

# MEDICAL INNOVATION PLAYBOOK.





Sponsored by the Council for American Medical Innovation and Cleveland Clinic.

## Introduction

Each year, nearly \$100 billion is spent in the United States on healthcare related research, with an increasing proportion of the breakthrough research being carried out in academic medical centers. While continued medical progress relies on enhanced academic-industry collaboration, the information available on the academic commercialization system function across these institutions is not uniform and often difficult to access.

The *Medical Innovation Playbook* is the first-ever comprehensive study of technological innovation and commercialization at the nation's top healthcare centers.

We believe this in-depth, comprehensive characterization of how each of the top medical centers has organized to stimulate innovation and its commercial application should have broad reach. The *Medical Innovation Playbook* will offer profiles of dozens of academic institutions and medical centers that will provide an easy-to-understand guide that will be a resource for practitioners, academic executives, trustees, companies, entrepreneurs and investors.

The *Medical Innovation Playbook* will be invaluable to institutions as they benchmark their work against other medical centers and study best practices. Because these programs are evolving, the profiles offer the prospect of new approaches and new collaborations in medical innovation. While the *Playbook* will profile the approach of the different institutions, it will not evaluate their respective performance.

#### The *Medical Innovation Playbook* Beneficiaries

The *Playbook* will help widen the user's understanding of these diverse commercialization programs and activities, while providing information that supports and enhances medical innovation. The *Medical Innovation Playbook* will be a resource for:

• Industry, Investors, and Entrepreneurs: Individuals and companies throughout the United States and internationally will find the *Medical Innovation Playbook* a unique and unrivaled resource as they explore collaborations and opportunities with academic medical centers. They will be able to easily and efficiently explore programs by institution, state, and technology area.

- **Practitioners:** Program managers in healthcare institutions and academic medical centers will be able to consult the *Medical Innovation Playbook* for comparative information and insights about others' programs as they strive for greater success within their own programs and expand their collaborative and partner networks.
- Public Officials: The Medical Innovation Playbook will provide state and federal policy leaders with the opportunity to expand their perspective on medical innovation inside healthcare and academic medical centers, enhancing their understanding of the contributions these organizations make in advancing medical innovation and improving the quality of patient care.
- Strategists and Researchers: The Medical Innovation Playbook will support policy development and research in many aspects of the medical innovation field. It will be a resource for comparing the United States approaches with those of other nations.
- News Media and General Public: Local and national news media have vigorously reported on medical innovations. The *Medical Innovation Playbook* will support both of these audiences in assessing the contributions healthcare institutions and academic medical centers make in advancing medical innovation and enhancing the quality of patient care.

The healthcare institutions' and academic medical centers' profiles will be "point-in-time snapshots" of the missions and operations of the programs as of fall of 2012. Because programs and priorities continually evolve, we expect the profiles will be regularly updated on a dedicated website developed for this purpose.

- Christopher M. Coburn
  Executive Director, Innovations
- Debra Lappin
  Council for American Medical Innovation

#### The Medical Innovation Playbook Process

The *Medical Innovation Playbook* is being prepared over a 12-month period through the active participation of academic medical centers and the support of an outstanding steering committee:

**Darren Carroll**, Vice President, Corporate Business Development, Eli Lilly and Company **Guy Chisolm, PhD**, Professor of Cell

Biology and Vice Chair of the Lerner Research Institute, Cleveland Clinic

**Christopher Colecchi**, Managing Director, Broadview Ventures

**Paul DiCorleto, PhD**, Chair, Lerner Research Institute, Cleveland Clinic

**Richard Foster, PhD**, Managing Partner, Millbrook Management Group LLC

Jan Garfinkle, Founder and Managing Director, Arboretum

Thomas Graham, MD, Chief Innovation Officer, Cleveland Clinic

James Mawson, Global Corporate Venturing Arundeep Pradhan, Associate Vice President for Technology Transfer and Business Development at Oregon Health & Science University Harry Rein, General Partner, Foundation Medical Partners Roy Silverstein, MD, Chair, Department of Medicine, Medical College of Wisconsin Steve VanNurden, President and CEO,

Fitzsimons Redevelopment Authority

#### The *Medical Innovation Playbook* Selection Criteria

Academic medical centers have been selected for inclusion in the *Medical Innovation Playbook* based on two criteria: (1) cumulative healthcare research budget; and (2) current measureable outcomes associated with technology commercialization program activities.

**Initial Survey.** The first step in developing the program profiles is a short on-line survey addressing topics that include an institutional profile, technology commercialization program overview and structure, program operations data, intellectual property policy, and outcome metrics.

**Follow-Up Interview.** A follow-up interview delves deeper into specific operational, structure and partnership topics.

#### Profile Development and Compilation.

A comprehensive profile developed for each institution is vetted and approved for inclusion in the *Medical Innovation Playbook* by the participating institution. **The Medical Innovation Playbook Publishing Schedule.** *The Medical Innovation Playbook* will be published online in 2013, as well as in printed and E-book format.

# Participating Institutions\*

Beth Israel Deaconess Medical Center **Boston University** University of Cincinnati Cincinnati Children's Hospital Medical Center Clemson University **Cleveland Clinic** University of Colorado - Boulder The Florida State University Georgetown University Indiana University Johns Hopkins University University of Miami University of Michigan Massachusetts Institute of Technology Memorial Sloan-Kettering Cancer Center University of Nebraska Medical Center North Dakota State University Northwestern University The Ohio State University The Pennsylvania State University University of South Florida Stony Brook University The University of Texas System Upstate Medical University Vanderbilt University Washington University in St. Louis Yale University \*As of November 1, 2012

We hope that you will add the full *Medical Innovation Playbook* to your reading list next year. Included in this preliminary version of the *Playbook* are eight *Playbook* profiles of leading technology commercialization programs.

## **Medical Innovation Playbook: Metrics**

To date, 27 institutions (listed on pg. 3) have participated in the *Medical Innovation Playbook* project. Their combined experience over the past year alone encompasses more than 4,100 invention disclosures, 1,000 executed licenses and options, \$520 million in license revenues, 130 startup companies created, and 2,200 filed patent applications.

### **Distribution of Healthcare Invention Disclosures by Type**



### Healthcare as a % of Key Commercialization Metrics



Note: All respondents include institutions with an exclusive focus on healthcare (e.g. hospitals, medical colleges); data are annual unless otherwise stated.

## **Institution Profiles**



www.clemson.edu/curf



## Clemson University

#### **Institution Profile**

Clemson University, a nationally ranked public research university, was founded as a land-grant university in 1889 in Clemson, South Carolina thanks to a bequest from Thomas Green Clemson. An American politician, statesman, and former United States Superintendent of Agriculture, Clemson was also a champion of formal scientific education.

Clemson's 1,400-acre campus on the shores of Lake Hartwell in the rolling foothills of the Blue Ridge Mountains is home to more than 17,000 students and 1,300 full-time faculty who teach and conduct research in Clemson's nine colleges and various centers and institutes. Clemson research efforts have focused on three central areas: transportation, environment, and health. The Clemson bioengineering department is internationally recognized for significant contributions in the field of biomaterials engineering, while the world-class Clemson University International Center for Automotive Research (CU-ICAR) and its four specific research areas, drive innovation in automotive and motorsports research. Clemson University is also home to the largest seed and genetic plant inventory in the world.

While Clemson University does not have a medical school, the university works closely with researchers at the Greenville Hospital System's Patewood campus and the Steadman Hawkins Clinic of the Carolinas. Greenville is located on the Interstate 85 corridor and is a two-hour drive from Atlanta and Charlotte. In recent years, Greenville has become home to many new businesses from all over the country.

Clemson University researchers also collaborate with colleagues from the state's two other research universities, the University of South Carolina (USC) in Columbia, and the Medical University of South Carolina (MUSC) in Charleston. Founded in 1823, MUSC became the tenth medical school in the United States and the first in the Deep South. Their ten-story MUSC Medical Center, opened in 1955, is an academic health institution with a strong reputation in neuroscience, cardiovascular medicine, and drug sciences, while their MUSC Foundation for Research Development is their focal point for technology transfer.

Improving healthcare through innovation is one of the major goals of Clemson researchers. The "Clemson hip," a popular joint replacement adhesive that helps secure metallic devices into bone when bone cement is used, is a Clemson innovation from the Department of Bioengineering that has produced \$7.4 million in licensing income during the two decade lifetime of the patent.

