Research collaboration pairs Yale experts with industry scientists to accelerate the development of new drugs to treat cancer

When Robert J. Alpern, M.D., dean of the School of Medicine, was asked recently to prepare a brief overview of the current state of drug discovery for a symposium at Yale’s West Campus, a familiar phrase came quickly to mind: “It was the best of times, it was the worst of times …”

It’s an apt description. On the one hand, we live in what some call the “post-Gleevec era,” a time when basic research conducted over decades is bearing fruit in the form of remarkably effective, targeted drugs. But the cost of drug development has risen exponentially as clinical trials and regulations have grown more complex. The average total cost to develop a single approved drug is now pegged at a staggering $1.3 billion, a 60 percent increase since 2005.

Early-stage research carried out by academic scientists in settings like the School of Medicine is unveiling more potential drug targets than ever. But research grants are not designed to sustain the many additional steps involved in drug discovery, and academic researchers lack resources to explore these targets further. The expense and complexity of bringing drugs to the marketplace have understandably made pharmaceutical companies risk-averse and selective about which targets to pursue. The resulting gap between academia and industry has become known as the Valley of Death: only a miniscule number of promising discoveries manage to traverse this chasm, and even fewer result in drugs approved for clinical use.

To begin to bend this troubling curve, some pharmaceutical companies have been building scientific alliances with universities, a trend that has picked up momentum in the past few years. In March, President Richard C. Levin announced that Yale University had forged a multi-year research alliance with Gilead Sciences, Inc., a biopharmaceutical company based in Foster City, Calif., to accelerate the discovery and development of new drugs to treat cancer.

Gilead will provide up to $50 million to support cancer research at the School of Medicine over four years, and a total of up to $500 million—the largest corporate commitment in Yale’s history—for the full 10 years outlined in the agreement. Yale maintains ownership of all intellectual property generated by medical school research, and Gilead will have the first option to develop any compound it deems promising.

“The collaboration brings together one of the world’s top research universities and a biopharmaceutical company dedicated to addressing unmet medical needs, with the goal of finding new treatments for cancer,” Levin said. “This truly is transformative support that leverages Yale Cancer Center’s top scientists, our West Campus technology investments, and the resources of the new Smilow Cancer Hospital. I can’t think of a better partner to have in this collaboration than Gilead.”

The project will be governed by a six-member Joint Steering Committee chaired by Joseph “Yossi” Schlesinger, Ph.D., chair and William H. Prusoff Professor of Pharmacology at the School of Medicine. The committee will also include medical school scientists Richard P. Lifton, M.D., Ph.D., chair and Sterling Professor of Genetics and Howard Hughes Professor of Medicine in 2010. “The team at Yale seems to be very open, and wants to support and leverage each other’s work to accelerate science. At the Stem Cell Center, I felt that Haifan has developed a unique sense of community and bonding between the different teams.”

In the YSCC’s human embryonic stem cell (iPSC) facility, the donation will support the introduction of a unique sense of community and bonding between the different teams. In the YSCC’s human embryonic stem cell (iPSC) facility, the donation will support the introduction of induced pluripotent stem cell (iPSC) technology, which will bring scientists closer to tailoring patient-specific cells for the treatment of disease. Discovered in 2006, iPSCs are typically derived from ordinary adult cells such as skin cells—not embryonic cells—but, like hESCs, they can self-renew indefinitely and can develop into any kind of bodily cell or tissue. Because iPSCs are genetically matched to the donor, they may not induce a rejection response by the immune system, an important characteristic in developing personalized treatments for individual patients.

The new iPSC initiative at the YSCC will be supervised by In-Hyun Park, Ph.D., assistant professor of genetics, one of the world’s first scientists to develop iPSC technology. Park’s work has focused on the basic biology of stem cells and on the use of stem cells to...

Donation from leading Asian foundation will advance stem cell science

The Li Ka Shing Foundation (LKSF), Asia’s largest philanthropic organization, has made a $1.5 million donation to the Yale Stem Cell Center (YS SCC). The donation will fund improvements in two of the YSCC’s four core laboratories that will benefit the work of more than 60 faculty members and numerous trainees across the campus.

