academic clinicians compared to those working in the private sector.

While industry has reservations about the time and efforts involved in working with academia, those in university settings have hesitations about the control that a sponsor can have upon the data collected in a clinical trial. Scientists in academia fear that science will be tainted or be presented in a one-sided fashion, or that the work will be buried if results are not exactly as desired. Many researchers in academia also are accustomed to self-autonomy, and are not always motivated to follow a protocol designed by another scientist. These concerns need to be addressed to keep all parties involved comfortable with their role in this collaboration. Discussions about publications are generally negotiated during contracting, and many companies and universities are developing master agreements to help minimize the need to debate for each clinical trial that results. While many opportunities for publication arise from research, some are not necessarily related to the drug being studied. Pharmaceutical companies can accomplish their own goals while also allowing academics to pursue publications that may result from findings about a disease being studied. Since extensive medical histories are collected in clinical trials, making this data available to researchers may give insight to disease that would not have been attainable without the large number of patients being seen in multicenter trials. For example, a study that includes subjective and objective grading of a clinical sign associated with a disease that is being treated not only gives the opportunity for publications on the efficacy and safety of the drug treating the disease, it also creates a possible paper on the correlation between the grading methods used in the study. By allowing these types of peripheral examinations, it is possible to afford different publication roles to sponsors and academics in order to make academic researchers feel they still have the self-autonomy they desire as a result of their participation.

The pharmaceutical industry can benefit greatly by bringing academic insight to clinical research. While many clinical research sites are willing and very capable of following a protocol and collecting data, academic scientists are willing to discuss unusual findings with medical monitors. Often, a study of a drug may bring side discoveries about that are worthy of publication but are not of consequence or interest to industry. In addition, bringing academic leaders into participation in a clinical trial can help in early protocol development, since these clinicians are generally willing to bring their expertise to the table when invited.

Building a relationship with a sponsor not only builds the bridges needed to take academic discoveries to the population as possible life-altering medical treatments but creates other opportunities for the clinical aspect of research to be conducted at their facility. A large university oversees both the basic science researchers and the clinicians who work directly in-patient care. While those scientists who develop an early drug, candidate may wish to move toward other discoveries, clinical researchers at the same institution may be interested in working on the clinical research as a drug is further developed. These clinical researchers are generally involved in patient care and have an interest in providing possible treatments to patients when current treatment is lacking. Patients often seek answers from physicians in academia, hoping that the latest developments in patient care are likely to be known an available in these centers for learning. Universities see the opportunity to participate in clinical research as a way of potentially helping these patients.

Utilizing academic sites in a clinical trial not only benefits a university by having early access to the latest clinical possibilities, it also benefits a sponsor by lending outside credibility to a clinical trial. Academics at all levels earn prestige and promotions from authoring publications and offering these opportunities to the clinicians working on a clinical trial can be a positive outcome for both entities. A paper written by someone with a reputation for conducting clinical research for many different pharmaceutical companies, rather than an employee of a pharmaceutical company, often conveys more credibility to results, even with funding sources listed in the publication. Industry benefits by having subject matter experts involved in its trials and in the dissemination of the results.

Many of the conflicts between academia and industry arise simply from the differing perspectives of the two factions [4]. Understanding the needs of both groups may make it easier to develop compromises in the future that could create mutually beneficial relationships in academia and industry. Both need to work together with clear goals that benefit both sides [5], not just as a contract-for-services, but as a relationship that furthers science and innovation but gives credit to all of those who are conducting the work. Pharmaceutical companies want to produce viable drugs to bring to market. Those working in academia wish to collectively discover new possible drugs, write publications on new findings and be a part of the cutting edge of patient treatment. Both industry and academia reach these goals with a final endpoint of a treatment reaching the general population.

Rather than focusing on the differences between academia and industry, it is more advantageous to examine the benefits that result in both sides working together. As universities work to streamline the process for working with industry, sponsors recognize that those in academia are well respected scientists who lend insight and large patient populations to clinical trials. Universities recognize that working with industry gives their clinical researchers and patients of their medical centers early knowledge and access to cutting edge treatments. Recognizing the benefits and working to achieve the goals of both entities can help pharmaceutical companies and universities build relationships in which all parties work effectively and advantageously together.

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