In 2010, Clemson University had \$82.7 million in federally sponsored research activities, with \$26.1 million designated for healthcare related research. Of the \$9.1 million in industry-sponsored research expenditures, \$3 million was for healthcare efforts.

#### Technology Commercialization Office (TCO)

The Clemson University Research Foundation (CURF), established in 1982, supports research enterprise and business incubation at Clemson University. An executive director and board of directors drawn from public and private sector leadership govern and direct CURF. At Clemson, the Office of Technology Transfer within the Division of Research works closely with CURF to commercialize University intellectual property through licensing agreements, new company formation, and incubation of fledgling businesses based on new technologies developed at Clemson. CURF also acts as the legal recipient of gifts, contracts, and grants from industry, public and private non-profits, and government agencies for the performance of research associated with Clemson.

Over the past decade ending in 2011, technology transfer has generated 648 disclosures from faculty, students, and staff, induced 110 issued patents, and

achieved over \$28 million in gross royalty revenue received. In addition, licensees of university intellectual property reinvested over \$1.7 million in sponsored research and formed 15 start-up companies, with many located within the state.

In fiscal year 2011 alone, Clemson University disclosed a university record 124 new technologies, with key emphasis areas including biomedical/biotechnology, automotive and transportation, advanced materials, and information technologies.

The 2011 CURF budget of \$856,000 covered staff salaries and benefits, legal fees, research investments, and other operational needs. There are three and a half full-time employees, with two dedicated to the management of approximately 100 disclosures annually. Healthcare disclosures are typically 65% device; 5% drug/therapeutic; 10% diagnostic; and 20% software, with one licensing manager handling these efforts. They also manage 51 cumulative active licenses, 11 for healthcare. In 2010, 82 inventions were disclosed; 15 were healthcare related. Seven licenses were executed that year; none for healthcare. In addition, 37 patents were filed. 8 for healthcare inventions. Of the 20 patents issued, 4 were for healthcare. Total licensing revenue in 2010 was \$1.064 million, with \$35,000 from healthcare related inventions.

#### Fit Within The Organization

CURF operates as a separate organization within Clemson University. The Office of Technology Transfer's chief function is to facilitate innovation within Clemson University. Its officers track, evaluate, protect and commercialize inventions made by Clemson faculty and students, including the creation of new companies.

#### **TCO Structure/Function**

The goal of the Office of Technology Transfer is to move technology out of the Clemson laboratories and into commercial markets. Once a new confidential disclosure form is received by CURF, it is reviewed by the Clemson University Intellectual Property Committee to assess the novelty of the invention, protectability, and marketability of potential products or services, size and growth potential of the relevant market, amount of time and money required to further develop, and potential competition from other products/technologies.

Innovation is a journey, not a destination. If it's determined that Clemson has ownership interest in the invention, a CURF representative is assigned to assist the inventor and develop an appropriate commercialization strategy. As part of the strategy, CURF will contract with outside patent counsel for intellectual property protection. CURF technology commercialization officers will also help identify potential licensees through existing relationships, market research, and the CURF website. Financial return from a license is split: 40% inventor; 20% institution; 20% administration; and 20% other. CURF owns and operates several facilities that support business incubation and enable Clemson University

research activities. For medical research, CURF currently maintains a floor of laboratories at the Greenville Hospital System's Patewood Memorial Campus, with additional laboratory space available at the Medical University of South Carolina.

The state of South Carolina is committed to building a vibrant knowledge-based economy. A cornerstone of this long-standing commitment is the visionary SmartState Program, which was established by the South Carolina General Assembly in 2002 and funded through the South Carolina Education Lottery. The program authorizes the state's three public research institutions—Clemson University, University of South Carolina, and the Medical University of Sough Carolina—to use the funds to create Centers of Economic Excellence. Each Center is awarded from \$2 million to \$5 million in state funds, which must be matched on a dollar-for-dollar basis with non-state funds.

The SmartState Program supports research in areas that will help companies grow in the state and build a technology-rich economy. To date, the program has provided \$45 million to Clemson for support of 16 endowed chairs in Centers of Economic Excellence (COEE).

The world-renowned Clemson University International Center for Automotive Research (CU-ICAR) now has four endowed chairs. Clemson, along with the Medical University of South Carolina (MUSC) and the University of South Carolina (USC) has also established a COEE in Advanced Tissue Biofabrication to develop processes for the production of complex tissues and organs, utilizing three-dimensional layering of individual cells; the Health Facilities Design and Testing COEE, again with MUSC and USC, collaborate to improve delivery of healthcare services; the Regenerative Medicine COEE with MUSC is focused on the regeneration and re-modeling of tissues and organs for the purpose of repairing, maintaining, or enhancing organ functions; while the Tissue Systems Characterization center, housed in Clemson's Institute for Biological Interfaces of Engineering, will seek alternatives to animal testing and allow Clemson researchers to further explore novel technologies with the potential to serve as new diagnostics, medical device and therapeutic products.

#### **TCO** Initiatives/Programs

CURF helps enhance commercialization possibilities at Clemson through a variety of internal and external initiatives. The CURF website serves as a main portal of information and it highlights the latest Clemson innovations. As part of their outreach program, CURF personnel have informal monthly interactions with faculty at the Medical University of South Carolina and at Greenville Hospital System, one of the nation's most respected healthcare systems, located 30 minutes away from Clemson. With the opening of the University of South Carolina Medical School-Greenville in 2012, CURF has expanded its regular presentations. Medical conferences, trade shows, cold calls, mailing of summaries, and consultants all help market Clemson technologies.



www.clevelandclinic.org/innovations

## **Cleveland Clinic**

#### **Institution Profile**

Founded in 1921 by four renowned physicians, Cleveland Clinic is a nonprofit, multispecialty academic medical center established to provide outstanding patient care based upon the principles of cooperation, compassion, and innovation. Cleveland Clinic is recognized as one of the nation's top four hospitals by *U.S. News & World Report* and is celebrating its 18th consecutive year as America's top heart center.

Medical research and innovation is ingrained in the culture of Cleveland Clinic. Over the years, its physicians have contributed substantially to the advancement of patient care, from the very beginning with Clinic co-founder George Crile's novel carotid clamp and forceps clamp, through coronary angiography breakthroughs, the first heart bypass surgery and pioneering heart transplant work, to the recent first-ever near-total face transplant in the United States.

Cleveland Clinic's Lerner Research Institute is home to laboratory-based, translational and clinical biomedical research and includes 650,000 square feet of research facilities and more than 1,200 scientists and support personnel who generated in excess of 1,360 healthcare related studies and journal publications in 2011.



Cleveland Clinic sponsors one of the nation's largest physician-graduate training programs. In 2002, Cleveland Clinic created a tuition free medical school dedicated to developing physician-scientists. Cleveland Clinic Lerner College of Medicine combines education and research in an innovative five-year program that mentors medical students to become the next generation of physician investigators.

#### Technology Commercialization Office (TCO)

Innovations, the Clinic's corporate venturing arm, was established in 2000 to promote innovation for improved treatment of the sick through the deployment of Cleveland Clinic technology. Innovations' business development mission includes bringing breakthrough innovations to market by commercializing new technologies and capabilities developed at Cleveland Clinic through spin-off companies, licenses, consulting and joint ventures. In 2012, it was ranked as one of the top four healthcare corporate venturing units in the world by *Global Corporate Venturing* magazine.

#### **Cleveland Clinic continued**

Innovations operates as a departmental unit within the executive administrative structure and reports to the Chief of Staff in the Office of Professional Staff Affairs. Its budget covers legal fees, staff salaries and benefits, strategic translational research investments and other operational needs.

65 Innovations employees are dedicated to the management of more than 250 disclosures annually; executing 35 licenses and dozens of other transactions annually; and creating, capitalizing and governing numerous new companies each year. The most active departments measured by disclosures are the Heart and Vascular Institute, Neurological Institute, Anesthesia, Biomedical Engineering and Orthopaedics. The disclosure profile breakdown is: 58% device, 23% software, 11% therapeutic, 7% diagnostic, and 1% biological materials.

#### Fit Within The Organization

Innovations main function is business development. Among its key functions are to facilitate innovation, track, evaluate, protect, and commercialize inventions made by Clinic physicians and researchers, including the creation of new companies for the right opportunities. Innovations assists in the development of Materials Transfer Agreements and Sponsored Research Agreements, particularly when associated with a technology under Innovations management. In addition, Innovations personnel lead applications for government supported translational research funding and manage research operations resulting from such funds. Further, Innovations leads efforts to in-license diagnostic tests for utilization in the Clinic's Pathology and Lab Medicine Institute and the Clinic's Reference Laboratory.