In announcing the contribution, Yale University President Richard C. Levin said, “We are grateful for the Li Ka Shing Foundation’s generosity, which benefits today’s medical research in order to develop tomorrow’s cures. This significant donation will allow the Yale Stem Cell Center to continue to make available to its members the current technologies used in stem cell research.”

YSCC Director Haifan Lin, Ph.D., professor of cell biology, first met LKF Director Solina Chau during a trip to Hong Kong last year, but Chau says it was more than the proposal on behalf of the YSCC Lin sent later that won LKF’s support.

“We have all been great admirers of the work of Yale for 100 years in China,” says Chau, who visited the School of Medicine in 2000. “The team at Yale seems to be very open, and wants to support and leverage each other’s work to accelerate science. At the Stem Cell Center, I felt that Haifan has developed a unique sense of community and bonding between the different teams.”

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Prime movers at Gilead Sciences in the new initiative with the School of Medicine are (clockwise from left) Howard Jaffe, a 1982 alumnus of the medical school and president and chairman of the board of the Gilead Foundation; Linda Sianc Higgins, vice president, Biology; and William Lee, senior vice president, Research.

Medical Institute investigator, and Thomas J. Lynch Jr., M.D., the Richard Sackler and Jonathan Sackler Professor of Medicine, director of Yale Cancer Center, and physician-in-chief at Smlow Cancer Hospital. They will be joined by Gilead scientists Howard Jaffe, M.D., a 1982 alumnus of the School of Medicine and president and chairman of the board of the Gilead Foundation; William A. Lee, Ph.D., senior vice president, research; and...

// Gilead (page 8)
Tackling an information explosion

Chair worries that the U.S. is not ready for the coming deluge of medical data

For a leader in a field at a pivotal moment of transition, Brian R. Smith, M.D., is modest, equating his role as chair of the Department of Laboratory Medicine to mostly “filling out pieces of paper.” But Smith’s department, with a mission that combines both service and research, is critical to patients at Yale-New Haven Hospital and many other institutions in New England and beyond, as well as to the work of other medical school departments.

Members of the department study the components of blood and other bodily fluids to better understand and treat disease, including those measured in the familiar lab tests ordered by doctors. Each day the department produces about 75,000 lab results for patients at the hospital and for Yale Medical Group, the medical school’s clinical arm. The department’s research mission is necessarily broad, says Smith, professor of laboratory medicine, medicine, and pediatrics, because “our discipline covers essentially all of physiology and pathophysiology,” with the strongest focus on immunology, hematology, and cellular therapy.

Smith’s own research has explored the interface between the immune and coagulation (clotting) systems in blood diseases, cardiovascular disorders, and metastatic cancer. His work on these two critical physiological pathways ultimately help to reduce complications associated with heart-lung bypass machines and the administration of blood transfusions. After attending Princeton as an undergraduate, Smith received his M.D. from Harvard Medical School, and completed his internship and residency in internal medicine at the Peter Bent Brigham Hospital in Boston. He completed fellowships in hematology, oncology, hemato-oncology, and research pathology at the Brigham, the Dana-Farber Cancer Institute, and Children’s Hospital in Boston before joining Harvard’s faculty in 1981. He came to Yale in 1989.

Fifty years ago, a patient’s laboratory tests might include analyses of two or three factors, and a technologist might spend a full day generating the results. Now, Smith says, it often takes less than an hour to obtain 20 or more results for one patient. As technology alters the medical landscape, the field is facing an information explosion that demands new ways of managing and interpreting the data. Genomics alone, which now allows rapid sequencing of the billions of base pairs in the human genome, has brought formidable challenges to laboratory medicine.

Labs will soon routinely perform complex genomomic and proteomic analyses impossible just a few years ago, vastly improving diagnosis by increasing reliance on informatics. “Humans are very good at some qualitative pattern recognition, but computers are far better at consolidating multiple quantitative analyses for diagnostics or following the results of therapy.” But aside from technical problems, maintaining vast stores of patient information raises ethical questions. If whole genomes of patients are sequenced many years before genetic advances reveal new risk factors for diseases, “Do we try to find every patient previously sequenced and call each of them back with the new information?” Smith asks. He predicts an ever-increasing interaction of specialists in laboratory medicine with other physicians to evaluate the clinical significance of the rapidly proliferating options available in laboratory diagnostics.

