

Biotechnology- Academic Sponsored Research Engagement Opportunities: Eight Guiding Principles

Biotechnology Innovation Organization
Technology Transfer Committee
June 2017

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Introduction

When biotechnology companies and universities work in tandem to push the frontiers of biotechnology based knowledge, they become a powerful engine for innovation and economic growth.

Universities and industry have been collaborating in biotechnology based research activities for over a century, but the rise of a global knowledge economy, and fundamental changes in the marketplace regarding the manner in which industry acquires and develops innovations, has intensified the need for strategic partnerships that move beyond the traditional funding of discrete research projects.

This success also requires academic research centers and the biotechnology industry to engage far beyond the conventional exchange of research for funding thrown over the wall. When both entities work well, strategic partnerships merge the discovery-driven culture of the university with the innovation-driven environment of the biotechnology company. But to make the chemistry work, each side must overcome the cultural and communication divide that can impair biotech industry-university partnerships and undercut their potential.

On the academic side, in addition to maintaining the spirit of research pursuits for the common good, there is also a growing trend in support of the commercialization of discoveries from basic research into medical products for the marketplace, a transformation facilitated by groundbreaking legislation in the U.S. beginning with the Bayh-Dole Act.

For industry's part, sponsored research with academic partners broadens the search for innovative R&D approaches and scientific knowledge in order to expand industry's capacity to address complex, unmet medical needs.

The Biotechnology Innovation Organization's Technology Transfer Committee has been reviewing the fundamental needs of both parties involved in sponsored research efforts, and has identified eight guiding principles that can be valuable to universities and industry in pursuing sustained sponsored and translational research collaborations.

Eight Sponsored Research Guiding Principles

Guiding Principle # 1: Successful university-industry collaborations reflect an understanding of the mission and culture of each partner:

Successful sponsored research transactions require all parties – industry and academia – to identify the core mission of their organizations early in the process and defining the scope and focus of the proposed alliance.

Guiding Principle #2: Alliance management resources are essential:

Industry and university participants engaging in strong alliance management strategies devote resources, energy and attention to maintaining relationships and working together in an ongoing effort to facilitate productive, transparent outcomes to ensure sponsored research success.

Guiding Principle #3: Universities and industry participants should understand the objectives and benefits to each party that will result from collaborations:

Goals, objectives, and timelines for completion are essential for productive end results in partnerships; each party must understand and support the objectives and proposed research benefits of the other party.

Guiding Principle #4: Commitments in sponsored research agreements should ensure legal integrity and consistency:

Commitments contained in sponsored research agreements concerning future research results shall be consistent with all applicable laws and regulations and with any contractual obligations the University or biotechnology company may owe to others.

Guiding Principle #5: Parties should have a clear focus on each other's licensing strategies:

Both industry and academia must commit to engaging in open and honest discussions to develop creative and effective licensing strategies that promote global access to innovation. The mutual goal should be an authentic partnership where each party understands the collaboration goals and objective of the other party and is committed to each party achieving success.

Guiding Principle #6: Parties should focus on streamlining negotiation protocols:

Universities and biotechnology industry should focus on the benefits to each party that will result from collaborations by streamlining negotiations to ensure timely conduct of the research and the development of the research findings.

Guiding Principle #7: Negotiator training is essential:

In order to effectively navigate towards an overall success rate for the institution, all sponsored research officers, contract negotiators and licensing officers, and especially those early in their careers, must understand how each research collaboration with which they are engaged reflects forces in the larger world of biotechnology development.

Guiding Principle #8: Partnerships should work to lower the cost of transactional efforts:

Systematically reducing transactional costs should be a major combined effort of both the university and biotechnology industry sector. This includes broader efforts to engage interpersonally through these partnerships in order to lower communication barriers among participants.

Conclusion

Sponsored research agreements are essential to driving innovation, and ongoing efforts to improve and enhance these relationships will further academic research-biotechnology industry's shared mission to develop lifesaving products and technologies.

Through this year-long review of best practices in sponsored research relationships, that informed the development of these guiding principles, the BIO Technology Transfer Committee recognizes that sponsored research agreements are unique, creative devices each of which reflects the needs and interests of the parties involved and requires a delicate balance of risks and benefits to all of the parties.

Sponsored research agreements are essential to driving innovation, and ongoing efforts to improve and enhance these relationships will further academic research-biotechnology industry's shared mission to develop lifesaving products and technologies.

BIO's Technology Transfer Committee will in 2017-2018 continue to work with industry and academic partners to improve these alliances, creating long lasting partnerships and collaborations.

Appendix A: Examples of Sponsored Research Agreements with Biotechnology Industry Sponsor

Pfizer's Centers for Therapeutic Innovation (CTI)

The Centers for Therapeutic Innovation (CTI) is a network of partnerships that aims to accelerate and transform drug discovery and development. Through the CTI, Pfizer partners with leading academic medical centers and disease foundations with the aim of translating promising science into clinical candidates.

Pfizer's CTI was launched in 2010 at the University of California San Francisco, and now has locations in Massachusetts, New York and California. The CTI facilities are located on or near academic campuses, which allows academic partners to work closely with Pfizer scientists to translate research ideas into clinical applications, with the ultimate goal of moving a therapeutic hypothesis through Proof-of-Mechanism (PoM) in humans.

CTI partners receive intellectual property rights and are granted milestone payments and royalties tied to the advancement of mutually agreed upon drug candidates.

Pfizer and the University of California San Francisco¹

In 2010, the University of California San Francisco and Pfizer formed a partnership called the Center for Therapeutic Innovation (CTI) to accelerate the translation of biomedical research into new medications and therapies for patients.²

Under the terms of the agreement, Pfizer committed up to \$85 million in research support and milestone payments over five years if the partnership lead to the development of significant new therapies for diseases with high unmet medical need.

