

Academic-Industry Partnerships for Biopharmaceutical Research & Development: Advancing Medical Science in the U.S.



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This project was sponsored in part by a grant from the
Pharmaceutical Research and Manufacturers of America (PhRMA)

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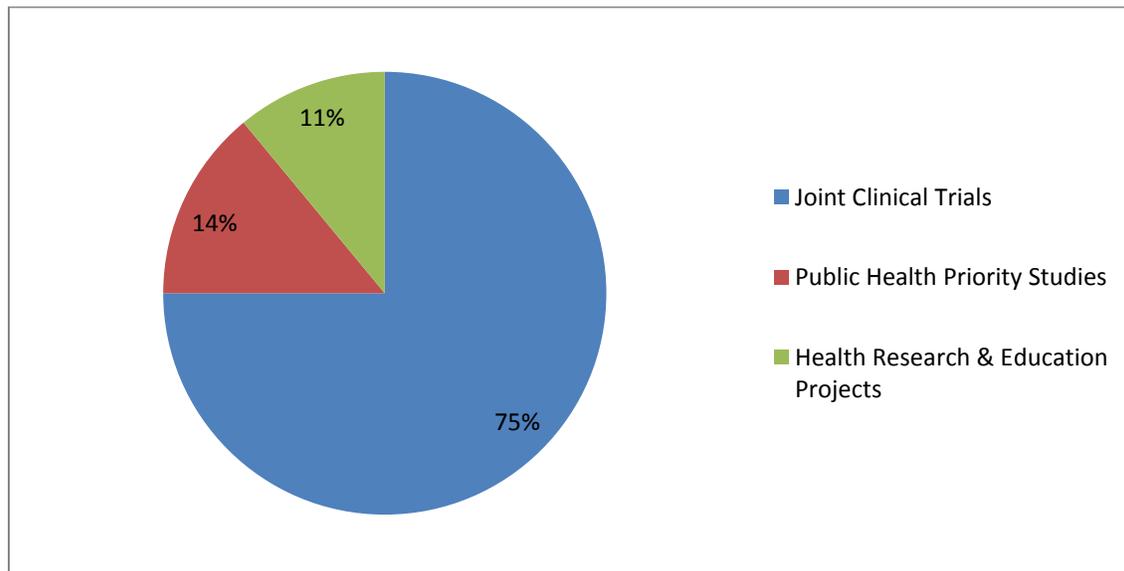
Executive Summary

Two trends in the research and development (R&D) of new medical products have been building throughout the last several decades, culminating in the expansion of academic-industry partnerships in numbers and types to such an extent that they have become a more prominent feature of the broader landscape of partnerships in biomedical innovation. On the academic side, the trend was commercialization of discoveries from basic research into medical products for the marketplace, a transformation facilitated by ground-breaking legislation in the U.S. beginning with the Bayh-Dole Act. On the industry side, it was externalization of the search for innovative R&D approaches and scientific knowledge in order to expand the capacity to address complex, unmet medical needs such as Alzheimer's and Parkinson's disease.

The goals of the study by the Tufts Center for the Study of Drug Development (Tufts CSDD) were two-fold: 1) to examine a sample of primary data and typify the kinds of research projects that academic-industry partnerships actually entail – “the what”; and 2) to review secondary data from the trade and professional literature as well as public and private sector websites to describe and categorize the organizational nature of these partnerships – “the how.”

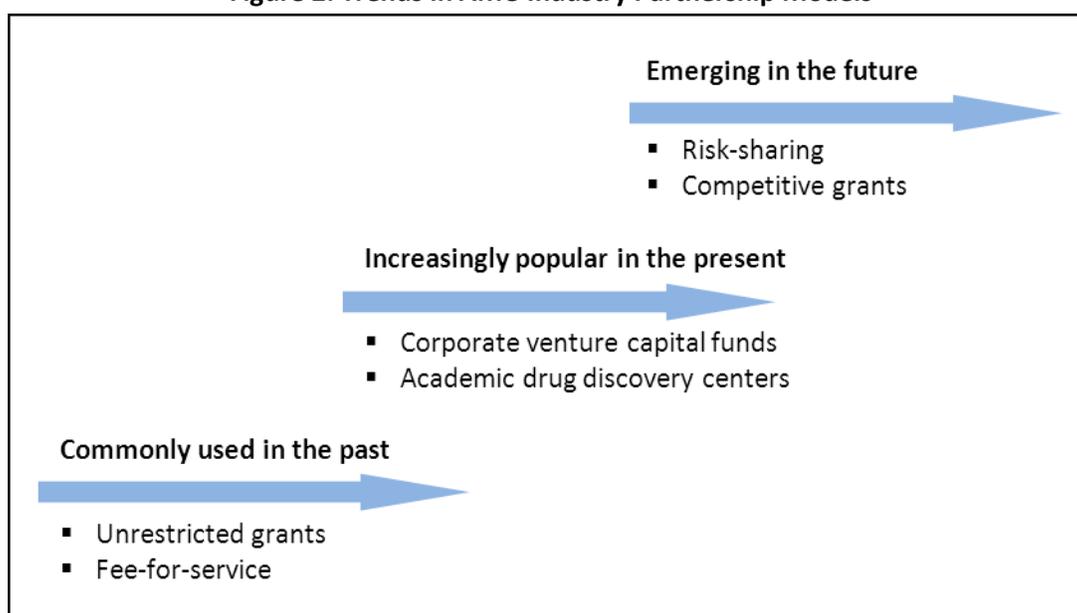
In terms of “the what,” CSDD reviewed primary data from over 3,000 grants involving close to 450 industry sponsors and 22 medical schools in 15 or about one-third of states and determined that they fell into three major classifications: conventional clinical trials focused on new drugs/indications (75%); conventional clinical trials targeting particular public health priorities identified by Tufts CSDD (14%); and, health research and education programs and studies (11%), as shown in Figure 1. This part of the study was not intended to capture all industry collaborations with academia (e.g., consortia) or all types of partnerships (funded versus non-funded); rather, it was intended to provide insight into one particular type of partnership, grants from industry sponsors to academic medical centers (AMCs).

Figure 1: Breakdown of Grant Types



Secondary data from a variety of sources including company websites, newspaper articles, academic articles, investor analyses, and consultant reports were employed to describe “the how,” i.e., the actual ways and means of the working relationships between AMCs and their industry partners. While it is generally accepted that these partnerships have become an increasingly common approach both to promote public health objectives and to produce healthcare innovations, it is anticipated that their nature will continue to evolve over time (see Figure 2), and many believe that their full potential have yet to be realized. The relationship between AMCs and biopharmaceutical companies is naturally complementary and historically has lent itself to the formation of joint research enterprises. In fact, about half of all biotechnology firms have been founded by university scientists, many of whom still have their academic affiliations, and a recent survey of AMCs indicated that over half of their researchers already conduct drug and device clinical trials.