In conjunction with Cleveland Clinic Law Department, Innovations plays a leading role in identifying and managing conflict of interest (COI) issues relating to the commercial exploitation of Clinic innovations. Innovations' Executive Director is an active member of the COI committee, and assists in the creation of Conflict Management Plans to protect individual and institutional interests.

#### **TCO Structure/Function**

Innovations consists of functional teams that work closely with one another: Commercialization/Licensing, New Ventures, Alliances, Integrated Business Solutions, Operations, and Technology Development.

When new disclosures are received, they are vetted for start up potential and then routed to Licensing or New Ventures, as appropriate. For certain technologies, the pathway is not immediately obvious; in those cases, parallel paths of evaluation and development are pursued until a preferred commercialization route becomes evident. The systems, operations and approach of Innovations are specified in a 60+ page Policies and Procedures Manual. A best practice, the Manual captures twelve years of learning and operational refinement to optimize the innovation and commercial outcomes of Cleveland Clinic.

The Licensing team consists of 11 professionals dedicated to evaluation, marketing, protection and licensing, and management of intellectual property (IP). The Licensing team is also responsible for government reporting and license compliance functions.

The Product Development Fund (PDF), an internal translational fund included within the Innovations office budget, is used to accelerate commercialization. The PDF investment is used to validate technology, decrease investment risk, and strengthen and clarify patent protection. There are 20–25 competitive awards per year, averaging \$30,000 per award with a 6- to 12-month performance period. The Clinic's dedicated internal prototyping group, Medical Device Solutions, plays a major role in validating technology with PDF support.

The Clinic's Commercialization Council provides final approval of PDF awards. The Commercialization Council consists of two dozen prominent Clinic physicians and researchers, and meets monthly to advise on internal strategy regarding institutional policies and programs related to innovation and review PDF applications.

The New Ventures team consists of six professionals and is dedicated to creation, capitalization and governance

of start-up companies from Cleveland Clinic technology. When a platform technology merits a start-up company, New Ventures will identify the largest market opportunities and most active investment sectors to position the start-up appropriately.

The Innovation Advisory Board (IAB) guides the work of Innovations especially related to company creation, financing and governance. The IAB, made up of 16 prominent venture investors and industry executives, and its committees meet up to a dozen times a year and advise on deal strategy, company creation, investments, market conditions, investor recruitment, and portfolio management.

The IAB vets deals for Clinic start-ups and provides guidance on Clinic investments into such companies. Investments in Clinic start-ups are made from the \$15 million Ohio BioValidation Fund (OBVF), which is managed by Innovations, and are typically \$250,000-\$500,000 per eligible spin-off. The OBVF is an evergreen fund capitalized by the Clinic and by Ohio's Third Frontier Program – a multi-billion dollar technology-based economic development initiative that supports existing industries and fosters the formation and attraction of new companies in Ohio's emerging industry sectors.

Also involved in start-up creation are Executives in Residence (EIR). These current or former CEOs and/ or venture investors work with Innovations staff to accelerate the highest potential technologies to new products. There are currently four EIRs working with Innovations.

The Clinic has been awarded more than \$150 million in technology development funding from the Ohio Third Frontier program, including \$60 million for the Global Cardiovascular Innovation Center (GCIC) consortia. The GCIC staff comprises the bulk of the Technology Development team and the consortia provides funding for commercialization by attracting established companies to Ohio, accelerates their product development efforts, and supports start-up company incubation within the 50,000 square foot facility.

#### **TCO** Initiatives/Programs

Innovations engages in a variety of special internal and external initiatives that enhance commercialization at Cleveland Clinic. The annual Medical Innovation Summit gathers innovation leaders from every aspect of healthcare. The Summit attracts more than 1,000 registrants and draws top CEOs, venture investors, medical leaders, and journalists who meet for three days to assess the state of innovation in healthcare and to consider the most promising technologies and the issues affecting their deployment in a given clinical field.

Innovations has a formal departmental outreach program with Cleveland Clinic physicians, making 3-4 dozen presentations annually during which the Innovations mission and commercialization process are described to potential inventors.

Innovations also holds Inventor Forums to expose Clinic staff to other inventors who have successfully traversed the commercialization pathway, as well as successful investors in innovations and technology start-ups. Cleveland Clinic inventors are recognized through the Clinic's annual Inventors Award Dinner and the annual Sones Innovations Award, which goes to the top innovator of the year.

Following industry best practices, Innovations holds Structured Invention sessions, where prominent physicians in a particular department or discipline are brought together to brainstorm potential solutions to the most pressing patient care needs in their medical area. A facilitator leads these sessions, with other participants, such as patent counsel, engineers, or other subject matter experts, augmenting the group. Structured Invention is an iterative process – concepts arising from a session are evaluated for patentability and feasibility, and results are discussed with the group at subsequent sessions during which the concept is modified or replaced with new ideas.

In 2011, Cleveland Clinic launched its Healthcare Innovation Alliance network. A groundbreaking partnership was established when Cleveland Clinic and MedStar Health agreed to create an alliance to benefit patients through collaborative innovation projects, research, clinical investigation, and commercialization application. MedStar Health is the largest healthcare provider in the Maryland and Washington, D.C. regions and its nine hospitals, the MedStar Health Research Institute, and 20 other health-related companies are recognized regionally and nationally for excellence in medical care.

The alliance is a joint effort of Innovations and the MedStar Institute for Innovation (MI2), with collaboration on multiple fronts, beginning with MedStar utilizing Innovations' comprehensive technology development and commercialization services infrastructure. The integration of capabilities between the two organizations will focus on development and rapid deployment of new technologies.

In early 2012, North Shore-LIJ Health System joined the Healthcare Innovation Alliance. The System is the largest provider in New York State and has 15 hospitals and more than 200 other facilities across the New York metropolitan area. The goal is to enhance the discovery, development, deployment, and commercialization of new technologies originating from North Shore-LIJ's clinical facilities and its Feinstein Institute for Medical Research. Over the past decade, the Feinstein Institute, which has more than 200 active patents in 80 distinct technologies, has created 11 start-up companies. Another alliance was formed in May 2012 with the University of Notre Dame for a collaborative relationship for joint development and commercialization of medical innovation. With 50 inventor disclosures annually, the Alliance network offers the university an opportunity to create a commercialization pathway for innovative healthcare technologies.

In the summer of 2012, Cleveland Clinic formed commercialization alliances with Promedica Health in Northwest Ohio and The Ohio State University. The Promedica alliance is very similar to Medstar and North Shore except on a slightly smaller scale. The OSU partnership created the largest commercialization network in Ohio. The first joint effort will be to identify 20 high-profile medical technologies and decide how they can best be commercialized.

Innovations directly supports the Clinic's core business development functions through its Integrated Business Solutions group. This eight person, multi-disciplinary group, provides deal making, analysis, and engagement to further commercial and novel products based on uniquely compelling Cleveland Clinic competencies as well as those tied to external collaborations.

# **W** INDIANA UNIVERSITY

www.iurtc.iu.edu



## Indiana University

#### **Institution Profile**

Indiana University, a nationally ranked public university, was founded in 1820 and later recognized as "The University of the State" in 1852. IU has a core 1,900-acre campus at Bloomington with 32,000 students, another core campus at Indianapolis, and six regional campuses across the state, with a total student population of more than 110,000.

Herman B. Wells, the visionary eleventh president of Indiana University from 1938 to 1962 understood the unique contribution that faculty could make to the economic life of the state. Addressing state business leaders at the height of the Great Depression, he said, "We certainly can do something about providing the research and the research facilities that make a significant contribution to the welfare of our state and nation."

IU has certainly invested in research over the decades, with scores of university researchers looking for new ways

to fight and cure disease and protect the environment. One of the world's fastest supercomputers, the IU Data Capacitor, and the high-speed TeraGrid network are just some of the big IT tools now used to analyze massive amounts of data and foster scientific collaboration at the university. As of the last ranking, IU is first in the Big Ten in endowed chairs and professorships. In addition, IU has consistently brought in more sponsored research dollars than all of Indiana's public and private research universities combined. In the 2012 fiscal year, IU faculty was awarded more than \$154 million in NIH-sponsored funding to support their research and service activities. The Indiana University School of Medicine in Indianapolis educates the second largest medical student body in the U.S. Founded shortly after Johns Hopkins, Harvard, and Western Reserve in 1903, it has been a great source of medical innovation, with the faculty performing many firsts in the state, including transplants of the kidney, liver, cornea, bone marrow and pancreas. IU research was responsible for the first effective treatment for

#### Indiana University continued

testicular cancer, as well as the development of the human papillomavirus (HPV) vaccine, and many other life-saving advances. Located two miles away are the international headquarters for Eli Lilly, the tenth largest pharmaceutical company in the world. The company's presence has resulted in much mutual collaboration with IU researchers and faculty with both early- and late-stage innovations.