The partnership, which could advance up to 10 projects at a time, established an open network of researchers to foster collaboration and exchange between UCSF and Pfizer scientists. The goal was to identify

¹ "UCSF partners with Pfizer to improve drug discovery, development." UCSF News Center. November 16, 2010. <https://www.ucsf.edu/news/2010/11/5826/ucsf-partners-pfizer-improve-drug-discovery-development>

² "Pfizer's Centers for Therapeutic Innovation Partners with UCSF to Expand Drug Discovery Capabilities." UCSF News Center. May 29, 2013. <https://www.ucsf.edu/news/2013/05/106276/pfizer%E2%80%99s-centers-therapeutic-innovation-partners-ucsf-expand-drug-discovery>

promising experimental molecules and quickly move them into proof-of-concept studies and clinical trials.

The collaboration allows UCSF and Pfizer to find and fund early-stage research projects. Projects are identified periodically through a process that includes an announcement of requests for proposals, proposal submissions, and reviews by a steering committee composed of leading Pfizer and UCSF scientists.

In 2013, the partnership was expanded to include the development of small-molecule drug candidates.

In January 2017, UCSF and Pfizer renewed the CTI partnership agreement to identify and develop biologic compounds against both known and novel targets.³ They highlighted two ongoing research projects as examples of the collaboration:

- Development of a treatment for malignant brain tumors in young children due to a genetic mutation with a novel small molecule kinase inhibitor, which involves three researchers from UCSF's Department of Neurological Surgery.
- Accelerated development of a novel immune-modulatory agent to treat Type 1 diabetes, which involves CTI, a UCSF scientist, and the Juvenile Diabetes Research Foundation.

The collaborations between UCSF and Pfizer CTI are managed by UCSF's Office of Innovation, Technology and Alliances.

Pfizer and the University of Southern California⁴

In 2013, Pfizer's Centers for Therapeutic Innovation (CTI) began a new partnership with the University of Southern California. Through the program, selected USC researchers would have access to Pfizer's proprietary drug discovery tools and technologies and support for investigational new drug- and clinical-enabling functions (toxicology, regulatory, etc.)

Apollo Therapeutics Fund⁵

³ "UCSF, Pfizer Renew Research Collaboration, Citing Progress in Drug Discovery Research." UCSF News Center. January 9, 2017. <https://www.ucsf.edu/news/2017/01/405461/ucsf-pfizer-renew-research-collaboration-citing-progress-drug-discovery-research>

⁴ "USC and Pfizer agree on new partnership." USC press release. June 26, 2013. <https://news.usc.edu/52691/usc-and-pfizer-agree-on-a-new-partnership/>

⁵ "Consortium of world-leading UK universities and global pharmaceutical companies launch £40 million fund to drive therapeutic innovation." Apollo Therapeutics press release. January 25, 2016. <http://apollotherapeutics.com/launch/>

In January 2016, the Apollo Therapeutics Fund was created by a unique collaboration between three pharmaceutical companies (AstraZeneca, GlaxoSmithKline and Johnson & Johnson) and the technology transfer offices responsible for commercializing the research from Imperial College London, UCL (University College London) and the University of Cambridge.

The £40 million (US \$57 million*) fund will provide translational research funding for early-stage therapeutics projects arising from the three universities.

In addition to the early-stage funding, the collaboration involves the active participation of the industry partners who will bring commercial drug development expertise. Projects will be shaped at a very early stage to optimize the chances of onward development.

The consortium aims to convert outstanding academic science from the three universities into medicines for a broad range of diseases. The fund will bring academic preclinical research through to the stage of development at which it can either be taken forward by one of the industry members following an internal bidding process or be out-licensed.

Each industry member will contribute £10 million (US \$14.2 million*) over 6 years to the venture and may provide in-house expertise and additional resources to assist with the commercial evaluation and development of projects. The Tech Transfer Office (TTO) for each university (Imperial Innovations, Cambridge Enterprise and UCL Business) is each contributing a further £3.3 million (US \$4.7 million*).

The Apollo Investment Committee, comprising representatives from each member organization, will make all investment decisions. All therapy areas and all modalities including small molecules, peptides, proteins, antibodies, cell and gene therapies are in scope. For projects that become successful therapies, the originating university and TTO will receive 50% of future commercial revenues or out-licensing fees and the remaining 50% will be divided amongst all Apollo members.

Apollo will be based at Stevenage Bioscience Catalyst, which is a bio-incubator/accelerator joint venture between the Department for Business Innovation and Skills, GlaxoSmithKline, Wellcome and Innovate UK.

* US dollar amount was calculated using the exchange rate on the date of the press release, Jan. 25, 2016.

Biogen and University of Pennsylvania⁶

In May 2016, Biogen announced a major R&D alliance with the University of Pennsylvania to study gene therapy and gene editing technologies. The collaboration will primarily focus on the development of therapeutic approaches that target the eye, skeletal muscle and CNS.

Biogen will work with James Wilson, M.D., Ph.D., Professor of Medicine and Pediatrics, and Director of Penn's Gene Therapy Program, and Jean Bennett, M.D., Ph.D., Professor of Ophthalmology and Cell and Developmental Biology and Director of the Center for Advanced Retinal and Ocular Therapeutics. Both are recognized leaders in gene therapy in the Perelman School of Medicine at the University of Pennsylvania.

Collaboration Overview

Under this broad research and development alliance, Penn will combine its extensive gene therapy resources and expertise to develop therapeutic candidates under the various collaboration programs using both existing and newly developed AAV vectors and will also aid in the development of new manufacturing approaches needed to support commercialization of gene therapy products. Biogen will in turn, leverage both its therapeutic area and target identification expertise and drug development capabilities to help advance the collaboration programs into the clinic and toward approval.

In addition to developing AAV gene replacement programs, the collaboration will also explore new therapeutic targets using both next-generation AAV vectors and genome editing technologies. Biogen expects these AAV gene transfer capabilities to be important for future gene therapy products and to pursue application of genome editing technology for numerous disease indications.

Deal Terms

Under the terms of the agreement, Penn may receive up to \$2 billion in research funding, options and milestone payments. Biogen will make an upfront payment to Penn of \$20 million with an additional \$62.5 million committed to fund R&D costs extending over the next three to five years in seven distinct preclinical research and development programs conducted by the Wilson and Bennett laboratories.