The increasing adoption of electronic medical records may eventually pave the way for improved informatics systems. But the information overload about to take place in medicine is unprecedented, Smith says. “We need a national debate, and I think we’re moving in that direction,” he says.
Charitable gift annuities: a good choice for today’s economy

Frustrated by low returns on your investments? Worried about volatility in the stock market? A charitable gift annuity is a good investment option in today’s economy. Yale can help you maximize your investment returns while safeguarding your funds and supporting medical research in the future. A charitable gift annuity can provide fixed income to you now at an attractive rate.

Benefits
- You receive an immediate income tax deduction for a portion of your gift.
- Your lifetime annuity is backed by all of Yale’s assets.
- Your annuity payments are treated as part ordinary income, part capital gains income and part tax-free income.
- You have the satisfaction of making a significant gift that benefits you now and the School of Medicine later.

For more information or a personalized charitable gift annuity illustration, visit yaleplanyourlegacy.org/GiftAnnuity.php or contact Jancy Houck, Associate Vice President for Development and Director of Medical Development, at 203-436-8560.

Rate Information for Immediate and Deferred Gift Annuities

Immediate Gift Annuity

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Symposium is ‘once-in-a-lifetime event’

A roster of top biomedical scientists visits Yale for two days of talks and intellectual exchange, along with a generous helping of good cheer

It was the hottest ticket in town—and you didn’t even need a ticket.

This spring, 15 of the top minds in science convened on New Haven for the School of Medicine’s Bicentennial Symposium, “Biomedicine in the New Century.”

Held on April 28 and 29 and open to the public, the symposium drew capacity crowds, filling the nearly 450 seats of the Mary S. Harkness Auditorium, the medical school’s largest lecture hall, and overflowing to a nearby 150-seat auditorium at the Anlyan Center for Medical Research and Education, where a live broadcast of the sessions was available.

The throng had come to hear the latest thoughts and research updates from a star-studded scientific cast, which included seven Nobel Prize winners, on topics ranging from the neurobiology of memory to the crisis of inequity in health care to the next generation of targeted cancer drugs.

The symposium was a signature event in the celebration of the School of Medicine’s Bicentennial, which has been marked during the 2010–2011 academic year with the publication of Medicine at Yale: The First 200 Years, a richly illustrated book-length history of the school; a documentary film by Emmy Award-winning director Karyl Evans; a performance by the Yale Medical Symphony Orchestra of an original musical composition commissioned for the occasion; and, most recently, the Association of Yale Alumni in Medicine’s June Reunion Weekend, which featured several special Bicentennial-related talks, events, and exhibits.

“This bicentennial symposium was a once-in-a-lifetime event for the School of Medicine,” says Robert J. Alpern, M.D., dean and Ensign Professor of Medicine. “We find ourselves in a great era of advances in biomedical research. When we got together to decide how best to celebrate our anniversary there was uniform agreement that it had to include a scientific symposium featuring a group of scientists of the highest regard.”

What helps patients to survive a heart attack?

Rates of mortality after heart attack vary as much as twofold between the highest- and lowest-performing hospitals, a discrepancy that has not been fully explained.

To explore this question, Research Scientist Leslie Curry, Ph.D., M.P.H.; Elizabeth H. Bradley, Ph.D., professor of public health; and Harlan M. Krumholz, M.D., the Harold H. Hines Jr. Professor of Medicine, visited in U.S. hospitals ranked in either the top or the bottom five percent in mortality rates. As reported in the March 15 issue of the Annals of Internal Medicine, the team interviewed 158 staff members, and identified five factors at work in the best hospitals: an organizational culture emphasizing top-notch care; deep involvement of senior managers; participation in clinical decision-making by all health care professionals, including nurses and pharmacists; clear communication and coordinated efforts among departments; and an approach to solving problems based on sharing knowledge and learning from mistakes rather than pointing fingers.

“These essential ingredients are not expensive,” Bradley says. “If we could implement our findings in more hospitals, we could improve quality without adding to costs.”
April 15 Members of the U.S. Army held an event at the School of Medicine to describe the Army Medical Department’s humanitarian operations around the world. General Stanley McChrystal (Ret.), former commander of U.S. forces in Afghanistan and now a senior fellow at Yale’s Jackson Institute for Global Affairs, was a featured speaker at the event, titled Common Ground: Army Medicine in Support of Humanity.