The Indiana University School of Dentistry, founded in 1879, is one of the oldest dental schools in the nation. Beginning in 1950, research started on a therapeutic toothpaste that could prevent tooth decay. A patent was issued to IU in 1952 for the first fluoride dentifrice, and Crest, launched nationally by Proctor and Gamble in 1956, soon became the market leader for decades. Funds from the fluoride patent helped establish the Oral Health Research Institute at IU, a world-renowned product testing site.

#### Technology Commercialization Office (TCO)

The Indiana University Research & Technology Corporation (IURTC), which was formed in 1997, fosters the advance of all scientific research at the university. The Office of Technology Commercialization (OTC), with offices in Indianapolis and Bloomington, aggressively seeks out, supports, and markets all Indiana University intellectual property and business development activities.

Strong relationships between IU researchers and private industry have helped build Indiana's thriving life sciences and information technology industries. Since 1997, IURTC has worked with faculty and students to develop more than 1,600 inventions, over 300 patents and 41 start up companies. The biggest success so far for IURTC has been ANGEL Learning, a course management system start-up company created by IU researchers and nurtured by IURTC. The sale of the company in 2009 for \$100 million represents the largest commercial transaction linked to the sale of a university start-up that IU has ever experienced.

There are 15 full-time OTC employees. The 2011 OTC operating budget of \$2.3 million covered staff salaries and benefits, legal fees, research investments, and other operational needs. For fiscal year 2011, technology transfer generated 175 disclosures from faculty, students, and staff. Twenty-eight patents were issued and 39 licenses were executed, with a total licensing revenue of \$11,125,616 for the year. Personnel also manage 272 cumulative active licenses.

#### Fit Within The Organization

All of Indiana University's various commercialization efforts fall under the aegis of the Indiana University Research & Technology Corporation (IURTC), which has offices in Indianapolis and Bloomington. The Office of Technology Commercialization is a part of IURTC and focuses on development of innovative technologies at all eight university campuses, including the medical school and school of dentistry. The director of this department reports directly to the president and CEO of the IURTC.

#### **TCO Structure/Function**

The mission of the Office of Technology Commercialization is to protect the rights of the inventor, the university, and any investors by obtaining the necessary patents and copyrights for these discoveries and to meet the university's intellectual property obligations to any research sponsors. In addition, licensing experts help market inventors' discoveries for commercial use, either by licensing to an existing company or helping them start up their own.

Once an invention disclosure form is completed by an inventor, it is reviewed by IURTC members through bi-weekly meetings at which all technology managers plus a patent attorney, investment fund manager, representative from the vice chancellor for research's office, and associate dean of entrepreneurship from the medical school are in attendance.

The information and feedback provided enables the IURTC technology manager to determine what legal protections are needed, if any, as well as to begin

targeting potential business partners. Commercialization revenue at Indiana University is distributed with 35% going to the inventor, 15% to the inventor's laboratory, 15% to the school or institute, and 35% to the Office of Technology Commercialization.

#### **TCO** Initiatives/Programs

The Office of Technology Commercialization helps enhance commercialization possibilities at Indiana University through a variety of internal and external initiatives. Dozens of informal outreach meetings with Indiana University OTC staff are held annually to alert department chairs, new faculty and student inventors about technology commercialization possibilities.

IURTC does all it can to support medical innovation, whether it be drugs, medical devices or healthcare IT. As early stage investing on the life science side has decreased over the last few years, there is now an increased need for proof of concept programs to support commercial validation studies of early stage IU technologies. With that in mind, the spInUp Program was started in 2011 by IURTC to serve as the catalyst to help promising university inventors launch their ideas into the marketplace through the formation and development of new high-tech companies directed by an entrepreneur that can help secure funding grants.

In spite of the global recession, Indiana's universities and state government have worked together to support technology-driven research that will translate into jobs, firms, and exports. The BioCrossroads Initiative is a public-private partnership that was established to offer funding and assistance and forge stronger strategic partnerships between IU and other universities and the Indiana life sciences industry. The goal is to form comprehensive discovery-to-product-development approaches and mechanisms. This important catalyst for life sciences ideas provides funding and helps advance Indiana's next generation of growth and innovation.

Indiana University, along with the IU School of Medicine, Purdue University and the University of Notre Dame, also collaborate through multi-institutional initiatives including the Indiana Innovation Alliance and the Indiana Clinical and Translational Sciences Institute (CTSI), which are designed to accelerate the pace of taking medicine from the "bench to the bedside." In 2008, CTSI established a \$25 million award to fund collaborative university-industry translational research. To harness the immense creativity at Indiana University for the good of the entire state, the \$10 million Innovate Indiana Fund was established to invest in companies originating from Indiana University and help them achieve commercial success. Infusion of capital and expertise in company formation helps these portfolio companies achieve success.

Affordable office and lab space is available to IU inventors in the process of refining discoveries or starting new companies. In 2002, IURTC established the Indiana University Innovation Center-Indianapolis, a 62,000 square-foot business incubator dedicated to establishing new life and health science start-up companies, with a 40,000 square-foot incubator, the Indiana University Innovation Center-Bloomington, following in 2009. Additional economic development centers have also been established around the state in Bloomington, Evansville, Fort Wayne, Gary, Kokomo, Richmond, and South Bend.



www.mskcc.org/research/office-technology-development

## Memorial Sloan-Kettering Cancer Center

#### **Institution Profile**

Memorial Sloan-Kettering Cancer Center (MSKCC), the world's oldest and largest private institution devoted to cancer prevention, treatment, research, and education, was founded in 1884 in New York City as the New York Cancer Hospital. Today, MSKCC is one of the nation's premier cancer centers committed to exceptional patient care, leading-edge research, and unparalleled educational programs.

Memorial Sloan-Kettering Cancer Center is one of 41 National Cancer Institute-designated Comprehensive Cancer Centers. Each year, Memorial Hospital physicians treat more than 400 different subtypes of cancer, and its surgeons perform more than 20,000 operations. Research at the Sloan-Kettering Institute, MSKCC's basic-science research division and one of the nation's leading biomedical research institutions, is dedicated to understanding the biology of cancer through programs in Cancer Biology and Genetics, Cell Biology, Developmental Biology, Structural Biology, Computational Biology, Molecular Biology, Molecular Pharmacology and Chemistry, and Immunology. "The scientific policy of the Institute rests upon the principle that basic advances through research are made only by the creative genius of individual scientists," said former General Motors executive Alfred P. Sloan, who in 1945 joined forces with another former GM executive, Charles F. Kettering, to establish the Sloan-Kettering Institute. Today's research staff includes more than 100 laboratory investigators, 400 research fellows, and more than 200 graduate students (both PhDs and MD/PhDs). Memorial Sloan-Kettering faculty includes 12 members of the National Academy of Sciences, seven Howard Hughes Medical Institute investigators, and 18 Institute of Medicine members.

Together with patient care and education, research is a vital component of Memorial Sloan-Kettering's mission. In 2011, more than \$177 million in federal and industry-sponsored research funding was received. Some of this funding went to support more than 400 clinical trials for pediatric and adult cancers, many of which were led by MSKCC physicians. Memorial Sloan-Kettering physicians and scientists have a long and distinguished tradition of applying laboratory discoveries to the development of new and moreeffective therapies for the treatment of cancer, and have made significant contributions to the transformative developments of the past several decades.

A notable example was the discovery of a human growth factor called G-CSF. In the mid-1980s, MSKCC scientists identified and purified G-CSF, which stimulates the proliferation of neutrophils (a type of white blood cell) that are often depleted as a result of chemotherapy for cancer. In collaboration with Amgen, recombinant G-CSF (Neupogen®) was developed and has significantly improved the survival of patients by reducing the frequency and severity of infections during treatment.