Each program may trigger milestones that range from \$77.5 million to \$137.5 million per product as well as royalties payable on net sales of

⁶ "Biogen Announces Collaboration with University of Pennsylvania on Multiple Gene Therapy Programs." Biogen press release. May 16, 2016. <http://media.biogen.com/press-release/investor-relations/biogen-announces-collaboration-university-pennsylvania-multiple-gen>

products. Biogen also receives an option to license next generation AAV vectors for certain indications from Penn, for Biogen's use outside of the collaboration. Separate from the agreement, Biogen is also entering into a license agreement with REGENXBIO for the exclusive rights to use adeno-associated virus serotype 8 (AAV8) or 9 (AAV9) technologies developed in Dr. Wilson's laboratory, for which REGENXBIO holds a worldwide patent license from Penn. The AAV8 and AAV9 technologies will be used in ophthalmic collaboration programs with Penn.

Bayer HealthCare and UC San Francisco

In 2011, Bayer HealthCare and University of California San Francisco announced a 10-year master R&D agreement in conjunction with the grand opening of Bayer's U.S. Innovation Center in San Francisco.⁷

In an effort to speed the process of translating basic science into novel medicines, the master agreement established the basic terms for the company and the university to collaborate on research projects, outlining principles of who owns the intellectual property, and how discoveries can get published in scientific journals. Financial terms of the master agreement were not disclosed.

In 2012, Bayer opened an incubator space called CoLaborator to provide entrepreneurs with basic laboratory facilities and access to Bayer scientists.

In 2015, Bayer HealthCare announced that three research collaborations to expedite the identification of potential therapeutic targets and development of drug discovery tools had been established under the master agreement.

The joint projects established between 2011 and 2015⁸⁹ were:

- Application of protease substrate profiling libraries for the identification of novel drug targets for NETosis in inflammatory and immune disorders.
- Computational modelling to predict and optimize the immunogenicity of therapeutic proteins, such as the therapies used to treat hemophilia A.
- Expression and purification of a key metabolic transporter, focused on the field of oncology.

⁷ "Bayer Nuzzles Up Even Closer to UCSF, Strikes 10-Year Master R&D Agreement." Xconomy.com. January 10, 2011. <http://www.xconomy.com/san-francisco/2011/01/10/bayer-nuzzles-up-even-closer-to-ucsf-strikes-10-year-master-rd-agreement/#>

⁸ "Bayer's Bay Area formula." SciBX. October 30, 2014.

<http://www.nature.com/scibx/journal/v7/n42/full/scibx.2014.1225.html>

⁹ "Bayer HealthCare Commemorates Fourth Anniversary of its Master Agreement with University of California, San Francisco." Bayer HealthCare press release. January 8, 2015.

<http://www.prnewswire.com/news-releases/bayer-healthcare-commemorates-fourth-anniversary-of-its-master-agreement-with-university-of-california-san-francisco-300017601.html>

Bristol-Myers Squibb and Duke Translational Medicine Institute¹⁰

In 2012, Bristol-Myers Squibb Company and Duke Translational Medicine Institute (DTMI) formed a strategic relationship to broaden interactions between the two organizations.

For the first project, DTMI translational researchers worked with Bristol-Myers Squibb scientists on the clinical development of BMS-986020, an orally available lysophosphatidic acid 1 (LPA1) receptor antagonist under investigation to treat idiopathic pulmonary fibrosis (IPF). The cross-organizational team planned to co-develop and co-implement the protocol for a Phase II study and undertake biomarker validation studies.

The company and the university expected that future projects would include working together to accelerate promising investigational drugs into proof-of-concept studies, improving enrollment in clinical trials, and developing disease educational programs.

Duke Translational Medicine Institute was formed in 2006 when it received one of the first Clinical and Translational Science Awards (CTSA) given by the National Institutes of Health (NIH).

Johns Hopkins University and Eisai

In 2011, Johns Hopkins entered into a drug-discovery research collaboration with Eisai to develop proprietary small-molecule drugs for a range of brain conditions such as schizophrenia, pain, brain tumors and Alzheimer's disease.¹¹

The Johns Hopkins Drug Discovery Program develops high throughput screening (HTS) assays for novel therapeutic targets that are in alignment with Eisai's interests. Once validated, the HTS assay is transferred to Eisai to screen its proprietary compound library. The collaboration provides Eisai access to novel therapeutic targets identified at Johns Hopkins University. Eisai also holds an option to in-license optimized compounds derived from the HTS hits.

¹⁰ "Bristol-Myers Squibb and Duke Translational Medicine Institute Form Strategic Relationship to Broaden Interactions." Bristol-Myers Squibb press release. February 28, 2012. <http://news.bms.com/press-release/partnering-news/bristol-myers-squibb-and-duke-translational-medicine-institute-form-st>

¹¹ "JHU enters into broad drug discovery collaboration with Eisai." The JHU Gazette. October 24, 2011. <http://archive.gazette.jhu.edu/2011/10/24/jhu-enters-into-broad-drug-discovery-collaboration-with-eisai/>

One project in the JHU-Eisai collaboration is a Cystine/Glutamate Antiporter program to develop brain penetrable system x_c^- inhibitors as novel therapeutic agents for the treatment of neuroinflammatory disorders. (See <https://drugdiscovery.jhu.edu/our-projects/cga/>.)

Another long-term joint project has been focused on studying chemotherapy-induced peripheral neuropathy (CIPN). (See <https://drugdiscovery.jhu.edu/our-projects/eribulin/>.)

GSK and the University of North Carolina at Chapel Hill¹²

In 2015, the University of North Carolina at Chapel Hill and GlaxoSmithKline formed a partnership to focus on discovering a cure for HIV/AIDS.

According to the news announcement, GSK planned to contribute its expertise and knowledge in medicines discovery, development and manufacturing and UNC-Chapel Hill would contribute its research and translational medicine capabilities, including access to patients and funding. The University would provide laboratory space on its medical campus for the HIV Cure Center and a small research team from GSK was to move to Chapel Hill to be co-located with UNC researchers.

The university and company formed a jointly-owned company called Qura Therapeutics to handle the business side of the partnership, including IP, commercialization, manufacturing and governance. Through Qura Therapeutics, GSK promised to invest \$4 million per year for 5 years to fund the initial HIV Cure center research plan.