Figure 2: Trends in AMC-Industry Partnership Models



A close and synergistic relationship between these sectors is critical to ensuring a robust national biomedical research capacity. Biomedical R&D is one area where the U.S. is still the global leader in terms of R&D investment and number of new medicines. However, the economic contributions of industries involved in biomedical innovation, particularly biopharmaceutical R&D, is increasingly seen as an area of opportunity for other countries, particularly China and India which are investing billions to build an R&D infrastructure modeled after the U.S. system. At the same time that other countries are increasing R&D spending, total U.S. spend across the public and private sectors has remained level. Sustaining productivity in medical research is critical for the health of the economy as well as U.S. competitiveness in the global marketplace and underscores the importance of fostering partnerships between AMCs and industry to harness the full potential of new scientific discoveries.

Introduction

The R&D ecosystem in the U.S. is rapidly evolving to adapt to a plethora of changes in the healthcare environment, here and abroad. Historically, the public sector has been a major contributor to basic research on drugs and biologicals, while the majority of the work on discovery, preclinical and clinical testing, regulatory approval, manufacturing and product distribution that put medical products on store and pharmacy shelves was carried out by the private sector. Growing scientific, public health, and economic challenges that emerged in the late twentieth century necessitated the creation of new incentives, such as the Bayh-Dole Act, to further facilitate co-operation between the private and public sectors. This engendered a new model of private-public-partnerships in R&D, “bringing together funds, scientific knowledge and centres of excellence,”ⁱ that according to a report for the European Commission in the early 2000s was the secret formula for the U.S. lead in innovation and global competitiveness. Today, that model is undergoing further optimization to ensure adequate support of the public sector foundations of the R&D enterprise at a time of shrinking federal and state budgets and to maintain a competitive private sector capable of keeping up with advances in science and technology to better address unmet medical needs worldwide.

After decades of success in bringing new medicines to market, the U.S. biopharmaceutical industry has been increasingly challenged since that report was released at the turn of this century. Better and more rapid means for identifying risks, quantifying these risks pre-approval, and managing them during the post-approval period have improved safety. FDA’s quality-by-design program (i.e., designing products and processes that maximize efficacy and safety profiles and product manufacturability) and regulatory science initiative (i.e., developing new tools, standards and approaches to assess safety, efficacy, quality and performance of products) are being implemented to address the expansion of the scientific knowledge base as well as the increasing complexity and variety of development and manufacturing processes. However, these regulatory responses to the evolving R&D environment have not come without considerable expense. Regulatory burden is one reason R&D spending has approximately doubled every 8.5 years since 1970.ⁱⁱ There have also been increased demands from payers to demonstrate cost and comparative effectiveness both pre- and post-approval. Shrinking revenues as a result of patent losses of top-selling products and the shift toward increased utilization of generic medicines has exacerbated an already challenging business environment, in which the top 10% of new drugs account for more than 50% of the value of all new drugs launched in the same period, and only 2 of 10 medicines cover the average costs of new drug R&D.ⁱⁱⁱ With the increasing focus on addressing complex, and challenging diseases at an ever-increasing cost, the need to pursue novel strategies has never been greater.

Strategies adopted by industry to improve productivity are both extrinsic and intrinsic in nature. Among the extrinsic strategies that industry pursues are mergers and acquisitions (M&A); joint ventures; and licensing to increase access to promising markets, technology platforms, and products. On the intrinsic side, they are implementing such measures as disease area prioritization and portfolio optimization (i.e., balancing research projects to minimize risk while maximizing potential for return on investment), integration of new technologies and development tools, and selection of appropriate milestones for

assessing success of projects in progress. All this in the pursuit of better decision-making – about which targets to pursue, when and how to terminate specific development programs, how to efficiently allocate resources, and what type of development portfolio to build.^{iv}

In addition to these strategies, biopharmaceutical companies are increasingly forming partnerships with the public sector, in particular universities and academic medical centers, to identify breakthroughs in basic research that may translate into clinical development opportunities and to access leading science and medical talent. As the scope of some of the scientific challenges are so large, collaboration is viewed as increasingly important to making significant progress. For example, the Coalition Against Major Diseases, which includes multiple biopharmaceutical companies, research institutions in the U.S. and Europe, and a range of foundations, recognized that given the complexities associated with Alzheimer's and Parkinson's disease, extensive collaboration between the public and private sectors would be necessary to facilitate the development of effective treatments. For its part, academia welcomed the opportunity to further expand its long-standing and already extensive relationship with industry in biomedical R&D. For example, according to a recent survey of 3,000 personnel at 50 AMCs, nearly one-quarter of the respondents said they were engaged in Phase III trials, while another one-third said that they were involved in Phase II or I research. In fact, while many researchers at AMCs conduct basic research (54.7%), which is typically non-clinical, only about one-third (33.6%) do so exclusively.^v

A close and synergistic relationship between these sectors is critical to ensuring a robust national biomedical research capacity. Biomedical R&D is one area where the U.S. is still the global leader in terms of R&D investment and number of new medicines. However, the economic contribution of industries involved in biomedical innovation is increasingly seen as an area of opportunity for other countries, particularly China and India. China's rate of research spending is 4 times that of the U.S., and along with India they are increasing their R&D expenditures by 10% per year.^{vi} At the same time, overall R&D spend in the U.S. across the public and private sectors has remained level. Sustaining productivity in medical research is critical for the health of the economy as well as U.S. competitiveness in the global marketplace and underscores the importance of fostering partnerships between AMCs and industry to harness the full potential of new scientific discoveries.

I. Next Generation Academic-Industry Partnership Models Emerge

Enactment of the Bayh-Dole Act by Congress in 1980 fostered public-private collaborations by promoting the commercialization of government-funded research, allowing universities and other non-profit entities to retain patents resulting from work funded by federal grants. The Act also provided the government with the right to intervene and assume ownership, if academic researchers fail to pursue practical application of their ideas (i.e., the “use it or lose it” policy). Prior to Bayh-Dole, university laboratories had served primarily as centers for basic biological research endeavors, with little concern for commercial application. Bayh-Dole created an environment that fostered partnerships and rapid translation of scientific research into market-directed health care applications.