More recently, MSKCC investigators played leadership roles in the discovery and development of two new drugs — abiraterone acetate (Zytiga<sup>®</sup>) and enzalutamide (Xtandi<sup>®</sup>) — approved by the US Food and Drug Administration in 2011 for the treatment of metastatic prostate cancer.

Memorial Sloan-Kettering physician-scientists also led pivotal preclinical and clinical studies of two additional new drugs—ipilimumab (Yervoy<sup>™</sup>) and vemurafenib (Zelboraf<sup>®</sup>)—that led to the 2011 FDA approval of these therapies for the treatment of advanced melanoma.

#### Technology Commercialization Office (TCO)

At Memorial Sloan-Kettering, scientists, physicians, researchers, and administrators strive to develop and commercialize scientific and medical inventions— endeavors aimed at making more-effective and affordable cancer treatments available to patients around the world. One of the institution's greatest strengths is the close interactions between laboratory and clinical investigators, which facilitates the translation of research from the laboratory to new treatments and therapies for patients.

While most research focuses on cancer, Memorial Sloan-Kettering scientists also work to develop new therapeutic strategies for immune system disorders, infectious diseases, and related conditions.

The Office of Technology Development (OTD) is responsible for managing the discoveries of Memorial Sloan-Kettering Cancer Center investigators. Established in 1995, the OTD's staff of 15 full-time employees evaluates, protects, markets, and licenses new inventions and negotiates agreements for sponsored or collaborative research, confidential disclosures, and material transfers.

Because Memorial Sloan-Kettering is committed to developing affordable technologies for worldwide use, the OTD considers both the social and financial benefits of all new opportunities.

The 2011 OTD operating budget of \$1.99 million covered staff salaries and benefits, research investment, and other operational needs. In 2011, 81 healthcare inventions were disclosed, 38 licenses executed, 71 patents filed, and five start-up companies created. Licensing revenue of \$58.3 million was earned in 2011. OTD staff currently manages 281 healthcare licenses.

#### Fit Within The Organization

The Memorial Sloan-Kettering Cancer Center's Office of Technology Development is responsible for managing the discoveries of its inventors. The OTD Director reports to the Vice President of the Research and Technology Management division, which has overall responsibility for overseeing the inventions and technology that result from research conducted at Memorial Sloan-Kettering.

#### **TCO Structure/Function**

Medical technologies—devices, diagnostics, research tools, therapeutics, and vaccines—created at Memorial Sloan-Kettering focus on cancer and related diseases, as well as on general biomedical uses.

When a scientist, physician-scientist, or surgeon has completed invention disclosure information, it is reviewed by OTD licensing managers who develop

#### Memorial Sloan-Kettering Cancer Center continued

strategies to license and patent the technology. They then explore options for moving the research forward, whether it is toward manufacturing; human trials and FDA approval; by licensing patents to an established pharmaceutical or biotechnology company; or by forming a start-up company.

The Office of Technology Development at Memorial Sloan-Kettering Cancer Center uses a variety of methods to help their researchers identify discoveries that may have potential clinical applications. While the strength of the institution has historically been in drug discovery, which is an expensive and lengthy process, OTD managers have recently been focusing their efforts on non-drug innovations, particularly those coming from the surgical staff.

At Memorial Sloan-Kettering, there are nearly 100 highly experienced surgeons, all of them leaders in their fields, who are constantly exploring how to make surgery safer and more effective, how to perform surgery on patients with advanced cancers, and when to use surgery in combination with the appropriate drugs or other therapies. Regularly scheduled meetings organized by the OTD are held with the surgical faculty to review with them how the discovery and licensing process works. Within an hour of the first meeting, information about a new invention was e-mailed to the OTD.

The OTD maintains a busy agenda of activities to educate Memorial Sloan-Kettering's faculty on a broad range of topics—from the basics of patenting to intellectual property, business development, and managing conflicts of interest. In an effort to engage faculty, the OTD hosts Riverside Chats. This monthly seminar series, which is usually attended by more than 100 guests, is open to faculty, graduate students, and postdoctoral fellows from Memorial Sloan-Kettering and other biomedical research institutions in New York City and the surrounding area. Invited experts in technology transfer, patents, and venture capital funding address the groups.

For hospital faculty who are more entrepreneurial and already interested in starting their own companies, the

OTD typically sponsors three Boot Camps a year to help them develop skills in the many activities associated with launching and growing a business.

Memorial Sloan-Kettering has 36 core facilities that provide a wide range of expert services and research technology. Some of these facilities are focused on therapeutic discovery, development, and manufacturing, which enables investigators to advance medical innovations in-house as far as necessary to attract the involvement of commercial entities.

The Technology Development Fund is another MSKCC resource that helps investigators turn basic discoveries into commercial products. Established in 2009, the fund makes awards of up to \$500,000 to kick-start the development of new therapies and technologies. Experts with extensive experience assessing the commercial potential of new discoveries review proposals submitted by faculty. To date, the fund has financed the development of 10 projects.

Other funding initiatives are available from the BioAccelerate NYC Prize, a citywide competition that funds biomedical research that has the potential to spur local business development and create new jobs. Awardees win grants of up to \$250,000 and are paired with senior industry executives who help the investigators develop and commercialize their projects. To help advance drug development and speed the benchto-bedside process, Memorial Sloan-Kettering has also teamed with a number of corporate and noncorporate groups. For example, MSKCC and six other research groups in New York City have joined the Centers for Therapeutic Innovation (CTI). Sponsored by Pfizer, Inc., CTI is a unique open-innovation partnering model that has presented Memorial-Sloan-Kettering basic- and translational-science investigators and postdoctoral fellows with the opportunity to work with Pfizer staff to jointly pursue scientific and clinical research. The goal of the funded integration is better testing of clinical hypotheses and, ultimately, accelerating the rate at which new medicines are brought to patients in need.



www.tco.osu.edu

## The Ohio State University

#### **Institution Profile**

The Ohio State University is a public land grant institution founded in 1870 as the Ohio Agricultural and Mechanical College. Located in the state capital of Columbus, about 65,000 students attend this Big Ten university. The 3,400-acre-university is a stronghold of intellectual development, with a faculty comprised of many award winners, including a Noble prize winning physicist, as well as members of the National Academy of Sciences and the National Academy of Engineering. The Ohio State University has rapidly grown into one of the largest research organizations in the nation. Their success in obtaining NIH and other grants has advanced the construction of extensive laboratory and clinical infrastructure. The National Science Foundation ranks Ohio State 10th in total research expenditures (including the health sciences) among public and private universities, seventh among public universities, and second in industry-sponsored research.

The Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard

J. Solove Research Institute—is one of only 41 National Cancer Institute (NCI)-designated Comprehensive Cancer Centers and only one of seven centers funded by the NCI to conduct both Phase I and Phase II clinical trials.

The Ohio State University Medical Center is one of the founding members of the P4 Medicine Institute. The Institute is the country's only non-profit research organization dedicated to accelerating the emergence and adoption of healthcare that is predictive, preventive, personalized, and participatory (P4 Medicine) and makes an impact on our society. The Institute's goal is to bring together resources and capabilities from industrial, academic, federal, and public sector entities that share a common interest in developing and implementing personalized medicine.

The OSU Medical Center will serve as the clinical demonstration site to the P4 Medical Institute's pilot projects to test collaborative and innovative ideas

#### The Ohio State University continued

and technologies that will transform the healthcare industry. With the opening of the new Technology Commercialization and Knowledge Transfer headquarters at South Campus Gateway in Spring 2012 and innovative partnerships established with Ohio University and Cleveland Clinic, Ohio State is speeding up and intensifying its focus on bringing cutting-edge research to the marketplace. The goal is to create an entrepreneurial spirit on campus and harness university inventions that will help drive Ohio's economy.

In 2011, OSU had \$493 million in federally sponsored research activities, of which about two-thirds went to healthcare research expenditures. Of the \$120 million in industry sponsored research expenditures, approximately \$40 million went to healthcare sponsored ventures.

#### Technology Commercialization Office (TCO)

The Technology Commercialization and Knowledge Transfer Office was established in 1982 to function as a fully integrated manager for all Ohio State University (OSU) inventions. This group is responsible for handling all patent and licensing activity and distribution of royalties and payments received related to industrial partnerships. Commercialization revenue is distributed with approximately one-third going to the inventor(s), almost half to the inventing college, and the rest to administration.

In 2011, the Technology Commercialization and Knowledge Transfer Office overhauled its operations and committed new funding to building a new model for translating research to products and driving economic development through robust start-up creation. A record 21-full-time employees, along with 18 interns, handle licensing, with four full-time employees dedicated to healthcare inventions. The office currently manages 172 active licenses, 50 of them healthcare related.