GSK and University of Texas MD Anderson Cancer Center¹³

In 2014, the University of Texas MD Anderson Cancer Center announced a research alliance with GlaxoSmithKline (GSK) to strengthen its efforts in advancing therapies that train the body's immune system to combat cancer.

Through this venture, GSK and MD Anderson work together to identify new therapeutic approaches, evaluate patient responses in clinical trials and use those insights to develop immunotherapy drugs.

¹² "Carolina, GSK Announce Novel Partnership to Accelerate Search for HIV Cure." UNC press release. May 11, 2015. <http://research.unc.edu/2015/05/11/carolina-gsk-announce-novel-partnership-to-accelerate-search-for-hiv-cure/>

¹³ "MD Anderson announces immunotherapy collaboration with GSK." MD Anderson press release. April 8, 2014. <http://www.mdanderson.org/newsroom/news-releases/2014/collaboration-with-gsk.html>

The collaboration is part of MD Anderson's Moon Shots Program, the institution's 10-year commitment to more rapidly develop therapies and other interventions to significantly reduce cancer deaths.

Novartis and the University of Pennsylvania¹⁴¹⁵

In 2012, the University of Pennsylvania and Novartis announced a global research and licensing agreement to further study and commercialize novel cellular immunotherapies using chimeric antigen receptor (CAR) technologies. The agreement, which followed a Penn research team's 2011 publication of breakthrough results in several chronic lymphocytic leukemia patients treated with this personalized immunotherapy technique, paved the way for studies that have the potential to expand the use of CAR therapies for additional cancers.

In 2016, the Novartis-Penn Center for Advanced Cellular Therapies (CACT) on the Penn campus in Philadelphia was opened. The Center is devoted to the discovery, development and manufacturing of adoptive T cell immunotherapies through a joint research and development program led by scientists and clinicians from Penn, Novartis, and the Novartis Institutes for Biomedical Research.

Under the terms of the agreement, Penn grants Novartis an exclusive worldwide license to the technologies used in an ongoing trial of patients with chronic lymphocytic leukemia (CLL) as well as future CAR-based therapies developed through the collaboration. Novartis will invest in the establishment of the CACT and future research of the technology. Additional milestone and royalty payments to Penn are also part of the agreement.

Sanofi-Aventis and Columbia University Medical Center¹⁶

In 2011, Sanofi-Aventis announced a research collaboration with Columbia University Medical Center for the development of innovative diabetes medicines. The collaboration was a three-year project with the laboratory of Dr. Gerard Karsenty to investigate the role of the osteoblast-secreted peptide, osteocalcin, in diabetes management.

¹⁴ "University of Pennsylvania and Novartis Form Alliance to Expand Use of Personalized T Cell Therapy for Cancer Patients." University of Pennsylvania press release. August 6, 2012. http://www.uphs.upenn.edu/news/News_Releases/2012/08/novartis/

¹⁵ "Novartis-Penn Center for Advanced Cellular Therapeutics Unveiled at Penn Medicine." University of Pennsylvania press release. February 16, 2016. <https://www.pennmedicine.org/news/news-releases/2016/february/novartispenn-center-for-advanc>

¹⁶ "Sanofi-Aventis enters into Research Collaboration with Columbia University to Develop New Diabetes Treatments." Sanofi-Aventis press release. March 24, 2011. <http://www.prnewswire.com/news-releases/sanofi-aventis-enters-into-research-collaboration-with-columbia-university-to-develop-new-diabetes-treatments-118568724.htm>

Under the collaboration, Sanofi-Aventis sponsored research in Dr. Karsenty's laboratory and had an option to license and develop existing patents and results that may arise from the research into potential diabetes treatments. Financial terms of the agreement were not disclosed.

Novartis, UC San Francisco and the Broad Institute¹⁷¹⁸

In 2016, Novartis entered into a microbiome-focused research collaboration with University of California San Francisco and the Eli & Edythe Broad Institute of MIT and Harvard.

The Novartis-Foundry Sequence-to-Molecule Pipeline project is a four-year, \$8.1 million collaboration that will use bioinformatics, synthetic biology and other tools to predict the chemical structures of compounds that can be made by microbiomes.

The Novartis Institutes for BioMedical Research (NIBR) and the Broad Institute, which is a collaboration between MIT and Harvard, already published their first joint discovery – on the connection between gut bacteria and the development of type 1 diabetes – was published in the journal [Cell](#) in April 2016.

This partnership was announced in conjunction with the federally-funded National Microbiome Initiative.

Biogen and Columbia University¹⁹

In 2015, Biogen and Columbia University Medical Center entered a strategic alliance to conduct genetics discovery research on the underlying causes of disease and to identify new treatment approaches. As part of the \$30 million agreement, a sequencing and analysis facility and shared postdoctoral program was to be established at Columbia to support collaborative genetics research.

¹⁷ "Novartis teams with Broad, UCSF to discover drugs in microbiome data." FierceBiotech. May 13, 2016. <http://www.fiercebiotech.com/it/novartis-teams-broad-ucsf-to-discover-drugs-microbiome-data>

¹⁸ "Collaborating to unlock secrets of the microbiome." Novartis Institutes for BioMedical Research, NERD blog. April 28, 2016. <https://www.nibr.com/stories/nerd-blog/collaborating-unlock-secrets-microbiome>

¹⁹ "Biogen Idec and Columbia University Medical Center to Conduct Collaborative Genetics Research." Columbia University Medical Center press release. January 9, 2015.

<http://newsroom.cumc.columbia.edu/blog/2015/01/09/biogen-idec-columbia-university-medical-center-conduct-collaborative-genetics-research/>

The collaboration enables Biogen and Columbia to investigate the genomes of patients showing unusual treatment responses and to explore the connections among genes, pathways, and disease processes.

Cook Medical and Purdue²⁰²¹

In 2014, Cook Medical and Purdue Research Foundation formed a partnership to fund emerging biomedical and life sciences technologies developed at Purdue University. The not-for-profit Foundry Investment Fund matches funding from other investors to provide capital to commercialize Purdue innovations or expertise in the areas of human and animal health and plant sciences. In March 2017, Purdue reported that the Foundry Investment Fund has spent \$3.2 million of its \$12 million total to help 10 startups and one academic school. <https://www.prf.org/otc/startups/funding/foundry-investment-fund.html>

MedImmune and University of Maryland²²

In 2013, MedImmune, AstraZeneca's global biologics research and development arm, entered into a five-year, \$6 million collaboration with the University of Maryland Baltimore.