Throughout the 1980s and 1990s, the Bayh-Dole Act gave rise to the practice of creating technology transfer offices within the universities in order to commercialize ideas or products discovered by their academic scientists, thus making new scientific and technological developments accessible to a wider range of users, as well as ensuring that the universities protect their intellectual property rights and receive appropriate financial benefits from their research efforts. It is hard to overstate the impact of the Bayh-Dole Act, which has contributed to a wide range of new medical products entering the marketplace and expanded career opportunities for academics as technology transfer officers and entrepreneurs.^{vii} Historically, half of all biotechnology firms were founded by university scientist/entrepreneurs; the majority of these scientist/entrepreneurs continue to maintain their academic affiliations.^{viii}

In the 2000s, companies have pursued a variety of approaches to improve productivity and increase efficiency and decrease attrition ranging from efforts to revitalize R&D through in-licensing of new technology platforms to revamping internal management structures.^{ix} Still other companies have pared down early stage research capacity to concentrate on core strengths in later-stage clinical development and marketing. Many companies have also expanded R&D collaboration vertically with grants, licensing, and acquisitions, as well as horizontally with private-public-partnerships and pre-competitive collaborations. Universities have been an important beneficiary of this trend. In 2006, approximately 60% of all research funding to universities was provided to support the academic life science research enterprise.^x The same study found that “[a]cademic-industry relationships provide substantial, tangible benefits to both the science and the scientist” and that while the amount of funding provided by the private industry ranged from between one-tenth to one-half of the total support they received across funding sources, “working with industry opened new lines of research and formed productive collaborations.”^{xi}

Since the National Institutes of Health (NIH) budget stopped increasing in the early 2000s, the nation’s medical research institutions have experienced flat or declining funding from federal agencies and typically from state budgets as well. According to the National Science Foundation, academic institutions with a medical school (so-called AMCs), on average received 69% of their R&D funding from federal, state, and local governments in FY 2009,^{xii} so even a modest decline in funding can have a broad impact. In FY 2011, NIH was funded below its FY 2010 level, which it stated would result in only 18% of all grant applications being approved in FY 2011, the lowest acceptance rate on record at NIH,^{xiii} and the overall NIH budget request for FY 2013 is flat again at about \$31 billion.^{xiv} Historically, states have played a critical role in building and sustaining the university infrastructure through funding to universities and research institutions. Compounding the funding challenge faced by AMCs, however, the recent economic downturn has led many states to reduce funding support for universities. Even when government funding is sufficient to maintain the basic foundation for the R&D enterprise at AMCs, industry support is critical for advancing innovation.

The research interdependence between industry and academia, however, goes beyond just funding. Benefits that inure to industry from partnering with academia include the opportunity to diversify their portfolios into unmet medical needs without risking critical levels of capital and the opportunity to work collaboratively with leading researchers and research in a pre-competitive environment of open data

exchange. Academia, meanwhile, benefits from the expertise, resources and development capabilities of industry. At a 2011 forum sponsored by the Massachusetts Biology Council (MassBio) on industry-academic collaborations, it was noted that without ongoing academic-industry collaborations, few investigators at universities will have experience with the actual process of drug development and little to no understanding of the way the biopharmaceutical industry actually works.^{xv} Other benefits are complementary in nature. For example, academic researchers often provide the specific building blocks for putting together an R&D project, such as knowledge of particular pathways or disease processes, the tools necessary to study it, and the continuity of focus that results from long careers. The biopharmaceutical industry can supply the general framework of investigational compounds, the capacity for synthesis and scale-up, and expertise in all aspects of drug development, regulatory approval, and marketing, as well as provide critical funding.^{xvi,xvii,xviii}

Benefits aside, the increasing number and scope of academic-industry partnerships have also served to cast the limelight on barriers to this field of collaboration. Such high pressure and high stakes relationships will always be dogged by mutual complaints that can be ascribed to differences in both practice (e.g., industry adherence to strict project management goals) and philosophy (e.g., academia drive to “publish or perish”). At a recent meeting on the subject, industry panelists voiced some of the most common complaints: academic scientists, in their view, may not always be team-oriented, nor accustomed to operating under the confines of contracts with strict deadlines, budgets, and deliverables, as well as being unfamiliar with the larger picture of product development timelines and regulatory requirements. For its part, academia can sometimes have a different view than their industry partners of what the goal is and what happens when the goal is reached. It is critical that when partnership agreements are negotiated the terms are openly discussed and clearly detailed. In particular, there needs to be mutual agreement on ownership of intellectual property, financial return arrangements, and the nature and timing of resource contributions by each partner. Relationships sometimes fail at the negotiation stage if all parties are not fully aware of the workings of the collaboration environment and the requirements of the contractual arrangements; thus, technology transfer offices are playing an increasingly important role in negotiating the parameters of such collaborations.^{xix,xx}

II. Study Methods and Findings

While there is a substantial amount of literature on the topics of public-private sector interaction in biomedical R&D as well as the more specific component of academic-industry relationships, few investigators have undertaken the task of categorizing and quantifying these latter relationships as they have evolved in nature and expanded in number dramatically in recent years. In this study, the Tufts Center for the Study of Drug Development (Tufts CSDD) utilized both primary and secondary data to achieve two study goals. The first was to assess the primary data from university and government databases in order to categorize the kinds of research projects that academic-industry partnerships actually entail – “the what”. The second was to review secondary data from trade and professional

literature, and government, university, company, and non-governmental organization websites in order to describe and categorize the organizational nature of academic-industry partnerships – “the how”.

A. “The What” of AMC-Industry Partnerships

In order to describe, and to some extent quantify the types and nature of studies performed under the auspices of academic-industry partnerships involving AMCs in the United States from 2008 to 2010, CSDD compiled an original database from publicly available information extracted directly from the websites of, or otherwise provided by, allopathic medical schools listed by the American Association of Medical Colleges. After initially reviewing the websites of a subset of all listed medical schools across the country, chosen randomly by searching both alphabetically and reverse alphabetically, a subset of 20 states¹ was selected and data from one or several AMCs within each state were reviewed (typically based on data availability and completeness). Available information on each grant was collected, including the grant title, industry sponsor, principal investigator, grant value, and the year the grant was established.

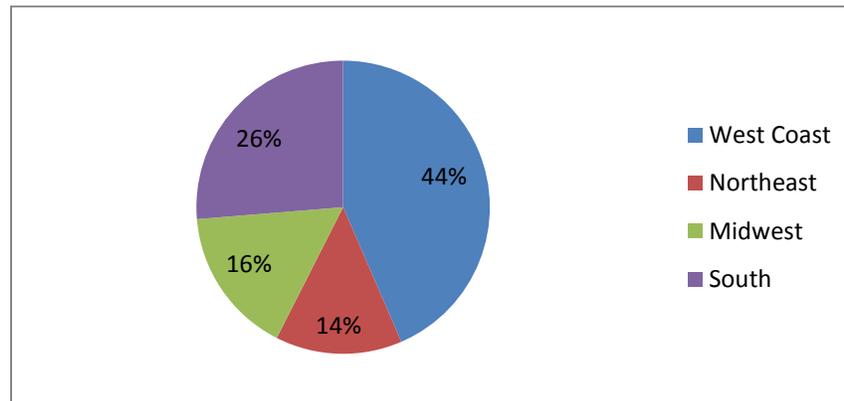
AMCs do not routinely make information on industry-funded research projects publicly available. For those schools that did not provide funded grant lists on their website, CSDD contacted the university directly. Not all selected AMCs in all selected states complied with our request. In the end, CSDD captured data on 3,278 grants from 443 different sponsor companies to 22 universities in 15 states,² with a regional distribution as seen in Figure 3 (West Coast = CA; Northeast = CT, MA, NY, VT; Midwest = AZ, CO, IL, MI, NM, OH; South = AL, GA, NC, TX).