In 2012, 319 inventions were disclosed, with about half in the healthcare sector. The percentage breakdown was 10% device, 10% drug/therapeutic; 10% diagnostic; 5% software, and 65% for all others, mostly engineered materials and coatings. In 2011, 42 licenses were executed, with about half occurring in the healthcare sector. A total of 5 new start-up companies were created, with 4 of those in the healthcare related space. Licensing revenue earned in 2011 was about \$2.8 million.

The most active departments as measured by invention disclosures are the Wexner Medical Center and the College of Engineering.

#### Fit Within The Organization

Until 2011, the Technology Commercialization and Knowledge Transfer Office operated as a unit within the Office of Research. The office now reports into the Senior VP for finance and a new organizational structure has been developed.

#### **TCO Structure/Function**

With a new Vice President, Director, additional staff in place at the Technology Commercialization and Knowledge Transfer Office, and a new headquarters on campus, OSU is intensifying its focus on accelerating the process of bringing cutting-edge research to the marketplace. Once an inventor submits his or her invention online, it then goes directly to a customized database where it becomes an online record. It then goes to a newly developed triage and assessment system to investigate the uniqueness and business potential of an invention. A cornerstone of the Office's new philosophy is to include students in every phase of the discovery, assessment, and commercialization process. Graduate students also play a critical role in the triage phase of an invention. Inventions that pass through the screening criteria are then sent to independent College Review Boards comprised of business and venture experts that assist in the strategy, direction, milestones, and selection of technologies that receive further development.

As a sign of Ohio State University's new commercial thinking, OSU and Ohio University teamed up in 2012 to create a new seed and venture capital fund that addresses the pain of commercialization for early stage university technologies. The fund will seed early stage ideas and leverage existing resources to create a capital efficient funding model that flows seamlessly into Series A and B funding rounds.

In July, 2012, the Technology Commercialization and Knowledge Transfer Office formed a commercialization alliance with Cleveland Clinic, a public-private partnership whose goal is to increase the speed at which the two institutions create new medical products, patient care processes, software, healthcare consumer products, and spinoff companies. This partnership created the largest medical commercialization network in Ohio.

The first joint effort will be to identify 20 high-profile medical technologies and decide how they can best be commercialized. Healthcare focused software tools and neurostimulation technologies will be the initial focus areas that the Technology Commercialization and Knowledge Transfer Office and Cleveland Clinic will explore under the partnership.

#### **TCO** Initiatives/Programs

The Technology Commercialization and Knowledge Transfer Office engages in a variety of special internal and external initiatives that enhance commercialization. The new storefront headquarters at South Campus Gateway features video kiosks with demonstrations of OSU breakthrough inventions in medicine, bioengineering, agriculture, and other areas. In an effort to turn research into viable businesses, professors, doctors, researchers, business leaders, and students come here to regularly shop for and discuss technology.

The Technology Commercialization and Knowledge Transfer Office has created a unique environment and dozens of specialized programs, including: CoStart, the OSU student commercialization group; Entrepreneurial Scholars group, which establishes a peer-to-peer network for faculty; an Ideation Lab; a software prototyping center; and a New Ventures group for start-up creation. Many other programs designed to encourage creativity and innovation have either been launched or are in the final planning stages.

A first-ever Drug Development Institute started in collaboration with the James Comprehensive Cancer Center has established a specialty group of talent and resources to accelerate the development of new therapeutics and diagnostic technologies. In addition, monthly WakeUp StartUp morning pitch sessions at the commercialization headquarters allow innovators 10 minutes and six slides to pitch a product or business and then match talented university entrepreneurs with faculty experts and potential investors.





www.pennstatehershey.org/ webtechnologydevelopment/home

## The Pennsylvania State University

#### **Institution Profile**

Pennsylvania State University, a nationally ranked public research university, was founded in 1855 as a landgrant institution with a mission of teaching, research, and service. When Evan Pugh, the first president of Penn State arrived in 1859, he immediately established a laboratory to carry out original scientific investigations. That ethic of study, discovery, and publication has characterized Penn State since its earliest days and led to the University's recognition as one of today's leading research universities in the United States.

More than 44,000 undergraduates and 2,288 faculty are at the University Park campus of Penn State, which sits on 8,556 acres in State College. Penn State has 23 additional locations across Pennsylvania. The Penn State Milton S. Hershey Medical Center, 90 miles away in Hershey, is the site of the Penn State College of Medicine, where medical research is conducted. In addition, the Penn State Hershey Cancer Center, which opened in 2009, is another source of medical innovation. Scientists there are currently researching the role of tobacco leading to cancer and the impact of nanotechnology in delivering new cancer treatments to individual cancer cells.

The Cancer Center filed an application with the National Cancer Institute in 2010 to become a designated Comprehensive Cancer Center to develop and translate scientific knowledge from promising laboratory discoveries into new treatments for cancer patients.

Penn State is a research university of great accomplishment both nationally and globally, with a faculty of distinction. The Penn State Research Foundation, which was formed in 1934, fosters the advance of all scientific research at the university. The Office of Technology Management (OTM), located at University Park, aggressively seeks out, supports, and markets Penn State intellectual property. Efforts for the identification, development, support and commercialization of innovative medical technologies take place principally through the Office of Technology Development (OTD), which is located in Hershey. Basic and clinical research is conducted at the Penn State Hershey Medical Center and is supported by more than \$100 million in awards from federal, state, and private agencies, and businesses.

While Penn State has made a national name for itself in defense-related initiatives, agriculture sciences, and engineering technology, improving healthcare through innovation is now one of the major goals of Penn State researchers. Its greatest health innovation, the Penn State Heart, an artificial heart approved by the FDA, grew out of research begun in the 1970s by mechanical engineers and medical faculty working on the world's first mechanical blood pump, and this led to the first implantation of this artificial heart in a patient in 1985 at the Hershey Medical Center. When it comes to healthcare, Penn State's recent research efforts have focused on two central areas: medical devices and oncology.

Overall, Penn State ranked ninth in the nation in total research and development expenditure from all sources in 2011, a clear indication of the University's preeminence as one of America's research powerhouses. More than \$2 million in research activity takes place at Penn State each day. For every \$1 million that flows into Pennsylvania in support of research at Penn State, thirty-six jobs are created, and the ripple effect of that economic impact is vast. In 2011, Penn State had \$805 million in federally sponsored research activities, with \$129 million designated for healthcare related research expenditures, \$8 million was for healthcare efforts.

#### Technology Commercialization Office (TCO)

The Penn State Research Foundation supports research enterprise and business incubation at Penn State. An executive director and a board of directors drawn from public and private sector leadership govern and direct the Foundation. The Office of Technology Development located in Hershey works closely with the Office of Technology Management at University Park to commercialize University intellectual property through licensing agreements, new company formation, and incubation of fledgling businesses based on new healthcare technologies developed at Penn State. OTD also acts as the legal recipient of gifts, contracts, and grants from industry, public and private non-profits, and government agencies for the performance of research associated with Penn State.

For fiscal year 2011, technology transfer generated 144 disclosures from faculty, students, and staff; 47 disclosures were for healthcare innovations. 23 licenses were executed that year, with 1 for a healthcare invention. In that same year, 85 patents were issued; 11 for healthcare related inventions.

The 2011 budget of \$3.4 million covered staff salaries and benefits, legal fees, research investments, and other operational needs. There are 13 full-time OTD employees, 4 dedicated to licensing, and 1 specifically dedicated to healthcare. The percentage breakdown of healthcare disclosures in 2011 was 60% for drug/ therapeutics, 15% for devices, 5% for diagnostics, 5% for biologics, 10% healthcare IT, and 5% other. The OTD personnel also manage 158 cumulative active licenses, 43 for healthcare. Total licensing revenue in 2011 was \$2.9 million, with \$600,000 coming from healthcare related inventions.

#### Fit Within The Organization

All of Penn State's various research efforts fall under the aegis of the Penn State Research Foundation. The Office of Technology Development, located at the Penn State College of Medicine, focuses on development of innovative technologies at Penn State Hershey, including the Medical Center and College of Medicine. The Director of this department reports directly to the Associate Vice President for Health Sciences Research at the University Park campus. The Office of Technology Development's chief function is to facilitate medical innovation within Penn State. Its officers track, evaluate, protect and commercialize inventions made by Penn State faculty and students, including the creation of new companies.