In 2014, the initial research collaboration was expanded to include the University of Maryland, College Park and the [University of Maryland, Baltimore County](#).²³

The first research projects in the collaboration included:

- Oncology: evaluate a molecule that simultaneously inhibits suppression of anti-tumor immunity and boosts activation of tumor-reactive T cells.
- Respiratory, Inflammation and Autoimmunity: evaluate the role of specific phagocytes in inflammatory diseases.
- Cardiovascular and Metabolic Disease: explore the mechanism and role of stem cells in cardiac regeneration.

²⁰ "Purdue, Cook to launch \$12M life sciences seed fund." *The Indianapolis Star*. February 4, 2014. <http://www.indystar.com/story/money/2014/02/04/purdue-cook-to-launch-12m-life-sciences-seed-fund/5206515/>

²¹ "Cook Medical, Purdue partnership drives life-improving innovations to the public." *Purdue University Research Foundation News*. March 15, 2017. <https://www.purdue.edu/newsroom/releases/2017/Q1/cook-medical,-purdue-partnership-drives-life-improving-innovations-to-the-public.html>

²² "MedImmune and University of Maryland, Baltimore announce five-year, \$6 million research collaboration to drive science innovation in Maryland." *MedImmune press release*. September 25, 2013. <https://www.medimmune.com/about-us/media/medimmune-and-university-of-maryland-baltimore-announce-five-year-6-million-research-collaboration-to-drive-science-innovation-in-maryland-20130925.html#>

²³ "MedImmune Expands USM Research Collaboration." *UMD press release*. April 29, 2014. <https://umdrighnow.umd.edu/news/medimmune-expands-usm-research-collaboration>

- Infectious Diseases: explore the immune system-stimulating properties of key innate immune system proteins for use in novel vaccines.
- Infectious Diseases: study a novel nanoparticle vaccine delivery system with unique stability and immune-stimulating potential.

Gilead Sciences and Yale University²⁴

In 2011, Gilead Sciences Inc. and Yale School of Medicine announced the formation of a multi-year research collaboration focused on the discovery of novel cancer therapies. The research effort initially spanned four years with an option to renew for up to ten years.

Gilead committed to provide \$40 million in research support and basic science infrastructure development during the initial four-year period, and a total of up to \$100 million over ten years should the collaboration be extended through that timeframe. Gilead would have the first option to license Yale inventions that result from the collaboration.

Yale and Gilead planned to develop a multi-disciplinary research program to search for the genetic basis and underlying molecular mechanisms of many forms of cancer. Scientists from both organizations will work together to identify new molecular targets that provide better understanding of the basis of disease and enable development of novel targeted therapies, including new therapies that overcome drug resistance that develops in some cancer patients treated with current targeted therapies.

In 2014, Yale announced a three-year extension of the research collaboration with Gilead Sciences. The renewal called for Gilead to provide \$30 million in additional funding for research support.²⁵

LabCorp and Duke University²⁶

In 2010, Duke University Medical Center and Laboratory Corporation of America (LabCorp) announced a joint venture to commercialize new biomarkers. The collaboration, The Biomarker Factory, was designed to speed the translation of newly discovered biomarkers into widely available clinical tools that can measure individual therapeutic responses, predict disease progression, and evaluate biologic or disease-causing processes.

²⁴ "Yale and Gilead Sciences announce Cancer Research Collaboration." Yale press release. March 30, 2011. <http://news.yale.edu/2011/03/30/yale-and-gilead-sciences-announce-cancer-research-collaboration>

²⁵ "Yale and Gilead Sciences extend cancer research collaboration." Yale press release. October 23, 2014. <http://news.yale.edu/2014/10/23/yale-and-gilead-sciences-extend-cancer-research-collaboration>

²⁶ "Duke, LabCorp combine forces to create The Biomarker Factory." Duke press release. April 27, 2010. <https://corporate.dukehealth.org/news-listing/duke-labcorp-combine-forces-create-biomarker-factory>



The [Biomarker Factory](#) combines Duke's excellence in biomarker discovery and validation with LabCorp's expertise in the development and commercialization of innovative diagnostic and laboratory tools.

Appendix B: International Sponsored Research, Best Practice Examples

Apollo Therapeutics Fund¹

In 2016, the Apollo Therapeutics Fund was created by a collaboration between three pharmaceutical companies (AstraZeneca, GlaxoSmithKline and Johnson & Johnson) and the technology transfer offices responsible for commercializing the research from Imperial College London, UCL (University College London) and the University of Cambridge.

The £40 million (\$57 M USD) fund will provide translational research funding for early-stage therapeutics projects arising from the three universities.

In addition to the early-stage funding, the collaboration involves the active participation of the industry partners who will bring commercial drug development expertise.

The fund will bring academic preclinical research through to the stage of development at which it can either be taken forward by one of the industry members following an internal bidding process or be out-licensed.

Each industry member will contribute £10 million (\$14.2 M USD) over 6 years to the venture and may provide in-house expertise and additional resources to assist with the commercial evaluation and development of projects. The Tech Transfer Office (TTO) for each university (Imperial Innovations, Cambridge Enterprise and UCL Business) is each contributing a further £3.3 million (\$4.7 M USD).

The Apollo Investment Committee, comprising representatives from each member organization, will make all investment decisions. All therapy areas and all modalities including small molecules, peptides, proteins, antibodies, cell and gene therapies are in scope. For projects that become successful therapies, the originating university and TTO will receive 50% of future commercial revenues or out-licensing fees and the remaining 50% will be divided amongst all Apollo members.

Apollo will be based at Stevenage Bioscience Catalyst, which is a bio-incubator/accelerator joint venture between the Department for Business Innovation and Skills, GlaxoSmithKline, Wellcome and Innovate UK.

