Opening Industry-Academic Partnerships

Research and development today is about networking, sharing, and partnering. Collaborations between industry and academia are promoted by open innovation programs, which have become a near-universal model for R&D. Pharmaceutical and biotechnology companies offer university researchers access to resources and funding. Academic scientists bring in-depth expertise and basic research data to the table. Open innovation has exploded into megapartnerships of academia, industry, government agencies, and private organizations. These consortia have the potential to solve major medical and public health issues, if they can set terms and goals that reward all parties. By Chris Tachibana

A line between industry and academic research began blurring in the late 20th century. Biotechnology companies such as Genentech in South San Francisco encouraged their scientists to pursue side projects and publish results. Universities started pushing technology transfer and translating research into products. Today, partnerships between corporations and academia are common, although success requires careful advance planning.

Industry-academic collaborations are like partners skilled in different dances trying to reach a compromise between waltz and salsa. Rhythms, pace, and expected outcomes can be frustratingly at odds, as university researchers prioritize education and basic research and corporate scientists pursue products and profits. Success depends on finding common goals and negotiating plans that pay off financially and intellectually for all parties.

Let’s Start at the Very Beginning

An entry-level option for academic and industry investigators who want to collaborate is co-advising a Ph.D. student. The Danish Ministry of Science, Innovation and Higher Education sponsors an Industrial Ph.D. program that, in its current form, has funded more than a thousand projects since 2002, most in health, natural sciences, and technology. The European Commission Marie Curie Actions has a similar initiative based on the Danish program.

Industrial Ph.D. projects highlight the difficulties of satisfying both academic and business interests. Some professors say they appreciate the funding and credit for graduating a Ph.D. student, but are challenged to find projects that advance their research while meeting an industry need. For students, however, working in industry while getting a university degree is a chance to experience both worlds.

Julie Christina Grew has a Master’s degree in public health and is earning an industrial Ph.D. with the University of Copenhagen and the medical device company Medtronic, whose world headquarters is in Minneapolis, Minnesota. Grew’s project is an anthropological analysis of patients with devices similar to pacemakers that monitor heart rhythm. She hopes her research will launch a career in patient-oriented work for a pharmaceutical or medical device company. Grew appreciates the networking opportunities that come with her training. “It’s a chance to get into industry and see what it is like to take something from an idea to real life, to make things better for patients with chronic diseases,” she says.

At Medtronic Denmark, Elisabeth Reimer Rasmussen’s expertise in health economics, policy, and public affairs made her a natural fit to be Grew’s industry contact. Although the company was not seeking to host a Ph.D. student with an anthropologist’s outlook, Rasmussen says Grew’s fresh perspective has already changed thinking about patient satisfaction. And corporations know, says Rasmussen, “If you want to stay ahead, you have to see things in different ways.”

Make Connections

Industry and academic scientists whose careers are already underway can connect through initiatives from companies, governments, and private organizations. Industry Fellowships from the Royal Society, the United Kingdom’s national academy of science, support open-ended industry-academic collaborations. “The guiding principles of the fellowship are pure, excellent science,” says Joe Sweeney, professor of catalysis and chemical biology, University of Huddersfield, West Yorkshire, England. Sweeney has a fellowship to work with AstraZeneca, which has its corporate headquarters in London and its research headquarters in Södertälje, Sweden, and he is helping to increase continued>

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networking and knowledge-sharing among the program’s participants. The business exposure is a benefit, he says: “My own university research has improved through what I’ve learned from industry practices about management, engagement with funding agencies, and identifying translational opportunities.”

On the industry side, Lilly, headquartered in Indianapolis, Indiana, has a program that encourages scientists at the pharmaceutical company to collaborate with university researchers. The Lilly Research Awards Program (LRAP) funds precompetitive research proposals developed jointly by Lilly and university scientists. **James Stevens**, a Lilly distinguished research fellow, says the goals are fostering innovation and cultivating professional relationships. “LRAP allows our scientists to pursue lifelong learning,” he says. “But we also expect returns on investment in innovation and in the development of our scientists.” LRAP allows Lilly scientists to work with academic researchers on high-risk projects. Experiments are conducted at the academic laboratory, and Lilly scientists contribute data analysis, project planning, and other virtual activities.

**Open Wide**

Also virtual, but more directly targeted to Lilly interests is the Open Innovation Drug Discovery initiatives. **Alan Palkowitz**, Lilly vice president of discovery chemistry and technologies, says open innovation programs are born of the realization, especially by pharmaceutical companies, that “we can’t do it alone; our current challenges are too big and complex.”

The program is a global, crowdsourced drug candidate search. Scientists working on molecules with therapeutic potential in specific areas such as anti-angiogenesis send them to Lilly. Company scientists perform high-throughput assays and screens and send data to the scientists. “Access to external compounds in exchange for biological data—that’s the currency we have developed,” says Palkowitz. “We evaluate the commercial potential of compounds to be optimized into drug candidates. In exchange for the data, Lilly gets first right of access for promising compounds.”

Cultivating long-term relationships is a goal. Palkowitz describes the academic partners as customers as well as collaborators and says Lilly wants the scientists to return to the program as they find new drug candidates. Lilly crafts agreements that ensure confidentiality about the scientists’ compounds, offer mutually beneficial intellectual property rights, and allow publication of the data. Says Palkowitz, “This program will live and die based on the experiences the scientists have, so we put effort into serving their interests, first and foremost.”

While the Lilly model is virtual, Pfizer is investing in an open innovation model based on face-to-face, side-by-side collaborations. The company, which has corporate headquarters in New York, deployed 90 of their own scientists to Centers for Therapeutic Innovations (CTIs) at three U.S. locations so far: San Francisco/San Diego, New York, and Boston. The CTIs have Pfizer laboratory space near academic medical research centers and five-year collaboration agreements with universities.