#### **TCO Structure/Function**

Commercialization of medical technology has now become a major focus at Penn State and this message is getting out both to the Penn State community and the investment marketplace. The goal of the Office of Technology Development is to identify and help develop innovative technologies. Once a new confidential disclosure form is received and deemed viable, a commercialization committee comprised of the head of OTD, Penn State department chairs, and several investment and biotech experts from the community who work with OTD assesses it. Commercialization revenue at Penn State is distributed with 40% going to the inventor, 10% to the inventor's department, 10% to the school or institution, and 40% distributed elsewhere.

#### **TCO** Initiatives/Programs

The Office of Technology Development in Hershey helps enhance commercialization possibilities at Penn State through a variety of internal and external initiatives. The OTD website serves as a main portal of information and it highlights the latest Penn State innovations. Dozens of informal outreach meetings with Penn State OTD staff are held annually to alert potential faculty and student inventors about technology commercialization and this has resulted in an increase in disclosures by a factor of three in just one year after hiring a new OTD director in 2011.

An initiative called the Innovation Café was successfully launched in 2012 at the Hershey Center for Applied Research. This regular monthly forum and networking breakfast brings the faculty and staff of Penn State together with regional stakeholders to find ways to help ideas grow into the next promising method for preventing or treating disease. It's proven to be an effective platform to engage with investors, entrepreneurial faculty, talented students, and industry professionals committed to creating a vibrant start-up community.

As part of the *Discovered In PA, Developed in PA Program* from the Pennsylvania Department of Community and Economic Development, the OTD recently secured a \$425,000 grant that will help connect faculty to a team that can study a scientist's innovative idea and potential, help develop a business plan, and launch a company.

In addition to the 118-acre Innovation Park business incubator near Penn State's University Park campus in State College, OTD offers business incubator space at the Hershey Center for Applied Research. Opened in 2007, this three-story structure contains over 80,000 square feet of available rental space for research teams of all sizes, from start-up companies to departments of Penn State University.



## VANDERBILT

www.vanderbilt.edu/cttc

## Vanderbilt University

#### **Institution Profile**

Cornelius Vanderbilt gave \$1 million in 1873 to found the university that bears his name. This proved to be the only major philanthropic gift that Vanderbilt, the New York-based railroad and steamboat tycoon, made in his lifetime. Vanderbilt had a vision of a university that would "contribute to strengthening the ties that should exist between all sections of our common country." Not only has Vanderbilt's vision been achieved over the past century, but thanks to the university's research efforts, this vision has been broadened and now helps strengthen ties throughout the world.

Vanderbilt University welcomed 200 students in 1875 as members of its first class. Located on a 380-acre campus in the middle of Nashville, Tennessee, Vanderbilt, which is now a leading private research university, has 6,800 undergraduates and 6,000 graduate students. The Vanderbilt University School of Medicine, which first conferred medical degrees in 1875, is one of the country's leading research institutions. In 2010, the medical school was one of the top recipients in NIH grant funding, with over \$300 million. Collaboration is relatively easy for researchers at Vanderbilt due to sheer physical proximity; most everyone is within a 12-minute walk of each other. The Vanderbilt Medical Center is a comprehensive healthcare facility that comprises the Vanderbilt University Hospital, the Monroe Carell Jr. Children's Hospital at Vanderbilt, the Vanderbilt-Ingram Cancer Center, the Nashville Veteran's Administration Medical Center, the Vanderbilt Stallworth Rehabilitation Hospital, the Vanderbilt School of Medicine, and the Vanderbilt University School of Nursing.

Researchers at Vanderbilt University and its Medical Center regularly pose innovative solutions to some of the most challenging questions facing us today. The medical center recently teamed with the School of Engineering to create the Vanderbilt Initiative in Surgery and Engineering (ViSE) to create innovations in the healthcare arena. Primarily funded by federal research funds, the center engages with industrial partners for the commercialization of the intellectual property it generates, the early evaluation of industrial devices and techniques, and the joint development of innovative solutions.

#### Vanderbilt University continued

The combination of cutting-edge research and a distinguished medical center creates an invigorating atmosphere where researchers collaborate to solve complex problems affecting health and society. In 2011, university faculty across all disciplines received over \$587 million in external funding for research. Major areas of research and discovery at Vanderbilt include drug development, personalized medicine, biomedical informatics, and imaging.

Biomedical research at Vanderbilt has long been recognized for its significant contributions to the advancement of medicine. Four professors from the university and medical school have gone on to win Nobel Prizes for their outstanding scholarship, which has ranged from better discoveries concerning the replication mechanism and genetic structure of viruses (1969) and discovery of the metabolic regulating compound cyclic AMP (1971), to a better understanding of enzyme chemistry (1972), and the discovery of epidermal growth factors (1986).

Vanderbilt has the largest biomedical informatics group in the country, with over 70 faculty members involved in the science underlying the acquisition, maintenance, retrieval, and application of biomedical knowledge and information to improve patient care, medical education, and health sciences research. From this group has come WizOrder, the most successful Vanderbilt medical innovation to date. This physician order entry and decisions support system was developed at the Vanderbilt University Medical Center to reduce medication errors. Researchers spent six years perfecting the computerized system so that it automatically screened medication orders against the patient's known drug allergies, potential drug-drug interactions, and weight based guidelines. The system alerts when orders appear unsafe or inaccurate.

Six years later, the technology was licensed for commercial development as the first Computerized Physician Order Entry (CPOE) system and marketed as Horizon Expert Orders (HEO) by McKesson Corporation. CPOE is now used in hospitals throughout the country to help decrease delays in order completion, reduce errors related to handwriting or transcription, allow order entry at point of care or off-site, and provides error checking for duplicate or incorrect tests, allergies or doses.

Vanderbilt, already the national leader in imaging sciences, now has the country's first 15.0 Tesla MRI scan system. Using the device, scientists within the Vanderbilt University Institute of Imaging Science are developing ultra-high field MRI applications and techniques for innovative molecular imaging studies in cancer biology, neuroscience and metabolism studies, and to advance translational imaging research that may benefit human clinical care.

#### Technology Commercialization Office (TCO)

Research is one of Vanderbilt University's core missions. To support that mission, the Vanderbilt Center for Technology Transfer and Commercialization (CTTC) office, formed in 1990 with just one employee, commercializes intellectual property that will have a high potential impact on society (leading to cures for human ailments and better health) and also have an impact on local community by spurring economic growth. The various agreements made by CTTC with industry and others have led to financial benefits for the university's inventors, departments, and schools.

There are now 25 full-time CTTC employees. The 2011 budget of \$5.9 million covered operational needs, salaries, legal fees, and research investments. Throughout the years, more than 2,000 disclosures have been made by Vanderbilt faculty and staff. In 2012, invention disclosures at Vanderbilt reached an all-time high of 190 compared to 37 in 1991. In addition, 40 U.S. patents were issued to Vanderbilt compared to seven in 1991. Over \$75 million in revenue has been generated by commercialization of Vanderbilt intellectual property since 1991. Commercialization revenue was more than \$9.2 million in 2011 compared to \$137,000 in 1991. Since its inception, CTTC has launched or assisted in the creation or financing of more than 50 new ventures based on Vanderbilt innovations.

#### Fit Within The Organization

The Center for Technology Transfer and Commercialization is aligned under the Vanderbilt Institute for Clinical and Translational Research to more effectively access and influence the flow of innovations and development taking place at the university. CTTC staff members have their pulse on the groundbreaking ideas at the university and are best positioned to effectively protect, evaluate, and commercialize Vanderbilt's research innovations.

#### **TCO Structure/Function**

The mission of the Center for Technology Transfer and Commercialization is to service the Vanderbilt community, thereby optimizing the flow of innovation to the marketplace and generating revenue that supports future research activities, while having a positive impact on society. The office helps obtain necessary patents and copyrights for intellectual property but true value creation lies in the transfer of early-stage academic technologies to industry partners that turn them into valuable products.

CTTC is positioned to assist inventors in making sound, market-driven decisions when determining if the technology is ripe for a license to an existing company or whether to embark on an entrepreneurship pathway and, if the decision is made to move ahead, to improve the new venture's odds of success. If an inventor expresses an interest in creating a new company, CTTC will evaluate issues related to capital and technology development, regulatory hurdles and reimbursements, time to market, and competing products and companies. This vetting escalates from an internal review of the business opportunity to an external review by seasoned entrepreneurs, investors, and other key opinion leaders. A few of those projects will become candidates for internal incubation, whereby development funds will be identified and translational research and risk mitigation will commence. Others will move into the more traditional marketing and licensing pathway.