¹ "Consortium of world-leading UK universities and global pharmaceutical companies launch £40 million fund to drive therapeutic innovation." Apollo Therapeutics press release. January 25, 2016. <http://apollotherapeutics.com/launch/>

Biomarker Enterprise to Attack Diabetic Kidney Disease (BEAt-DKD)²

In 2017, a consortium of 30 universities and companies launched the Biomarker Enterprise to Attack Diabetic Kidney Disease (BEAt-DKD) project. BEAt-DKD is a 5-year public-private partnership funded by the Innovative Medicines Initiative, member companies from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Juvenile Diabetes Research Foundation (JDRF) and the state of Switzerland. The total budget of the project is €28.9 M (\$31M USD).

The ultimate goal of the project is to identify targetable mechanisms and pathways underlying initiation and progression of DKD, as well as to identify and validate biomarkers of disease progression and treatment responses, representing first steps towards precision medicine in DKD.

BEAt-DKD participants are Lunds University, University of Helsinki, University Medical Center Groningen, University of Oxford, University of Eastern Finland, University of Dundee, University of Exeter, Institute for Pharmacological Research Mario Negri, University of Turku, The University Medical Center Freiburg, University of Bristol, University of Leeds, University of Hull, University Hospital Center of Bordeaux, University Clinic Erlangen, Medical University Innsbruck, University Hospital Regensburg, Medical university of Vienna, University of Bari Aldo Moro, Lypotype, University of Michigan, Swiss Institute of Bioinformatics, Juvenile Diabetes Research Foundation, AbbVie, Sanofi-Aventis, Astellas, Eli Lilly, Bayer Pharma, and Novo Nordisk.

Dementia Discovery Fund³

In 2015, the UK Government announced the creation of a Global Dementia Discovery Fund to boost investment in research towards the development of novel treatments for dementia.

The DDF is a venture capital fund which invests in projects and companies to discover and develop novel, effective disease-modifying therapeutics for dementia. Seven pharmaceutical companies (GSK, Biogen, Lilly, Takeda, Pfizer, Johnson & Johnson, and Astex, a subsidiary of Otsuka), the UK's Department of Health and charity Alzheimer's Research UK have invested in the DDF so far. The fund is managed by SV Health Investors.

² <https://www.imi.europa.eu/content/beat-dkd>
<https://www.fau.eu/2017/02/27/news/research/beating-kidney-disease-together/>

³ <http://theddffund.com/>

Ebola Vaccine Development Consortia⁴

In 2015, Johnson & Johnson's Janssen Pharmaceutical formed an Ebola Vaccine Development Consortia and announced that the consortia had received a €100 M (\$118M USD) grant from the Innovative Medicines Initiative (IMI) to accelerate the development of an Ebola vaccine regimen.

The announcement said that the funds would support four projects. Three of the projects were designed to address the need to accelerate Phase I, II and III trials, and scale-up production of the prime-boost vaccine regimen. The fourth project would investigate innovative ways and technology to raise awareness and acceptance of vaccination campaigns.

The organizations joining Janssen include the London School of Hygiene & Tropical Medicine, University of Oxford, Institut National de la Santé et de la Recherche Médicale (INSERM), La Centre Muraz, Bavarian Nordic, Vibalogics, Grameen Foundation and World Vision of Ireland.

European Prevention of Alzheimer's Dementia⁵

In 2015, 35 companies and universities launched a 5-year collaborative research initiative to study Alzheimer's Dementia. The European Prevention of Alzheimer's Dementia (EPAD) initiative received a €64 M (\$74.4M USD) grant from the European Innovative Medicines Initiative.

The EPAD program aims to create a novel environment for testing numerous interventions targeted at the prevention of Alzheimer's dementia defined as a delay in the onset of clinical symptoms among people with preclinical evidence for AD pathology.

The partners of the initiative includes Janssen Pharmaceutica, University of Edinburgh, University of Oxford, Barcelonabeta Brain Research Centre, Synapse Research Management Partners, Karolinska Institutet, Center for Alzheimer Disease Research, Stichting VU-VUmc, University of Cambridge, Medical Research Council UK, Berry Consultants, University of Geneva, Radboud University Nijmegen Medical Centre, Cardiff University, Centre Hospitalier Universitaire de Toulouse, Quintiles, Alzheimer Europe, Erasmus Universitair Medisch Centrum Rotterdam, Hpital de la Salpêtrière, Institut National de la Santé et de la Recherche Médicale (INSERM), University of Leicester, IXICO Technologies, Araclon Biotech, Fraunhofer-Gesellschaft, Eisai, Sanofi-Aventis Research and Development, Novartis Pharma, Boehringer Ingelheim International, Eli Lilly & Co, H. Lundbeck, Takeda Development Centre Europe, AC Immune, Biogen Idec, Pfizer and UCB Biopharma

⁴ <https://www.jnj.com/media-center/press-releases/johnson-johnson-announces-formation-of-ebola-vaccine-development-consortia-gains-funding-from-innovative-medicines-initiative>

⁵ <http://ep-ad.org/>

Global Health Innovation Technology Fund⁶

The Global Health Innovation Technology Fund (GHIT Fund) was established in 2013 to fund research and development of new medicines, vaccines, and diagnostics to fight infectious diseases in the developing world.

The GHIT Fund was established as a public-private partnership between the Government of Japan, a consortium of Japanese pharmaceutical companies (Astellas Pharma, Daiichi Sankyo, Eisai, Shionogi, and Takeda) and the Bill & Melinda Gates Foundation.

GSK's Discovery Partnerships with Academia (DPAc)⁷

GSK launched its Discovery Partnership with Academia (DPAc) unit in 2010.

DPAc's goal is to expedite promising basic research into drug discovery and development, with the potential to bring innovative new treatments to patients. Each selected project works as a joint team, with the academic and GSK scientists sharing data and working toward common goals.

The academic researcher supplies depth of scientific knowledge, creativity and a novel concept. The DPAc team provides drug discovery and development experience, applied research expertise and the considerable resources of GlaxoSmithKline (GSK) R&D.

To be considered for DPAc, academic research proposals must have a clear therapeutic hypothesis, a defined target that can likely be addressed with a drug-like molecule and be led by researchers with deep target and disease expertise, access to model systems and clinical samples to progress the target.