1. Carolyn W. Slayman, Ph.D., Sterling Professor of Genetics, professor of cellular and molecular physiology, and deputy dean for academic and scientific affairs (left), with McChrystal (center) and Army personnel.

2. A medical Deployable Rapid Assembly Shelter (DRASH) unit was on display in Harkness Ballroom. The unit, which includes a surgical bed and a variety of essential medical equipment, can be set up and functioning in less than an hour and represents the next level of care after battlefield treatment.

March 17 On Match Day each spring, fourth-year students at medical schools across the country receive word of acceptance in residency training programs. At Yale, all of the 77 graduating medical students who had entered the National Resident Matching Program learned they had “matched.”


2. Kseniya Golubets and Annie Engberg.


April 26 At the Yale Club of New York City, Carolyn M. Mazure, Ph.D., professor of psychiatry and psychology, associate dean for faculty affairs, and director of Women’s Health Research at Yale (WHRY), spoke about the latest biomedical research that WHRY is supporting and conducting. (From left) WHRY Advisory Council members: Diane Young Turner, Kitty Northrop Friedman, J.D., Mazure, Roslyn Milstein Meyer, Ph.D., and Fran DeToro.

April 27 The 32nd annual Seton Elm and Ivy Awards, presented at Yale’s Woolsey Hall, honored people and organizations that further partnership between New Haven and Yale.

1. New Haven Mayor John DeStefano Jr. (left) and Yale University President Richard Levin (right) with medical students.

2. Oluwarotimi Okunade, Charisse Mandimika, Amy Moreno, and Jorge Ramallo-Pardo of the Yale chapters of the Student National Medical Association and Latino Medical Student Association, which were honored with an Ivy Award for their work encouraging New Haven high school students to pursue careers in the sciences and health professions.

3. Georgina Lucas, deputy director of the Robert Wood Johnson Foundation Clinical Scholars Program at Yale, also received an Ivy Award.
**Turner syndrome seen sooner with new test**

Turner syndrome (TS) is a relatively common genetic condition in females in which some or all of the X chromosome is deleted, causing stunted growth and heart and kidney problems. TS can be diagnosed with a karyotype (above), but these are labor intensive and impractical as a routine test, so the disorder often goes undiagnosed until girls reach 10 years of age. In the March issue of the Journal of Clinical Endocrinology & Metabolism, Scott A. Rivkees, M.D., professor of pediatrics, and colleagues describe a genetic test for TS that is quicker, less expensive, and more amenable to large-scale use than karyotyping. The new screen, which analyzes variations in DNA at 18 sites on the X chromosome, diagnosed TS with almost perfect accuracy in 92 females without TS and 74 females known to have TS based on prior karyotype analyses.

The team notes that very short girls could be tested early for TS, enabling intervention with growth hormone and treatments for organ defects. "If broadly used in the clinical setting at young ages, this test can prevent the delayed recognition of TS," Rivkees says.

**Small brains reveal a gene’s outsize role**

Microcephaly is a developmental disorder characterized by significantly reduced brain size and a smaller number of neurons, as well as profound mental retardation. Although several genes have been implicated in this disorder, little is known about its cellular and molecular underpinnings.

In a study published May 1 in The American Journal of Human Genetics, Murat Günel, M.D., Nidhefi-German Professor of Neurosurgery and professor of genetics and neurobiology, and collaborators analyzed DNA from three families affected by an extreme congenital form of this condition resulting in a 90 percent reduction in brain size and abnormal layering of cells in the cerebral cortex.

The team homed in on mutations shared by family members in a gene known as NDE1. In the developing nervous system, NDE1 proteins accumulate at centrosomes—structures critical for cell division—in cells that generate neurons, but the NDE1 mutations found in these families undermine this clustering. These data are evidence for crucial roles of NDE1 and centrosomes in normal production and organization of neurons during development. Also, Günel says, evolutionary changes in NDE1 over 1 billion years may underlie the greater size and complexity of human brains relative to those of non-human great apes.