#### **TCO Initiatives/Programs**

The Center for Technology Transfer and Commercialization is the medium through which companies access intellectual property that is created in the course of performing research and caring for patients at Vanderbilt.

New ventures can generate substantial return on investment for Vanderbilt and contribute to the economic growth and diversification of the local, regional, and state economies. Recently, a significantly increased CTTC office budget and hiring of new staff members is an example of the renewed commitment of the university to commercialization of technology. Both formal and informal outreach is now made throughout the year to the various Vanderbilt schools and departments by CTTC to alert Vanderbilt faculty and researchers about licensing possibilities for their intellectual property.

CTTC is currently exploring new ways to move technologies along the development pathway, whether by pursuing proof-of-principle experiments or building and testing prototypes. These specific maturation activities reduce the licensing risk for industry partners and increase the likelihood of successful licensing outcomes.

CTTC administrators work closely with the governor and the state economic commissioner to help develop funding initiatives to support translational research, a strong suit for Vanderbilt, as well as funding for startups. Since Tennessee is a low tax state, funding is limited and is mainly destined for matching grants for venture financing of startups. A recently launched proof of concept fund, however, will provide some necessary gap assistance for early-stage inventions that show promise.



www.research.wustl.edu/Offices\_Committees/OTM/ education/Pages/TechnologyTransferWorkshop.aspx



#### **Institution Profile**

Washington University in St. Louis, a private research university with both undergraduate and graduate programs, was founded in 1853. It has a 169-acre campus in the heart of St. Louis with a total student population of more than 13,000.

The university has a long history of challenging its faculty and students to seek new knowledge. Its programs, administration, facilities, resources and activities combine to further its mission of learning, teaching and research. The research endeavor at Washington University in St. Louis is among the world's most productive and effective. Research efforts thrive on a rich history of success, deep support from many sources, well-established collaborations with industry and academic colleagues and—most importantly engaged faculty, students, and staff who pursue new and practical knowledge. Washington University faculty are distinguished for their research and creative activities. 23 Nobel laureates have been associated with the university, nine doing the major part of their pioneering research here. Washington University School of Medicine is the largest research enterprise at the university and is a worldrenowned center for clinical, translational and basic science research initiatives aimed at advancing human health around the globe. It receives \$400 million or more annually from NIH for its research efforts.

The biotechnology revolution that has transformed the landscape of healthcare began at the benches of Washington University scientists and clinician-scientists. The spirit that drives these endeavors has enabled the university to establish multidisciplinary, collaborative research initiatives, such as BioMed 21. Launched in 2003, BioMed 21 created a multidisciplinary and translational-research imperative for basic scientists and clinician-researchers to address the biggest questions about disease: why they develop, how they affect us and how we can cure them. Its goal is to rapidly convert the knowledge of the genetic blueprint of human beings into effective, individualized treatments. Since its inception, BioMed 21 has secured a \$50 million grant to enhance clinical and translational research, \$14 million in two grants for neuroscience research and many millions in additional research by individual scientists.

Faculty are also successful in winning support for their research from many sources, including the federal and state governments, corporations, foundations, nonprofit agencies, individuals and the university itself. During fiscal 2011, \$567.4 million was received in total research support, including \$437.4 million in federal funding.

#### Technology Commercialization Office (TCO)

Washington University's Office of Technology Management, which was formed in 1985, services the entire university's commercialization efforts. The primary medical innovators are located on the medical school campus, which is associated with Barnes-Jewish Hospital and St. Louis Children's Hospital. The medical complex sits on the side of Forest Park, one of the largest urban parks in the country. On the west side of the park is the 169-acre Danforth campus, which houses the schools of engineering, arts and sciences, social work, law, business and design and visual arts.

The biggest success so far for OTM has come from the licensing of the monoclonal antibodies used in the immunoassay for CK-MB (creatine kinase). Discovered in the laboratory of Jack H. Ladenson, PhD, these were later developed into a successful commercial test widely used in hospitals throughout the world to diagnose heart attacks. The tests have made the university significant sums of money, at one point providing a fifth of its annual technology licensing revenue. Revenues from Dr. Ladenson's innovation also led to the endowment of three faculty chairs and two undergraduate scholarships at the university for students from underdeveloped countries. Washington University is widely recognized for its broad research base, which has been a rich source of potential medical innovation. The Hope Center for Neurological Disorders brings together world-leading scientists and clinician scientists to collectively focus on mechanisms of neurodegeneration and neural repair, while the Consortium for Translational Research in Advanced Imaging and Nanotechnology, or C-TRAIN, brings together physicists, chemists, engineers, cell biologists, computer software engineers, and physicians to speed the development of more precise imaging agents and targeted therapies for the early detection and treatment of heart disease and cancer.

Washington University School of Medicine, founded in 1891, is another major source of innovation. The School has had a 120-year history of success in research, education and patient care. One of the first four department heads recruited in 1910 was Joseph Erlanger, who went on to win the 1944 Nobel Prize in Physiology or Medicine. Since then, 16 Nobel laureates have been associated with the School of Medicine.

Of the many research highlights from the School, a few include screening tests to diagnose Alzheimer's disease; creation of the first positron emission tomography (PET) scanner; pioneering use of insulin to treat diabetes; decoding the entire genome of a cancer patient and using the result to alter the course of treatment; and serving as a major contributor of genome sequence data to the Human Genome Project.

In addition to the School of Medicine, Barnes-Jewish Hospital, St. Louis Children's Hospital, and the Alvin J. Siteman Cancer Center are all located on the Washington University Medical Center campus. The doctors and researchers at these institutions have realized many licensing opportunities.

There are 18 full-time Office of Technology Management employees. In 2011, medical school faculty generated 45 healthcare related licenses, and two healthcare start-ups were launched. That same year, 58 healthcare related patents were issued and the medical school's licensing revenue reached \$4.9 million (out of \$6.3 million for the entire university). Seven licensing personnel in the Office of Technology Management oversee 1,300 healthcare related cumulative active licenses.

#### Fit Within The Organization

At Washington University, all of the research efforts are monitored by the Office of the Vice Chancellor for Research. The director of the Office of Technology Management (OTM) reports directly to the Vice Chancellor for Research.

OTM assists in the transfer of technology to private companies while generating income to support research and education. The mission of OTM is to license intellectual property so science uncovered in the university laboratories may benefit society through direct impact on health and quality of life. The current portfolio contains active and pending patents in areas of technology ranging from gene therapies to novel cancer drugs.

Revenue that comes from licenses, patents and research agreements is shared among the inventors, the university, and OTM. At present, 40% of revenue goes to the dean of the school represented by the faculty member. The dean then distributes these funds to the faculty member's department or directly to his or her lab. Separately, the faculty member receives 35% of the total revenue. The rest of the revenue—25%—goes to OTM. Overall, 75% of monies generated by licenses, patents or research agreements goes back to the inventors or to departments within the university, which supports Washington University's mission.

#### **TCO** Initiatives/Programs

The mission of the Office of Technology Management is to extend the value of Washington University research to the community and to move new ideas into the marketplace faster. Licensing managers help commercialization possibilities through several internal and external initiatives throughout the year designed to expose faculty members to increased entrepreneurism. OTM also offers various programs throughout the year that provide entrepreneurial training for faculty who are interested in starting a company. As medical technology commercialization has become more successful at the university, newer faculty are attracted to Washington University because they want to see their technologies cross the barrier from science into the commercial arena.

A goal of OTM is to integrate technologies into startup opportunities. The university's Bear Cub Fund helps researchers who want to move inventions from their laboratories towards commercialization. The fund, which supports innovative translational research not normally backed by federal grants, offers awards of \$20,000 to \$75,000. Since 2008, Bear Cub has funded 21 projects and provided almost \$1 million to university researchers to enable them to demonstrate the commercial value of their innovation.

BioGenerator, a privately funded non-profit organization created to facilitate the formation of science companies in the St. Louis region, provides assistance with preseed or seed funding for new company formation. In addition, university entrepreneurs ready to start a business in St. Louis have access to the Arch Grants Business Plan Competition. First launched in 2012, Arch Grants winners receive funding, free legal advice, accounting, marketing and computing support, as well as access to St. Louis' angel investment network.

# What's on Your Reading List?

For more information visit www.themedicalinnovationplaybook.com





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