CTI projects—currently, about 20 are in progress—begin with academic scientists proposing research on protein-based drugs, such as therapeutic antibodies. Accepted proposals, evaluated by a joint industry-academic committee, receive staff funding, supplies, and access to company resources such as antibody libraries and instruments. Pfizer and academic scientists do the research, directed by Pfizer project managers. The endpoint is a proof-of-mechanism clinical trial, after which Pfizer has the first option to develop the potential therapy. Collaboration barriers such as material transfer agreements are removed in advance. Intellectual property arrangements recognize academic interests: at project completion, if Pfizer is not interested, rights to the candidate therapy revert to the university for further study or development.

**Stuart A. Aaronson**, chair of oncolgical sciences, Icahn School of Medicine at Mount Sinai in New York City, and **Gadi Bornstein**, Pfizer associate research fellow, are collaborators at the New York-based CTI. Their project is developing therapeutic antibodies against an oncogenic target. “It’s been a good experience,” says Aaronson. “We feel like we’re moving together to a common goal, and we’ve had consensus so far on what’s important to pursue.” Although they have clear deadlines and deliverables, the academic scientists have not felt limited, says Aaronson. “Every scientist appreciates that learning more about the target is helpful to the whole project.” Success depends on this mutual vision and contribution, says Bornstein. “The academic scientists have the biological experience with the target system, and Pfizer has the drug discovery expertise.”

CTI projects have hard deadlines, and they are not basic research projects. The mechanism “doesn’t work for everybody in academia and is not a replacement for NIH grants,” says **Anthony Coyle**, Pfizer chief scientific officer, adding that “total transparency” is crucial. “Up front, everyone must appreciate that funding strictly depends on meeting timelines, so goals and expectations must be aligned, with everyone on the same page about priorities, specific aims, and go/no-go decisions. But we work as a team to achieve pre-agreed steps.” In the next year or so, Coyle expects the first clinical trials from CTIs to start, with three to five candidate proteins identified for trials each year, starting in 2013.

**Get Everyone Into the Act**

Open innovation is now a megamodel, underlying partnerships of companies, universities, government agencies, and philanthropic organizations. The Innovative Medicines Initiative (IMI) is a public-private endeavor based in Belgium with a €2 billion (approximately US$2.6 billion) budget. Funding comes from the European Commission (EC) and in-kind contributions such as research activities from members of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Governed by EFPIA and EC representatives and guided by scientific advisors and European Union member state representatives, the IMI is accelerating new medicine development. **Michel Goldman**, executive director, says that the IMI was founded in 2008 because European investment in drug development was declining, with severe economic effects: “To the EC and
EFPIA, it was clear that the only way to restore European competitiveness in drug development was through collaboration.”

The IMI funds multinational consortia of companies, universities, hospitals, small businesses, regulatory agencies, and patient organizations. Projects address areas ranging from diabetes to schizophrenia. From the perspective of managing one of the world’s largest private-public partnerships, Goldman says that teamwork among diverse entities can happen “if all parties agree to work toward common objectives, and if each partner is given a clear mission and is carefully evaluated to make sure they are adding value.”

The IMI acts as a trusted neutral party that brings businesses, universities, and government agencies together. By cooperating, these diverse entities can take on challenges that are important to all partners, but neglected because they are high risk or have low profit potential, such as developing new antibiotics. Goldman says the IMI also provides a platform for agencies such as the U.S. Food and Drug Administration and the European Medicines Agency to discuss novel regulatory approaches to getting drugs to patients quickly while ensuring safety and efficacy. As part of the IMI’s educational mission, it has five programs for training in regulatory science, including programs in pharmacovigilance and new approaches to toxicology.

GlaxoSmithKline, headquartered in London, is participating in IMI antibiotic initiatives. Andreas Heddini is a medical advisor with the company, and confirms the importance of the IMI in bringing together parties whose interests don’t always align. The IMI is crucial for advancing antibiotic development, says Heddini. “This is a critical area for infectious disease, but it has been neglected for decades. The initiative is great because it has three components: it leads to an increased understanding of resistance mechanisms, brings new candidate drugs forward, and provides a way to share data, including about what does not work.”

Data and knowledge-sharing are also essential to the TB Drug Accelerator program. This tuberculosis initiative is just one of many programs supported by the Bill & Melinda Gates Foundation, a philanthropic organization based in Seattle that invests in global health. The TB Drug Accelerator partners include the U.S. National Institutes of Health, six research institutions, and seven pharmaceutical companies. The Wellcome Trust, a charitable organization based in London, is also a contributor.

A major challenge to fighting tuberculosis is the six-month treatment regimen, says Ken Duncan, Gates Foundation deputy director of Global Health Discovery. The TB Drug Accelerator program is seeking medicines that shorten the therapy to a month or less. Companies in the partnership supply compound libraries and drug discovery expertise to the effort, while academic partners contribute knowledge about the disease and facilities for screens and assays. The Foundation, says Duncan, provides financial support and project coordination, setting timelines and milestones and monitoring progress. “Our most important function,” he says, “is integration—bringing everybody together.”

Duncan, who spent 16 years at GlaxoSmithKline working on diseases of the developing world, says companies in the TB Drug Accelerator program have an unusually open agreement. This includes sharing drug candidate structures and positive and negative results. The consortium will put data in the public domain as quickly as possible, to help prevent research redundancy. While the commercial potential might not be immediate, Duncan says the collaboration could yield concrete rewards for the companies, such as new R&D avenues from identification of novel drug targets. In addition, he says, “the scientists get to apply their energy and expertise to help solve a medical problem and have an impact on global health.”