For the subset of grants for which funding amounts were reported, it totaled approximately \$300 million.³ It should be noted that even for AMCs that do provide the information publicly, typically it was limited to specific grant-funded projects; therefore, the database does not capture every type of collaboration between AMCs and industry, such as licensing agreements, royalties, milestone payments, etc., nor does it capture consortia or partnerships that did not involve transfer of funds from industry to universities. It should also be noted that based on data cleaning subsequent to initial data collection, it appears that universities do not distinguish between biopharmaceutical sponsors and affiliated foundations or venture capital entities when listing the source of individual grants (Tufts CSDD also found that other data sources such as ClinicalTrials.gov did not distinguish between companies and affiliated entities, e.g., Eli Lilly and Company versus Lilly Endowment, Inc.).

¹ Alabama, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Maryland, Massachusetts, Mississippi, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Texas, Virginia, Washington

² Alabama, Arizona, California, Colorado, Connecticut, Georgia, Illinois, Massachusetts, Michigan, New Mexico, New York, North Carolina, Ohio, Texas, Vermont

³ Actual reported amounts were \$255,928,039, but only 78% of the grants listed funding amounts. For a few multi-year grants it was difficult to tell whether the grant amount was the annual disbursement or the entire grant amount, so \$300m is probably a conservative estimate.

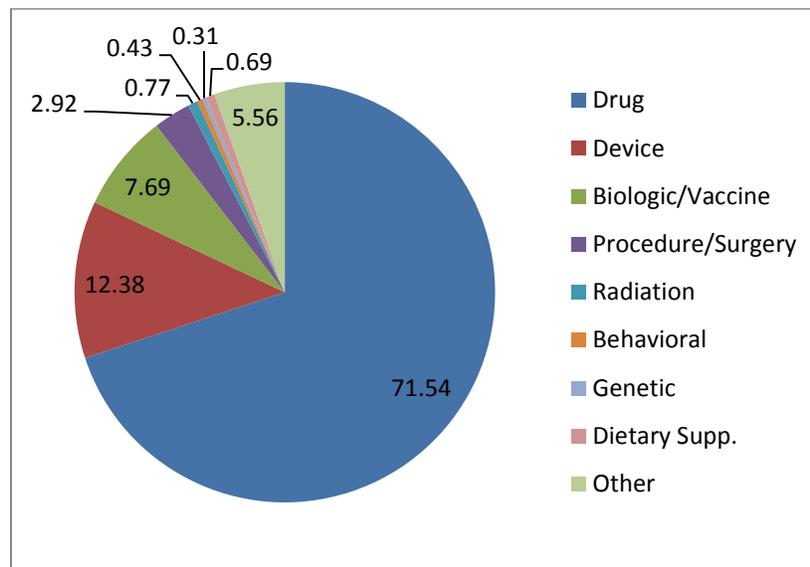
Figure 3: Breakdown of Grants in the Partnership Database by Region

Categories of Grants

Tufts CSDD reviewed 3,278 grants, compiled the information into a database, and for purposes of categorization determined that they fell into three major classifications: joint clinical trial (75%); public health priority studies (14%); and health research and education projects (11%). This report will focus on the latter two given that they better characterize the recent trends in “the what” of academic-industry partnerships.

1. Joint Clinical Trials

Joint clinical trials were collaborations between AMCs and industry that were by-and-large conventional clinical studies and trials focused on a particular type of therapeutic intervention as seen in Figure 4:

Figure 4: Trials by type of intervention in selected states 2008-2010 (% of trials)⁴

⁴ Note that the data for this figure was drawn from an analysis of postings on <ClinicalTrials.gov> for the same AMCs during the same time period, for 20 selected states, and is likely representative of the breakdown of intervention types in the Joint Clinical Trials subset of the CSDD database.

2. Public Health Priority Studies

Some 14% of the over 3,000 grants examined were comprised of otherwise conventional clinical trials in areas of research considered by the authors to represent types of studies of high public health priority and/or study environments best provided by AMCs for the reasons described below. These priority grants can be grouped for discussion into the following four sub-categories (see Table 2 for percentage of public health priority studies in each sub-category):

- *Comparative* clinical studies in which two or more treatments are compared with one another.
- *Oversight* studies (long-term, registry, and pre-clinical) in which privacy, patient care, and open science concerns dictate that AMCs are the most appropriate venue in which to conduct these.
- *Vulnerable* population studies for which AMCs can provide the optimum environment for patient care (compassionate access, elderly, neonatal, and minority patients).
- *Breakthrough* investigations (e.g., nanotechnology, translational, and pharmacogenomics) in which AMCs can provide an environment for pre-competitive collaboration and cross-disciplinary fertilization – research in these breakthrough areas often involve collaboration among various disciplines within the university panoply of science and technology programs including clinical, basic, and applied scientists as well as bioengineering and biogenetics.

Table 2: Percentage of public health priority studies in each of four sub-categories⁵

Category	Percentage of Studies
Comparative	46%
Oversight	35%
Vulnerable Population	14%
Breakthrough	9%

3. Health Research and Education (HR&E) Projects

The third overall category of grants was health research and education (HR&E) projects comprised of partnerships that were not clinical trials or studies investigating a particular compound, but involved a range of activities listed below, and further described in this section of the white paper. For purposes of description and analysis these HR&E projects were categorized as follows (see Table 3 for percentage of HR&E grants in each sub-category):

- Basic Medicine (non-clinical foundational studies of the impact of diseases and/or drugs through various disciplines such as biochemistry, microbiology, physiology, pathology, as well as observational studies of health interventions, etc.)
- Education (full spectrum of teaching and learning opportunities beyond basic medical school curriculum)

⁵ Please note that grants may fall in more than one category, therefore percentages do not sum to 100%.

- Special Patients (focuses especially on vulnerable or underrepresented patient populations utilizing direct measures of patient response, e.g., patient preferences, patient-reported-outcomes, quality-of-life, etc.)
- Translational (translation of basic to applied research, especially involving biomarkers, bioimaging and bioinformatics project)
- Services and Training (broad-based or specific programs for utilization and/or training related to specialized equipment, laboratory and/or medical services)
- New Technology (in particular: nanotechnology, pharmacogenomics and novel diagnostic tools)

Table 3: Percentage of health research and education projects by sub-category

Category	Percentage of Projects
Basic Medicine	30%
Education	23%
Special Patient	16%
Translational	15%
Services & Training	8%
New Technology	8%

Basic Medicine

The basic medicine category within the HR&E projects group illustrates three important points:

- The industry is funding and working collaboratively with the academic component of the public sector on basic research that contributes broadly across the entire spectrum of biomedical R&D, not just for products in its portfolio
- For some diseases and conditions industry grants supplement NIH funding, while for other diseases, it provides almost the entirety of the funding, except for relatively limited amounts from non-profits
- Often the biological targets or mechanisms being studied are little understood involving diseases that have proved refractory to effective treatment. To highlight these points it's important to note that the NIH spends over a \$1 billion per year on research for certain categories of disease and conditions that it has determined are high priority, including aging, diabetes type 2, HIV/AIDS, neurodegenerative diseases, and substance abuse. However, it spends much less, sometimes by an order of magnitude, on many other diseases and conditions that have a significant impact not only on health and longevity but also on the quality of life and work productivity of the vast majority of U.S. citizens.^{xxi}

The following are some examples of academic-industry collaborations selected from among a hundred or so HR&E grants that advance basic medical knowledge and practice: a study of brain mechanisms that

control insomnia and major depressive disorder; an investigation of the interrelationship of depression, anxiety, and bipolar disorders in adolescents with epilepsy; and, an examination of renin inhibition and its impact on obesity-associated insulin resistance.