The first partnerships were with universities in the UK: University College London, University of Dundee, University of Edinburgh and University of Cambridge. Other partnerships have since been established with researchers at University of Paris Descartes, Fred Hutchinson Cancer Research Center, Vanderbilt University, Technion – Israel Institute of Technology, UC San Diego, Université de Sherbrooke, and UC San Francisco.

GSK and National University of Singapore⁸

GlaxoSmithKline launched the Academic Centre of Excellence (ACE) in 2010 to foster collaborations on projects of mutual interest to GSK and Singapore Investigators.

ACE is a virtual research network pursuing projects of mutual interest to GSK and Singapore academic scientists and developing partnerships to accelerate translational research and progress our shared goal of making new medicines available to the patients that need them.

⁶ <http://ghitfund.org/>

⁷ <http://www.dpac.gsk.com/>

⁸ <http://www.ace.gsk.com/>

Projects adopted by GSK receive funding and resources tied to periodic review. Selection of projects is determined by the Steering Committee, which is comprised of members from the Singapore biomedical research community (Biomedical Research Council, National Medical Research Council, National University of Singapore, Duke-National University of Singapore) and GSK senior leadership.

Integrated Cardio Metabolic Centre (KI/AZ ICMC)⁹

In 2013, AstraZeneca entered into collaboration agreement with the Karolinska Institutet to establish the Integrated Cardio Metabolic Centre.

The collaboration aims to identify and validate novel targets within cardio-metabolic diseases and focuses on research themes, including cardiac regeneration, islet health (diabetes) and diabetic nephropathy across modalities like small molecules and biologics.

During the initial 5-year contract period, AstraZeneca contributes up to \$20M USD annually.

Janssen Biotech and Monash University¹⁰

In 2017, Monash University in Australia signed multiyear research and commercialization deal with Janssen Biotech Inc. for the early detection and prevention of rheumatoid arthritis. The agreement was facilitated by Monash Innovation, part of the recently established Enterprise portfolio at Monash University, and Johnson & Johnson Innovation.

Johnson & Johnson and the Karolinska Institutet¹¹

In 2015, the Karolinska Institutet signed a collaboration agreement with Johnson & Johnson Innovation. As part of the collaboration, Johnson & Johnson Innovation will establish a life science innovation hub at Karolinska Institutet to work with Karolinska Institutet Holding AB, to support and drive the growth of life science companies rooted in academic medical research.

⁹ <http://ki.se/en/medh/integrated-cardio-metabolic-centre-icmc>

¹⁰ <http://www.monash.edu/news/articles/monash-announces-collaboration-with-johnson-and-johnson-innovation-for-rheumatoid-arthritis-detection-and-tr>

¹¹ <http://ki.se/en/news/karolinska-institutet-launches-new-collaborations-for-innovation-and-research>

Lygature (The Netherlands)¹²

In 2016, two Dutch organizations, CTMM and TI Pharma, merged to form Lygature, a not-for-profit organization that manages public-private partnerships involving academia, industry and society. Lygature is focused on pioneering solutions in medical technology and pharmacotherapy.

Lygature maintains strong links with the Dutch innovation infrastructure, but operates independently from the Dutch government.

Merck and the Weizmann Institute of Science (Israel)¹³

In 2016, Merck and the Weizmann Institute of Science extended their research collaboration with a new framework agreement focused on immuno-oncology and immunology. Merck is funding each of the two research areas with up to €1 M per year over a 3-year period, with an option for multiple successive extensions of 2 years each.

Merck has had research and development collaboration ties with the Weizmann Institute since 1978.

MSD and A*STAR¹⁴

In 2016, Singapore's Agency for Science, Technology and Research (A*STAR) and MSD (known as Merck & Co. Inc., in USA and Canada) formed a two-year collaboration aimed at improving cellular delivery of macrocyclic peptides, a class of molecules that can potentially access therapeutic strategies that have been refractory to traditional approaches.

¹² <https://www.lygature.org/>

¹³ "Merck and Weizmann Institute Sign New Framework Agreement on Research Collaboration." February 16, 2016. <https://wis-wander.weizmann.ac.il/people-and-events/merck-and-weizmann-institute-sign-new-framework-agreement-research-collaboration>

¹⁴ <https://www.a-star.edu.sg/News-and-Events/News/Press-releases/ID/4879/ASTAR-and-MSD-establish-a-new-research-collaboration-to-advance-peptide-therapeutics.aspx>

National Network of Excellence in Neuroscience (Israel)¹⁵

In 2013, Teva Pharmaceutical Industries announced a neuroscience research collaboration to bring together 10 of Israel's leading universities and teaching hospitals to focus on new therapeutic approaches to neurological, neurodegenerative and psychiatric illnesses.

This initiative, the National Network of Excellence in Neuroscience (NNE), is an open network that brings the researchers together and provides a working interface with industry, where experts in drug development from Teva interact with academic researchers in order to increase the potential to translate basic science into therapeutic options.

Novartis Institute for Tropical Diseases¹⁶

In 2016, the National University of Singapore opened the VIVA-NUS Centre for Translational Research in Acute Leukaemia (CentRAL). The VIVA Foundation for Children with Cancer, a Singapore-based charity, led the \$10 million funding.

Pfizer and Global Medical Excellence Cluster (GMEC) - Rare Disease Consortium¹⁷

In 2014, Pfizer began a 5-year collaboration with the Global Medical Excellence Cluster (GMEC) to create the Rare Disease Consortium.

The Global Medical Excellence Cluster (GMEC) is a group of six UK universities: Cambridge University, Imperial College London, King's College London, Queen Mary University London, Oxford University and University College London.

The Rare Disease Consortium creates joint research teams between academia and industry. It combines the scientific and clinical resources of the GMEC cluster with Pfizer's discovery and development resources to potentially accelerate treatment discovery.