"Breakthrough treatment" offers an option for those asthma patients whose attacks cannot be controlled with conventional drugs

Asthma can be difficult to treat, so physicians at the Yale Center for Asthma and Airway Disease (YCAAD) are always searching for novel therapeutic approaches to treat severe cases for which drug treatment has proved ineffective. A case in point is bronchial thermoplasty (BT), a new minimally invasive procedure made possible by a device recently approved by the FDA that uses radiofrequency energy to treat moderate to severe asthma.

Each year thousands of patients visit YCAAD, which recently became the first center between Boston and New Jersey to offer BT. Because YCAAD’s multidisciplinary approach creates an ideal setting for performing and refining the procedure, the center is one of 30 in the country participating in a phase IV post-market trial of the new device.

Asthma symptoms result from an excess of smooth muscle cells in the airways of the lungs. When various triggers cause airway inflammation, bronchial muscle cells contract and constrict the airways, making breathing difficult. In BT, a flexible camera known as a bronchoscope is adapted with the BT device to gently heat and eliminate smooth muscle. This prevents the airways from constricting.

The studies that led to FDA approval of the BT procedure showed that it significantly mitigated asthma symptoms and flare-ups of the disease, improving asthma patients’ quality of life.

“With this breakthrough treatment, we are confident we will be able to alleviate much of the suffering of our patients with severe asthma,” says Geoffrey L. Chupp, M.D., associate professor of medicine and YCAAD director. “In the past, these patients received high doses of medication and continued to suffer from frequent asthma attacks and limitations on routine daily activities, as well as frequent emergency room visits. Bronchial thermoplasty gives new hope to these asthmatic patients and a non-drug option to control their disease.”

Jonathan Puchalski, M.D., assistant professor of medicine and director of the Thoracic Interventional Program in the medical school’s Section of Pulmonary and Critical Care Medicine, performs the BT procedure with the help of a team that includes Kimberly Belb, R.N., Suzanne Koshis, R.N., and Kelsey Johnson, P.A. Patients are sleepy during the procedure but breathing on their own, and they are usually able to go home afterwards.

Because the BT procedure itself can sometimes trigger an asthma attack, it is generally performed in three outpatient sessions in which different regions of the lungs are treated, spaced about three weeks apart.

One patient who was recently treated with the procedure at YCAAD had suffered from severe asthma his entire life. With poor lung function, he was chronically short of breath and determined if they’re a candidate for BT or some other advanced or investigative treatment,” says Chupp. “YK1-40 might be a clinically useful marker of responsiveness.”

Puchalski believes that BT is a promising treatment for some patients who obtain unsatisfactory results from asthma inhalers or oral medications such as beta-agonists. “This new procedure offers a potential upgrade for treatment over inhaled drugs or other medications because we are attacking the problem at its very root,” he says. Chupp agrees: “For those with severe asthma, this is a terrific option where medication can fall short.”
Marc Hambrecht, Ellison Medical Foundation. Mechanisms of Age-Related Decline in Age-Related Macular Degeneration. 1 year, 5,000

Robert J. Tomko, American Society for Clinical Pharmacology. Characterizing the Pharmacokinetics of People at Risk of Developing Alzheimer’s Disease. 1 year, 6,000

Mary E. Tintinall, American Federation for Aging Research. 2 years, 250,000

Nina Kadan-Lottick, American Foundation for Pharmaceutical Education. Promoting and Retaining of Diversity in Predoctoral Biomedical Education. 2 years, 250,000

Ziba Razinia, Lymphoma Society. 1 year, 5,000

Roger J. Jou, The Mayday Fund. Grant for Research. 1 year, 2,000

E Coatney, Satellite Healthcare, Inc. 1 year, 2,000

Li Ka Shing

Chen Shao, Hille and Preston Foundation. 1 year, 5,000

Janus O. Pardee, Foundation for Cancer Research. 1 year, 5,000

Grace C. Teng, California-Columbia Medical Research Foundation. Cell Proliferation and Development. 1 year, 5,000

Eon Joo Park, California-Columbia Medical Research Foundation. Characterizing the Role of KRAS in Neural Cell Lineage. 1 year, 5,000