Education

While it is generally acknowledged that the education process for medical practitioners and researchers is lengthy and expensive, what is sometimes less well recognized is that the process never stops. In fact, the learning process often becomes even more intense and costly as practitioners advance and specialize, especially as new medical technology and the scientific knowledge base rapidly increase in breadth and complexity. As seen from the types of activities included in Table 4, education grants provided by industry to AMCs covered a wide range of activities for an even wider range of medical needs:

Table 4: Education grants provided by industry to AMCs (n=76)

Type of Activity	Examples of Activity Focus
Educational grants: fellows, residents, scholars	anti-angiogenesis, autoimmunity, orthopedics, orthopedic resident training
Fellowship programs	rheumatology, pediatric nephrology, interventional cardiology, hematology/oncology, psycho-pharmacology, vascular medicine, minimally invasive gynecological surgery, movement disorders, dermatology
Grand Rounds	orthopedic surgery, gastro-intestinal, hematology, internal medicine
Board review courses, CME, workshops, and conferences	continence, chronic obstructive pulmonary disease, hematology/hemophilia, inflammatory bowel disease, epilepsy, emergency medical services, neonatal intensive care, rheumatic diseases, multiple sclerosis
Medical outreach & education centers/programs	Ayurvedic medicine (traditional Indian medicine), surgical sciences, international radiology, health care system basics for medical professionals
Visiting professorships, preceptors	surgery, neuropsychiatry, endocrinology

Special Patient Populations

For purposes of this study, we categorized a grant as special patient if it met any of the following five criteria:

- Projects that addressed under-served (e.g., rural patients whose communities lack access to AMCs), under-represented (e.g., minorities), or especially vulnerable patient populations (e.g., high-risk pediatric), such as: promoting the utilization of recent biomedical advances in endocrinology at the community practice level
- Projects that focused on understudied areas of research, often involving common but little understood patient responses, such as: evaluating stress response and treatment of depression in non-professional dementia caregivers
- Projects that developed new tools for capturing patient perspectives and outcomes or new treatment protocols to improve patient convenience, quality of life, such as: the evaluation of the clinical use of nutraceuticals – in this case a medical food for chronic wound management
- Projects that focused on public health threats, rare and/or neglected diseases, such as: the use of sodium nitrite to kill biofilms of cystic-fibrosis-related pathogens
- Projects that assessed the socioeconomic considerations of patient care, including the optimum utilization of health care resources, such as: studying the utility of special tests to examine the effectiveness of certain monitoring and treatment modalities to improve long-term outcomes for leukemia patients.

Translational Medicine

Biopharmaceutical companies increasingly are forming partnerships with AMCs to not only identify promising pathways for potential breakthrough therapies through basic research in medicine, but also to guide their translation into clinical development of new medical products. This translational research is embodied by the goal of the bench-to-bedside feedback loop in which medical practitioners in the clinic more readily communicate findings with bench scientists and vice-versa. In negotiating this feedback loop, certain research roadblocks have to be crossed: transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention and initial testing in humans (T1); the translation of results from clinical studies into everyday clinical practice and health decision making (T2); and, translating results into medical guidelines and standards of practice (T3). Translational medicine includes projects that have both a specific emphasis on a particular translational problem, such as identifying better animal models for human diseases, or a more general focus on new technology and research tools to improve translational research, in particular – biomarkers, bio-imaging and bioinformatics. Among the HR&E grants were 40 that could be described as translational. Examples include a bio-imaging project utilizing magnetic resonance imaging (MRI) to identify high-risk rheumatoid arthritis patients; an effort to train expert readers (a customary practice for clinical trials of molecular imaging agents) on interpretation of results from studies with experimental radiopharmaceuticals in Parkinson's Disease at multiple AMCs across the country; and, utilization of a minimally invasive laser system to treat enlarged prostate.

Services and Training

Collaborative partnerships for services can be extremely broad arrangements to support general research, laboratory services, clinical trial operations, collaborative drug development or, professional services, for example procurement of fasting blood samples for development of a gastrointestinal disease test panel or development of a specimen acquisition protocol. Others may be narrowly focused, but in the aggregate encompass a broad range of activities, including facility or equipment sharing, provision of clinical services or samples, or synthesis of materials as exemplified by the clinical lab service agreement between a company and a medical school for sickle cell anemia.

Partnerships were categorized as training if they were specifically focused on providing training on new equipment or techniques such as:

- Vascular intervention simulator training
- Advanced ophthalmological training opportunities for fellows and residents
- Collaborative rheumatology musculoskeletal ultrasound training

New Technology

While most categories encompass projects that involve new technology, this category is comprised of projects specifically focused on three emerging fields of medical innovation: nanotechnology, pharmacogenomics, and novel diagnostics. Examples in each of these areas are provided below:

- Nanotechnology generally involves the use of materials, devices, or other structures of submicroscopic size from 1 to 100 nanometres (e.g., development of nanoparticles for identifying and treating prostate disease and, to engineer an artificial kidney)
- Pharmacogenomics evaluates individual genetic variations to account for differences in patient responses to drugs (e.g., conducting long-term follow-up for patients exposed to gene therapy with retrovirus-based treatments)
- Novel diagnostics are new methods for assessing the existence of or progression/regression of disease states (e.g., an interactive, web-based data capture system used jointly by an academic medical research center and a company to track outcomes over time in patients with rheumatoid arthritis on a variety of medicines in a real world setting).

B. “The How” of Academic-Industry Partnerships

While we were able to utilize primary data from the AMCs themselves to illustrate and categorize “the what” of the academic-industry partnership project landscape, we had to rely on secondary data from the professional and trade literature to attempt to describe “the how,” i.e., the actual ways and means of their working relationships. There is general agreement that academic-industry partnerships have increased in number and expanded in variety and scope, and changed in nature as well. Among both major firms and leading universities, they are often operating more than one model with multiple partners,^{xxii} as described below.