¹⁵ http://www.tevapharm.com/research_development/rd_partnerships/nne/

¹⁶ http://www.nuhs.edu.sg/wbn/slot/u3819/Press%20release%20-%20VIVA-NUS%20CentRAL%20Lab%20opening-4March2016_final.pdf

¹⁷ <https://www.pfizer.co.uk/content/rare-disease-consortium>

Pfizer and the Weizmann Institute of Science (Israel)¹⁸

In 2016, the Weizmann Institute of Science and Yeda Research and Development Co., its commercial arm, announced that they entered a multi-year arrangement with Pfizer Inc. The collaboration involves hosting a Pfizer medicinal chemist (rotating on a yearly basis) at the Institute to assist with advancing target selection and high-throughput screening, as well as leading development campaigns for programs that enter the National Drug Discovery Institute (DDI). If projects of mutual interest – those that hold promise in addressing unmet medical needs -- are identified, Pfizer and Yeda will evaluate the potential for research and development agreements.

Precision Cancer Medicine Institute¹⁹

In 2014, Oxford University received a £35M (\$56.29M USD) development grant from UK Research Partnership Investment Fund to launch a Precision Cancer Medicine Institute. This was to be matched with over £75 million of investment in financial contributions and support in kind from partners in the project.

The Precision Cancer Medicine Institute plans to research the use of proton beam therapy and carry out research into a wide range of cancer therapies, including the use of genomics and molecular diagnostics, advanced cancer imaging, trials of new drugs and minimally invasive surgery.

The partners include Cancer Research UK, Roche Diagnostics, GE Healthcare, Mirada Medical, Brandon Medical, Blue Earth Diagnostics, and the University of Florida Health Proton Therapy Institute. The proposal also indicated that ProNova Solutions would a proton beam research facility within the new institute.

Roche and Monash University²⁰

In 2016, Monash University in Australia announced a research collaboration agreement with Swiss-based Roche (F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.). The collaboration aims to develop next generation treatments for autoimmune diseases, focused on proteins targeting novel molecular pathways.

The partnership will enable the multi-disciplinary research team and Roche to work together to advance and translate existing and new intellectual property into novel treatments.

¹⁸ "Weizmann Institute of Science Announces Visiting Scientist Agreement with Pfizer Inc." June 5, 2016. <https://wis-wander.weizmann.ac.il/people-and-events/weizmann-institute-science-announces-visiting-scientist-agreement-pfizer-inc>

¹⁹ "Giant £132m investment in cancer research at Oxford University." October 23, 2014.

<http://www.ox.ac.uk/news/2014-10-23-giant-%C2%A3132m-investment-cancer-research-oxford-university>

²⁰ <http://www.monash.edu/industry/success-stories/roche>

Structural Genomics Consortium (SGC)²¹

The SGC (Structural Genomics Consortium) is a not-for-profit, public-private partnership which started in 2003. In June 2017, the Structural Genomics Consortium announced that they had received a \$33M investment in their fourth phase. The funding includes \$11 million in federal funding through Genome Canada, \$5 million through the Government of Ontario, and an additional \$17 million through pharmaceutical companies.

The core mandate of the SGC is to determine 3D structures on a large scale and cost-effectively - targeting human proteins of biomedical importance and proteins from human parasites that represent potential drug targets.

In its third phase, the SGC was funded by 13 separate organizations: AbbVie, Boehringer Ingelheim, the Canada Foundation for Innovation, the Canadian Institutes for Health Research, Genome Canada, GlaxoSmithKline, Janssen, Lilly Canada, the Novartis Research Foundation, the Ontario Ministry of Economic Development and Innovation, Pfizer, Takeda, and the Wellcome Trust.

Takeda Pharmaceutical Co. Ltd. and Kyoto University (Japan)²²

In 2015, Takeda formed a 10-year partnership with Japan's Kyoto University to develop potential stem cell treatments for an array of diseases.

Under the \$270 million agreement, Takeda and the Kyoto University's Center for iPS Cell Research Application (CiRA) will collaborate on projects using induced pluripotent stem cells to discover new therapies. The partnership will investigate the use of stem cells as potential treatments, and as tools for discovering new small-molecule drugs.

²¹ <http://www.thesgc.org/>

<http://www.thesgc.org/news/toronto/new-support-structural-genomics-consortium-and-open-science>

²² "Takeda inks a \$270M stem cell deal with Kyoto University." FierceBiotech. April 17, 2015.

<http://www.fiercebiotech.com/story/takeda-inks-270m-stem-cell-deal-kyoto-university/2015-04-17>

Translational Oncology Network²³

In 2013, Bayer Healthcare launched the Translational Oncology Network in partnership with six research institutions in Singapore: Cancer Science Institute of Singapore, National University of Singapore; Duke-NUS; National University Cancer Institute Singapore (NCIS); National Cancer Centre Singapore; Singhealth Singapore General Hospital; and A*STAR's Singapore Bioimaging Consortium (SBIC).

The network planned to enhance Bayer Healthcare's R&D partnerships in Singapore through the joint development and evaluation of novel treatment options and joint activities such as workshops and lectures.

The partnership was an extension of existing relationships with Bayer HealthCare Singapore.

Unrestricted Leveraging of Targets for Research Advancement and Drug Discovery (ULTRA-DD)²⁴

In 2015, the ULTRA-DD (Unrestricted Leveraging of Targets for Research Advancement and Drug Discovery) Consortium received a €21.2 M (\$23.36M USD) grant from Europe's Innovative Medicines Initiative to validate targets for drug discovery.

ULTRA-DD is a consortium of 10 partners comprising academics at the University of Oxford, ETH-Zurich (Switzerland), Karolinska Institutet (Sweden) the University of Toronto (Canada), and scientists in Bayer, DiscoverRx, Janssen, Novartis and Pfizer.

The aim of ULTRA-DD is to define and validate new targets for drug discovery by generating high quality research tools and profiling them in models of human inflammatory and auto-immune diseases using patient and human primary-cell derived assays and tissue. These reagents, and associated knowledge, will be made available to the research community without restriction. Targets selected will be linked to genetic and epigenetic signaling mechanisms, involved in the initiation and progression of inflammatory and auto-immune diseases.

²³ <https://www.a-star.edu.sg/News-and-Events/News/Press-releases/ID/1401/Bayer-HealthCare-extends-collaborations-in-Singapore-with-a-focus-on-Therapy-and-Diagnostics-in-Oncology.aspx>

²⁴ <http://www.ultra-dd.org/>

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