Robert J. Tomko, American Society for Clinical Pharmacology. Characterizing the Pharmacokinetics of People at Risk of Developing Alzheimer’s Disease. 1 year, 6,000

Estevez, Boston University. 1 year, $400,000; Charles H. Hood Foundation, 2 years, $400,000; W. M. Keck Foundation, 2 years, $600,000

Marc Hammarlund, Ellison Medical Foundation. Development of New Tools for Imaging the Brain. 1 year, 5,000

Fenella Khan, University of California, San Diego. Genome Technology. 1 year, 5,000

Chang-Shian T. Turette Syndrome, Inc. 1 year, 5,000

Robert J. Tomko, American Society for Clinical Pharmacology. Characterizing the Pharmacokinetics of People at Risk of Developing Alzheimer’s Disease. 1 year, 6,000

Robert M. Robohm, Alex’s Lemonade Stand Foundation. 1 year, 5,000

Evan J. Silbergeld, University of Maryland. Regulatory and Structural Analysis of the Drosophila Melanogaster Manual of Genome Project. 1 year, 5,000

Robert J. Tomko, American Society for Clinical Pharmacology. Characterizing the Pharmacokinetics of People at Risk of Developing Alzheimer’s Disease. 1 year, 6,000

Charles J. Lockwood, Cystic Fibrosis Foundation—US. 1 year, 50,000

Evan J. Silbergeld, University of Maryland. Regulatory and Structural Analysis of the Drosophila Melanogaster Manual of Genome Project. 1 year, 5,000

Marc Hammarlund, Ellison Medical Foundation. Development of New Tools for Imaging the Brain. 1 year, 5,000

Robert J. Tomko, American Society for Clinical Pharmacology. Characterizing the Pharmacokinetics of People at Risk of Developing Alzheimer’s Disease. 1 year, 6,000

Marc Hammarlund, Ellison Medical Foundation. Development of New Tools for Imaging the Brain. 1 year, 5,000

To study these RNA, the only effective way is to use deep sequencing.
In April, Herbert Boyer, Ph.D., a towering figure in molecular medicine, nearly 60 years, and his wife, Maria- grace, received the Peter Parker Medal, the medical school’s highest honor, for their outstanding contributions to the School of Medicine.

The award presentation was an anniversary of sorts, as it has been 20 years since the dedication of the Boyer Center for Molecular Medicine, one of the medical school’s most important research buildings. Boyer, who was a pedagogical fellow at the School of Medicine from 1965 to 1966, made the construction of that building possible with a $10 million gift, given in gratitude to Yale for helping him start his research career.

“The Boyer Center has been critical to the medical school during the past two decades, and its twentieth year marked the time to honor Herb and Grace Boyer with the Peter Parker Medal,” said Dean Robert J. Alpern.

This collaboration will lead to important advances in the understanding of the genetic basis of cancer as we collectively seek to develop novel targeted therapies for patients in areas of unmet medical need.”

In the collaboration, tumor samples will be analyzed to identify gene mutations that disrupt normal cellular functions and promote the uncontrolled cell growth and metastasis seen in cancer. Mutations are believed to underlie the development of two of the most significant targeted cancer therapies of recent years: Sutent, a treatment for stomach and kidney cancers, and Gleevec, a biotech industry trailblazer, which target protein kinases, proteins that may regulate blood vessel function.

As vice chair of the Department of Pharmacology, and as professor at the School of Medicine, Sessa was a post-doctoral fellow and senior scientist at the William Harvey Research Institute at St. Bartholomew’s Hospital Medical College in London.

Sessa joined the Yale faculty in 1993 as an assistant professor of pharmacology, and has been a full professor at the School of Medicine since 1999. He serves as director of the interdepartmental Vascular Biology and Therapeutics Program, and as chair of the Department of Pharmacology.

Sessa has authored or co-authored more than 200 research articles and papers.

His numerous honors include the American Heart Association’s Established Investigator Award; the Young Alumnus Award from the Philadelphia College of Pharmacy and Sciences; the American Society of Pharmacology and Experimental Therapeutics’ John J. Abel Award in Pharmacology; a Merit Award from the National Institutes of Health; the Robert M. Berne Distinguished Lectureship from the American Physiological Society; and the William Harvey Medal.