Models of AMC-Industry Partnerships

The landscape of partnerships and alliances funded through grants is highly diverse, with partnerships varying greatly in size and scope, depending on the nature of the agreement as well as the individual biopharmaceutical company or university involved. Table 5 provides a general overview of the landscape of different partnership types.

Table 5: Models of AMC-industry collaboration funded via grants^{xxiii,xxiv,xxv}

Model	Brief Description	Degree of use
1. Unrestricted research support	Company provides university with unrestricted research support that allows academic partner to operate with high degree of independence and allocate funds where needed	Widely used
2. Principal investigator	Company establishes relationship with single principal investigator to research specific problem, providing principal investigator with access to company resources and direction on research goals	Widely used
3. One company/one university	Company selects university with several principal investigators who work on specific or related area of study with master agreement to facilitate exchange of information and resources in long-term commitment to build ongoing relationship and development of strong knowledge base	Widely used
4. Fee-for-service	Company defines problem and solution, and contracts out specific projects to one or more universities	Widely used
5. Venture capital	Company provides experts with seed money to start company focused on specific problem via support of private investor venture capital funds or corporate venture capital funds	Increasingly used and evolving

Model	Brief Description	Degree of use
6. Corporate mini-lab/ "bioclusters"	Company researchers use university labs, facilities, and/or centers combining the expertise of academic scientists with the drug development capabilities and resources of industry	Increasingly used
7. University consortium	Company hires experts from several universities to collaborate on problem increasing access to sources of information and skill sets in holistic approach	Rare, but increasingly used
8. Large institute	Company provides large donation to fund existing academic institution or establishes a new center within institute with multiple investigators addressing same problem. In some partnerships, sponsors fund the team that solves problem first through next phase of research	Rare, but increasingly used
9. Competition	Company solicits ideas and compounds from academic scientists, provides access to validated means for evaluating them, and selects most promising for further support	Emerging
10. Industry/ government funded pre-competitive research centers	Research conducted collaboratively by entities that are ordinarily commercial competitors with government, industry, and/or foundations contributing funds and partners pooling resources and data sometimes with a focus on improving the tools and techniques for successful translation, and not on development of a specific product	Emerging
11. Academic Drug Discovery Centers (ADDCs)	Independent centers that share teaching affiliations with universities, seek external collaborations, especially multi-disciplinary and inter-organizational partnerships	Increasingly used
12. Risk-sharing models	Flexible arrangements in which the company shares control of the research project with academic institution while academic partner shares financial risk; partners contribute resources and assets and divide proceeds from commercialization based on the relative contribution	Emerging

Widely Used Categories (#1 to #4)

As Table 5 indicates, the “unrestricted research support,” “principal investigator,” “one company/one university,” and “fee-for service” models are considered to be widely used. However, anecdotal reports suggest that “unrestricted research support” may be on the wane. Our review of the AMC grants data would support that the other three models listed as widely used describes how approximately 90% of the over 3,000 grant projects that we reviewed were funded. While these models have generally constituted the mainstay of academic-industry partnerships historically, they are becoming less frequently used.^{xxvi}

As an example of a partnership between one company and one university, Sanofi and the University of California, San Francisco (UCSF) have an alliance to share expertise in diabetes research and identify drug targets that could lead to new therapies for diabetes. The \$3.1 million collaboration brings together scientists in three UCSF labs with Sanofi researchers to work together in translating academic science into potential new medicines.^{xxvii} Similarly, Sanofi is partnering with Stony Brook University to develop a potential treatment for tuberculosis and other bacterial infections.^{xxviii} As another example, Celgene Corporation is partnering with Boston University's Slone Epidemiology Center to support the design of registries to follow newly diagnosed patients with myeloma and myelodysplastic syndrome over the course of their illness. The registries will evaluate clinical, quality of life, and economic outcomes in relation to various treatments.^{xxix}

Venture Capital (#5)

Historically, venture and other private capital has been critical to fostering start-ups in the biopharmaceutical sector, including spin-offs, a model in which a university-based research project results in a separate corporate entity. This model is becoming less prevalent due in part to the unfavorable climate in which venture capital (VC) and other sources of private capital are increasingly risk adverse and less likely to provide capital funding for early stage projects. An emerging trend is the establishment of corporate venture capital (CVC) funds by a number of biopharmaceutical companies. In fact, between 2010 and 2011, CVC involvement was second highest in the biotech industry with nearly 18% of all deals involving CVC funds.^{xxx} Traditional VC and CVC fund support can take a variety of forms ranging from investment in transformative technologies that have the possibility of generating multiple products to shifting from investing in start-ups to investing solely in existing companies. In addition, some VC deals involve the commitment of resources from other entities, in which firms and research centers form a risk/profit-sharing arrangement. As one example, a \$200 million venture fund was created based on contributions from two multinational biopharmaceutical companies and Index Ventures to encourage the VC community to increase investments in early stage biotechnology companies.^{xxxi}

Corporate Mini-Lab/"Bioclusters" (#6)

The corporate mini-lab or "bioclusters" by definition involve the use of university labs, facilities, or centers by company researchers as exemplified by a relationship between AstraZeneca and the University of Pennsylvania. These two organizations have a collaborative research agreement to make use of their respective talents and resources in an effort to bridge the transition from drug discovery to development. Initially, the collaboration between Penn Medicine and AstraZeneca scientists will focus on generating new Alzheimer's disease drug candidates for the clinical development pipeline. "Penn Medicine's Center for Neurodegenerative Disease Research (CNDR) is providing rapid access to its drug compound screening assays and knowledge of the biology of tau and AstraZeneca scientists will supply basic research with access to the technologies and skills required to discover and develop new drug molecules."^{xxxii}

Another example of this model is Pfizer Inc.'s Centers for Therapeutic Innovation (CTI). Launched in November 2010, CTI is a unit of Pfizer, Inc., that serves to leverage academic expertise to lower R&D costs and improve productivity. CTIs have been established at the University of California, San Francisco

and the University of California, San Diego as well as at 8 Boston-based institutions and 8 New York City-based hospitals. At each location, Pfizer, Inc., is establishing laboratories to allow scientists to collaborate with university partners. Each laboratory will house a staff of antibody engineers, assay biologists, protein scientists, and project managers to focus on biotherapeutic modalities (antibodies, peptides, proteins) across all therapeutic areas.

University Consortium (#7)

The “university consortium” is a newer form of collaboration, and although still relatively uncommon, it is believed to be a burgeoning area of partnerships. Initiated in 2008 the Pfizer-funded Insulin Resistance Pathway (IRP) project typifies this model. Pfizer, Inc., entered a three-year partnership with a physiological modeling company and four major research universities – University of California at Santa Barbara, the California Institute of Technology, the Massachusetts Institute of Technology, and the University of Massachusetts – to study insulin signaling in adipose cells with the goal of developing new drugs to treat diabetes and obesity. The consortium brings together resources, lead pathways, and experts from each institution to enable a research endeavor that could not be undertaken at any one of the institutions alone. The academic centers receive funding for breakthrough research and retain the right to publish and/or patent any discoveries that they make in the area of basic biology.^{xxxiii}

Large Institute (#8)

Large institute collaborations occur when a company contributes money to fund an existing academic institution or establishes a new one. For example, Gilead Sciences, Inc., has entered into a research collaboration with the Yale School of Medicine to set up a multidisciplinary research program focused on advancing the understanding of the fundamental mechanisms of cancer, thus leading the way toward the discovery of novel cancer therapies. Under the agreement, Gilead will provide up to \$100 million if the collaboration is extended for the full 10 years. This would amount to the largest corporate commitment to Yale in the university’s history.^{xxxiv}

Announced in 2008, a 5-year, \$25 million-plus agreement between GlaxoSmithKline (GSK) and the Harvard Stem Cell Institute (HSCI) to advance stem cell science represents another example of a large institute collaboration. The two parties entered the unique alliance in order to hasten the development of treatments and cures for a range of diseases in six areas (neurological, cardiac, cancer, diabetes, musculoskeletal, and obesity) using stem cell science. GSK’s investment, which is one of the largest commitments to stem cell research made by a major pharmaceutical company, will fund research at Harvard University and in Harvard-affiliated hospitals, integrating HSCI’s stem cell expertise with GSK’s pharmaceutical capabilities to drive advances in drug discovery research. Additionally, funds will be provided to support early stage research.^{xxxv,xxxvi}

Competition (#9)

Another type of collaboration is one in which a biopharmaceutical company solicits ideas from scientists from outside laboratories and selects the best ones for further development. For example, Eli Lilly & Company invites researchers from academic institutions and small biotechs to submit molecules for screening as possible drug candidates via its Open Innovation Drug Discovery platform. If the molecule demonstrates potentially promising biological activity, Lilly has first rights to exclusively negotiate a

collaboration or licensing agreement with the submitter. The platform is designed to provide researchers a more convenient point of entry into Lilly's drug discovery and development process. The platform utilizes a secure website that offers Lilly's proprietary computational and informatics tools to aid scientists in the design and selection of molecules. Lilly then screens submitted molecules in its panel of disease-relevant phenotypic modules and well-validated target-based assays. So far, the platform has proven very popular as over 200 institutions have submitted about 23,000 compounds from 27 countries, and three collaborations have been announced to date.^{xxxvii}

Another example of a program that fits the competition model is GSK's Pharma in Partnership (PiP). Through PiP, GSK solicits proposals from academic scientists for new or alternative uses of GSK's stable of investigational compounds. Researchers may also be chosen through this program to help GSK focus its development plan on a select set of drugs in their R&D pipeline. Research ideas are submitted in the first instance to GSK's Academic Discovery Performance Units, which are small focused, integrated teams of clinicians and scientists that specialize in a specific disease or molecular pathway in partnership with academic groups. GSK plans to expand the PiP program, which currently exists in the US and UK, creating relationships with individual researchers throughout the world. This program allows GSK to forge a new kind of partnership – in which academics work more closely with the company, but still retain their independence. This model of collaboration is small-scale, long-term, and relatively low-cost. GSK will provide funding to support university facilities and research, and incentives to the lead researchers for chosen projects.

Industry/government funded pre-competitive research centers (#10)

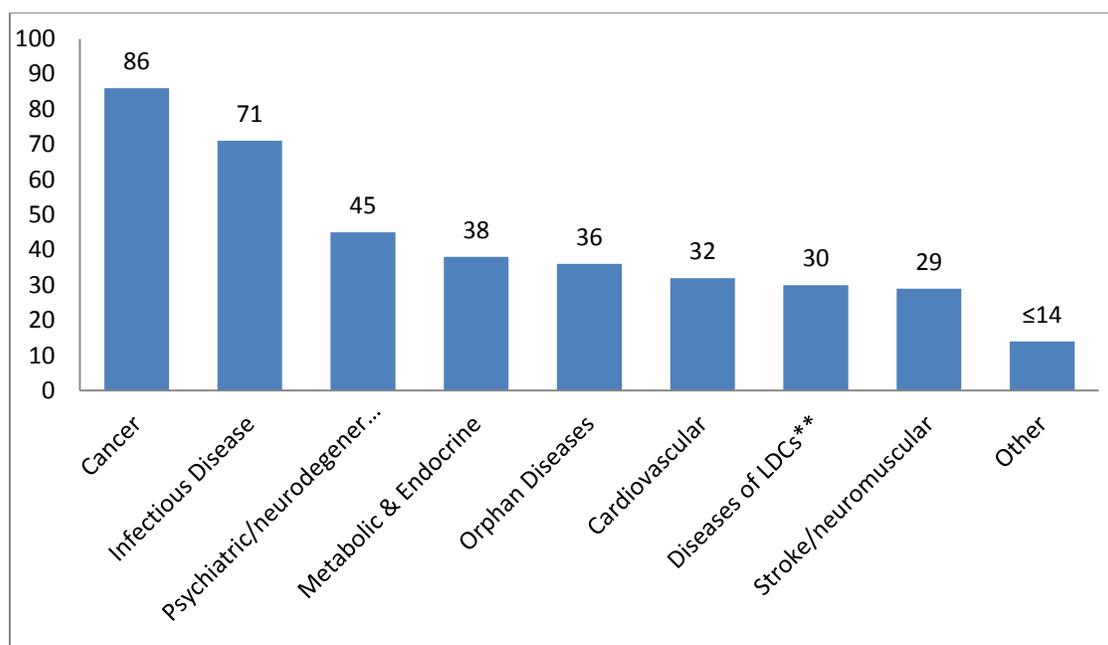
Precompetitive research is collaborative research that brings together various institutions who ordinarily are commercial competitors. According to comments given by Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA): “In contrast to the guarded nature of commercial scientific findings, the results of precompetitive research are meant to be made publicly available, subjected to scientific scrutiny, and contribute to knowledge that improves the prospects for invention-based competition...”^{xxxviii} One example of this type of collaboration is the Coalition Against Major Diseases (CAMD), a consortium under the auspices of the Critical Path Institute. CAMD members – which include biopharmaceutical companies, academic institutions, global regulatory agencies, patient advocacy groups, research foundations, scientific associations, and consultant groups – work collaboratively to accelerate the development of therapies for neurodegenerative diseases. CAMD is working toward creating common data sharing standards, establish databases of standardized clinical trial data, develop disease models, and identify biomarkers.

Academic Drug Discovery Centers (#11)

Academic Drug Discovery Centers (ADDCs) are independent centers affiliated with universities, which in essence represent a type of academic spin-off in reverse (i.e., industry entrepreneurs forming academic units), as much of the leadership and staff at these centers are from industry, and support from commercial sources can be as high as 50%.^{xxxix} As industry observers put it: “In general, these units are focused around a scaled-down pharma model comprising most of the functions required for small molecule drug discovery—including synthetic chemistry, high-throughput screening, absorption, distribution and metabolism analysis”.^{xl} Sometimes referred to as “mixed-ventures,” ADDCs maintain a

spirit of collaboration and combine the expertise of internal researchers of various disciplines, often partnering with external entities. This a fast-growing and rapidly evolving model; 60% of which were founded within the last 6 years. As noted in Figure 5, ADDCs most often direct their efforts toward broad therapeutic areas such as cancer and infectious disease with numerous potential targets. However, they also direct a significant amount of their efforts toward therapeutic areas with high unmet needs but more circumscribed sets of targets, such as orphan conditions and diseases of less developed countries.^{xli}

Figure 5: Percentage of ADDCs Indicating Focus on Particular Therapeutic Areas* based on survey of centers (2010)^{xliii}



*ADDCs may have more than one therapeutic area of focus

**Diseases of Less Developed Countries

The Moulder Center for Drug Discovery Research (MCDDR) at Temple University is a newly established ADDC in Philadelphia. MCDDR is a fully integrated facility that is used for both internal research within Temple University and for external collaborations with pharmaceutical and biotech companies and other universities. Combining the exploratory spirit of academia with industry expertise, scientists at MCDDR pursue high-risk projects, often for orphan diseases. Scientists at Molder have worked with companies in the United States and abroad to identify new drug candidates and prepare them for clinical trials. For example, the Center is working with Cureveda, a biotech company founded by scientists at Johns Hopkins University, to develop treatments for oxidative stress-related diseases, including diabetic neuropathy, cardiovascular disease and cancer. MCDDR is also working with another pharmaceutical company to develop treatments for metabolic syndrome.

Risk-Sharing Models (#12)

Risk-sharing arrangements are ones in which companies and academic institutions share the control of a research project and split the contribution of resources and assets. For example, New York University's (NYU) Applied Research Support Fund helps support prototype development and additional pre-clinical studies to improve licensing opportunities and other partnerships with biopharmaceutical companies. NYU's Fund recently increased its effort from 2-3 projects per year at \$50,000 each to 6-8 projects per year at \$75,000 each. Similarly, Children's Hospital of Boston is using its own funds to support the maturation of technologies with commercial potential; funds range from \$50,000 to \$150,000, depending on project stage.^{xliii} Through its Technology Development Fund, Children's Hospital Boston provides clinician-scientists with financial resources and technology development expertise in order to advance new ideas and discoveries that would otherwise not progress because they are considered too risky. The majority of the projects will involve co-development partners, such as contract research organizations (CROs), whose work will increase the technologies probability of finding a corporate partner to bring the new products to market.^{xliv}

In similar vein, Evotec has taken a risk-sharing approach with Harvard University and the Howard Hughes Medical Institute to ramp up beta cell regeneration for diabetes treatment. In this collaboration, all partners contribute financial resources and other assets. The proceeds from commercialization will be assigned depending on the relative contributions of partners over time. The agreement was structured with sufficient flexibility to allow for a variety of possible commercialization paths.^{xlv}

Conclusion

The relationship between AMCs and biopharmaceutical companies is complementary and naturally lends itself to the formation of joint research enterprises. Academia brings strong insight into the fundamental mechanisms of disease along with expertise in patient care and clinical practice. The biopharmaceutical industry possesses the knowledge and tools to translate basic research discoveries into practical applications in patients. Collaboration between the academic and industrial sectors is indicative of the increasingly synergistic relationship between academic research and commercial activity. As the translational gap between discovery and clinical development has become increasingly difficult to bridge, the recognition of the importance of partnerships has grown.

Industry and AMCs are exploring new types of collaborations and the variety of partnerships is expanding. Partnerships are increasing access to cutting-edge science, equipment, and resources at both universities and biopharmaceutical companies enabling the nation's R&D enterprise to tackle the most complex and challenging diseases and conditions. In the face of an increasingly challenging R&D environment and global competition, we are likely to witness the continuing proliferation of AMC-industry partnerships.

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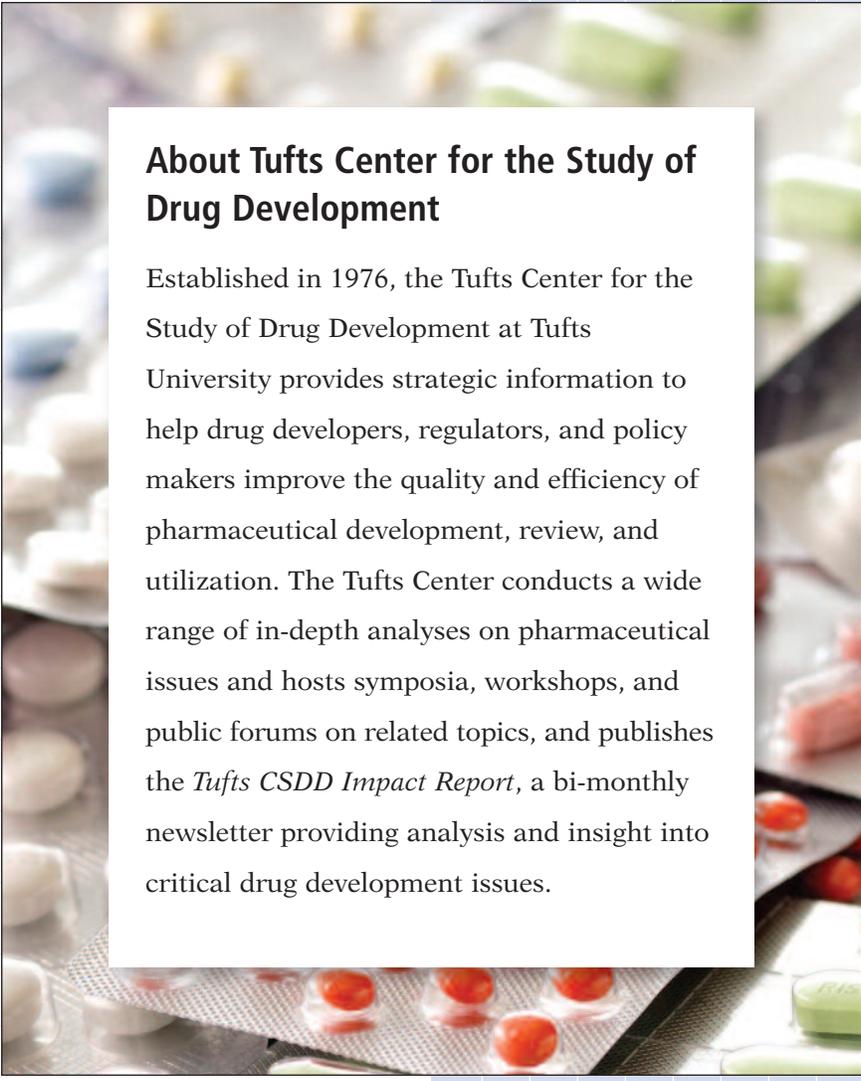
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